UK Data Service Study Number 854293

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

Wave 3 Supporting documents

12/03/2020

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

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24 month follow-up Handbook for Researchers

This handbook contains the most up-to-date information about the procedure for Time 3 of the IDEAL study, please follow the guidance in the handbook.

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.

The IDEAL study: Key contacts

For general enquires about the IDEAL project please contact:
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For project updates and other information please visit:

www.IDEALproject.org.uk

@IDEALStudyTweet

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 joined the team of co-investigators in 2015 to 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 Centre of Research in Ageing and Cognitive Health (REACH) based at the University of Exeter. The REACH group 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, Health and Care Research 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 3 Researchers Handbook for

This handbook contains the most up-to date information about Time 3 of the IDEAL study. Please follow the guidance in **this** handbook when working on Time 3.

In this handbook we have included the key information that you, as a researcher working on the IDEAL study, will need. There are three parts to this handbook: Time 3 follow-ups, Document management, monitoring and reporting, and Time 3 Case Report Forms.

- The first part of this handbook, Time 3 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 3 (T3).
- 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 T3. It provides instructions about how to administer and complete the CRFs.

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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Part I. Time 3 Follow-ups

1. An overview of Time 3

1.1. A brief guide to changes at T3

In Time 3 (T3) of the study you will be conducting follow-up assessments with participants approximately **two years** after they were seen for the initial assessment. The procedure for T3 is very similar to T2 with a small number of differences. The T3 changes are briefly outlined below and are then fully explained in the Handbook.

- At T2 participants were asked to consent to data linkage; at T3 participants **do not** need to be approached about data linkage.
- The content of the CRFs has been slightly altered. Most standardised measures remain the same as T2, but we have included some additional questions on future care needs and planning, use of assistive technologies and use of the internet.
- If the person with dementia is now in a care/nursing home there is now a section in the relative/friend CRF where they are asked about the factors that influenced the decision for the person to go into a care/nursing home.
- There have been changes to the open-ended questions at the end of the CRFs. In addition, we ask the participants about their experience of taking part in IDEAL.

1.1. New developments in the IDEAL study

As research network staff you will have a responsibility for ensuring the 24 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 were three additional studies running alongside IDEAL which may involve IDEAL participants; these will continue during T3:

- During Time 3 we will continue with the qualitative arm of the study. Dr Alex Hillman from Cardiff University will be re-interviewing a sample of participants (approximately 30 people with dementia and their carers) who were initially interviewed during T2 of the study. This group of participants were selected to be interviewed as they showed positive or negative changes in quality of life. 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 helps or hinders

the possibility of living well, and what factors are particularly important to them in relation to being able to live well.

- ***IDEAL Arts based project: A Life More Ordinary***
- ***The role of social class in the experience of dementia*** (A PhD project being done by Hannah Scott, a student at Cardiff University)
- ***Experience of working carers*** (A PhD project being done by Rachel Clarke, a student at the University of Sussex)
- At T3 there will be an additional linked study: **The DECIDE study**. The DECIDE study concerns the development and validation of a new quality of life measure for carers of people with dementia. Some sites taking part in IDEAL will be approached by the DECIDE research team to take part in this study. Carers taking part in IDEAL at these sites will be asked to complete the new quality of life measure at T3. As DECIDE is an add-on study to IDEAL, run by a different team of researchers, the DECIDE study will have a separate study handbook outlining the procedures for the study.

1.2. 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.

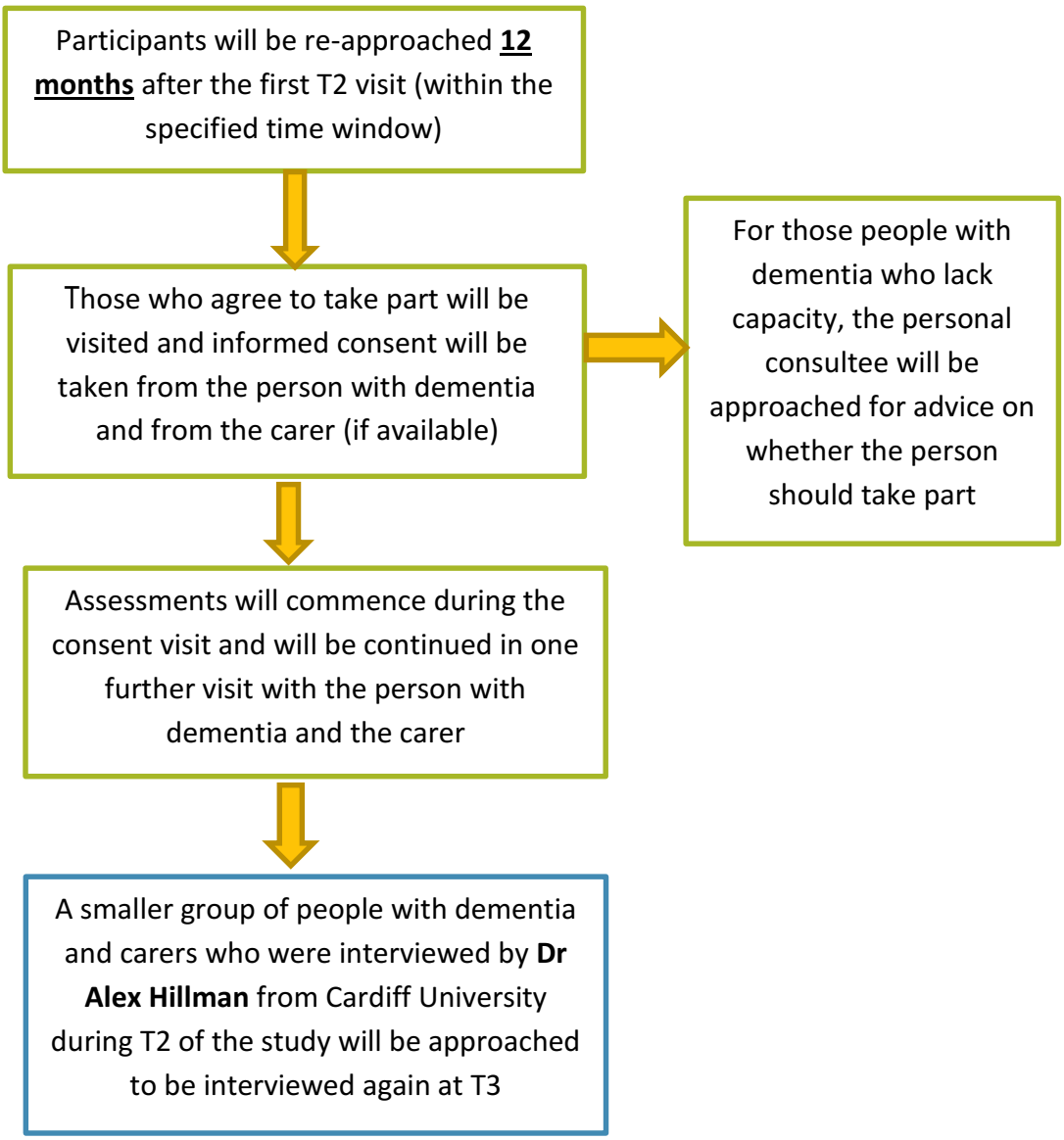
1.2.1. Design

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 Dr Alex Hillman from Cardiff University at T2 and T3 with a sample of participants that have shown 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 3 of the study.

1.2.2. Procedure

After T1 assessments participants are followed up 12 (T2) and 24 (T3) months later. The T3 follow-up should be scheduled **12 months after the T2 visit**. T3 assessments will be completed in **two visits** at the **participant's place of residence** 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 participant-carer dyad) as a token of appreciation for taking part in the study upon the completion of both assessments at T3.

Figure 1. Participant pathway through the study: Time 3



1.2.2.1. Study timelines

Timelines for recruitment and follow-up are provided below.

Milestone	Target date
Time 3 Follow-up assessment commences	**01/07/16**
Time 3 Follow-up assessment completed	**30/06/18**

1.2.3. Ethical approval

Sites will be notified of any ethical amendments, and relevant documentation will be circulated to add to the Investigator Site File (ISF). Please ensure you are up to date with the most current versions of ethically approved documents.

1.3. T3 training requirements

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 T3 training, you will have the opportunity to familiarise yourself with the procedures for T3, learn about the T3 CRFs, understand the importance of data quality, and learn about the DECIDE study. We require all research staff to provide details of their training attendance (on MACRO) for our records.

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.

1.3.1. IDEAL T3 Training

1. We will organise training sessions to provide detailed information on T3 of the study. For those researchers who are unable to attend one of the scheduled sessions we require that a nominated member of your team who has attended the training session cascade the training information provided at the training session to you. We will seek confirmation of this training process for our records.

2. All researchers involved in the study are expected to read and become familiar with the IDEAL Time 3 Researcher's Handbook and the CRFs **before** they commence assessments. This includes understanding the types of questions used and response keys for all items within the CRFs.
3. You will need to update your **training details** in the staff information section of **MACRO** to indicate that:
    a) You have received IDEAL T3 training. You will have the option of stating whether the training was provided by the co-ordinating centre team, by someone at your research site or 'other' (**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).
    b) You have read the IDEAL Time 3 study handbook. **Please note** that at T3 there is only one study handbook.
4. 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/. This is particularly relevant for new members of staff.
5. New site staff joining after T3 training should receive cascaded training on IDEAL procedures from someone who has previously attended IDEAL training sessions. Additional training for new site staff can be arranged with the co-ordinating centre.

1.3.2. T3 Training verification

We will be continuing with training verification in T3. This process will help us to resolve any issues with data quality at an early stage. We would appreciate your co-operation with this process.

For each researcher we will need to see the following CRFs for his/her **first** T3 participant:

Participant Time 3 CRF Part 1

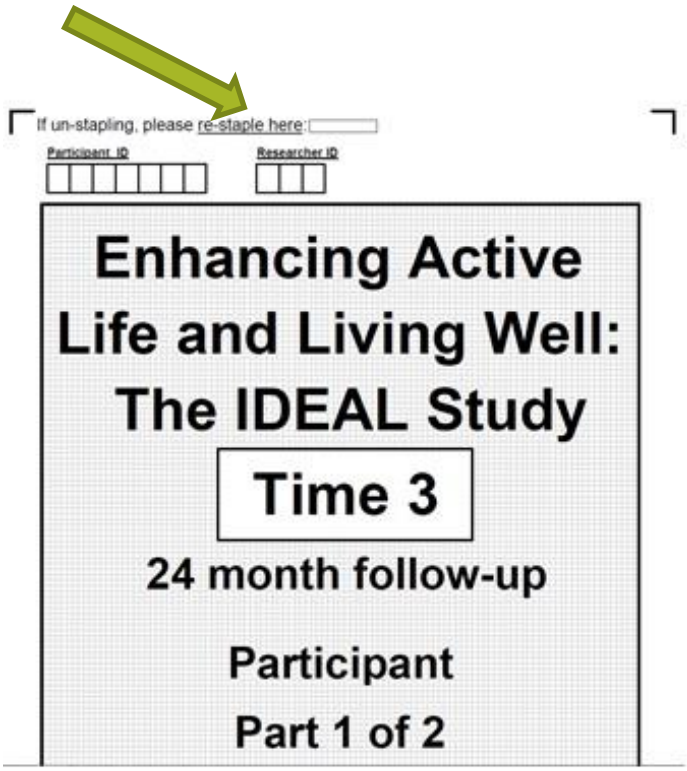
Participant Time 3 CRF Part 2

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 T3 process and before further follow-up assessments are conducted if feasible.

How to send training verification documents:

1. You can send an electronic copy of the CRFs to Dr Ruth Lamont: r.lamont@exeter.ac.uk. As the scanned CRFs will be a large file we advise that you put them in a compressed (zipped) folder.
2. You can alternatively photocopy the CRFs and send the copies to Dr Ruth Lamont at the University of Exeter co-ordinating centre using the coversheet and envelope provided. Note: the **original CRFs** should still be sent as part of the **courier returns** to **NWORTH**. Please ensure that when you are photocopying the CRFs you **do not damage them** when removing the staple.
3. If you have removed the staples on the CRFs to facilitate this process then please ensure you **re-staple** in the box indicated at the top of the CRFs.



Please retain the CRFs at your site until you have received feedback from us so that, if necessary, you can make changes to the CRFs before they are returned to NWORTH for data entry.

Feedback: The CRFs 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 how to improve completion of the CRFs. You will be asked to confirm that you have received and read this feedback. The feedback will also be sent to the local PI for information.

Please take the time to read this feedback and incorporate the information into your assessments to ensure these issues do not arise again.

Data quality issues and concerns are closely monitored. We expect a high standard of CRF completion and will engage with researchers to ensure that researchers adhere to this standard.

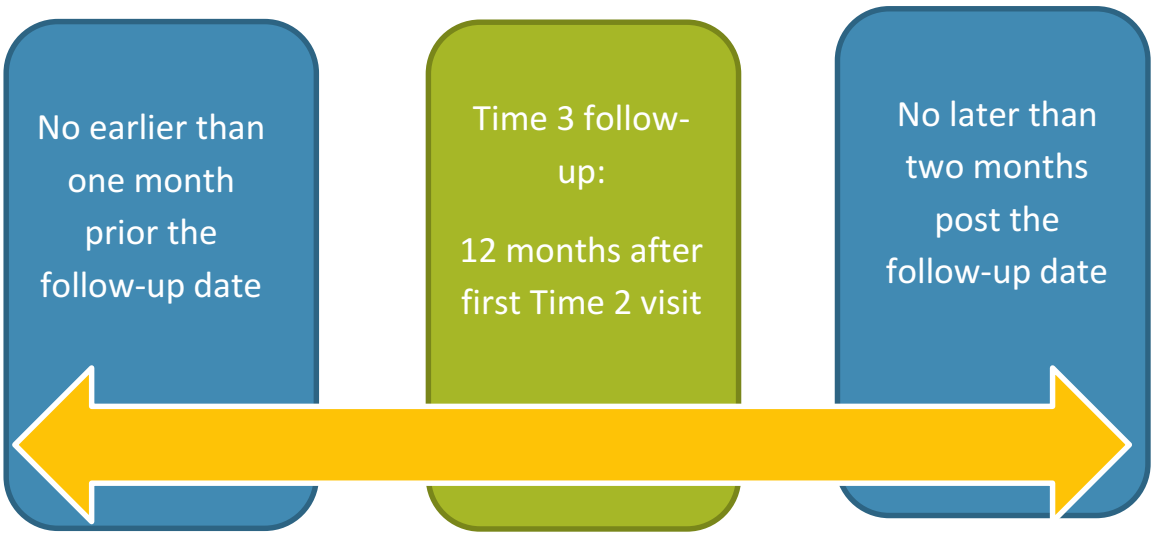
2. Re-contacting study participants

2.1. Timescales for follow-up

The T3 follow-up should be conducted **12 months after the first T2 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. We advise that you try to make contact earlier than anticipated to allow for variation in participant availability.

We are aware that there are circumstances (e.g. the participant is in hospital) where it may not be possible to conduct the follow-up visits within these timeframes. If there is going to be a slight delay (up to 4 months after the scheduled follow-up date) then please continue with the visits and make a note of the length of delay and the reason for this delay in the CRF 'field notes'. If this delay is more significant or would take the visit beyond the end of T3 data collection **(30/06/2018)**, then you may need to consider whether the participant should be withdrawn – please contact the co-ordinating centre to discuss this and agree the most appropriate course of action.

Figure 2. Time 3 follow-up timescales



When planning follow-up visits please be aware that **all** T3 follow-up assessments must be completed by **30/06/2018** so **you need to ensure that all assessments are completed by this date.**

For the majority of sites, T2 assessment will be ongoing as T3 commences. You should plan ahead so that you can facilitate these follow up visits as T2 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. T3 participants: who can take part?

1. We would like to follow up everyone who participated at **T2**.
2. There may be participants who took part in **T1** who were unable to take part in T2 (e.g. due to illness) who should now be approached again for T3. This would **not** include people who have asked to be withdrawn from the study at T2. The follow-up date for this group of participants would be **24 months after the 1st T1 assessment**.

As with 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 T3 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.

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

Key documents:

- ***IDEAL Follow-up Letter and Reply slip T3 (24 month) v1 200516***
- ***Participant information sheet for patient - version 3 - 050315 - initial***
- ***Participant information sheet for family member/friend - version 2 - 050315 - initial***

Participants (both person with dementia and carer) can be contacted by telephone or by letter to establish whether they are interested in continuing to participate in the study. Participants can be re-approached with the ***IDEAL Follow-up Letter and Reply slip T3 (24 month) v1 200516*** (**see Appendix 1**). You should include the ***Participant information sheet for patient - version 3 - 050315 - initial*** to help remind the participant about what the study is about. If applicable you can also include the ***Participant information sheet for family member/friend - version 2 - 050315- initial*** for the carer.

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.

It may be that both the person with dementia and carer re-enter the study at T3, but there may be variations to this with only one member of the dyad re-entering the study. It is important to remember that if the person with dementia withdraws at T3 we need you to engage with the carer to continue their involvement. We are also open to a new carer entering at T3 if those involved at previous time points are not available (see **Chapter 6** for guidance on changes in circumstances).

If the person with dementia has entered a care/nursing home you can still conduct assessments within this setting. In this instance if the person does not have a carer taking part in the study we will ask you to collect additional information about them from a paid carer working in the home (information about involving paid carers is in **Chapter 3**).

2.4.1. 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.

2.4.2. 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 3.*

3. Structure of visits

The structure of the visits at T3 is very similar to the structure of visits at T2 (except there is **no requirement** to consent people for data linkage at T3). See Figure 3 for a brief outline of these visits.

At T3 you should assess the person with dementia at his/her **place of residence**, so if she/he has entered a care/nursing home you can conduct assessments within this setting. 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 information about the person with dementia. See Figure 4 for an outline of these visits.

At T3, participants taking part in IDEAL will be visited on **two** occasions and all the assessments **must** be completed during these two 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. 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 3 CRF Part 2 in Visit 1; however, you need to ensure that the **MMSE** and **ACE-III** are administered on separate visits to avoid any carry over effects (guidance on administering the CRFs is provided in **Chapter 9**).

T3 Visit schedule

We recommend that the two visits for the T3 time point are conducted within a **4 week time frame** (same as T2). However, we do realise people may not be available within these 4 weeks and it may take longer, particularly if you need to approach the personal consultee. We would rather have a delay in participant assessments than the participant being withdrawn from the study. If there is going to be a slight delay (completing the 2 visits across a timeframe of up to 8 weeks), please continue with the visits and make a note of the length of delay and the reason for this delay in the CRF 'field notes'. If this delay is more significant or would take the visit beyond the end of the study time-frame (past **30/06/2018**), then you may need to consider whether the participant should be withdrawn (please make contact with the co-ordinating centre to discuss this).

Figure 3. Summary of the content of the T3 visits: person with dementia and carer

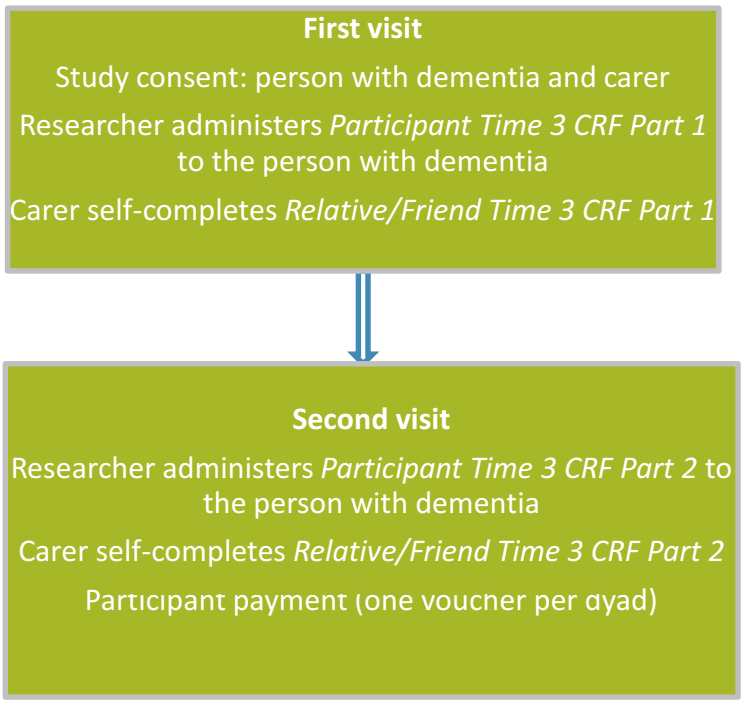
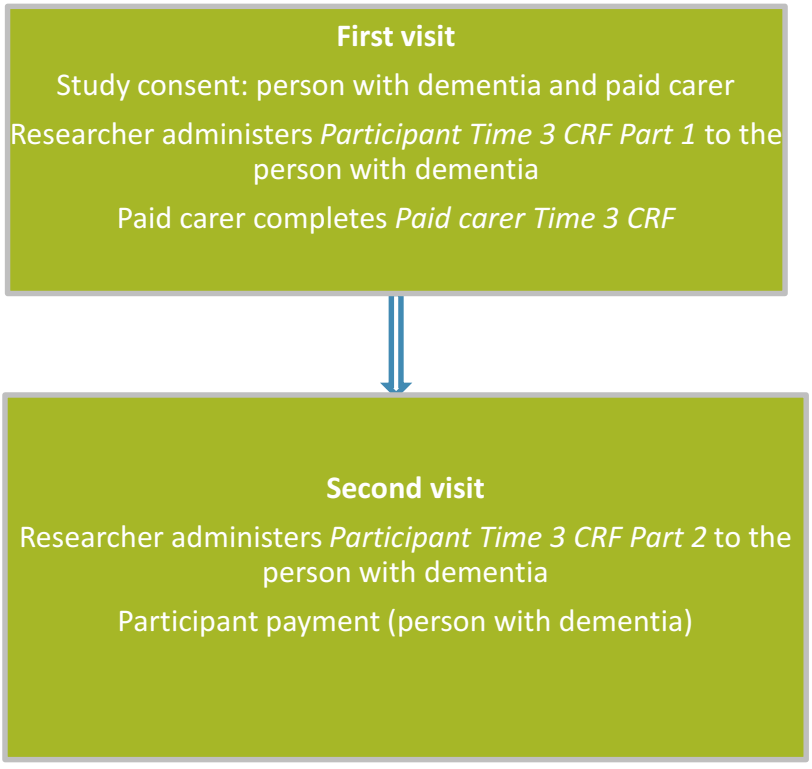


Figure 4. Summary of the content of T3 visits: person with dementia and paid carer

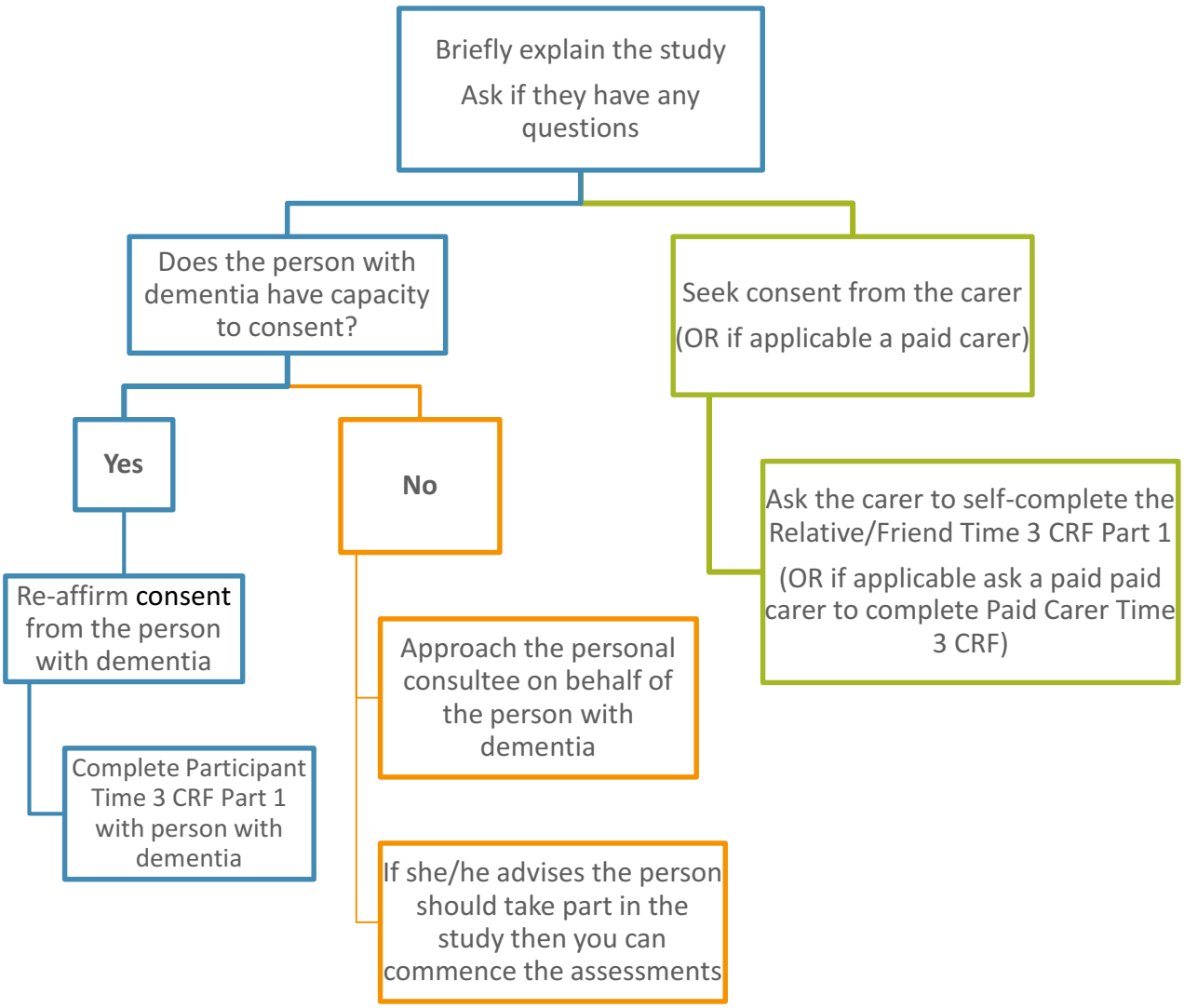


4. First visit

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. If the person with dementia is in a care/nursing home and does not have a carer taking part in the study then you can approach a paid carer for some information about the person with dementia. Figure 5 below outlines the procedure for the first visit if both the carer and person with dementia are present.

Figure 5. 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 person with dementia and carer. If only the person with dementia is taking part in the study then you just need to focus on the guidance for the person with dementia. **Please see section 4.3 for guidance for involving a paid carer.**

4.2. Guidance for person with dementia and carer

4.2.1. 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 or a paid carer is added). Please ensure you use the correct ID number on **all** study documents.

4.2.1.1. Documents to take with you

- ***Participant information sheet for patient - version 3 - 050315 - initial***
- ***Participant information sheet for family member/friend - version 2 - 050315 - initial***
- ***IDEAL Contact Details Form T3 (24 month) Follow-up v1 250516*** (you will need to complete a new form for T3)***.***
- ***Demonstration of capacity checklist (****to document whether or not the person with dementia has capacity).*
- ***Consent form for participant version 3 050315 24 month follow-up***
- ***Consent form for family member/friend version 2 050315 24 month follow-up***
- ***Personal consultee information sheet v2 050315 generic*** (in case it is needed)
- ***IDEAL Consent form for personal consultee version 4 24 month follow-up 200516*** (in case it is needed)

4.2.1.2. Assessment materials to take with you

- Participant Time 3 CRF Part 1
- Participant Time 3 CRF Part 2 (in case there is time to start this)
- Relative/Friend Time 3 CRF Part 1 (if applicable)
- Relative/Friend Time 3 CRF Part 2 (if applicable)
- Showcard booklet
- **[MMSE information removed]**

4.2.2. During the first visit

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

4.2.2.1. Summary of the study

There is not an information sheet for T3; however, you can use the ***Participant information sheet for patient - version 3 - 050315 - initial*** and the ***Participant information sheet for family member/ friend - version 2 - 050315 - initial*** to remind the person with dementia and/or carer of the aim of the study. Please ensure that you make the person with dementia and/or carer aware that they are now in T3 and the last phase of the study.

The first visit should start with a brief overview of the study and what taking part at T3 will involve. The person with dementia and/or carer should be reminded of their involvement in the study at T1 and T2 and given the opportunity to ask any questions. Once the person with dementia and/or carer expresses willingness to continue to take part in the study you can then reaffirm their consent.

4.2.2.2. Obtaining informed consent

This section outlines the procedure for obtaining informed consent in this study. T3 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.

Demonstration of capacity

The person's capacity to consent should be checked at each time point of the study. At T3 it is likely that for some people with dementia there may have been a deterioration in their condition which may impact on their capacity to consent. 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/T2 assessments, you may be able to judge whether she/he has deteriorated. 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***. 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.

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. Brief guidance on approaching personal consultees is provided in **Chapter 6.**

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.

4.2.2.3. The consent form

If the person with dementia has the capacity to consent, you will need him/her to sign the consent form. The carer will also need to sign the consent form for the family member/friend. Please ensure that you have used the correct consent forms and the latest versions and that all essential boxes are initialled:

- ***Consent form for participant version 3 050315 24 month follow-up*** **(see Appendix 2)**
- ***Consent form for family member/friend version 2 050315 24 month follow-up*** **(see Appendix 3)**

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.

If the participant has a physical disability, e.g. due to stroke, she/he will need to do his/her best to initial/sign the consent form. For instance, the participant may need to use the hand that has been less affected by a stroke. Please reassure the participant that it does not matter if the handwriting is untidy.

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

- The wrong consent form 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 or no ID number added to the consent form

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 7)**.

4.2.3. 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 9**). As with previous time points, the CRF for carers is designed to be self-completed.

You will need to:

(a) Administer the *Participant Time 3 CRF Part 1* to the person with dementia and complete the researcher ratings and checklist at the back of the CRF.

(b) Give the carer the *Relative/Friend Time 3 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.

4.2.4. End of the first visit

Prior to ending the first visit please:

(a) Ensure you have asked all the *Participant Time 3 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 person with dementia and/or carer for their continued involvement and establish the next visit date.

4.2.5. After the visit

(a) Complete any researcher ratings as required in the CRFs and check that you have filled in all the appropriate sections on the CRFs.
(b) Complete the checklist at the back of the CRF and record any field notes on the CRFs (if you have not already done so).
(c) Check the participant and relative/friend CRFs for any errors or missing data (see **Chapter 9** for common CRF completion errors).
(d) Score and record the MMSE score, which will be needed for Visit 2.
(e) 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.
(f) Photocopy the participants' consent forms and file appropriately.
(g) Ensure that the participants' documents are stored securely in a locked filing cabinet. Participant consent forms and the Contact details form must be stored separately to the CRFs.

4.3. Guidance for person with dementia and paid carer

If the person with dementia has moved to a care/nursing home which is still in your site's catchment area, we expect you to visit the person to conduct your assessments. We have briefly outlined the guidance here but for more detailed guidance, including how to identify a paid carer, see **Appendix 8** which provides a summary of the information provided in the **IDEAL Time 2 Researcher's handbook, Chapter 15.**

4.3.1. If the person with dementia moved into the home after T2

If the person with dementia has moved into a care/nursing home and has a carer taking part in the study then you can conduct the assessments in the home see **Appendix 8** which provides a summary of the information provided in **IDEAL Time 2 Researcher's handbook, Chapter 15.**

If the person does not have a carer taking part in the study, then we would like you to identify a paid carer working in the home who could provide some information about the person with dementia (see **Appendix 8** for further details). If you identify a paid carer who is willing to take part then as well as bringing the participant documents you will need to bring the paid carer documents at the **first visit.**

Key documents:

- ***IDEAL Consent form for paid carer 24 month follow up v2 200516 (see Appendix 4)***
- ***Information sheet for paid carers version 1 050315***
- ***Paid carer Time 3 CRF***

You will need to give the paid carer the **Information sheet for paid carers** and ask him/her to sign the **IDEAL Consent form for paid carer 24 month follow-up.** Once the paid carer has consented to take part in the study she/he needs to complete the Paid carer Time 3 CRF. Remember to record his/her contact details in the ***IDEAL Contact details form T3 (24 month) Follow-up v1 250516*** and recorded the consent in MACRO

For the procedure for the person with dementia follow the guidance in **4.1. - 4.2.5**.

4.3.2.The person with dementia was already in the home at T2

If the person was in a care/nursing home at T2 assessments then she/he can be re-assessed within the home at T3. If you approached a paid carer to provide some information about the person with dementia at T2 then you can see if the paid carer is still working at the home and whether she/he would agree to take part in the study again. If the paid carer does not wish to take part or no longer works at the home then you can approach a **different** paid carer to see if they would be willing to take part in the study. As well as bringing the participant documents you will need to bring the paid carer documents at the **first visit**:

Key documents:

- ***IDEAL Consent form for paid carer 24 month follow up v2 200516 (see Appendix 4)***
- ***Information sheet for paid carers version 1 050315***
- ***Paid carer Time 3 CRF***

5. Second visit

The aim of the second visit is to complete Part 2 of the CRFs with the person with dementia and/or carer.

5.1. Guidance for person with dementia and carer

5.1.1. Before the second visit

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

5.1.1.1. Documents to take with you

- ***T3 thank you card v1 230516 and the shopping voucher***
- ***IDEAL Participant Receipt of payment Time 3 v1 200516***

5.1.1.2. Assessment materials to take with you

- MMSE score from T3 visit 1 to decide whether to administer the ACE-III or TSI
- Participant Time 3 CRF Part 2
- Relative/Friend Time 3 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/pack

5.1.2. During the second visit

The second visit should last approximately **2 hours**. Guidance on administering these CRFs is provided in **Chapter 9**. You will need to:

(a) Give the carer the *Relative/Friend Time 3 CRF Part 2* to self-complete. Ideally, the carer should do this in a separate room.
(b) Administer the *Participant Time 3 CRF Part 2* to the person with dementia. Complete the researcher ratings and 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 3 CRF Part 2*.

5.1.3. End of the second visit

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.

5.1.4. Concluding T3

This will be the last face-to-face meeting from the project, although we are hoping to secure further funding to continue following up people with dementia and carers who are taking part in IDEAL. As well as giving the participants the ***T3 thank you card v1 230516***, please ensure the following information is provided to the participants:

(a) Thank the person with dementia and/or carer for their time and for their valued contribution to the project.
(b) Explain that this is the last face-to-face meeting from the project, but the research team hope to secure further funding to continue the study in the future (they will be contacted if this is the case).
(c) Explain that the study team will continue to keep in contact with them about the progress of the study and key findings through the study newsletter (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**:** www.IDEALproject.org.uk and @IDEALStudyTweet.
(d) The research team will inform them of any opportunities to continue to support the project.

5.1.5. 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 ***T3 thank you card v1 230516*** 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 are:

1. The ***IDEAL Participant Receipt of payment T3 v1 200516*** (a copy is provided in **Appendix 5**) 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 7)**
2. ***T3 thank you card v1 230516*** which is given with the ***shopping voucher***.

5.1.6. After the visit

(a) Score the ACE-III or the TSI (depending on which one you administered).
(b) Complete any researcher ratings as required in the CRFs and check that you have filled in all the appropriate sections on the CRFs.
(c) Complete the checklist at the back of the CRF and record any field notes on the CRFs (if you have not already done so).
(d) Check the participant and carer CRFs for any errors or missing data (see **Chapter 9** for common CRF completion errors).
(e) Ensure that the participants' documents are stored securely in a locked filing cabinet.

5.2. Person with dementia and paid carer

For the procedure for the person with dementia follow the guidance in **5.1. - 5.16**.

The paid carer should have ideally completed the Paid carer T3 CRF during the first visit. However, the paid carer may have been too busy during the first visit or needed more time to consider taking part in the study. If this is the case she/he needs to complete the CRF during the second visit.

6. Changes in circumstances

It is possible that at T3 there may have been changes in the participant's circumstances. She/he may have moved or may now wish to withdraw from the study. The **IDEAL Time 2 Researcher's handbook** contains extensive guidance on how to deal with changes in participants' circumstances. Below is a brief overview of the situations you may encounter, please refer to the **IDEAL Time 2 Researcher's handbook** for guidance on the following situations; however, **please ensure you use the correct documents for the T3 time point.**

6.1. The person has moved outside your site's catchment area

If the person with dementia and/or carer 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 **IDEAL Time 2 Researcher's handbook, Chapter 14** for full details).

- If only the carer has moved you may be able to post him/her the CRFs to complete.
- If the person with dementia has moved and you know his/her new address you will need to contact the person with dementia and ask permission to pass on his/her new contact details to the University of Exeter co-ordinating centre (recording his/her permission on the ***Telephone summary form***). If the person with dementia consents for you to pass on his/her new details, you will need to update the ***IDEAL Contact details form T3 (24 month) Follow-up v1 250516*** and send this form to the University of Exeter co-ordinating centre with the ***Telephone summary form.*** You will also need to inform the University of Exeter co-ordinating centre through MACRO using *CONSORT Time point 3*. The University of Exeter co-ordinating centre will then explore options for conducting follow-up assessments with that person.

6.2. An IDEAL participant has moved into your site's catchment area

If an IDEAL participant has moved into your site's catchment area your site may be asked to conduct the T3 follow-up assessments with the person with dementia (or person with dementia **and** carer). You will need to record this information in *CONSORT Time point 3.*

6.3. The carer has changed

It is possible that the carer may have changed and we would encourage you to approach this carer to see if they would be willing to take part in the study. If the new carer is willing to take part in the study she/he should complete the CRFs (see **IDEAL Time 2 Researcher's handbook, Chapter 12** for full details). You will need to ensure you use the correct documents for this time-point to consent the new carer into the study:

Key documents:

- ***Participant information sheet for family member/friend - version 2 - 050315 - initial***
- ***Consent form for family member/friend version 2 050315 24 month follow-up***

You do not need to change the ID number for the dyad (ID numbers remain constant throughout the study).

You will need to record in MACRO that the carer has changed. This information is recorded in *CONSORT Time point 3.*

6.4. What if the participant decides to withdraw?

At T3, it is possible that some participants may wish to withdraw from the study. They may choose not to participate in any of the T3 assessments, or may withdraw during the T3 assessment.

- 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.

If a participant withdraws after Visit 1 then you **still need** to return any CRFs she/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.

6.5. 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. For some participants you may have already been in contact with their personal consultee at T2.

6.5.1. 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 at T2 the contact details of the consultee were recorded in the Contact details form: T2. 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.
- 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.

6.5.2. Approaching a personal consultee

You may have already contacted the personal consultee at T2 or this may be your first contact with him/her. In both cases you will need to check that she/he is happy to act as personal consultee at T3 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 **IDEAL Contact details form T3 (24 month) Follow-up v1 250516**.

6.5.3. Contacting the personal consultee

If you contacted the participant's personal consultee at T2 then you may consider inviting him/her to come along to your first visit with the participant. If you have not contacted the personal consultee before then 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.

6.5.3.1. 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. You will need to give him/her the following documents:

- ***Personal consultee information sheet v2 050315***
- ***IDEAL Consent form for personal consultee version 4 24 month follow-up 200516***

6.5.3.2. 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 you have consulted the personal consultee at T2 or if she/he is a family member or friend then you may be able to telephone them directly to seek his/her advice. 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 ***IDEAL Personal consultee invitation letter 24 month follow-up v1 010516 (see Appendix 6).*** 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 version 2 050315 generic***
- ***IDEAL Consent form for personal consultee version 4 24 month follow-up 200516***

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.

6.5.4. 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 she/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 she/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 taken part in T1 and T2 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 she/he was not happy about continuing with the project.

6.5.5. 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.

6.5.6. 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 ***IDEAL Consent form for personal consultee version 4 24 month follow-up*** **200516** (see ***Appendix 7***).

6.5.7. 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.

6.5.8. 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.

Part II. Document management, monitoring and reporting

7. Data and document management

7.1. Key documents for T3

7.1.1. CRFs and associated materials

The CRFs and associated material that you will need for this study will be sent directly to your site (numbers according to your recruitment targets). The documents are as follows:

- ***Participant Time 3 CRF Part 1 v1 160516***
- ***Participant Time 3 CRF Part 2 v1 160516***
- ***Relative/Friend Time 3 CRF Part 1 v1 160516***
- ***Relative/Friend Time 3 CRF Part 2 v1 160516***
- ***Paid carer Time 3 CRF v1 160516***
- ***T3 Showcard Booklet*** (one per researcher)

Requests for additional CRFs: As before, all CRFs contain unique barcodes and only barcoded CRFs delivered directly to the sites should be used during research visits. **Please do not photocopy CRFs or use the CRFs provided for the ISF.**

All sites are sent enough CRFs to cover their full recruitment numbers; however, some replacements may be needed in exceptional circumstances (e.g. accidental damage). In this instance, requests for additional CRFs should be sent to Dr Ruth Lamont (r.lamont@exeter.ac.uk) with a minimum of a week's advance notice. Please be aware that this process takes time because we need to involve NWORTH in the preparation of additional barcoded CRFs, and the documents need to printed and tracked prior to release to the site.

In making the request for more CRFs please detail the numbers of each CRF needed (i.e. 2 x Participant Time 3 Part 1; 1 x Relative/Friend Time 3 Part 2); specify why the replacements are required (what has happened to the ones provided) and the date on which they are required.

We **do not** expect requests for whole T3 CRF packs to be replaced as this suggests that whole packs have been lost.

7.1.2. Other key study documents needed for T3

All study documents will be provided to your site electronically so that you have copies. Some of these should be printed by your site as they need to be populated with your site information (e.g. participant information forms). Other documents (e.g. participant thank-you card) will be printed and sent to you with the CRFs. The other key documents needed for T3 are:

Correspondence

- ***IDEAL Follow-up Letter and Reply slip T3 (24 month) v1 200516***
- ***IDEAL Personal Consultee Invitation letter 24 month follow-up v1 010515***

Participant information forms

- ***Participant information sheet for patient - version 3 - 050315 - initial***
- ***Participant information sheet for family member/friend - version 2 - 050315 - Initial***
- ***Personal Consultee information sheet version 2 050315 generic***
- ***IDEAL Information Sheet for Paid Carers version 1 050315***

Consent forms

- ***Consent form for participant version 3 050315 24 month follow up***
- ***Consent form for family member/friend version 2 050315 24 month follow-up***
- ***IDEAL Consent form for personal consultee version 4 24 month follow-up 200516***
- ***IDEAL Consent form for paid carer 24 month follow up v2 200516***

Researcher forms

- ***IDEAL Contact details form T3 (24 month) Follow-up v1 250516***
- ***Demonstration of capacity by researcher version 2 050315***
- ***Adverse Event Reporting form v1 090514***
- ***IDEAL Participant Receipt of payment Time 3 v1 200516***
- ***T3 thank-you card v1 230516*** (to go with the shopping voucher)
- ***CRF Returns Checklist T3 v1***
- ***IDEAL Participant information documents checklist Time 3 v1 200516***
- ***IDEAL Telephone summary form***

7.1.3. Participant payment vouchers

As with previous time points, each site will be provided with shopping vouchers to give to participant dyads **(do not give the participant and carer 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 confirming that the vouchers have been received by completing and returning the accompanying ***IDEAL Site receipt of payment vouchers Time 3 v1 200516*** to the University of Exeter co-ordinating centre (details on returning these below).

7.2. Returning documents to the co-ordinating centres

7.2.1. Documents to be returned to the co-ordinating centre

Each site will need to return to **NWORTH**:

1) **CRFs:** all the CRFs need to be returned (this includes incomplete CRFs).
   It is essential that only **full sets of data** are returned for participants who have not withdrawn (i.e. if the participant has only done CRF 1, only return his/her data when they have also completed CRF 2). Please collate all CRFs (participant/carer/paid carer as appropriate) and return together within the one courier collection.
   If participants have been **withdrawn from the study, you still need to return any CRFs** they have completed or started. Just return what has been done up to that point (please write 'withdrawn' on the CRF).
2) ***CRF returns checklist T3 v1*:** you will need to complete this form to inform us which CRFs you are returning.

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). **Please check all forms are complete**. Any issues with consent will result in an exception report being issued and will require the researcher to address the consent issues. This may involve a return visit to the participants.
2) ***IDEAL Contact details form T3 (24 month) Follow-up v1 250516*:** this must be completed for all participants who have consented to take part in T3 and copies returned to Exeter. It will note whether details remain the same or have changed and what the changes are. Although this is the last time-point in the study, it is important that we have the most up-to-date contact details in case of further follow-up or opportunities for participants.
3) Signed ***IDEAL Participant Receipt of payment Time 3 v1 200516***: we will need this document returned as evidence that participants have been paid**.**
4) ***IDEAL Participant information documents checklist Time 3 v1 200516*:** This should 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, and for those that have withdrawn, the time point of withdrawal and the number of completed CRFs.

Note: please retain copies (for your own records) of all the forms sent to the University of Exeter and the documents/returns checklists for both the University of Exeter and NWORTH.

7.2.2. How to return documents

We will send you envelopes and courier bags for returning study documents either to the University of Exeter co-ordinating centre or to the NWORTH Clinical Trials Unit (based at Bangor University). See Figure 6 for information on which documents get returned to the University of Exeter and which documents go to NWORTH.

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. Sites are given a yearly time-table of when to expect courier collections.

In advance of the collection: A reminder of your collection will be sent one week prior to your collection date. We will arrange for two packages to be picked-up from your site by the courier (one to be sent to the University of Exeter co-ordinating centre and one to the NWORTH trials Unit) unless you let us know otherwise. The courier will only pick-up the number specified in advance. If a collection is not necessary or possible, please let us know a minimum of three days prior to the collection.

Contact Helen Davey: H.E.Davey@exeter.ac.uk with all document return queries.

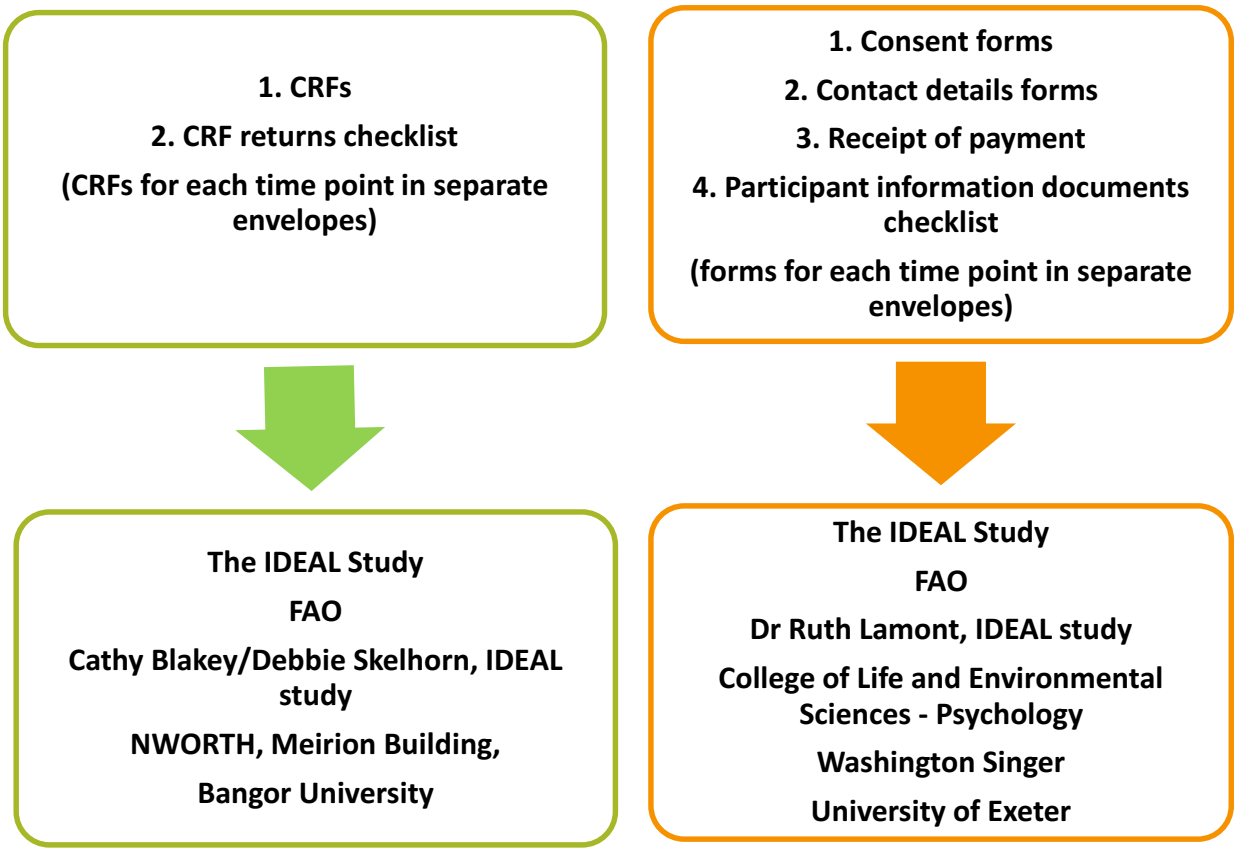
Preparing documents being returned to NWORTH:

- Put each set of CRFs in an envelope addressed to: Cathy Blakey/Debbie Skelhorn (NWORTH). Use one envelope per participant-carer dyad and do not put CRFs from multiple time points in one envelope.
- All envelopes should then be put in one of the provided A3 courier mail packs for the return of the CRFs addressed to NWORTH (Bangor).
- Separate returns checklists should be completed for each time point.

Preparing documents being returned to the University of Exeter co-ordinating centre:

- Put these in the provided A4 envelopes addressed to: Dr Ruth Lamont (University of Exeter). A separate envelope should be used for each time point (but not for each participant).
- All envelopes should then be put in one of the provided A4 courier mail packs for the return of all other documents to Dr Ruth Lamont, University of Exeter.
- Separate returns checklists should be completed for each time point.

Figure 6. Returning study documents



8. Study monitoring and reporting

8.1. Time 3 monitoring information

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. The T3 monitoring information for each month (along with any ongoing T2 monitoring information) 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. Your site's main and reserve MACRO contacts will be sent an email toward the end of each month as a reminder of this.

Excel file

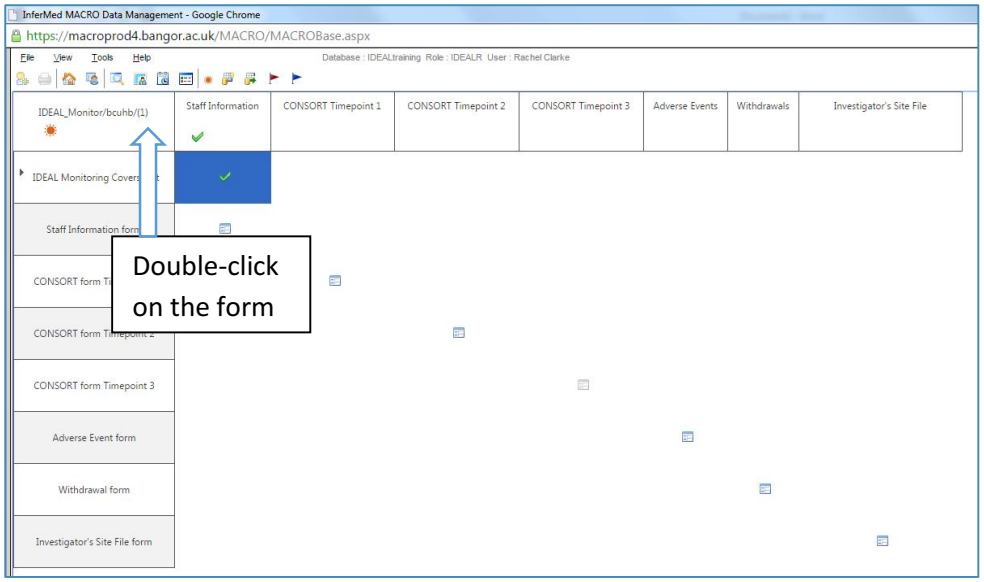
To support the upload of the monitoring information required by the project, your site will be sent an electronic version of an Excel file which can be used to record the information needed for *CONSORT Time point 3*. All researchers are advised to populate this Excel file and to ensure the site MACRO contact has access to this information prior to the deadline on the 5th of the month. The site's main MACRO contact should then make sure she/he is available to upload the information using the *CONSORT Time point 3* forms.

In addition, the site's MACRO contact has a responsibility to **keep researcher details updated (including training and staff departure), as well as completing Adverse Event forms, Withdrawal forms and ISF forms as required (as in the previous time points).**

8.2. CONSORT Time point 3

8.2.1. Activating CONSORT Time point 3

Before entering follow-up data, the *CONSORT Time point 3* 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 'T3 Start? Yes/No'. Once you have saved this form, you will be able to access the 'Consort form Timepoint 3'.

8.2.2. What data needs to be entered for Time point 3?

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 data entered at T3 will not necessarily be recorded in the same month at follow-up as it was recorded at T2 or baseline.

Once you access the form it will largely be the same as the T2 Consort forms. The only minor changes are noted below under their section headings.

Person with Dementia- How many people with dementia have reaffirmed consent during this month?

- **Removed drop down menu-** Data linkage information is no longer required at T3 and so this has been removed from the form.
- **New drop down menu-** asking if the participant *'Took part at T2?'* (options: *yes/no*). This is for the instances where the person with dementia was not available at T2 but back in at T3.
- **New drop down menu-** asking if the participant has a relative/friend (carer) involved at T3. This question has been added to gain clearer information about participants' circumstances. In particular, we would like to distinguish between: 1) Participants who do not have a carer taking part in IDEAL because they do not have a carer that could have taken part in the study (i.e. the participant is not receiving informal/unpaid support from anyone); 2) participants who do not have a carer taking part in IDEAL because the carer has declined to take part in IDEAL e.g. the carer did not wish to take part because of the time commitment involved.

  Relative/friend involved at T3?

  - *Yes- a relative/friend is taking part in IDEAL*
  - *No- the person's relative/friend did not wish to take part*
  - *No- the person has no relative/friend to nominate*

Carers- During this month how many PAID CARERS have consented to participate in the study?

- **New drop down menu**- asking if the paid carer was the same as the paid carer involved at T2.

  Paid Carer Same

  - *Same paid carer as previous time point*
  - *Different paid carer from previous time point*
  - *There was no paid carer involved at previous time point*

Part III. Case Report Forms

9. Case Report Forms

This section contains details of the CRFs that will be used in the IDEAL study at T3. It provides instructions on how to complete the CRFs. The CRFs are largely unchanged from T2. There are a few additional items and these have been included at the end of the CRFs; for instance, there is a new section where participants can tell us what they thought about taking part in the IDEAL study.

We have updated our guidance on the administration of the cognitive tests so please make sure you are familiar with these changes. We have updated the ACE-III guidance so please use this version for your T2 queries and guidance as well as for your T3 reference.

9.1. Main changes in CRFs for T3

At T3 the CRFs were changed in consultation with the IDEAL study team. Some IDEAL researchers provided feedback about amendments to help with the checklists and suggested other changes that we have implemented.

9.1.1. New CRF items

At T3 we have added a few new items to the end of the CRFs.

Participant and Carer CRFs

- Questions on loneliness from T1 have been added back in (6 items)
- We have added in two new well-being questions
- We ask about future care needs and planning
- At the end of the CRF we ask participants to reflect on their experiences of taking part in the IDEAL study

Carer CRFs only

- We ask the carer about his/her use of the internet to aid caring
- If the participant is now in a care home or nursing home we have added a short section about this

Carer CRFs only (unless no carer)

- We have added a short section on assistive technologies as part of the CSRI

9.1.2. Rationale for new measures

For the participant and the carer to answer

- We have added some loneliness questions previously used at T1 back in to allow us to see whether loneliness, assessed through a more detailed examination, has increased or decreased as the dementia progresses. For instance, it will be interesting to see whether loneliness increases or decreases in the carer of a participant that has moved into a care home or nursing home.
- To help aid comparison with other large nationwide studies we have included two well-being questions taken from the Office for National Statistics (ONS) questionnaire. This will help to show whether people with dementia and their carers differ in how they view their well-being compared with other populations.
- There is a section about planning for end of life (i.e. whether a lasting power of attorney or a "living will" has been setup). Due to the different constituent countries of Britain having different laws and terminology, these have been split into two subsections, a section for England and Wales and a section for Scotland.
- For all participants, as this is the final time point of IDEAL, we have included some additional questions that ask about the experience of taking part in the IDEAL study and taking part in research projects in general. This will help to tell us what aspects of the study were felt to be of benefit to the participants, and will inform the planning of future dementia studies.

For the carer only

- There are one or two questions about whether the carer uses the internet to aid caring for the participant, such as visiting websites or online forums that offer practical advice for carers of people with dementia. This will give useful information about changing technology usage and how the internet can help people with dementia and carers.
- We have added a brief section for the carer to answer if the participant is now in a care home or nursing home. This includes a question about what, if anything, has changed for the better or worse since the participant has moved into care.

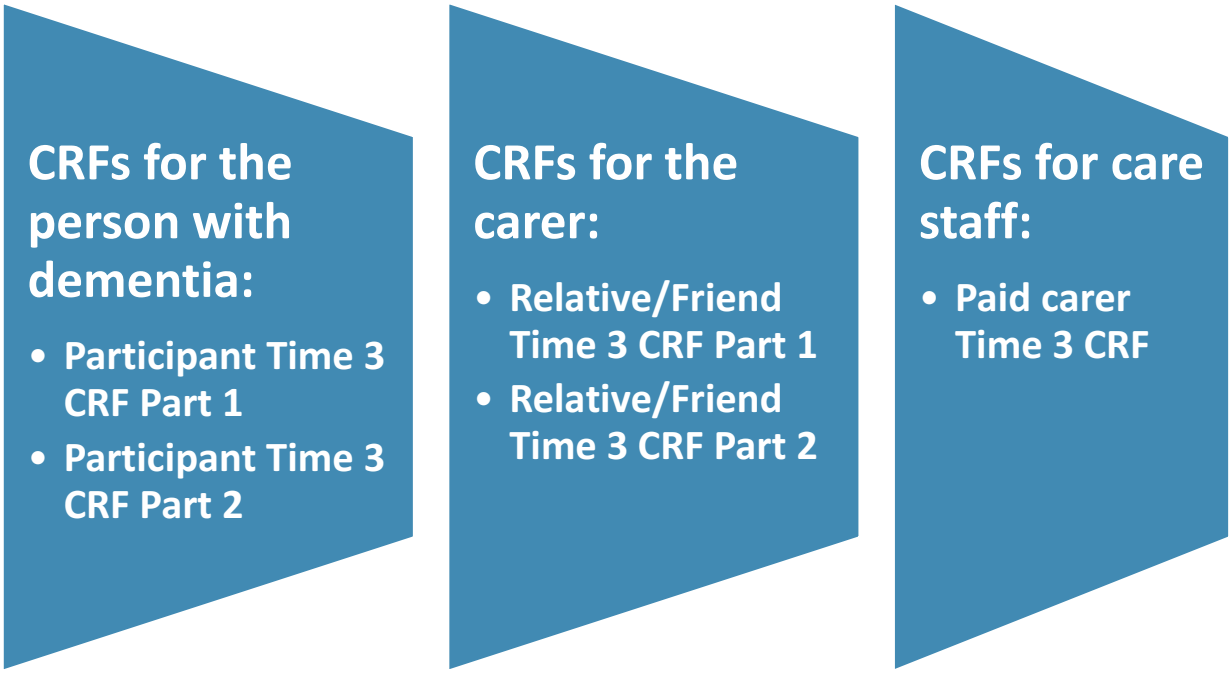
For carer only unless there is no carer

- There is one additional section that is primarily answered by carers. If **no carer** is involved in the study then it will be administered to the participant by the researcher. This forms part of the CSRI and is about the use of any assistive technologies (e.g. phone blockers) to help the person with dementia.

9.2. Types of CRFs

This section describes the CRFs being used in IDEAL. The CRFs for the person with dementia are called **'Participant CRF'** and the CRFs for the carer are called **'Relative/Friend CRF'**. The CRF for Paid carers is called **Paid carer CRF**. Information about the number of CRFs is provided in Figure 7.

Figure 7. CRFs for T3



9.3. Content of the CRFs

The ethos of the content of the T3 CRFs remains the same as at T2. The measures relate to components that we anticipate will change over time and that will have an effect on or influence the IDEAL study outcome measures: quality of life, well-being and life satisfaction. The CRFs consist of standardised measures and single items taken from existing questionnaires; with the one or two exceptions described already, the same measures and questionnaires that were included at T2 have been used in T3. The structure of the CRFs is the same as T2.

At the end of some of the CRFs there are open-ended questions, although the number of these has been reduced. 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.

9.3.1. CRFs for the person with dementia

9.3.1.1. Participant Time 3 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, stigma, loneliness, the ONS well-being scale and future care needs and planning.

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 3 CRF Part 1 and the Relative/Friend Time 3 CRF Part 1. If the FAST is not completed you will receive a data query so please do not forget to complete this rating.

Some elements in this CRF 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/since the last visit if over 12 months - the second question should be skipped, as it does not apply to this participant. This is indicated on the CRF.

9.3.1.2. Participant Time 3 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 to look up the participant's MMSE score which will be recorded in CRF 1.

At the beginning of the Participant Time 3 CRF Part 2 there are a number of screening questions to help you select the appropriate cognitive test for the participant; these are the same screening questions as T2. 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 should have a score for both the TSI and 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 3 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 3 CRF Part 1. The ACE-III administration and scoring is the same as at T2 including the additional guidance and boxes to cross where the participant is unable or unwilling to provide information. However, please note that we have **updated** the T2 verbal fluency guidance in this handbook.

The rest of Participant Time 3 CRF Part 2 is split into five sections:

First section

This has questions on physical health, dignity and respect, psychological well-being, accommodation, green/blue spaces, life space, society and community, social capital, social activities, cultural activities, and interests and activities. Some of the questions on accommodation and green/blue spaces can be skipped if the participant has not moved since the previous visit. **Please note**, we have changed the wording of the accommodation screening question as well as of the education question. At T2 these questions were worded to ask only about the previous 12 months; however, for some participants their previous visit may have been more than 12 months prior. These questions should be asked if the participant has moved since his/her last assessment even if this falls beyond the 12 month period (you can use this guidance for the T2 assessments).

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 carer 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 carer taking part in the study. This section contains questions on health conditions, sources of income and the CSRI. At Time 3 the CSRI contains a new section concerned with assistive technologies that the person with dementia has received.

Section D (new for T3)

This has questions on taking part in research in general and taking part in IDEAL specifically. This should be administered to the participant alone without input from the carer. This section may be completed before Section B if the carer is still completing his/her CRF.

Section E

The last section consists of the GDS since the relevant sections for the GDS rating (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. If the GDS is not completed you will receive a data query so please do not forget to complete this rating.

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/since the last visit - the subsequent accommodation questions should be skipped, as they do not apply to this specific participant. This is indicated on the CRF.

9.3.2. Relative/friend CRFs

9.3.2.1. Relative/Friend Time 3 CRF Part 1

As at T2, 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.

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). The CSRI contains a new section at T3 that asks about any assistive technologies that the person with dementia uses. This first 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.

Please note, we have changed the wording of the accommodation screening question and the education question. At T2 these questions were worded to ask only about the previous 12 months; however, at **T3** (and potentially **T2**) for some carers their previous visit may have been more than 12 months prior. Please make sure, if the carer has moved since the last

assessment, that his/her responses reflect this change of address, especially if this was more than 12 months period (you can use this guidance for the T2 assessments).

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 3 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 should only be completed by the carer **if the participant is in a care home** or nursing home. 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. This section should **not** be completed if the person with dementia is living in warden-controlled housing or assisted living accommodation.

Section D

The fourth 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.

9.3.2.2. Relative/Friend Time 3 CRF Part 2

This CRF contains questions that are only about the carer and the CRF is split into four sections. The CRF begins with a screening question. This tells the carer that there are different sections to be completed:

1. **Have you taken part in this study before?**
   (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 3 CRF* 2 (question 1 above) asks the carer to say whether she/he has taken part in the study before. It is possible that carers may not know or remember taking part in the IDEAL study before, 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 before. If you have not seen the participants before you should consult your site's internal records to see who has previously acted as the carer; you could also ask the researcher who conducted the assessments to tell you who the

carer was. It is essential that you know who has acted as the carer previously, since not only will you have to tell the carer if required whether she/he took part before but you will also have to record whether the carer has or has not changed since the last visit in the researcher ratings at the beginning of participant Time 3 CRF 1. If the carer is new to the project at T3 you should inform him/her that there is a section at the back that s/he 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 before (at T1, T2 or took part at both time points) 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, mood, the experience of supporting the participant, how the carer is managing, loneliness, the ONS well-being scale, and internet questions. 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 has not taken part before.

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 (new for Time 3)

This has questions on taking part in research in general and taking part in IDEAL specifically. This section must be completed by all carers.

Please make sure that all sections have been completed accurately.

9.3.3. CRF for paid carers

The paid carer CRF is largely unchanged from T2, although we have reduced the number of open-ended questions and added a screening question at the start of the CRF. 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 6** for information

on paid carers). 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.

If there was a paid carer involved in the study at T2 we would appreciate it if the same paid carer completed the CRF at T3; however, if this is not possible the involvement of a different paid carer is acceptable. This should be noted in the CRF.

9.4. Administering CRFs

9.4.1. CRFs for Relative/Friend

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.

Checking the CRF:

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.

9.4.2. Participant CRF administration guidance

It is essential that the ID numbers allocated to participants at T1 are used with the same participants at T3. 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, **even if it is a different paid carer from T2.**

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. This is essential to standardise administration.
- Showcards: For many questions you will need to show the participant a showcard containing the range of responses to the question. This is to facilitate a response from the person with dementia and to allow them to choose one of the response options for the measure. 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).**
- 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:

73. How would you describe your life as a whole? When you think about your life as a whole, everything together, how do you feel about your life? Would you say it is poor, fair, good or excellent?

☐ Poor ☐ Fair ☐ Good ☐ Excellent

- 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 incorrect 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 and T2. It is essential that this procedure is followed as we have had to lose data at other time points 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

- 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.

Common CRF completion issues:

- 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 as it makes it difficult for us to tell which is the correct answer. Instead you must completely cross out the box and write the correct information as close to the box as possible.

- **[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).

9.4.2.1. 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 T3 the checklist has changed slightly from T2; we have included the question numbers in brackets to help you to locate them. This was based on the recommendation of one of the site researchers and we hope this helps.

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 carer taking part in the study, each checklist in Section C of Participant Time 2 CRF Part 2 should have the "Not applicable" box crossed.

9.4.2.2. Field notes

Do not make any notes on the CRFs as this will affect the scanning of the CRF.

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 carer 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.

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.

9.4.2.3. People with physical or sensory impairments

Cognitive tests

A participant may not be able to complete the sections of the cognitive tests that require writing. **[MMSE information removed]** she/he may have more difficulty with writing the two sentences in the ACE-III. Where participants have specific difficulty with writing you should reassure the participant that it does not matter if the handwriting is untidy, and encourage the participant to try to write something. If the participant is unable to write a sentence you should score the missing data as zero. If the participant wrote something that you are unable to read please ask for clarification from the participant and write underneath what the sentence should say: this will not affect scoring. However, this should be avoided where possible. **[MMSE information removed]** For participants who are visually impaired we have created large versions of the ACE-III stimuli that can be used instead of those provided in the showcards; we can provide digital copies of these on request but they should only be used in exceptional circumstances. Often people with visual impairments have a magnifying glass to help see things more clearly and participants are welcome to use these where necessary. However, if the participant's own magnifying glass, the large stimuli, and encouragement that neatness will not be scored do not help the participant to read, write or draw the stimuli you may need to discontinue the ACE-III since 25% of the score depends on visually-presented stimuli.

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

This section of the handbook is to help you to administer the CRFs to people who may be more severely impaired. We have updated guidance particularly with reference to the functional ability questions in the CRF (you can use this guidance to help you with T2 CRF completion).

At T3 we anticipate that the abilities of most of the participants will have declined in some areas. Some participants may show more evidence of decline 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 extensive memory loss and difficulty communicating.

Based on feedback from researchers we have retained the number of showcards at T3. 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 retained the specific guidance or instructions in the CRFs when participants may find the questionnaires difficult to answer.

When to use the minimal data items

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 to indicate when the guidance for people with severe dementia should be implemented. 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 the same as they were at T2 and we have highlighted them by having a box around them. For example:

73. How would you describe your life as a whole? When you think about your life as a whole, everything together, how do you feel about your life? Would you say it is poor, fair, good or excellent?

☐ Poor ☐ Fair ☐ Good ☐ Excellent

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

Only use if MMSE is less than 10

☐ No ☐ Yes

It is important to note that:

1) At **T3 we have amended the guidance** in the CRF for this question as many researchers at T2 were using the yes/no responses for people with high MMSE scores even though the same participants were able to use the original response options at T1. At T3 the yes/no responses must only be used when the person has an MMSE score of less than 10 **and** is unable to give a response using the original response options. If the participant scores 10 or more on the MMSE then the original response option only **must** be used.

2) You must use the same response key for the whole of the section; i.e. if the participant is unable to use the usual response options 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.
3) If the participant is finding the questions difficult to answer then please prompt him/her. There are a number of different prompts that are available to you:
   - 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 difficulty now, but still manage to do it?".
   - You may infer the correct response based on how she/he gives his/her response, for instance, the participant may say yes, but the intonation may suggest 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 (below), the participant scored 10 on the MMSE and was able to use the usual response options:

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

Only use if MMSE is less than 10

[ ] 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

Only use if MMSE is less than 10

[ ] No [ ] Yes

In this example (below), the participant scored less than 10 on the MMSE and is unable to use the usual response options but was able to say yes or no to all the questions (if the participant scored 10 on the MMSE these responses would be incorrect):

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

Only use if MMSE is less than 10

☐ 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

Only use if MMSE is less than 10

☒ No ☐ Yes

In this example (below) the CRF has been incorrectly completed. The participant answered the first question using the usual response options 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 should 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

Only use if MMSE is less than 10

☐ 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

Only use if MMSE is less than 10

☐ No ☒ Yes

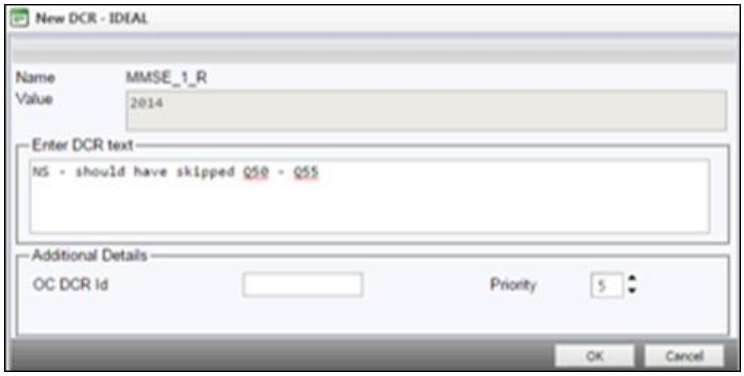
9.5. Data quality

Data quality refers to the quality of the information recorded in the CRFs. Having good quality data is important because errors in CRF completion can:

- Drastically slow down data entry
- Result in us not being able to use the data in our analyses.

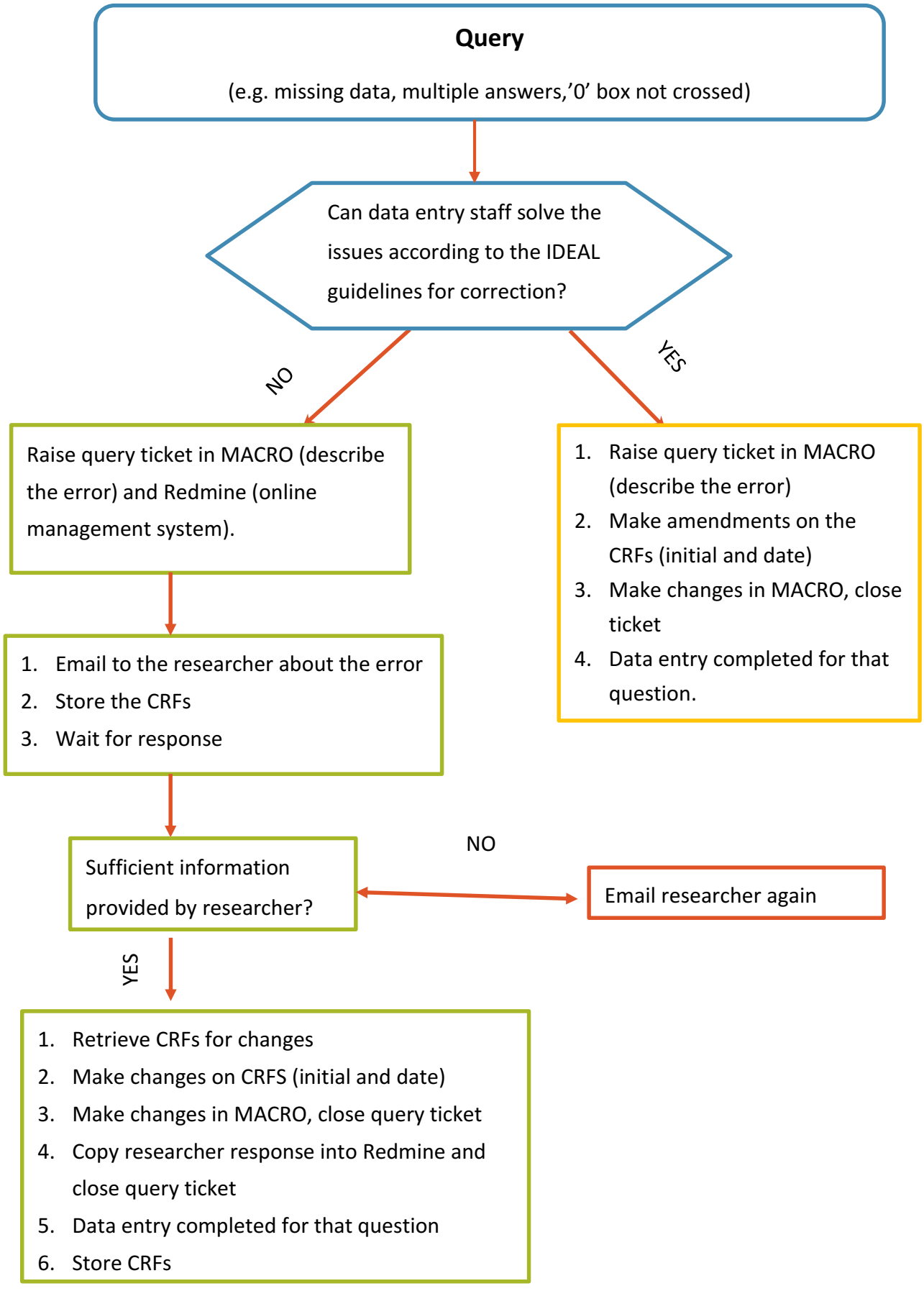
What is the impact of data errors on data entry?

These types of errors will slow down data entry and may mean that the data from the CRFs have to be manually entered instead of being Teleformed (electronically scanned) which is quicker process of data entry. Each time an error is identified we check to see whether it can be corrected; if it can, the data entry clerk has to manually amend the CRF and also add a data correction report (DCR) to the question in MACRO (as shown below). An amendment takes around 1 minute of data entry time. This may not sound like a time-consuming process; however, given the amount of data and the number of corrections which have to be made, errors do significantly increase the time taken for data entry.



If errors cannot be corrected by data entry clerks, they then must be queried with the researcher. This involves creating a DCR in MACRO, creating a ticket in the tracking system, sending an email to the researcher, and chasing queries that have not been answered. This can be a time-consuming process for both the data entry clerk and the researcher. If the query has been resolved the data entry clerk has to go back into MACRO, close the DCR, make the amendment, close the ticket, and amend the CRF. Some errors will involve the data entry clerks contacting the researcher for clarification. Figure 8 outlines the data query process.

Figure 8. Data query process



The condition of the CRFs

The condition of the CRFs can also have an impact on data entry. We cannot scan CRFs that have been:

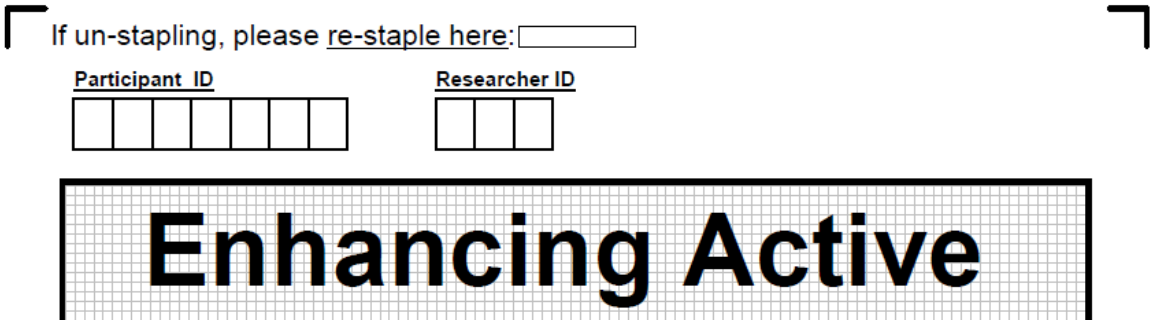
- Hole punched
- Damaged (e.g. by removing staples and then re-stapling).

Removing staples from CRFs

The corners of the CRFs are being damaged when the staple has been removed and then re-stapled. We have added some new instructions to the top of the front page of each CRF. If, for any reason, you remove the staple from the CRF please make sure that you do not damage the corner of the page when removing the staple. When you re-staple please do not staple in the corner as this may also damage the corner of the page.

If one page of the CRF is damaged the entire CRF has to be hand entered.

As you can see in the image we have added a box in the top-middle of the front cover where you must re-staple the CRF.



The impact of data errors on data analysis

Most errors cannot be corrected e.g. if two responses have been given for a question we cannot use the data for this question and so it is missing data. Missing data will cause problems in the analysis and increase the uncertainty of any estimates and conclusions. Although some statistical methods have been developed to reduce the impact of missing data, the most effective approach is to ensure the completion of CRFs and to prevent missing information in the first place.

What are the errors in the IDEAL CRFs?

Missing data

Participants have the right to decline to answer questions and we accept that there will be missing data because of non-responses. However, we tend to come across missing data in the sections the researcher completes. Missing data in these sections will be queried if there is no justification in the field notes. Common researcher self-complete questions with missing data are:

- Date of Diagnosis
- Diagnosis
- FAST stage
- GDS level
- Assessment took place
- Assessment situation

CRF completion errors

There are common errors that are specific to certain questions, especially 'not skipping' errors and 'ACE-III' errors, and these appear on the same questions in the CRFS of many different participants. Other errors can be more generic and arise frequently as we have seen throughout T1 and T2.

Errors can include

1. Not skipping questions that should have been skipped.
2. Not 'crossing' boxes
3. A sub-option being selected where the main option has been left blank.
4. Selecting multiple answers for a question when only one answer was needed.
5. Not marking boxes that should be marked e.g. not crossing '0' in the ACE-III.
6. Contradictions e.g. selecting both a given response option and 'none of the above' (in co-morbidity questionnaire) or selecting a response option and then selecting 'not applicable'.
7. Not scoring sub-sections of the ACE-III
8. Incorrectly scoring the ACE-III.
9. Illegible words e.g. in ACE-III verbal fluency.
10. Extra information written on the CRFs e.g. notes written on the form.

We have provided examples of completion errors below, showing how they have been corrected by our data entry clerks.

1. Not skipping questions that should have been skipped.

INCORRECT COMPLETION

Your accommodation

Now we would like to know about your home, including who lives with you, how long you have lived at this address and how satisfied you are with your accommodation.

45. How many adults (people aged 16 or over) are there in your household including you?

☐ One ☒ Two ☐ Three ☐ Four ☐ Five ☐ Other

If other, **please specify number:** ☐☐

46. How many children under the age of 16 years are there in your household?

☒ None ☐ One ☐ Two ☐ Three ☐ Four ☐ Five ☐ Other

If other, **please specify number:** ☐☐

If you did not take part in this study last year please skip to question 54

47. Have you moved house in the last year?

☒ No (skip to question 54) ☐ Yes

48. In which of these ways is your accommodation owned or paid for?

☒ Own it outright
☐ Buying it with the help of a mortgage or loan
☐ Pay part rent and part mortgage (shared ownership)
☐ Housing association rented housing
☐ Council-rented housing
☐ Private rented housing
☐ Live here rent-free (including rent free in relative's/friend's property, but excluding squatting)
☐ Squatting
☐ Care home
☐ Nursing home
☐ Sheltered accommodation (has a warden or scheme manager on site)
☐ Other; please specify:

☐ Don't know

As shown in the screen shot question 47 has been answered 'No' therefore question 48 should have been skipped.

CORRECTED CRF

47. Have you moved house in the last year?

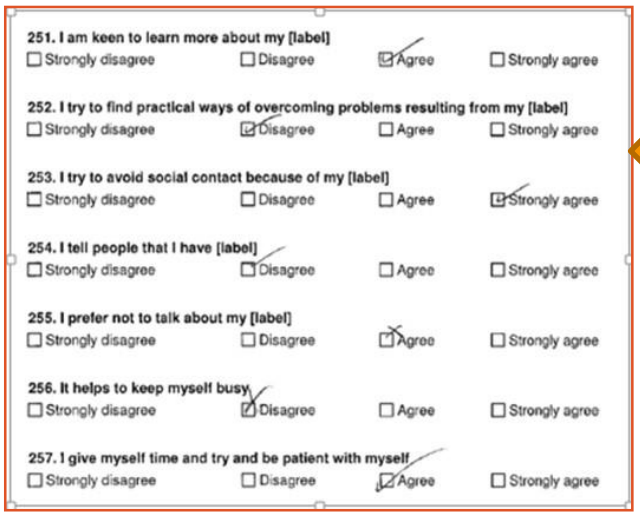
☒ No (skip to question 54) ☐ Yes

48. In which of these ways is your accommodation owned or paid for?

☒ Own it outright
☐ Buying it with the help of a mortgage or loan
☐ Pay part rent and part mortgage (shared ownership)
☐ Housing association rented housing
☐ Council-rented housing
☐ Private rented housing
☐ Live here rent-free (including rent free in relative's/friend's property, but excluding squatting)
☐ Squatting
☐ Care home
☐ Nursing home
☐ Sheltered accommodation (has a warden or scheme manager on site)
☐ Other; please specify:

☐ Don't know

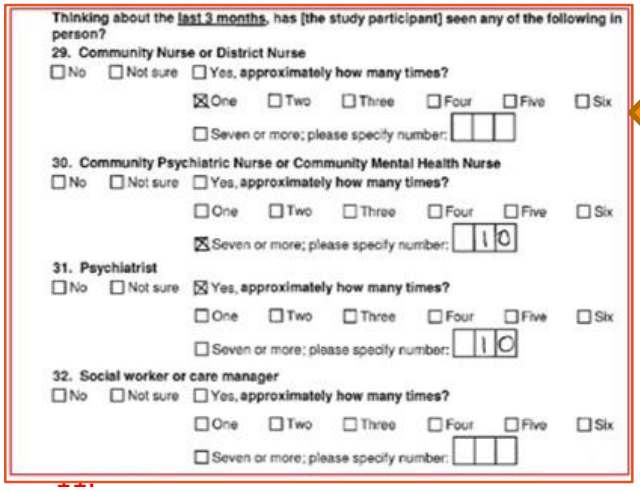
2. Not 'crossing' boxes



Please use 'X' not '✓' or '/' to record responses in the box. Ticks and invalid marks can cause issues with Teleform as the scanner may not recognise them.

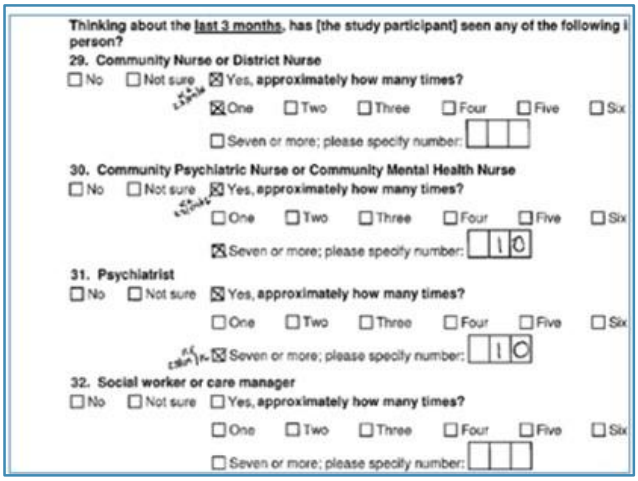
3. A sub-option being selected where the main option has been left blank

INCORRECT COMPLETION



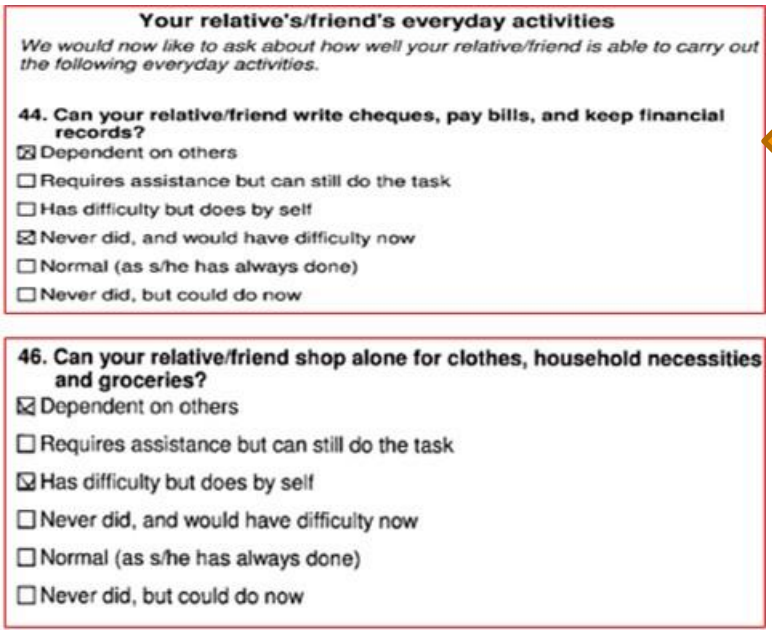
In this example the sub-option for Q29-30 has been selected but the main option has not.

CORRECTED CRF



4. Selecting multiple answers for a question when only one answer was needed

INCORRECT COMPLETION



Your relative's/friend's everyday activities

We would now like to ask about how well your relative/friend is able to carry out the following everyday activities.

44. Can your relative/friend write cheques, pay bills, and keep financial records?

- ☒ Dependent on others
- ☐ Requires assistance but can still do the task
- ☐ Has difficulty but does by self
- ☒ Never did, and would have difficulty now
- ☐ Normal (as s/he has always done)
- ☐ Never did, but could do now

46. Can your relative/friend shop alone for clothes, household necessities and groceries?

- ☒ Dependent on others
- ☐ Requires assistance but can still do the task
- ☒ Has difficulty but does by self
- ☐ Never did, and would have difficulty now
- ☐ Normal (as s/he has always done)
- ☐ Never did, but could do now

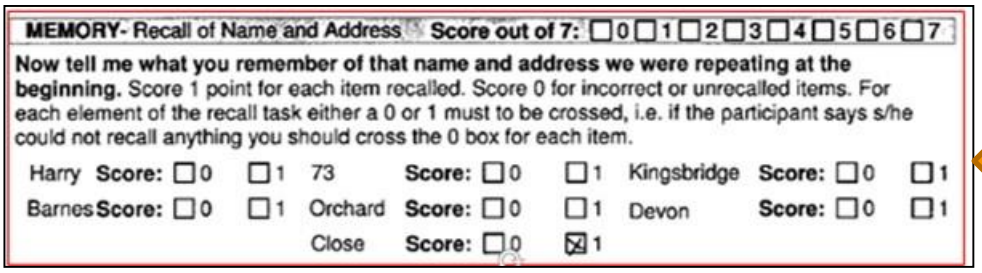
Questions 44 and 46 both have two answers selected when only one answer is allowed. As it is unclear which one is the correct choice, neither of the answers can be used. This means we cannot use the data from this question. In some cases multiple answers will need to be queried with the researcher.

CORRECT CRF COMPLETION

Make sure that only one response is selected

5. Not marking boxes that should be marked

INCORRECT COMPLETION



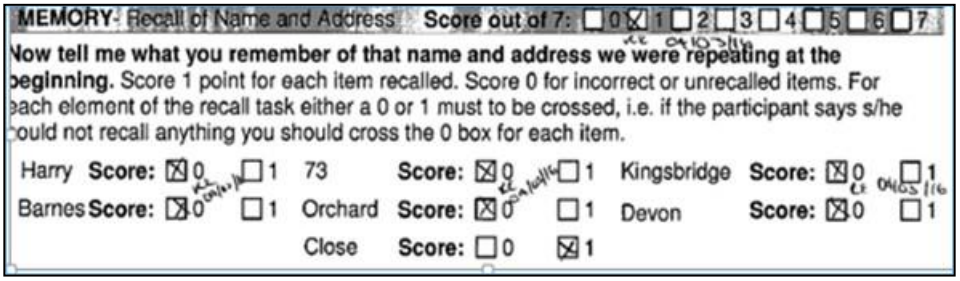
MEMORY- Recall of Name and Address **Score out of 7:** ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

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			

In this example the '0' boxes have not been marked. This is a common error.

CORRECT COMPLETION



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

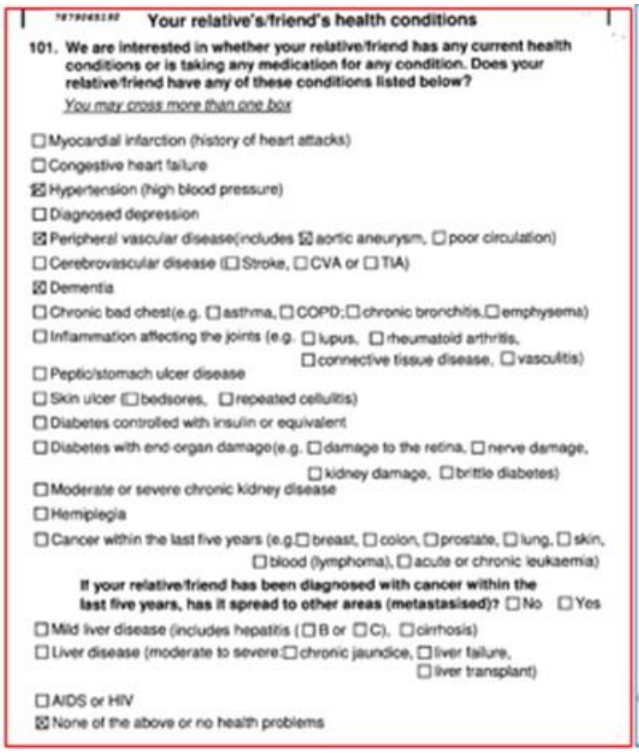
Now tell me what you remember of that name and address we were repeating at the beginning. Score 1 point for each item recalled. Score 0 for incorrect or unrecalled items. For each element of the recall task either a 0 or 1 must to be crossed, i.e. if the participant says s/he could not recall anything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

6. Contradiction

A 'contradiction' where the answers for a question are contradictory; for instance, where there are lists of possible response options and one or more items are selected as well as 'none of the above'. In these examples the error can be corrected by crossing out 'none of the above'.

INCORRECT COMPLETION



Your relative's/friend's health conditions

101. We are interested in whether your relative/friend has any current health conditions or is taking any medication for any condition. Does your relative/friend have any of these conditions listed below?

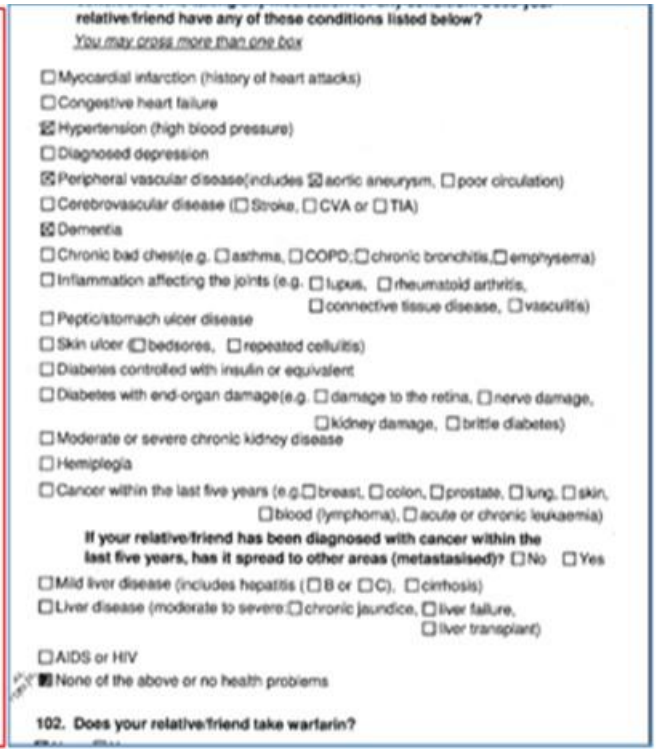
You may cross more than one box

- ☐ Myocardial infarction (history of heart attacks)
- ☐ Congestive heart failure
- ☒ Hypertension (high blood pressure)
- ☐ Diagnosed depression
- ☒ Peripheral vascular disease(includes ☒ aortic aneurysm, ☐ poor circulation)
- ☐ Cerebrovascular disease (☐ Stroke, ☐ CVA or ☐ TIA)
- ☒ Dementia
- ☐ Chronic bad chest(e.g. ☐ asthma, ☐ COPD, ☐ chronic bronchitis, ☐ emphysema)
- ☐ Inflammation affecting the joints (e.g. ☐ lupus, ☐ rheumatoid arthritis, ☐ connective tissue disease, ☐ vasculitis)
- ☐ Peptic/stomach ulcer disease
- ☐ Skin ulcer ☐ bedsores, ☐ repeated cellulitis)
- ☐ Diabetes controlled with insulin or equivalent
- ☐ Diabetes with end-organ damage(e.g. ☐ damage to the retina, ☐ nerve damage, ☐ kidney damage, ☐ brittle diabetes)
- ☐ Moderate or severe chronic kidney disease
- ☐ Hemiplegia
- ☐ Cancer within the last five years (e.g. ☐ breast, ☐ colon, ☐ prostate, ☐ lung, ☐ skin, ☐ blood (lymphoma), ☐ acute or chronic leukaemia)

If your relative/friend has been diagnosed with cancer within the last five years, has it spread to other areas (metastasised)? ☐ No ☐ Yes

- ☐ Mild liver disease (includes hepatitis (☐ B or ☐ C), ☐ cirrhosis)
- ☐ Liver disease (moderate to severe: ☐ chronic jaundice, ☐ liver failure, ☐ liver transplant)
- ☐ AIDS or HIV
- ☒ None of the above or no health problems

CORRECTED CRF



relative/friend have any of these conditions listed below?

You may cross more than one box

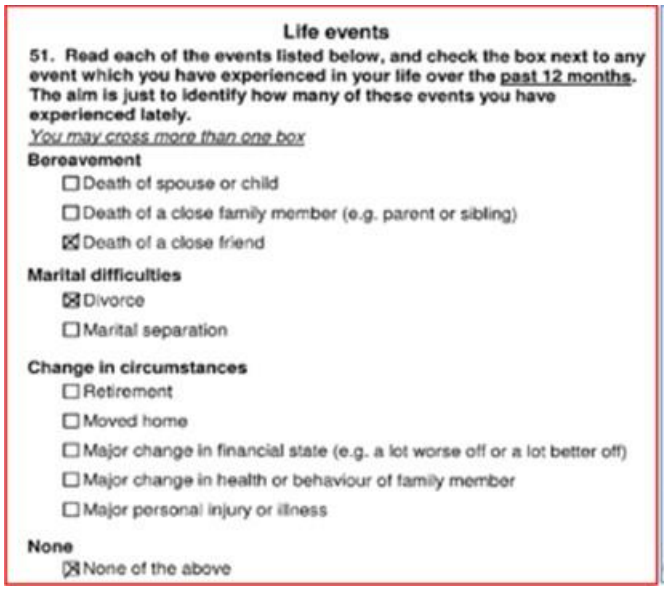
- ☐ Myocardial infarction (history of heart attacks)
- ☐ Congestive heart failure
- ☒ Hypertension (high blood pressure)
- ☐ Diagnosed depression
- ☒ Peripheral vascular disease(includes ☒ aortic aneurysm, ☐ poor circulation)
- ☐ Cerebrovascular disease (☐ Stroke, ☐ CVA or ☐ TIA)
- ☒ Dementia
- ☐ Chronic bad chest(e.g. ☐ asthma, ☐ COPD, ☐ chronic bronchitis, ☐ emphysema)
- ☐ Inflammation affecting the joints (e.g. ☐ lupus, ☐ rheumatoid arthritis, ☐ connective tissue disease, ☐ vasculitis)
- ☐ Peptic/stomach ulcer disease
- ☐ Skin ulcer ☐ bedsores, ☐ repeated cellulitis)
- ☐ Diabetes controlled with insulin or equivalent
- ☐ Diabetes with end-organ damage(e.g. ☐ damage to the retina, ☐ nerve damage, ☐ kidney damage, ☐ brittle diabetes)
- ☐ Moderate or severe chronic kidney disease
- ☐ Hemiplegia
- ☐ Cancer within the last five years (e.g. ☐ breast, ☐ colon, ☐ prostate, ☐ lung, ☐ skin, ☐ blood (lymphoma), ☐ acute or chronic leukaemia)

If your relative/friend has been diagnosed with cancer within the last five years, has it spread to other areas (metastasised)? ☐ No ☐ Yes

- ☐ Mild liver disease (includes hepatitis (☐ B or ☐ C), ☐ cirrhosis)
- ☐ Liver disease (moderate to severe: ☐ chronic jaundice, ☐ liver failure, ☐ liver transplant)
- ☐ AIDS or HIV
- ☒ None of the above or no health problems

102. Does your relative/friend take warfarin?

INCORRECT COMPLETION



Life events

51. Read each of the events listed below, and check the box next to any event which you have experienced in your life over the past 12 months. The aim is just to identify how many of these events you have experienced lately.

You may cross more than one box

Bereavement

- ☐ Death of spouse or child
- ☐ Death of a close family member (e.g. parent or sibling)
- ☒ Death of a close friend

Marital difficulties

- ☒ Divorce
- ☐ Marital separation

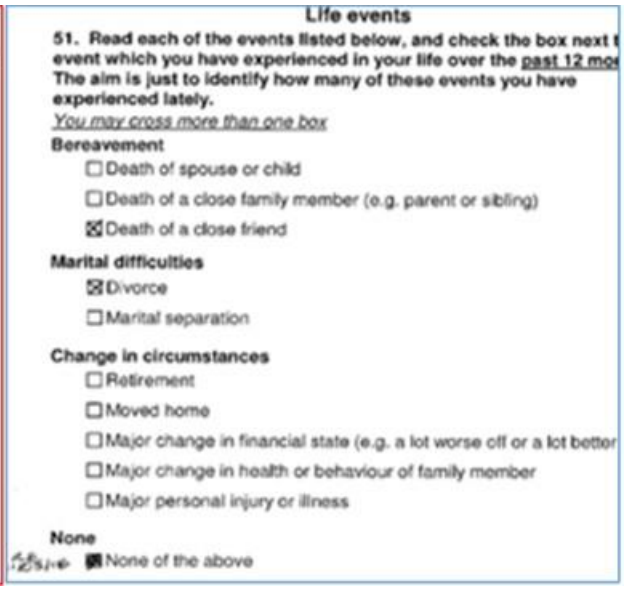
Change in circumstances

- ☐ Retirement
- ☐ Moved home
- ☐ Major change in financial state (e.g. a lot worse off or a lot better off)
- ☐ Major change in health or behaviour of family member
- ☐ Major personal injury or illness

None

- ☒ None of the above

CORRECTED CRF



Life events

51. Read each of the events listed below, and check the box next t event which you have experienced in your life over the past 12 mo The aim is just to identify how many of these events you have experienced lately.

You may cross more than one box

Bereavement

- ☐ Death of spouse or child
- ☐ Death of a close family member (e.g. parent or sibling)
- ☒ Death of a close friend

Marital difficulties

- ☒ Divorce
- ☐ Marital separation

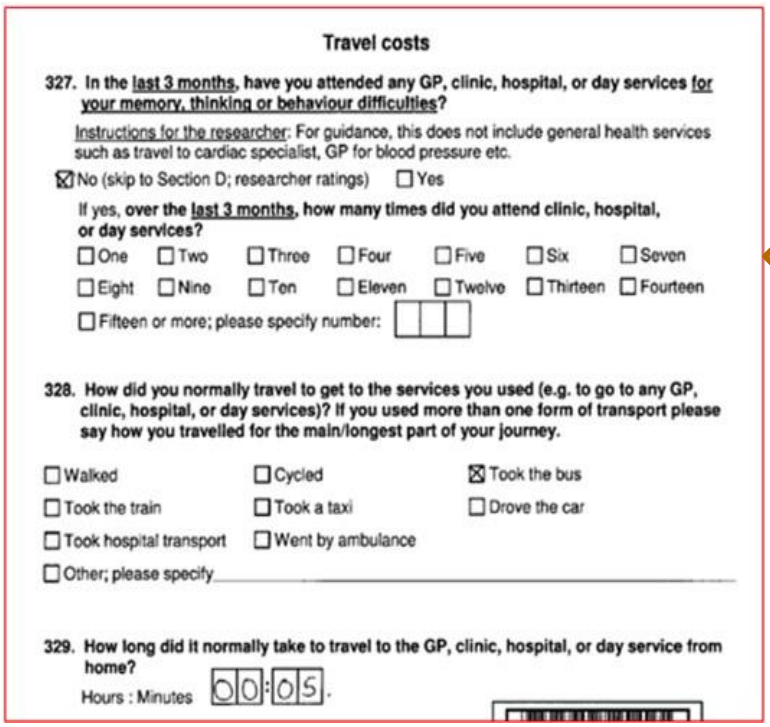
Change in circumstances

- ☐ Retirement
- ☐ Moved home
- ☐ Major change in financial state (e.g. a lot worse off or a lot better
- ☐ Major change in health or behaviour of family member
- ☐ Major personal injury or illness

None

- ■ None of the above

6. Contradictions *(continued)*



Travel costs

327. In the last 3 months, have you attended any GP, clinic, hospital, or day services for your memory, thinking or behaviour difficulties?

Instructions for the researcher: For guidance, this does not include general health services such as travel to cardiac specialist, GP for blood pressure etc.

☒ No (skip to Section D; researcher ratings) ☐ Yes

If yes, **over the last 3 months, how many times did you attend clinic, hospital, or day services?**

☐ One ☐ Two ☐ Three ☐ Four ☐ Five ☐ Six ☐ Seven
☐ Eight ☐ Nine ☐ Ten ☐ Eleven ☐ Twelve ☐ Thirteen ☐ Fourteen
☐ Fifteen or more; please specify number: ☐☐☐

328. How did you normally travel to get to the services you used (e.g. to go to any GP, clinic, hospital, or day services)? If you used more than one form of transport please say how you travelled for the main/longest part of your journey.

☐ Walked ☐ Cycled ☒ Took the bus
☐ Took the train ☐ Took a taxi ☐ Drove the car
☐ Took hospital transport ☐ Went by ambulance
☐ Other; please specify _____

329. How long did it normally take to travel to the GP, clinic, hospital, or day service from home?

Hours : Minutes 00:05

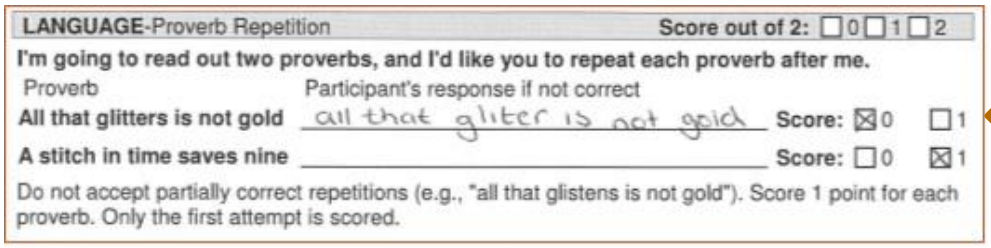
In this example it is not clear how the CRF should be corrected. Q327 is answered 'no' therefore the researcher should have skipped to section D. However, Q328 – Q330 have not been skipped so it is unclear whether Q327 has been answered incorrectly or whether the rest of the section should have been skipped. This error would be queried with the researcher.

CORRECT CRF COMPLETION

Make sure that you follow instructions about skipping questions

7. Not scoring sub-sections of the ACE-III

INCORRECT COMPLETION



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

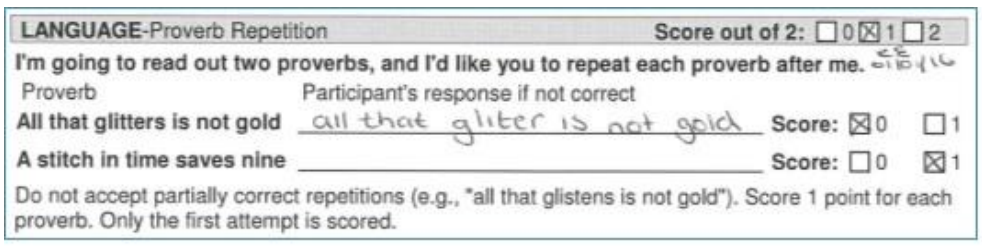
I'm going to read out two proverbs, and I'd like you to repeat each proverb after me.

Proverb	Participant's response if not correct	
All that glitters is not gold	all that gliter is not goid	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.

In this example the sub-score for Language-Proverb repetition has not been provided

CORRECTED CRF



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

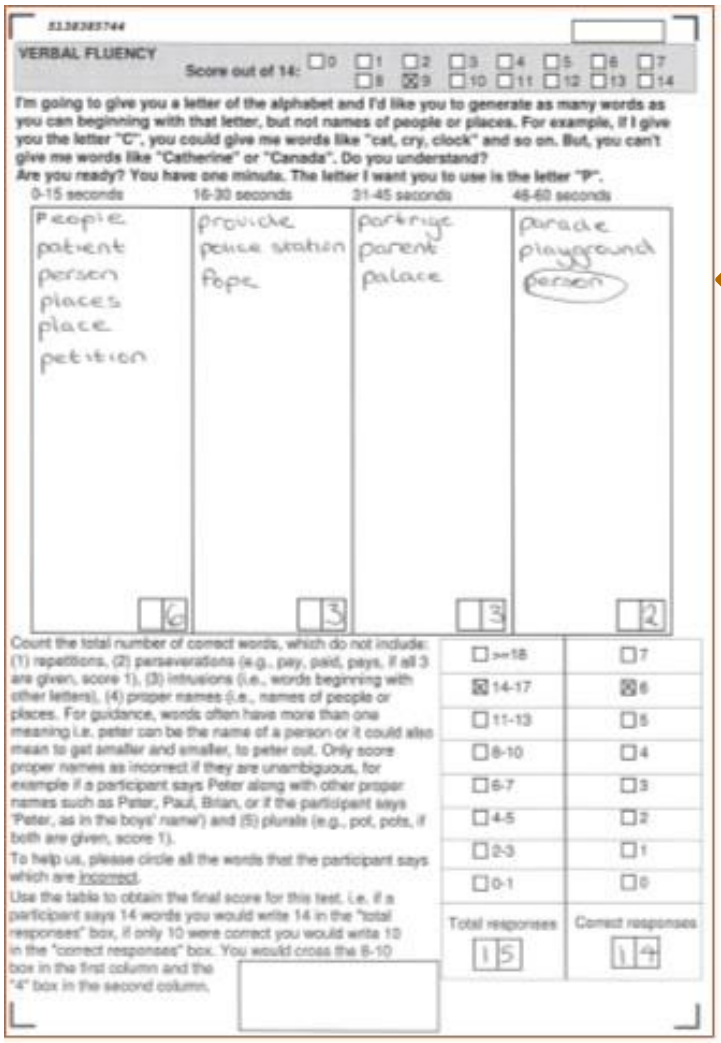
I'm going to read out two proverbs, and I'd like you to repeat each proverb after me.

Proverb	Participant's response if not correct	
All that glitters is not gold	all that gliter is not goid	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.

8. Incorrectly scoring the ACE-III

INCORRECT COMPLETITION



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
People	proviche	parkrige	parade
patient	peuse station	parent	playground
person	Pope	palace	person
places			
place			
petition			
6	3	3	2

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.

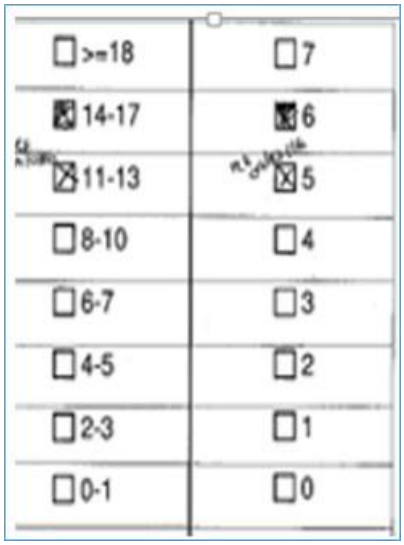
	☐>=18	☐7
	☒14-17	☒6
	☐11-13	☐5
	☐8-10	☐4
	☐6-7	☐3
	☐4-5	☐2
	☐2-3	☐1
	☐0-1	☐0
	Total responses: 15	Correct responses: 14

Often the verbal fluency section of the ACE–III contains errors. In this example 'place' and 'places' were both scored when only one should be allowed (as it is a perseveration). Therefore the score for this section is incorrect and this will impact on overall the total score.

CORRECTED CRF

People
patient
person
places
place
petition

5



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

How can data quality can be improved?

- Please read the instructions carefully when completing the CRFs. These will advise you how many responses are allowed for the question and when you can skip questions
- If participants give more than one answer, please try to 'probe' for detail and select the best answer.
- Please also check the carer's CRFs before leaving the interview.
- Check the CRFs for any completion errors before returning the CRFs for data entry.
- Check the scoring of the ACE-III. The online ACE-III trainer has a calculator you can use to score the ACE-III (https://www.mvls.gla.ac.uk/aceIIItrainer/)

9.6. Specific guidance on the completion of Cognitive measures

This section provides additional guidance on the administration and completion of some of the measures in the CRFs. We have slightly updated the MMSE guidance **[MMSE information removed]**. We have slightly amended the ACE-III guidance and updated the guidance in the verbal fluency subdomain. **Please make sure you are familiar with these changes and corrections.**

9.6.1. MMSE

The MMSE is located in the *Participant Time 3 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 previous time points, 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]

[MMSE information removed]

9.6.2. Test for Severe Impairment

The TSI is a cognitive screening tool for people with more advanced dementia. The TSI was designed to last no longer than 10 minutes.The TSI is located at the front of the Participant Time 3 CRF Part 2.

Guidance on the administration of the TSI

The TSI guidance is unchanged from Time 2, please refer to Chapter 8 (page 75) in the Time 2 handbook.

However, please note that the test is not suitable for people who are colour blind and the authors of the test have recognised this as a weakness. Please consult with the participant and/or the carer to find out whether the participant is colour blind before attempting to administer the test.

9.6.3. 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 3 CRF Part 2*.

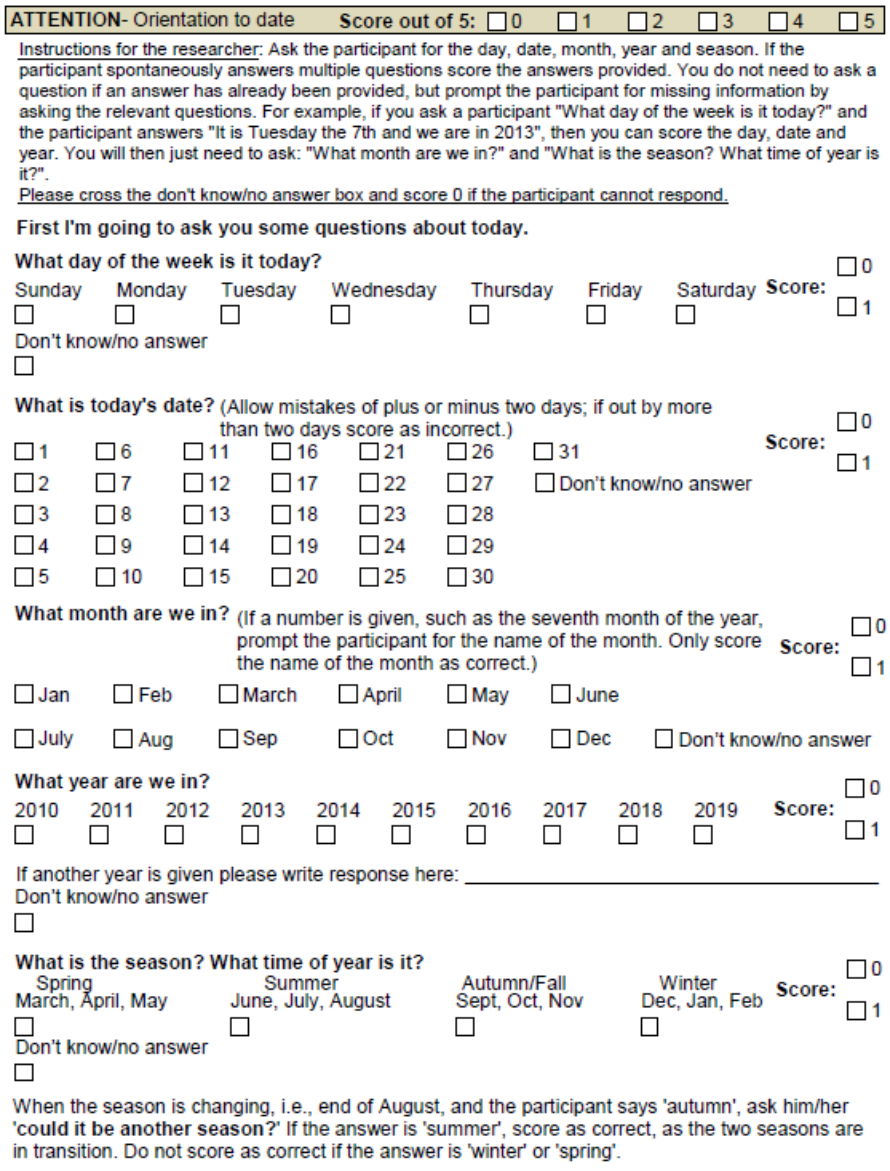
The ACE-III is unchanged from T2. The following provides some scoring or administration hints for commonly seen issues. As at T2 the ACE-III should only be administered to participants if they scored 10 or more on the MMSE.

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?

2010 ☐ 2011 ☐ 2012 ☐ 2013 ☐ 2014 ☐ 2015 ☐ 2016 ☐ 2017 ☐ 2018 ☐ 2019 ☐ **Score:** ☐0 ☐1

If another year is given please write response here: _____

Don't know/no answer ☐

What is the season? What time of year is it?

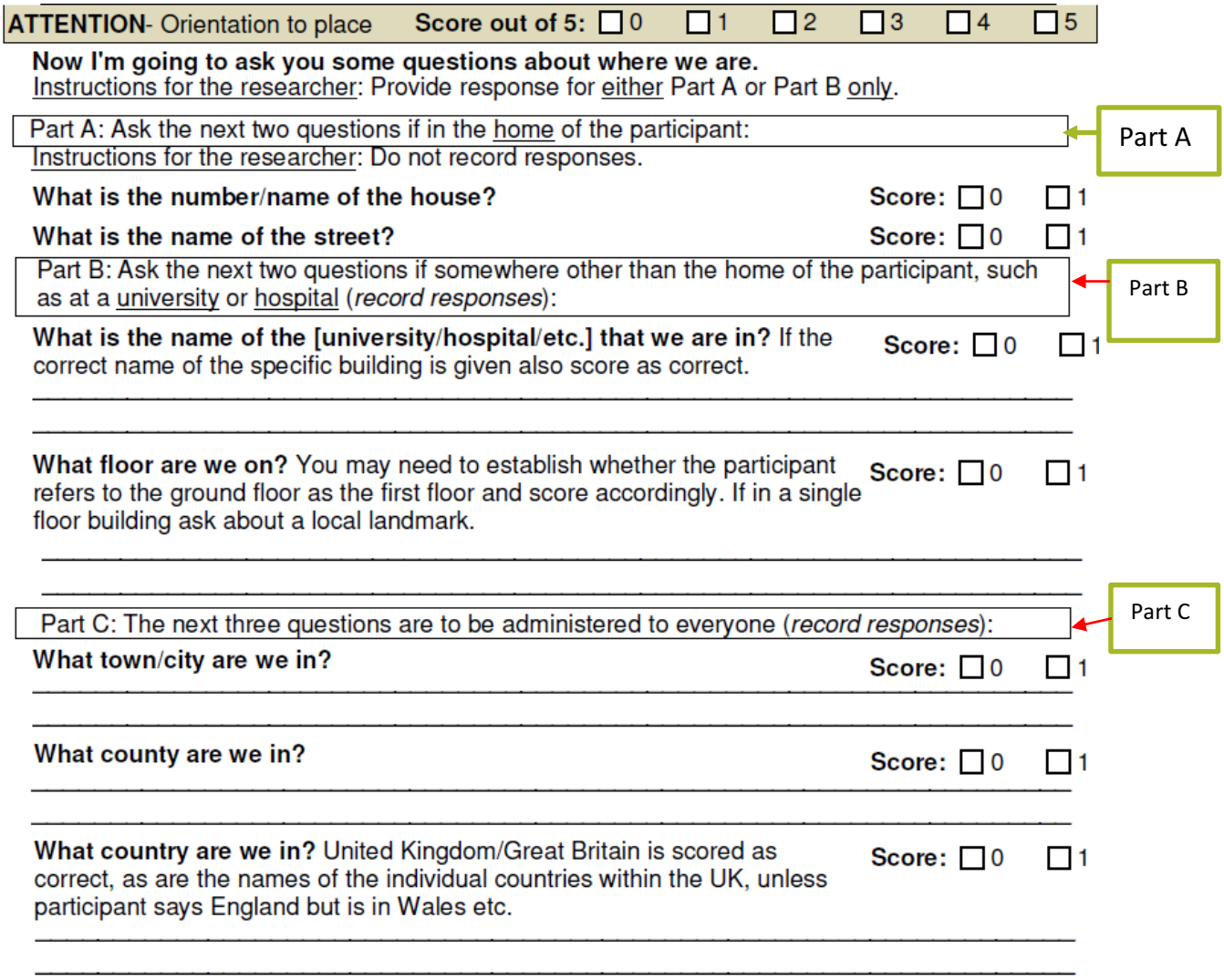
Spring March, April, May ☐ Summer June, July, August ☐ Autumn/Fall Sept, Oct, Nov ☐ Winter Dec, Jan, Feb ☐ **Score:** ☐0 ☐1

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'.

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



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. This continues to be a common error.

ATTENTION- Registration of 3 Items

You need to ask the participant to repeat 3 words

1. Score how many words they got correct on the first trial.
2. If they didn't get all the words correct you can repeat the words up to three times (three trials) to until they either get the words correct OR you run out of trials. You need to record the number of trials.

CORRECT SCORING

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 you would put a cross in the 1 box:

ATTENTION- Registration of 3 Items **Score out of 3:** ☐ 0 ☐ 1 ☐ 2 ☒ 3

I'm going to give you three words and I'd like you to repeat them after me: lemon, key, ball.
After the participant repeats, say: **Try to remember them because I'm going to ask you later.**
Score only the first trial (repeat 3 times if necessary).
Record number of trials needed (i.e. if the participant scored all 3 correct during the first trial you would cross the 1 box here: **cross only 1 box**): ☒ 1 ☐ 2 ☐ 3

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:

ATTENTION- Registration of 3 Items **Score out of 3:** ☐ 0 ☒ 1 ☐ 2 ☐ 3

I'm going to give you three words and I'd like you to repeat them after me: lemon, key, ball.
After the participant repeats, say: **Try to remember them because I'm going to ask you later.**
Score only the first trial (repeat 3 times if necessary).
Record number of trials needed (i.e. if the participant scored all 3 correct during the first trial you would cross the 1 box here: **cross only 1 box**): ☐ 1 ☒ 2 ☐ 3

INCORRECT SCORING

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:

ATTENTION- Registration of 3 Items **Score out of 3:** ☒ 0 ☐ 1 ☐ 2 ☐ 3

I'm going to give you three words and I'd like you to repeat them after me: lemon, key, ball.
After the participant repeats, say: **Try to remember them because I'm going to ask you later.**
Score only the first trial (repeat 3 times if necessary).
Record number of trials needed (i.e. if the participant scored all 3 correct during the first trial you would cross the 1 box here: **cross only 1 box**): ☐ 1 ☐ 2 ☒ 3

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, 78, **71**, **64** three are correct:

ATTENTION- Serial 7 Subtraction **Score out of 5:** ☐ 0 ☐ 1 ☐ 2 ☒ 3 ☐ 4 ☐ 5

Could you take 7 away from 100? I'd like you to keep taking 7 away from each new number until I tell you to stop.
If the participant makes a mistake, do not stop him/her. Let him/her carry on and check subsequent answers (e.g. 92, **85**, 79, **72**, **65** would give a score of 3).
Stop after five subtractions (93, 86, 79, 72, 65)
Record responses: 9 3 | 8 5 | 7 8 | 7 1 | 6 4

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

MEMORY- Recall of 3 Items **Score out of 3:** ☐ 0 ☐ 1 ☐ 2 ☐ 3

Which 3 words did I ask you to repeat and remember? Score 1 point for each correct item.
Instructions for the researcher: Do not prompt the participant for the items.

Cross the boxes for correctly recalled responses: ☐ lemon ☐ key ☐ ball ☐ no answer

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

There is guidance in the CRF on how to score this section.

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

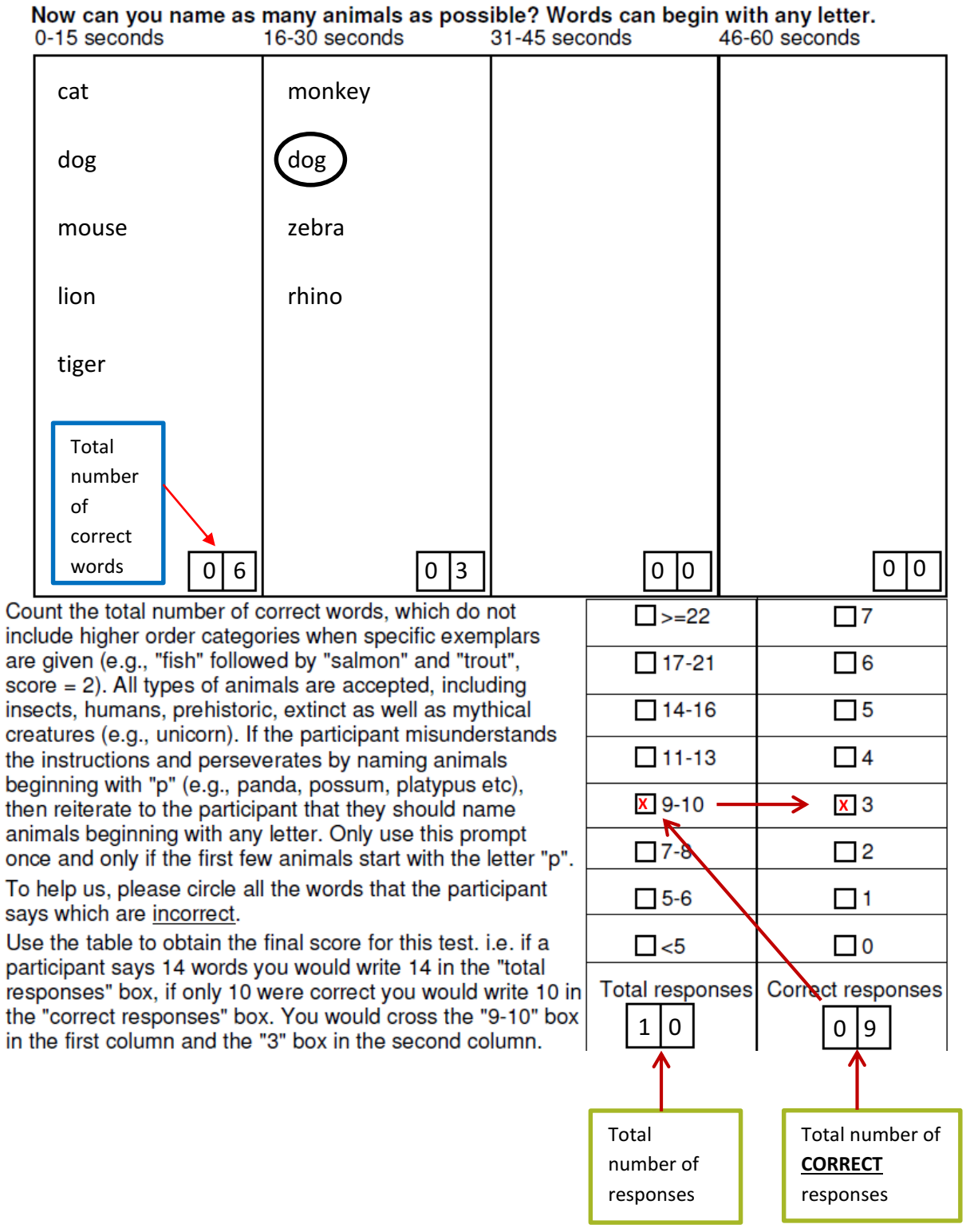
Total number of responses

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; puppy, dog; 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', she/he would score 20 points 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 also score 20. **In the IDEAL Time 2 Researcher's handbook this guidance was incorrect.**

- 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			

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

Please record the score for each command. 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 ask the participant what the sentence says and then 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

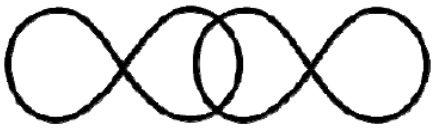
Please make sure that you record incorrect responses in the space provided. Incorrect responses can be recorded as either the name of the incorrect picture or the number, i.e. if the participant said "spoon" for which object is associated with the monarchy you would write either 'spoon' or '1' in the 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

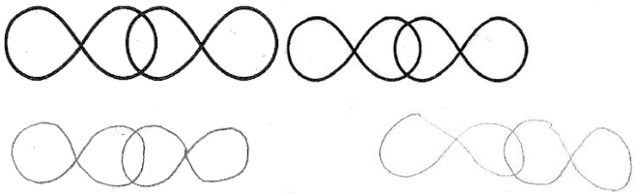
Copy the shape in the space next to it.
A score of 1 is given if two infinity loops are drawn and overlap. Both infinity loops must come to a point/cross and must not look like circles.

Please copy this shape in the space provided

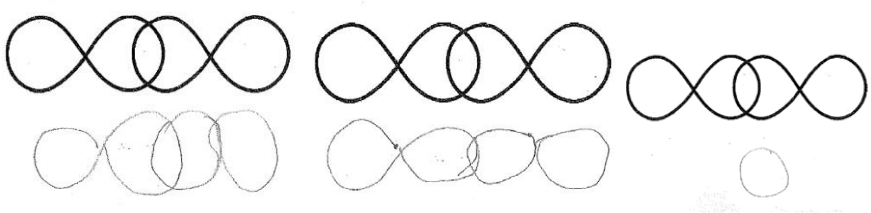


For one point both infinity loops must cross somewhere and they must not look like circles.

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



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

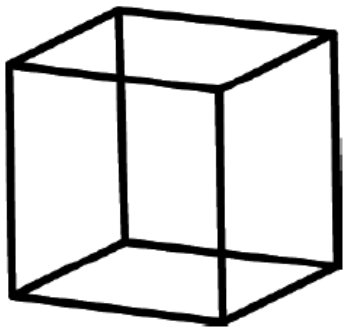


VISUOSPATIAL ABILITIES- 3D Wire Cube

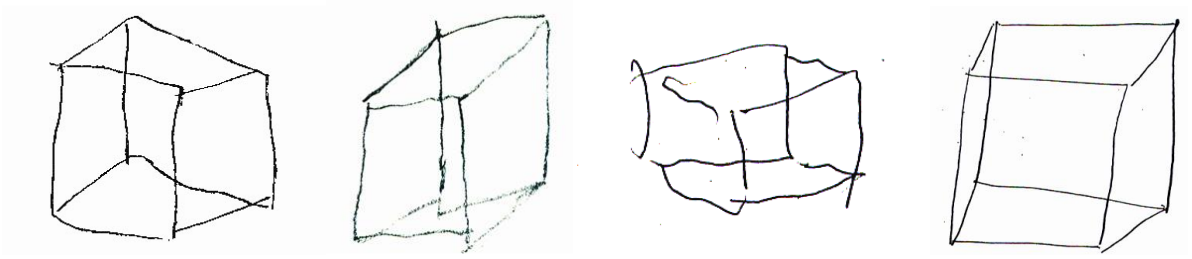
VISUOSPATIAL ABILITIES- 3D Wire Cube **Score out of 2:** ☐ 0 ☐ 1 ☐ 2

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.

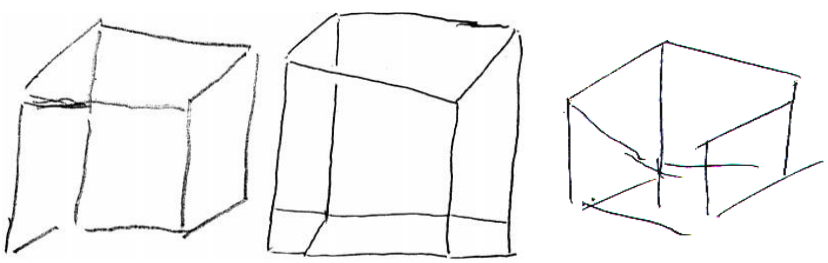
Please copy this shape in the space provided



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 them while drawing.
The following scoring criteria are used to give a total of 5 points (please choose the appropriate number for each of the three parts).

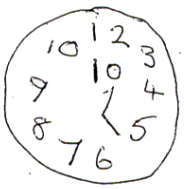
Circle	☐ 1	point maximum if it is a reasonable circle
	☐ 0	
Numbers	☐ 2	points if all numbers are included and well distributed within the circle
	☐ 1	point if all numbers are included but poorly distributed or outside of the circle
	☐ 0	points if not all numbers are included
Hands	☐ 2	points if both hands are well drawn, different lengths and placed on correct numbers (you might ask which is the small and which is the 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	

Make sure you complete the scoring

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

Scoring guide: *Example clocks that scored two*:

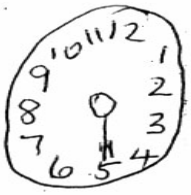
Circle (1); one hand placed correctly (1)



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

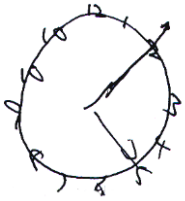
Example clocks that scored three:

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).

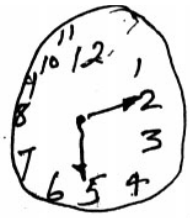
Circle (1), note that numbers are not inside the circle and there are 2 number 10s (0), hands placed correctly (2)



Example clocks that scored four:

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

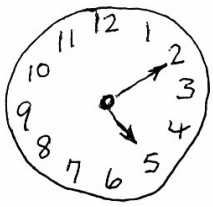
Circle (1); all the numbers but not proportionally distributed (1); both hands placed correctly (2)



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

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		

The zero boxes **must** 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.

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

This item contains extra guidance in the CRF. 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:

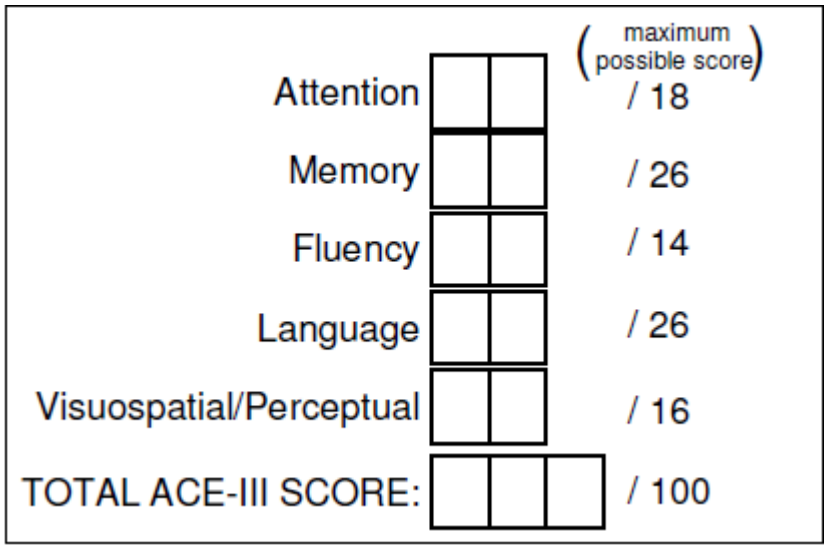
OK, I'll give you some hints:

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. Notice that the "recalled" box is not crossed for "Kingsbridge", the participant recognised this to be the correct answer but she/he did not recall it in the earlier item. 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: 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.



9.6.4. 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). The FAST is located in the *Participant Time 3 CRF Part 1* (Q170-171) and the GDS is located in the *Participant Time 3 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.

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 3 CRF Part 1* Q112-128) and (*Relative/Friend Time 3 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/levels of impairment. Please choose the most appropriate stage/level 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 3 CRF Part 1 there is 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 3 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/levels of the dementia process. Stage/level 1 is considered clinically normal for both measures, while a score of 3 is roughly the least severe stage/level 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 since these participants **do not** have dementia and **should not** be included in the study.

9.6.5. Client Services Receipt Inventory (CSRI)

At T3, 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). Guidance on the administration of the CSRI can be found in **Chapter 8** of the **IDEAL Time 2 Researcher's handbook**. At T3 an additional question has been added to the CSRI**.**

Assistive technologies

Questions 326 – 336, Section C of the Participant Time 3 CRF Part 2
Questions 220 – 230, Relative/Friend Time 3 CRF Part 1

Q326. This question gives examples of assistive technologies such as call blockers, GPS locators and exit sensors.

Call blockers are used to stop nuisance calls. GPS locators built in to portable devices such as wristbands or watches that use satellite technology to help locate people when they get lost (e.g. buddi, Keruve). Exit sensors can be used to notify a monitoring centre if a person has left and not returned to the property within a specified period of time. Also in this question we ask about carbon monoxide and smoke alarms that are linked to a monitoring call centre (please note that people may refer to such monitoring centres as, for instance, 'Lifeline' or 'Careline' call centres). The reason for asking only about 'monitored' alarms is that otherwise we will be recording the use of standard non-monitored smoke and carbon monoxide alarms. So the interviewer should check that if the participant mentions such alarms, they are in fact linked to a monitoring centre.

Assistive Technologies

Now we're interested in whether your relative/friend has received any technologies (you may have heard these referred to as assistive technologies) to help manage his/her difficulties with memory, thinking or behaviour.

Here are some examples of these types of technologies:

- *Exit sensors, bath overflow, smoke or carbon monoxide alarms that are linked to a monitoring call centre (e.g. Lifeline)*
- *GPS locators, mobile phone or smartphone location services, telephone blockers*

220. Has your relative/friend received any of these technologies?

☐ No (skip to question 231)

☐ Not sure

☐ Yes

For each type of technology your relative/friend has received, please do the following:

1. Write down the type of technology in the space provided (e.g. telephone blocker)
2. If the technology was received in the last year, cross the 'received in past year' box
3. Indicate who or which organisation paid for each item. *Please cross as many organisations as apply.*

		Who/which organisation(s) paid for this?				
Write the type of technology	Cross if received in past year	Council	NHS	Voluntary or charity	Self	Other
221.	☐	☐	☐	☐	☐	☐
222.	☐	☐	☐	☐	☐	☐
223.	☐	☐	☐	☐	☐	☐
224.	☐	☐	☐	☐	☐	☐
225.	☐	☐	☐	☐	☐	☐
226.	☐	☐	☐	☐	☐	☐
227.	☐	☐	☐	☐	☐	☐
228.	☐	☐	☐	☐	☐	☐
229.	☐	☐	☐	☐	☐	☐
230.	☐	☐	☐	☐	☐	☐

References

British Psychological Society (2008). *Conducting research with people not having the capacity to consent to their participation: a practical guide for researchers*. British Psychological Society, Leicester, UK.

Hodges, J. R. (2005). *Addenbrooke's Cognitive Examination – ACE-R Revised version. Scoring and Instructions guide*.

[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. IDEAL Follow-up Letter and Reply slip T3 (24 month) v1 200516

Appendix 2. Consent form for participant version 3 050315 24 month follow-up

Appendix 3. Consent form for family member/friend version 2 050315 24 month follow-up

Appendix 4. IDEAL Consent form for paid carer 24 month follow up v2 200516

Appendix 5. IDEAL Participant Receipt of payment Time 3 v1 200516

Appendix 6. IDEAL Personal Consultee Invitation letter 24 month follow-up v1 010515

Appendix 7. IDEAL Consent form for personal consultee version 4 24 month follow-up 200516

Appendix 8. Guidance on assessing people with dementia who have moved into a care/nursing home (adapted from IDEAL Time 3 Researcher's handbook)

[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 s/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 and the personal consultee consent form.

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

Thank you for taking the time to read the information.

[To be printed on Participant Identification Centre headed notepaper]

Yours sincerely

[local research site/network staff/research team]

[ENCLOSE]:
Personal Consultee Information Sheet

[To be printed on Participant Identification Centre headed notepaper]

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

[Date]

Dear [name]

Enhancing active life and living well: the IDEAL study

I am contacting you because you very kindly participated in the previous stages of the IDEAL research study, together with **[name of relative/friend].** I am writing to invite you to consider taking part in the final stage of this study. 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 this 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 earlier stages 12 and 24 months ago. If possible we would also like to talk with **[name of relative/friend],** as we did previously, to gain his/her perspective.

Please find enclosed a copy of the Information Sheet that tells you more about the IDEAL study and your involvement.

[delete as appropriate - 'summary of study for follow-up' form no longer in use at T3]

- Person with dementia (IDEAL Participant information sheet for patient - version 3 - 050315 – Initial)
- Relative/friend (IDEAL Participant information sheet for family member friend - version 2 - 050315 – Initial)
- Paid carer (IDEAL Information Sheet for Paid Carers version 1 050315)

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 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 study, 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: the IDEAL 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:

[To be printed on study centre headed paper]

ENHANCING ACTIVE LIFE AND LIVING WELL: THE IDEAL STUDY

SUMMARY OF THE STUDY FOR FOLLOW-UP

What is the purpose of the study?

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

What is involved?

Participation in the next stage of the study will involve talking with a researcher, filling in some questionnaires and completing some simple tasks as you did in earlier stages of the study. We will also talk with your relative/friend.

Can I choose whether or not to take part?

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

What if something goes wrong?

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

Living well and enhancing active life: the IDEAL study

Contact details form: T3 (24 month) Follow-up

Please complete this form for all participants at T3 follow-up

PRINT CLEARLY

Date: _____

Participant Identification number: _____

Researcher Identification 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 carers/informants 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 <u>personal consultee</u> changed from the previous timepoint?
No _____
Yes _____ **(If yes, please provide the new information below)**
Is this a new <u>personal consultee</u>? 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.)

- **<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