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Practical Tips for Researchers

*Older adults with mild cognitive
impairment & dementia*

*By Professor Andrea Tales
& Professor Tony Bayer*

College of Human and Health Sciences
Coleg y Gwyddorau Dynol ac Iechyd



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First published 2014 by SWANSEA UNIVERSITY

ISBN 978-0-9567462-3-8

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With many thanks to Mary Sansbury who very kindly funded the original booklet.



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Introduction

In undertaking any research the dignity, privacy, safety, comfort and wellbeing of all participants is paramount. This must be addressed and ensured at all stages of the process.

Equally important is the recognition that individuals may have personal needs related to their age, background, culture, general health, or mobility as well as specific needs related to impairment of cognition and/or physical frailty.

The success of research involving such participants is therefore contingent upon the researcher's awareness of such factors and their ability to overcome their potential impact upon the success of the study. It is important, however, not to generalise or stereotype and to recognise each participant's personal needs, so ensuring that they have a positive experience of research participation.

Always be aware that your appropriate conduct as a researcher helps to 'preserve' the participant's enthusiasm for taking part in future studies.

Here we highlight issues many of which may appear simplistic. However, if considered from the planning stages of your study and throughout, they will greatly improve the experience of the participant (and those who may accompany them) and help to ensure the validity and success of your project.

We do not provide formal guidelines for research design or methodology, nor do we approach the issues of Ethics, Research and Development, Consent, Data Protection or Health and Safety legislation. You should liaise with these and other relevant organisations at the earliest point possible in your research plan.





Study Protocol And Design

Initial Steps

When formulating the research protocols necessary for funding, ethics and research and development applications and as the proforma of your proposed study, consider the following:

- Seek advice at an early stage from the clinicians and others who may be assisting you with recruitment.
- Discuss the practicality, feasibility and time scales of recruiting the number of participants required for an appropriately powered study (taking into account the risk of participant attrition).
- Identify any research-related training needs within your group. For example, are there particular issues related to working with older adults and individuals with cognitive impairment or dementia and in the 'informed consent procedure'? Are Disclosure and Barring Service (DBS) checks required?
- Allocate specific roles to members of your team to spread the load, e.g.
 - Lead researcher
 - Assistants
 - Information technology lead
 - Technical support/adviser
- Seek advice from ethics committees via NRES (www.nres.nhs.uk)
- Involve potential participants and their representatives (e.g. Age Cymru, Alzheimer's Society etc.) in initial discussions and throughout the process.
- Produce recruitment 'Inclusion and Exclusion' criteria. If your study involves patients, ensure that such criteria are relevant for any future clinical application of the results.
- With respect to information sheets and written consent forms, consider the possibility that some individuals may be illiterate or unable to write, or have very poor vision; determine how this could be addressed.
- Take into account the general health of the participants. Will potential factors related to mobility, frailty or prescribed and non-prescribed medication bias or inadvertently influence study outcomes, rendering interpretation difficult?

Task and Response Requirements

As the efficiency and integrity of many aspects of information processing vary with respect to age, you need to consider the potential confounding effects of such variation. You might want to ask yourself the following...

- Have you piloted the study with a representative sample of your intended study participants? Can all individuals perform your tasks at the level required for valid statistical analysis and interpretation of the results; for example, with few errors?
- Is the sight, hearing and manual dexterity of all participants at a sufficient level to meet task requirements? For example, the keys on a computer keyboard are often small and thus can be difficult to see and press.
- Are the tasks, related instructions and levels of complexity appropriate for all participants?
- Have you made provision for an adequate practice session? This may be particularly important for individuals with any cognitive impairment. If your study outcome may be affected by practice or number of trials, have you taken into account that individuals with cognitive impairment may require more practice than cognitively healthy controls?
- Do you need to control for age-related slowing of information processing (for example reaction time) when comparing younger and older adults?
- In computer-based tasks, make the mapping of key press to response as simple as possible, i.e., avoid complex rules for assigning a key press to a stimulus.
- If a pen and paper response is required, can the participants hold the pen?
- Have you made provision within the test procedure to remind participants of the task instructions and to allow for the interruption of the task if necessary? Could your study outcome be affected by such interruptions? Consider giving the same reminders and breaks to all participants (e.g. those with and without dementia) to ensure that the procedure is identical.
- Is each trial/session of adequate length, i.e., taking into account variability in thinking time and response speed?
- Bear in mind that some participants may have a limited concentration span and vary with respect to distractability.
- Should you consider introducing a participant refreshment break within your test period? If so, consider the potential effects of caffeine and smoking upon participant performance.
- Does the researcher require a break too?

Sensory Function

- Can the participants adequately see/hear/feel your stimuli under test conditions? Such factors should be taken into account with respect to inclusion and exclusion criteria and included within the participant information sheets.
- Remember to ask participants to bring any hearing aid or glasses. Are hearing loops or magnifying 'sheets' available?
- Have your participants had recent vision/hearing tests? If not, you might need to consider arranging such tests prior to your research session or include them in your protocol. Although extra costs may have to be added to your grant application, such tests will ensure that study outcome is not affected by an inability of the participants to see or hear adequately. Ensure any such tests are included in your ethics and research and development applications.
- Might you need to account, or correct for, individual differences in vision and hearing?
- Might glasses/contact lenses/hearing aids/cochlear implants, cataracts or cataract surgery affect your study outcome? Can your equipment accommodate such factors, i.e., can glasses or hearing aids be worn during testing?
- Speak clearly and slowly. However, make sure you avoid shouting.

General Health

- Do your inclusion/exclusion criteria and/or analysis plan take into account the potential for co-existing medical/health conditions or mental health issues? Have you taken into account any medication (prescribed, over-the-counter, or herbal treatments), other non-drug interventions that participants may be taking, or physical limitations?
- If a testing period occurs over a long period of time, might participants need to bring medication with them? Are there procedures in place in case of a medical issue?
- Do certain participants have specific dietary needs or the need for freedom to eat and drink when they wish e.g. during a test session?

General Mobility

- Does your study protocol/inclusion/exclusion criteria take into account potential mobility issues?
- Is your equipment and venue fully accessible to all?
- Is manual dexterity, fine motor control, or stamina and muscle strength required in order to use your equipment? Might individual differences in such factors affect study outcome?
- Is equipment, such as computer screens, head rests, response pads and chairs and tables, adjustable for the needs of the individual?
- Are there any physical demands associated with your study that an individual might find difficult, such as sitting or standing in one position for a considerable period of time? If so, can your test periods accommodate breaks from testing and/or rest periods? Does your protocol and room booking schedule take into account the time needed for rest periods?



Participant Recruitment

If a clinician is to recruit participants for your study (essential if you are recruiting NHS patients) it is important that they are involved at the design/feasibility stage. Clinicians can provide invaluable information, advice and support. For successful recruitment you and the clinician might want to consider the following issues:

- How will potential participants be identified and approached and by whom, when and where?
- What is the time line for this? Who is allowed to have access to patient records? (NB Initial contact should always come from clinical staff or other gatekeepers).
- Will the clinician realistically have access to enough people to meet the requisite statistical power for your study? Should you aim to recruit via more than one clinician/centre?
- Does the clinician have enough facilities and time to collaborate and recruit over the required study period?
- Can equipment/staffing and other resources cope with the recruitment protocol and timescales?
- What type of recruitment do you require? Is it a convenience sample, consecutive, or random selection?
- Are there procedures in place to control against bias? Should recruitment be performed by individuals other than the researcher in order to avoid potential unintentional biases in testing and outcome interpretation?
- Be prepared for inconsistency in the rate of recruitment. Holiday periods can result in a substantial reduction in the numbers of people recruited or available for testing (plan for the holidays of the researchers too!).
- Allow for participant attrition (i.e., ensure that you can approach and recruit more participants than you will need) to ensure that the study remains adequately powered.
- It is important to ensure that your ethics, research and development approval and funding allow for the recruitment of volunteers until you have tested the number required to fulfil the needs of your study. If recruitment is slow, do you need to apply for a study extension?
- Who will discuss the study with the potential participant (and others if appropriate) and send out information sheets? Who holds the individual's contact details? Should the approach come from the clinician? (NB Researchers should not contact

people directly and non-responders to the initial invitation cannot be contacted unless the ethics approval specifically allows for this).

- If an individual agrees in principle to take part what happens next? Who makes the appointment and liaises between all parties?
- Be aware that your participant may have forgotten consenting to being approached about the study. What do you do if this happens?



Organising Appointments

Contacting Potential Participants

- Do you have all the correct contact details for the participant and any accompanying person in line with Data Protection and ethics approval?
- Where appropriate, has the clinician agreed with the potential participant that you are going to contact them and when?
- How are you going to make contact? By letter or telephone? Remember that some individuals may have difficulty with reading or hearing and understanding, with repetition often necessary. Others may not be able to write notes at speed (i.e. during a telephone call). If appropriate liaise with the individual and family/carer/friend and confirm any appointment made over the telephone in writing.
- Ensure written appointment information is clear and straight forward to understand. Avoid lengthy letters and jargon.
- You might need to consider the potential difficulties in making an appointment with a person who has a significant memory problem. They may forget to write down the appointment or they may place the appointment in a diary or calendar but forget to check them. The study itself may also be forgotten.
- The participant and any accompanying person may appreciate a 'reminder' telephone call the day before the testing session. If they need to bring anything with them (e.g. list of medication, reading glasses, hearing aid, walking aid), then this is a good opportunity for a reminder. Such a call also allows you to check that they are still able to attend and that they are well. Remember that consent is a process and it is good practice to ensure participants are still happy to proceed and not simply too polite to say no.
- Have you contingencies in place if your participant arrives late, early or not at all?

Accompanying Persons

Participants may wish to bring someone with them. If so, you might want to consider the following:

- Ensure that their needs/requirements (e.g. caring responsibilities for children, partners, friends) are taken into account.
- You may need to consider privacy and/or confidentiality issues that may be raised by someone accompanying your participant.

- If your participant has to be alone for testing ensure that both the participant and anyone accompanying them are aware of this in advance.
- Is a chaperone, support-worker, carer, advocate or interpreter required? If so, include this in your protocol, ethics and research and development applications and when planning visits.
- Remember to apply for adequate funding to fully cover transport for both participants and accompanying persons in grant applications.
- If a long waiting time is expected warn the accompanying person of this in advance. Let them know if they are expected to stay for the whole testing period, or if they can go away and come back later.

Individual Requirements

These should be discussed with participants and any accompanying persons when appointments are being made so that they can be in place in advance.

- Does any information need to be transcribed?
- Are there are issues with mobility, or general or mental health that need to be accommodated?
- If participants and any accompanying persons will be with you for more than an hour or two, it is polite to offer refreshments. Check that they are suitable for everyone. Would they prefer to bring their own refreshments?

Venue and Testing Room

- Book well in advance and have a back up venue in case needed.
- Ensure that you are familiar with the venue so that you can inform your participants in advance of its location and facilities.
- Is it signposted and easy to find? Can you provide a simple map, clear instructions and a contact phone number in case anyone gets lost? Put out your own notices if necessary or arrange to meet initially at a very obvious public space such as the main desk or reception area and then accompany your visitors to your testing room.
- Is it accessible for all? Are there stairs to negotiate? If so, is there also a lift?

- Ensure that you know the important/emergency numbers and procedures associated with the site and explain these clearly to your participants e.g. point out the emergency exit. Are tests of fire alarms planned?
- Ensure colleagues know where you are, who you are with and how long you plan to be there if you are working alone. Refer to your institution's lone worker policy for guidance.
- If testing at a participant's home you have less control over the environment. Be prepared to ask if the television can be turned off, for cats and dogs to be under control, etc.
- In the 'testing' room is there enough room for any equipment, researcher(s), participant and any accompanying person? Is there space to manoeuvre a wheelchair or mobility aid? Is the room free from hazards, uncluttered and well lit?
- Is the temperature and ventilation adequate? Is it possible to control these?
- Are there other people near to the testing room who could provide assistance if required?
- Is the room quiet enough for the purpose of your study?
- If the participant needs to be seated during testing ensure that the chair is suitable for their potential needs. Avoid chairs with wheels and very low or soft chairs which are difficult to get in to and out of.
- If participants have to be seated at a table, does the height of the chair meet that of the table? Is there enough leg room under the table; is a foot rest available to aid comfort and stability? Can the table accommodate a wheelchair user? Is there room for you to sit at the table also?
- Be aware that semi-dark or dimly lit rooms may cause disorientation and uneasiness, especially for a person with dementia. Controllable lighting levels are ideal. Be aware that for some studies (of vision for example) variability in ambient light levels (due to lighting or windows) may influence results.
- It may be necessary to have darkened rooms for some studies. Discuss this in advance with the participant and perhaps ensure that, if appropriate, they are not alone in such a room for testing.
- If a person has been wearing an electroencephalography (EEG) cap with associated gels, or have been in a scanner or eye tracker, try and ensure that there are facilities, including a mirror, they can use to tidy or wash and dry their hair before they leave.

Facilities

- Is suitable reading matter available if waiting times are prolonged? Are there refreshment and toilet facilities nearby?
- If delays occur, provide your participants/ accompanying persons access to a phone to inform others if necessary.
- Do you have access to a photocopier/scanner to take copies of consent forms etc. for the participants.
- Do you have someone to help you if needed (e.g. another researcher) so that the participant does not have to be left alone at any point (this may be especially important if the participant has dementia).
- Ensure that if transport is required it can be changed at short notice if necessary and that appropriate facilities are available until the participant has been collected and left the premises.
- Ensure rooms, such as toilets, are labelled. Many doors can be confusing and disorienting for individuals with dementia.

Transport

- Be prepared to take charge of arranging transport for participants and for accompanying persons. Check that it is appropriate for their needs.
- Remember that some individuals will not be able to drive, or may not wish to do so. Plan for funds to be available to pay return transport costs such as car mileage, parking, bus/train fare/taxi fare. Be clear on how these costs are met, the need for receipts and whether participants have to initially cover the costs themselves and then can claim back the costs. Offer to assist with completing claim forms.
- Where possible pay the taxi company in advance or set up an account with them so that payment is not expected from, or left to, the participant. Make sure the participant knows not to pay the taxi.
- For those travelling by car ensure parking details (e.g. locations and costs) are sent out well in advance of the appointment. Are there parking facilities? Do spaces have to be booked in advance by yourself or can the participants just turn up and park. What happens if they cannot find a space?
- Provide information about public transport, i.e., times, cost and nearest bus stop, cycling routes and whether there are covered bike stands.

Time and Date of Appointment

- Make arrangements well in advance and confirm in writing.
- Individuals may prefer to travel outside rush hours.
- Be aware of any routines the participant might follow with regards to their daily life, hobbies and social interaction and with regard also to their care, support, treatment and routine and that of any accompanying persons.
- Be aware that people may have times of the day when they are 'better' than others. The person themselves and/or the individual accompanying them, may have some advice and preferences about this. Schedule appointments accordingly.
- Consider whether your study outcome measure may be influenced by time-of-day effects, sleep patterns or medication schedules.
- Remember that some participants may need to eat/drink or visit the toilet during the testing period. Try to avoid an individual's normal meal times and rest times.
- Testing individuals with dementia may take longer than anticipated. This should be taken into consideration when planning more than one participant test period per day. The participant should not be rushed. Take this into account when booking transport too.
- Remember that people may need to cancel appointments at short notice and that some may not be able to let you know in advance; some factors can be completely out of their control. Have a contingency plan.
- Consider in advance how often you would be prepared to reschedule missed appointments and how you will communicate to participants that you will no longer include them in your study if a certain number of appointments are missed (N.B. this very much depends on the reasons given for missing the appointment, but in certain circumstances it may not be appropriate for the researcher to pursue further appointments).

Testing Checklist

The Day Before

- The participant and accompanying person may appreciate a telephone call to remind them of the appointment. Such a call may also alert you to any changes in the circumstances that may preclude their successful attendance/testing etc.
- Confirm transport details.
- Test all equipment.
- Ensure that you have all the necessary resources and documentation and details necessary for the testing session. List all the things you need to do and the time line for the day.

On Arrival : Meeting and Greeting

- Introduce yourself, thank the participant for coming and check that they are well and happy to continue.
- Check that the arrangements for and the journey itself were OK.
- Be aware that a participant may arrive at the wrong location; perhaps they have misunderstood the directions.
- Do you need to pay the taxi driver?
- Check arrangements for return journey.
- Would they like to use the toilet; don't necessarily ask this directly, you can just point out the facilities. Show them where it is; wait within view if necessary, especially if the toilets are some way from the testing area area.
- Offer to take and store safely any coats, hats, bags etc, but be accommodating if individuals want to hold on to their belongings.
- Offer refreshments if appropriate.
- Would they like to telephone anyone to let them know they have arrived safely and where they are?

- Sit down with them and allow plenty of time to discuss the study and to explain what is going to happen. Allow plenty of time for questions and answers and for completing consent forms and other paperwork.
- In line with your ethics approval, reassure participants that all information given is treated in the strictest confidence, but check your local policy on disclosure, i.e., what to do if a participant discloses certain information.
- If necessary is there a reception and a receptionist to 'meet and greet'? If so, let them know in advance whom you are expecting, when and for what purpose. Ensure that you are contacted when your participant arrives.
- Ensure you leave a message with the receptionist or with the participant if you are held up at all in getting to the reception or to the testing room.
- Have you contingencies in place if participants arrive early, late or not at all?
- Consider a contingency plan in the event of you being unable to attend (e.g. illness) and who can contact participants on your behalf (e.g. your supervisor/colleagues).
- Wear name badges

The Test Session

- Be prepared to repeat instructions in different ways and several times, particularly for the individual with dementia, or cognitive impairment, or poor hearing.
- Allow a practice session. Be prepared for the inability of some participants to complete the tests and the possibility that some will choose at this stage not to continue, or may wish to stop part way through.
- Be aware that during the test session a person with dementia may forget what they have to do, or indeed why they are there with you. Take time to discuss and to answer questions several times.
- Be aware that patients may be anxious about leaving the person they have come with or be anxious about keeping them waiting.
- Be aware that participants may ask for feedback about scores and performance. Does your protocol/ethics take account of this? What can and will you tell them? Is a debrief session included? What will you do if you identify unexpected results that may have clinical significance?
- Do not forget to offer rest periods and toilet and refreshment breaks.

- If a participant becomes upset explain that they can have a break at any time and can also stop and withdraw from the study at any point and without giving a reason.
- Arrange transport and offer debriefing at another time if someone wishes to stop and withdraw. Note down and honour an expressed wish not to be contacted again.

After Testing

- Check that the participant is well. Offer them the chance to relax and refreshments/toilets.
- Check that you have all the information and test results that you require, i.e. that your protocol is complete.
- Thank the participant and accompanying person for attending and taking part. Answer any questions.
- Consider provision of a handout with a clear summary of key points and contact details for future reference.
- Ensure that the participant is aware that they can contact you at a later date if they want further information about the study and to ask further questions.
- Explain what will happen next. Is this the end of their involvement or are there follow up and other stages? Ensure any further instructions have been given in writing.
- Explain what is going to happen with the results of the study. Will the participants be told about the outcome when they are published? Will they get a summary beforehand?
- Ensure they have not forgotten bags, glasses, coats etc.
- Stay with them until transport arrives. Escort them off the premises. Make sure colleagues at the site know that you have finished and that the participants have left the building.
- If appropriate, check that the person has returned home and is well.
- Consider writing to thank the participant and any accompanying persons for taking part.

Make yourself a 'testing' check list; for example...

	Check
<i>Availability/booking of testing room</i>	
<i>Appointment date & time</i>	
<i>Transport arrangements</i>	
<i>All arrangements sent in writing to participant in advance</i>	
<i>Reminder phone call (day before)</i>	
<i>Refreshments arranged/tissues</i>	
<i>Informed colleagues of participant testing: location and times</i>	
<i>Help available for testing if required</i>	
<i>All paperwork in order and available/copy of protocol for you to refer to</i>	
<i>All information sheets and consent forms and similar in a folder and ready</i>	
<i>Check all equipment etc is in place and is working</i>	
<i>Suitable chairs and tables in place</i>	
<i>Have participant contact details to hand in case you need to get in touch</i>	
<i>Someone available to meet and greet</i>	
<i>Receipt book for reimbursement of transport costs</i>	





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