

# ‘Do I have the capacity to make capacity judgements?’ Researcher reflections from a person-centred dementia support study

Dementia

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## Abstract

**Background and purpose:** Adults lacking capacity are under-represented in research; therefore, the evidence-base surrounding their support needs is inferior compared to other populations. Involving this group in research is fraught with challenges, including researcher uncertainties about how to carry out capacity judgements. Whilst ethical guidelines and principles provide overarching guidance, there is a lack of detailed guidance and evidence-based training, incorporating practical ‘on the ground’ strategies and advice on communication practices. Experiences and reflections on research procedures used to gauge and address capacity are under reported, resulting in a lack of shared knowledge within the field.

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**Design:** To help address this, we engaged in researcher (co)meta-reflection on the informed capacity judgement procedure for initial consent, within our current, person-centred dementia intervention feasibility study. Our objective was to identify areas to improve our approach, but to also put forward suggestions for wider change within ethical research practice.

**Results:** Findings reveal challenges and facilitators relating to six areas: ‘Conducting time sensitive research whilst remaining person-centred and building relationships’; ‘Information sharing and supporting communication’; ‘Applying the process flexibly’; ‘The role of the carer and the consultee process’; ‘Judging assent and dissent’ and ‘Researcher related factors’. We questioned our ‘capacity to make capacity judgements’ in terms of both our skills and research time constraints.

**Conclusions:** Based on our experiences, we argue for greater open discussion between researchers, Patient and Public Involvement contributors and Research Ethics Committees at initial project planning stages. We recommend training and guidance focuses on building researcher skills in applying a standard process flexibly, emphasising naturalistic, conversational approaches to capacity judgement. A crucial consideration for funders is how this time-intensive and sensitive work should be factored into bid application templates and funding grants. Learnings from this article have potential to inform evidence-based guidance and training for researchers, consultees, funders, reviewers and ethics committees.

## Keywords

Dementia, research participation, capacity judgement, reflection on research practice, research practice recommendations

## Introduction

Approximately two-million adults in the UK will have significantly diminished capacity to make decisions about themselves at some point in time, because of long-term conditions such as dementia, learning disability or mental health difficulties, and short-term conditions such as concussion and delirium ([Care Quality Commission, 2017](#); [Shepherd et al., 2019a](#)). Instances of reduced capacity for decision-making may have recently increased due to the detrimental effect (through shielding and service closure) of COVID-19 on older people’s physical and mental health ([Shea et al., 2020](#); [Wu, 2020](#)), with a particular decline in wellbeing and cognition for people living with dementia ([Alzheimer’s Society, 2020](#)).

Individuals lacking mental capacity are an under-represented population in research ([Shepherd, 2016, 2019a, 2020a](#)). The evidence-base for care and support for populations lacking mental capacity is inferior compared to other populations ([Shepherd, 2020b](#)), and it is an ethical imperative to make consent procedures as clear, un-biased and non-burdensome for participants as possible ([Health Research Authority \[HRA\], 2019](#)). For those who may lack capacity, this process may be more complicated. Given that individuals included in research should represent the population to which findings will be applied, there is an enhanced need to ensure that this process is as streamlined, engaging, neutrally framed but also as person-centred as possible. Person-centredness involves taking active steps to understand people’s everyday experiences and creating an environment that promotes personhood (e.g. [Brooker, 2004](#); [Dewing, 2008](#); [Fazio et al. 2018](#); [Kitwood, 1997](#); [Mitchell & Agnelli, 2015](#)). Person-centred research practices take account of participant burden, for instance, unnecessarily long, detailed and jargon-filled ‘participant information sheets’ (PIS) can put people off participating before they have contact with the research team ([Lariviere, 2019](#)). In England and Wales, the Mental Capacity Act (MCA; [Department of Health, 2005](#)) outlines the process to follow if an adult lacks capacity to make

a certain decision due to an impairment or disturbance in the functioning of the brain or mind. Sections 30–34 provide broad guidelines for conducting research with adults who lack capacity. A statutory Code of Practice provides guidance on use of the act. This includes guidance on when and how to involve consultees to advise on the values and preferences of a person lacking capacity and whether they would have wished to take part in research had they been able to give consent. Researchers involved in decision-making regarding adults lacking capacity have a legal duty to take account of this guidance. Several authors have provided valuable, person-centred, guiding principles and recommendations for researchers when seeking informed consent in studies involving people with dementia (e.g. [Dewing, 2007](#); [Hegde & Ellajosyula, 2016](#); [Thorogood et al., 2018](#)). However, there is still a lack of detailed guidance on the real-life application of these principles, to help researchers gauge capacity for decision-making during recruitment, for example, advice on effective practical strategies and ‘in the moment’ communication practices.

There are numerous barriers to including adults who lack capacity in research that researchers could benefit from further guidance on. Right from the start of a project, challenges can be encountered when engaging with research ethics committees (RECs). RECs often, perhaps due to their own uncertainty and/or lack of guidance, provide inconsistent guidance and decisions for projects that aim to include those who lack capacity ([Griffiths et al., 2020](#); [Head et al., 2015](#)), potentially deterring researchers from including this population in research.

Another potential difficulty is the degree of information that may be needed to involve consultees for participants who do lack capacity to provide informed consent. Relatedly, the use of consultees can create an ethical dilemma: how to balance the emotional burden acting as a consultee and the ethical objective of enhancing opportunities for those who lack capacity to be involved in research. For example, it has recently become known that those acting as consultees may not have sufficient knowledge regarding legislation governing research with adults who lack capacity and more comprehensive information should be provided to them to enable informed decision-making ([Shepherd et al., 2018a](#); [2019c](#)). There is also often a misperception that the ‘best interests’ principle applies in research as it does in medical treatment, whereas what is required in research is a substitute judgement ([Shepherd et al., 2018b](#)). This lack of understanding may also account for the emotional and decisional burdens expressed by proxies making decisions about research ([Shepherd et al., 2019b](#)). Recently, this problem has been addressed by the development of an evidence-based decision-making tool for consultees ([Shepherd et al., 2021](#)). To enhance the potential of this kind of tool, it would be beneficial to understand more about how researchers can most effectively introduce the possibility of a carer being a consultee in the first instance.

A further barrier is that projects including adults lacking capacity are time and resource intensive ([Shepherd, 2020a, 2020b](#)). In the past, this element may not have been factored into funders’ decision-making processes. Funders, such as the National Institute for Health Research (NIHR), are now supporting research exploring the barriers of conducting research with marginalised groups ([Howard et al., 2015](#)). There is a need to address negative societal and professional attitudes towards the inclusion of adults with impaired capacity in research. Indeed, the US National Institutes of Health (NIH) have amended their ethical guidelines to protect adults lacking capacity *through* research rather than *from* research, adopting the position that they must be invited to participate in research unless there is a scientific justification for exclusion ([Spong & Bianchi, 2018](#)). As highlighted by [Shepherd \(2020a\)](#), funding bodies and ethics boards should have access to educational resources outlining the necessity of including adults who lack capacity in research.

Researchers are also concerned about the subjectivity of capacity judgements and the tensions between adhering to legislation and the principle of non-maleficence ([Fletcher et al., 2019](#)). There appears to be ambiguity around the logistics of administering capacity judgements including the

practicality of the process (e.g. measures to use, researcher competencies and confidence; Fletcher et al., 2019). While the MCA's vagueness around the meaning of capacity in relation to research allows researchers some flexibility, it also limits opportunities for a standardised process, and can cause researchers a great deal of uncertainty. There has been a call for greater knowledge exchange between researchers, sharing both positive and negative experiences of using the MCA to contribute to evidence-informed guidance and training in this area (Fletcher et al., 2019).

This article aims to share some sought after 'on the ground' experiences of researchers who have undertaken capacity judgements. Our objectives are to

1. Share our D-PACT MCA Department of Health (2005) informed capacity judgement procedure, for obtaining initial consent at the recruitment stage, within the context of an inclusive, person-centred recruitment pathway developed for the Dementia-Person Aligned Care Team (D-PACT) project. This was developed iteratively based on literature and practice during feasibility phase.
2. Present honest researcher reflections on the challenges and potential facilitators in using this procedure to make face to face (in-person) capacity judgements of people with dementia. This includes the involvement of carers in the decision-making process, within the pre-COVID-19<sup>1</sup> feasibility phase of the D-PACT study.
3. Widen the knowledge exchange in this area and inform future guidance and training for researchers, consultees, funders, reviewers and ethics committees.

### *Background to the D-PACT study*

The Dementia-Person Aligned Care Team (D-PACT) study is described in Box 1 and is currently at phase 1b.

Consenting to participate in the study entails agreeing to taking part in baseline and follow-up assessment interviews and having conversations with a Dementia Support Worker (DSW) on a regular but flexible basis (depending on support needs). In addition, participants are asked if they would be happy to be contacted during the study to take part in optional elements: a qualitative audio-recorded interview about their experiences of the support intervention and/or having one or two of their conversations with the DSW video or audio recorded. Potential risks and benefits are communicated in writing via a Participant Information Sheet (PIS) and verbally, for example, the potential that the DSW may support people to achieve their personalised aims (benefit) versus the potential for emotional distress to be caused by standardised assessment questions as well as qualitative interview questions (risk).

*Recruitment process.* D-PACT's informed capacity judgement procedure is situated within its larger recruitment process (developed in 2019–2021), which was designed to be closely aligned with

#### **Box 1.** D-PACT study.

The Dementia-Person Aligned Care Team (D-PACT) study is a 5 year research programme funded by the National Institute for Health Research, seeking to develop and evaluate a person-centred complex 'Dementia Support Worker' intervention, based in primary care, across two sites in the South West and North West of England.

Phase 1: (a) initial prospective theory-building in order to develop the intervention and (b) a pilot feasibility study, testing the acceptability and feasibility of the prototype intervention in a small number of GP practices. Through this phase, the intervention continues to be developed and recruitment processes are refined.

Phase 2: A three year randomised control trial, implementing the refined recruitment processes based on 1b and evaluating the intervention.

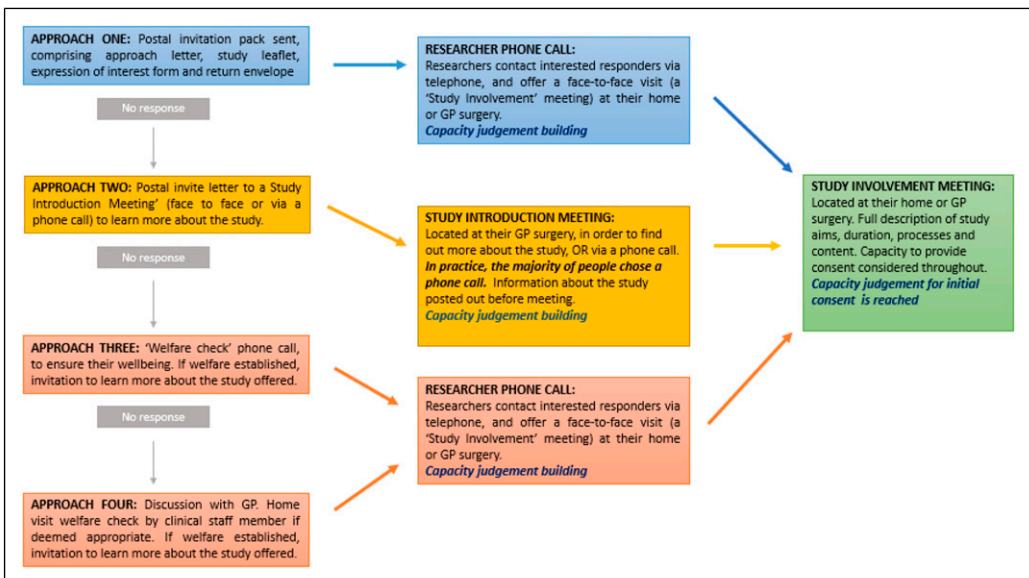
theories of person-centred dementia care. Traditional recruitment methods (e.g. opt-in letters) are often inappropriate for this population, due to many factors including written comprehension difficulties. Consequently, following initial identification of potential participants through GP practice dementia registers, our recruitment pathway includes four staged approaches involving a combination of letters, phone calls and home welfare visits (where appropriate, primarily to identify any unmet needs), at the same time aiming to avoid unwelcome pursuit. Declining to take part at any stage results in no further contact, and involvement requires actively opting in. See [Figure 1](#) for details on the four possible approaches and the points at which capacity judgement becomes relevant. These approaches were embedded within a wider person-centred recruitment approach.

## Methods

In this section, we provide a more detailed account of a specific component of the D-PACT recruitment process: the procedure used for judging capacity for initial consent. While D-PACT researchers have reflected on the project's recruitment process as a whole (recognising that each part affects the whole process), here, we focus on the team's reflections on this specific part of the process. This section also contains details on how we collected, organised, reviewed and reported on our reflections.

### The D-PACT capacity judgement procedure

Lack of a gold standard for capacity judgements ([Lepore et al., 2017](#)) makes objective comparisons of different approaches challenging; therefore, [Pennington et al. \(2018\)](#) advised that combining



**Figure 1.** Approaches within the recruitment process.

opinion (of researchers trained in capacity evaluation, or healthcare professionals) with use of a structured instrument makes for the most robust approach. Influenced by the informed capacity judgement outlined by the Newcastle 85+ project (Davies et al., 2010; Newcastle University, 2006), we developed our own structured procedure for judging a potential participant's capacity to consent to taking part in our feasibility study.

The main aim of the procedure was to judge whether the person with dementia was able to meet the requirements stated in the MCA Department of Health (2005), a key principle of which, is that individuals must be supported to understand information relevant to a decision, retain information, weigh up that information and communicate a decision by any means possible. Where people lack capacity, the procedure allowed for a personal or nominated consultee to be involved in decision-making, based on prior knowledge of the person's preferences and values.

The procedure we developed is outlined in Supplementary Appendix A and consists of a series of opportunities for participants to have main elements of the research explained, ask questions and convey, in their own words, what they understand the research to be about (and what their involvement would mean). Guidance was included for researchers on wording of explanations and questions. It was considered necessary to have this standard procedure in place, to support researchers, and provide a starting point for practice, thereby engendering confidence, but that this procedure should not be used rigidly. Rather, we aimed that the procedure should be flexible, and participant led, with researchers developing their own way of ascertaining capacity through questions or other conversational methods. We knew that we would be adapting this procedure as we went along and were aware that balancing the need for standardisation with our principal aim of taking a person-centred flexible approach would be an ongoing challenge. In fact, although the procedure was written as though a capacity judgement might take place all in one F2F meeting, we quickly recognised that a capacity judgement starts to build from the first telephone call (see Figure 1). This is further explored in 'Reflections'.

Before national COVID-19 lock-down, the capacity procedure, was carried out in 'study involvement meetings' (here on referred to as 'meetings'), where two researchers visited prospective participants (who had expressed an interest in participating) in their own homes or GP surgeries (based on the individual's preference) at a time convenient to them (e.g. taking into consideration personal care, medication and sleep routines). A decision was made to spend a substantial amount of time per meeting (up to 2 hr) to enable a person-centred approach, build relationships but also to be realistic in terms of fulfilling research objectives. We offered to simply share information (though format(s) suited to their needs/preferences), and only proceed with the consent process if people were ready to do so.

*Use of person-centred communication skills.* We aimed to create a relaxed, supportive and empowering space to enable people to demonstrate capacity where relevant and to consider what involvement would entail for them. To this end, we endeavoured to use person-centred communication skills such as sitting face to face, reducing distractions, allowing time, active listening, reducing utterance complexity, presenting one idea/question at a time, avoiding 'why?' questions, using gesture to support understanding, minimising use of pronouns, avoiding infantilising language/tone and conveying sincerity, calmness and kindness through facial expression and tone (e.g. de Vries, 2013; Volkmer, 2013). Person-centred engagement also involved recognising and accepting a person's reality as well as seeing individuals as people first rather than 'someone with dementia' or 'a carer' (Fazio et al., 2018).

## Sample

**Research participants.** Reflections in this article are based on the experiences of using the capacity judgement procedure with 23 participants we recruited during August 2019 to March 2020, when recruitment was paused due to COVID-19. Of these 23, 15 were recruited from Approach One, 5 from Approach Two and 3 from Approaches 3 and 4. Thirteen were judged as lacking capacity (around 57%), for whom a consultee declaration was obtained. All participants had informal carer support, most often from another family member. Eligibility for the study included a formal diagnosis of dementia (regardless of specific type) or significant cognitive problems which could indicate dementia. Eligibility extended to those who had no informal carer support. Exclusion criteria included a high score on the Addenbrooke's Cognitive Examination-III ([Mathuranath et al., 2000](#)), those receiving emergency hospital care or significant levels of secondary care and those in long-term residential or nursing care.

**Researchers.** An experienced team of healthcare researchers carried out capacity judgements. Some had research and clinical experience in neurogenic communication disabilities, and dementia care (LG and SG). Others had valuable transferable skills developed through a professional background in social work (AG) and undertaking research with vulnerable populations (AG, LW and HW). One team member with a background in speech and language therapy (SG) provided basic training in communication and dementia. The majority of capacity assessments in this phase of the study were carried out by two researchers, (AG and LW), supported by other team members. Two researchers attended each meeting allowing time with the person with dementia and carer separately, if deemed appropriate. Subsequent to the consent process, a range of outcome measures were carried out with both the person with dementia and the main carer within the overall meeting.

## Reflective process

We wrote detailed unstructured reflections after consent meetings, aiming to place ourselves and our practices under scrutiny, and transform practice ([Mortari, 2015](#)). 'Researchers, in order to be not mere technicians, but competent practitioners, should be able to reflect in a deep way' ([Mortari, 2015](#), p. 1). With this in mind, we reflected not just on the practical aspects of our research activities but on our associated cognitive processes and emotions. This allowed us to identify unexpected critical situations and reflect on how we would deal with them ethically ([Guillemin & Gillam, 2004](#)). Reflections were discussed within the team on an ongoing basis, and at times led to adaptations to research process. Later, in writing this article, we retrospectively used the written reflections as a basis for discussions amongst the authors, undertaking a process of (co)meta-reflection ([Thorpe & Garside, 2017](#)): reflecting on the original reflections as a group, iteratively and at a deeper level, to derive greater clarity of meaning and crystallise learning. We focused these discussions on transformative practice, identifying key learning points throughout the reflections (described below).

## Findings

This section reports on reflections based on implementing our first draft of the standard consent and capacity procedure ([Supplementary Appendix A](#)). We will demonstrate how ongoing reflections led to changes in how we approached this work, gradually incorporating increased flexibility. Reflections cover six main areas: (1) 'Conducting time sensitive research whilst remaining person-centred and building relationships'. (2) 'Sharing information: balancing ethical requirements with



supporting communication’, (3) ‘Applying the process flexibly’, (4) ‘The role of the of the carer and the consultee process’, (5) ‘Judging assent and dissent’ and (6) ‘Researcher related factors’. Reflections 1 and 2 are closely related and could both be said to relate to the tension between expectations around the research process and a desire to be person-centred. Some insights are supported by real case scenarios, in which we use pseudonyms. We conclude this section with a summary of the main learning points, framed as challenges to capacity judgements and potential facilitators (Table 1).

**Table 1.** Summary of learning points.

Challenges	Potential facilitators
<b>1. Conducting time sensitive research whilst remaining person-centred and building relationships</b>	
<p>Researchers can start to build a capacity judgement through informal conversation. This takes time and researchers face challenges when (a) constrained by the time-sensitive nature or research targets and (b) faced with participants who would rather get all the ‘research tasks’ done (once they know there are research tasks).</p>	<p>Ensuring that the researcher who makes the initial contact (e.g. by telephone), is the same researcher who is present at the first F2F meeting, so that there is continuity and a relationship can start to build.</p> <p>Providing more information to people about the possible advantages and disadvantages of extending the process over two meetings. This may allow people to make a more informed choice from the beginning OR offering two separate meetings (one to cover informed consent and one to cover data collection) as standard.</p>
<b>2. Information sharing and supporting communication</b>	
<p>There are tensions between what is required by the HRA when designing a Participant Information Sheets, addressing the communication needs of participants and research related time constraints. These tensions are exacerbated in a complex intervention development study in which there are many aspects of the research to convey.</p>	<p>Working alongside ethics panels, whilst developing innovative dementia-friendly research information materials. Open dialogue about what is required from the HRA and how it can be adapted to suit the target population</p> <p>Testing out information sharing methods in a feasibility study and making changes throughout, based on ongoing learning</p> <p>Enhanced training and ongoing support for researchers in adapting their own communication skills and using alternative forms of communication.</p>
<b>3. Applying the procedure flexibly</b>	
<p>Although the intention was to use a standard procedure, to increase consistency and give researchers confidence, in practice this created uncertainty and discomfort for researchers</p> <p>A standard procedure runs the risk of people with dementia feeling tested, thereby threatening person-centredness</p>	<p>Developing flexible, person-centred methods of judging capacity. Using naturalistic, conversational methods of observing for capacity to consent to research (researchers need time and support to develop the relevant skills).</p>

(continued)



**Table I.** (continued)

Challenges	Potential facilitators
<p>A standardised procedure may also increase the likelihood of opting for the consultee route It took time and practice to develop skills to apply flexibility</p>	<p>Continued debate on the value of standardised methods of capacity judgement, how they can be used flexibly and how much they can be replaced by implicit, observational methods.</p>
<p><b>4. The role of the carer and the consultee process</b></p>	
<p>Sometimes people with dementia are not as engaged and involved as they could be in the process. This can be because the conversation is weighted towards the carer and/or the carer might speak/answer on behalf of the person with dementia. In these situations, it is difficult to get a good sense of the person's capacity to consent to the research.</p>	<p>Drawing on carers' knowledge of the person with dementia and their communication needs, for example, involving carers in sharing information about the research, asking carers to tell you if they spot signs of fatigue, loss of attention or distress. Using strategies to engage the person with dementia, where the conversation is weighted towards the carer, for example, by saying their name, directing eye gaze/body orientation towards them and verbally signalling who is the expected next speaker.</p>
<p>Introducing the option of using a consultee declaration when the person with dementia has been judged to lack capacity to consent, carries the risk of signalling that the person with dementia has 'failed a test'. This can make it difficult for researchers to broach.</p>	<p>Using strategies to reduce the potential for people with dementia to experience the introduction of the consultee option as a negative evaluation of their competence: framing the informed consent stage as a process requirement; introducing the options of self-consent and consultee declaration as having equal value; and emphasising that the options are there to make it straightforward for everyone to take part.</p>
<p>We have so far only tested our procedure with people who have a main carer participating in the study. We have therefore had no opportunities to learn from situations where carers are unable to support the process.</p>	<p>Developing competence and experience in the capacity and consent process in supporting people with earlier stage dementia who do not have a main carer.</p>
<p><b>5. Judging assent and dissent</b></p>	
<p>Judging assent or dissent demands similarly careful consideration as the consent capacity procedure itself. As part of these judgements a researcher must interpret verbal and/or non-verbal behaviour which can be particularly challenging in this population.</p>	<p>Consulting with carers, drawing on their knowledge and experience of the person with dementia's behaviours to help interpret responses.</p>
<p>For people with advanced dementia, demonstrating behaviours that may or may not indicate dissent to take part in the research, researchers tend to err on the side of caution and exclude them from the research, as is advised in the literature (e.g. <a href="#">Black et al., 2010</a>)</p>	<p>Keeping careful records of the reasons for decisions.</p>

(continued)

**Table 1.** (continued)

Challenges	Potential facilitators
Sometimes researchers are left feeling uncertain about the decisions they have made.	Where cases have not seemed clear cut, discussing the decisions made as a team and reflecting on existing guidance.
<b>6. Researcher related factors</b>	
This work can be tiring, uncertain and emotionally draining for researchers	Having two researchers carrying out the informed capacity judgement procedure together Pairing newer researchers with those who have gained experience Prioritising training, supervision and peer support for researchers doing this work

HRA: Health Research Authority.

### *Conducting time sensitive research whilst remaining person-centred and building relationships*

Spending sufficient time with participants to build relationships, is central to a person-centred approach, particularly with individuals who have dementia (Webb et al., 2020). Unfortunately, the flexibility to conduct frequent and lengthy visits to participants' homes, especially in rural areas, is rarely factored into funding submission timelines. The informal conversations we had with participants could be lengthy and tangential, and it was sometimes difficult to switch focus onto the research. However, we needed to remain mindful that individuals with dementia and their carers often experience loneliness (Victor et al., 2020), particularly in rural areas of the UK such as the South West (Rural England, 2017). Although time-intensive, these conversations provided vital opportunities, not only for relationship building. Informal observations of potential participants' comprehension, expression and recall abilities provided crucial contributions to our ongoing capacity assessments. Therefore, we valued opportunities to make social connections with potential participants, including connecting over tea and biscuits. We also ensured that the same researcher maintained contact with potential participants throughout the recruitment pathway wherever possible.

#### **Box 2.** Case scenario.

Gloria, a woman with dementia lived with her family member Graham. Throughout the meeting Graham wanted to take time to discuss both of their personal circumstances, concerns and issues that he hoped would be supported through the intervention. Progressing onto the consent and capacity judgement procedure was interspersed with informal conversation, and as a result, Gloria became fatigued and lost concentration. We offered to return another day, but Gloria expressed a desire to do all the necessary research tasks in one sitting. We wanted to respect her wishes but were concerned for her wellbeing and aware of our two-hour time limit, imposed for ethical reasons. Balancing the need to complete research tasks, respecting Graham's need to talk, and protecting Gloria's welfare was challenging. A second visit was declined by the couple, so we did not complete all necessary questionnaires, resulting in missing data. Prioritising pressing tasks may have resulted in more research tasks being completed before fatigue set in but developing a shared understanding of prospective participants' circumstances (and through conversations, observing for contributions made by the person with dementia) is also an integral part of judging capacity and providing sufficient opportunity to consider study involvement.

Nevertheless, we found achieving a balance between creating a person-centred experience, while also meeting time sensitive research deadlines, challenging. In the interests of participant welfare, the D-PACT protocol limited visits to a maximum of two hours and, although participants were provided with the option of splitting capacity judgement/consent and data collection into two sessions, most participants expressed the desire to have only one. This led to some participants becoming fatigued and unable to complete the outcome measures. It also meant that researchers needed to make early decisions about capacity levels. Box 2 highlights these issues.

Person-centred adaptations, which we offered to aid capacity (e.g. using communication tools, consistency with researchers, working around care routines and using observational methods to gauge capacity) can lengthen the research process, leading to sessions running over time or data not being collected. On reflection, we could have provided participants with more information about the possible advantages and disadvantages of splitting the process over two meetings. We could also have completely adapted our process so that two separate meetings (one to cover informed consent and one to cover data collection) were offered as standard. Due to Covid-19 and the pause in the study, we did not have the chance to implement this adaptation to our F2F recruitment process.

### *Information sharing and supporting communication*

Just as observations made during ‘getting to know you’ conversations enable researchers to start developing capacity judgements, sharing information, and observing how people respond to and interact with that information, enables researchers to build on their capacity judgements. Where people have communication difficulties (affecting verbal and/or written comprehension, speech and/or expressive language), every effort should be made to find ways of adapting communication, so that they might understand information, retain it, weigh it up and communicate a choice about it (MCA, [Department of Health, 2005](#)), before judging they lack capacity.

#### **Box 3.** Case scenario.

Sam, a man with dementia, lived with his friend, Annie. At the time we were following our original procedures, sending the short study information sheet via post ahead of our meeting and then reading through the full information sheet together. The researcher sat with Sam to go through the sheet. Very soon it was clear that this would be too burdensome for him. Despite efforts to avoid rushing, highlight key elements and adapt communication to suit his needs, he had difficulties attending and quickly became fatigued. Adhering to the ethical requirements of the study, by trying to ensure people have opportunities to understand information, weigh it up and make a choice, in this way, was having a detrimental impact on his level of engagement and our ability to adequately judge capacity.

By contrast, we were using our updated procedure by the time we met with Sally, a woman with dementia, who was living with her daughter Maria. We sent both the short and full information sheets ahead of meeting them both, so they would have time to process and consider the contents. As a result, when we arrived at the meeting Maria had already talked through the study with her mother and they had prepared some questions for us to support a complete understanding. The meeting thus became an opportunity for clarification and further consideration of participation, rather than an on-the-spot ‘immediate recall’ scenario. The capacity judgement procedure was not as time-consuming, and Sally was able to remain engaged and alert throughout.

Neither Sam nor Sally were able to demonstrate that they could use the information presented to communicate a decision about participation, and therefore were not deemed to have capacity to consent to involvement in the study. Both did progress with participation through the consultee route. However, we considered that the experience of the study involvement meeting was much more relaxed and productive when the bulk of information had been provided in advance. It resulted in less risk of fatigue or distress, provided more opportunity for carers to be involved in the process and increased opportunities for a person to be able to demonstrate capacity.

It has been challenging to balance the ethical need to support communication through the recruitment process, with the time-sensitive nature of research, and HRA guidance on what research information needs to be conveyed to enable people to make an informed decision. Ennis & Wykes (2016, p. 4) observed that the HRA provide “...*only vague guidance on the drafting of information sheets*” and that information sheets have become longer and more complex over time; a possible reason being risk aversion’. We were recruiting for a complex intervention development study with many components and as a result our PIS was lengthy. Aware that this was far from ideal, we produced an additional shortened PIS which was posted prior to the meeting. In an attempt to support communication, we initially planned to go through the full PIS with potential participants face to face. However, we quickly realised this placed too much burden on participants, given the amount of information included. Therefore, we amended our approach, by offering to send the full PIS in advance of the meeting, so that carers and/or people with dementia would have the opportunity to read its contents in their own time, multiple times if wanted. This provided prospective participants the opportunity to think over their potential role in the study, and more opportunity to have things explained by, and consider uncertainties with, family members without researchers present. Subsequent meetings were then less formal, took less time, and individuals seemed more relaxed knowing that discussions about the research could centre on key areas of uncertainty rather than the whole study. Box 3 illustrates the impact of these changes.

However, we were keen to do more to aid communication and reduce fatigue and burden. With the support of our Patient and Public Involvement (PPI) contributors, we developed a dementia-friendly information tool with images illustrating three key elements of the research, to support researchers’ capacity judgements, particularly when talking to individuals with moderate dementia, where capacity was less evident. The idea was that the researcher would talk through this visual tool, rather than either PIS, pointing to the pictures if this was judged to enhance comprehension. There would be a series of opportunities built in, for potential participants to receive explanations of the three key elements of the research and to demonstrate understanding of those elements. Researchers would look for both verbal and non-verbal signs of comprehension and base judgements on these informal observations. As recall would likely influence capacity judgements, it was intended that the tool would be used as a conversational ‘prop’; a reminder present throughout the meeting.

Despite these ambitions for the tool, it proved difficult to know exactly when and how to introduce it into this research meeting, how to explain its purpose and how to best use it. On reflection, although there was initial training in communication strategies, it would have been beneficial to incorporate enhanced ongoing training and support for researchers. The introduction of a tool to support communication is never a simple intervention, no matter how low-tech (Moorcroft et al., 2019). Researchers need time to develop skills in identifying who the tool may help, as well as how to use and adapt it. We developed valuable communication strategies as we gained experience and confidence. However, further training in alternative communication would have enhanced our practice, enabling us to adapt our own verbal/non-verbal expression and use alternative methods of communication spontaneously (e.g. gesture, writing down key words and drawing) to support comprehension (including for those with hearing difficulties), and decision-making.

Information sharing is difficult to get right for this population yet forms an essential part of the capacity judgement procedure. The work of balancing information accessibility with adhering to ethical requirements is inevitably unique to every study and the kind of concepts needing to be conveyed. Therefore, we found it valuable to be able to test this out in a feasibility study and make changes throughout. For the future, we have learned that we should try to work alongside the ethics

panel whilst developing innovative and accessible research information materials. We may have assumed certain HRA requirements, and ethics panels do not necessarily know about dementia-friendly formats, so joint work and open conversation between the research team, the ethics panel and our PPI contributors from the start would be beneficial.

### *Applying the procedure flexibly*

Even for experienced researchers, judging capacity requires a very specific skill set, not easily and quickly acquired (for instance through online learning). Consequently, we initially found we followed the procedure more rigidly than intended and it took some time to develop confidence to apply the procedure flexibly. Having shared key information, we asked participants to express their understanding of what participation would involve, however, the abstract nature of the request led to confusion for people with dementia. We tried to put individuals at ease, explaining that our questions followed study requirements and were not intended as a ‘test’. Nevertheless, being ‘put on the spot’ inhibited people from demonstrating the true extent of their capabilities. Some people would convey a wish to help with the research even if they did not demonstrate a full understanding of what that might entail, for example, saying *‘well, they might find out what helps people with dementia’*. Having a standard procedure, to be used flexibly, was intended to empower researchers and give them confidence, but in our post-meeting discussions we reflected on how it had the opposite effect. We felt uncertain about how to apply the procedure flexibly; uncomfortable about seeming to test people we wanted to build a relationship with and lacking in confidence over the reliability of our capacity judgements.

At times, our personal and professional desire to maintain person-centredness felt at odds with our perceived need to adhere to the specified procedure and meet professional requirements around receiving valid informed consent. Over time and through team discussions, our application of the procedure shifted. As we became more skilled, our procedure became more implicit. We would integrate observations from initial phone calls, with the interactions happening in the moment (informal conversations and discussions about the research) in order to make a capacity judgement. Our approach became more naturalistic, building in conversational questions that allowed us to inform our judgements without alarming potential participants that they were being judged. For instance, after explaining the research, we might try to elicit general conversation about research. For example, (after explaining the study) we might ask questions such as: *‘What do you think about that?’ ‘Are there any bits that sound interesting?’ ‘Is there any of that you’d like to get involved with?’ ‘Are there any bits that worry you?’ ‘Have you taken part in research before?...I’d like to hear more about that’*. This allowed us to observe whether responses were on topic and coherent, to elicit further conversation that related to the current study, and from this to get a sense of whether people broadly understood what the research was about. For instance, one participant, when asked what she thought about what she had been told, said she thought the videoing sounded *‘OK, but I’ll have to make sure I’ve brushed my hair!’* which indicated to us that she had grasped the concept. We followed up with further discussion about the purpose of using video-recorded data and asked whether she had been recorded before. As this led to a conversation about relevant experiences, we felt confident she had understood this element of the study and were able to go on to explain how the data would be used and protected.

We reminded ourselves that the capacity judgement is always going to be subjective, and that it must be made on the balance of probabilities, that is, is it more likely than not that the person lacks capacity? (MCA [Department of Health, 2005](#)). It is important to keep records detailing why certain decisions have been reached, and this is more difficult when the procedure has been implicit, but it is

**Box 4.** Case scenario.

Evelyn, Jacob's wife, was particularly actively involved in the information sharing process. She conveyed the main elements of the information sheet to Jacob, emphasising aspects she felt would be most important to him. She was also active in supporting Jacob to provide the information we were asking for, not by telling him what to say, but by finding ways of rephrasing the question so he could better understand. The warmth and trust of the relationship, and her understanding of his values, preferences and communication abilities, meant she was able to ask the questions in highly adapted ways that we, as unfamiliar researchers, were not as well equipped to do. As a result, Jacob was able to self-consent.

not impossible. As Fletcher et al. (2019) noted, attempting to objectively measure capacity is challenging. Formal procedures, while useful in attempts to introduce standardisation, may increase the likelihood of researchers opting for the consultee route. Our early experiences would support this finding and may have resulted in the use of consultees as opposed to enabling people to consent for themselves in a few cases. Through ongoing discussion and experience, we were able to build in flexibility, which seemed to improve the experience for researchers and participants alike. The team continues to debate how best to balance a person-centred, flexible approach with consistency and standardisation. An element of standardisation will always be necessary, to ensure adherence to universal ethical principles, prevent people being consented inappropriately and alleviate researcher uncertainty.

### *The role of the carer and the consultee process*

We were alert to the relational dynamics of the conversation. We used to our advantage, the fact that often carers are often very 'tuned in' to the communication needs of the person with dementia, and skilfully support their involvement by simplifying information and using shared knowledge to put things in context (see Box 4). In addition, carers can spot signs of fatigue or loss of attention before researchers, so we found it helpful when they voiced these observations, allowing us to tailor our interactions accordingly.

Sometimes, however, conversations would be weighted towards the carer, and the carer might (often with the intention of reducing burden) speak/answer on behalf of the person with dementia. In these situations, it can be difficult to get a good sense of the person's capacity to consent to the research. We used strategies to try and re-engage the person with dementia, such as seeking their perspective by using their name, directing eye gaze/body orientation towards them and verbally signalling who the expected next speaker should be, for example, '*What do you think George (the person with dementia)?*'

In addition to supporting their family member through the process, 13 carer participants also acted as consultees. We experienced uncertainty about how to shift the conversation to the possibility of consultee involvement, once it had been judged that the person with dementia lacked capacity to consent. We did not want the person with dementia to feel they had just failed a test. This uncertainty reduced as our skill and flexibility increased, and as we became more able to judge capacity based on informal judgements (rather than explicit questions). We developed other strategies for limiting the risks that our move into talking about the consultee option might appear as a negative evaluation of peoples' competence. For example, we framed the whole informed consent stage as a research-specific procedural necessity before moving on to outcome measures/questionnaires e.g. '*It's part of the University's procedures that we have to have a record that you've agreed to sign up to the study and what that involves*', we introduced the options of self-consent and consultee-consent as having equal value e.g. '*It doesn't really matter*

which option we go for, because your involvement will be the same in the study whichever way we do this'; and emphasised that the options are there to make it straightforward for everyone to take part e.g. 'The important part is that you'd like to take part. Sometimes the paperwork can be a bit of a hassle, so some people find it easier to have one person complete the paperwork on behalf of both of you'.

In most cases, cognitive screening scores (completed post-consent), supported the decisions, although there were a small number of discrepancies. For example, one person for whom a consultee was involved had one of the highest Addenbrooke's Cognitive Examination-III (Mathuranath et al., 2000) scores of our participants (indicating less cognitive impairment). On reflection, had we had more time to get to know him, we may have pursued the self-consent process a little more determinedly. However, thinking across all our cases, we believe the collaborative approach we took within the meetings contributed to the decisions we arrived at being acceptable to all our participants and their carers/consultees.

Despite wanting to include people without a main carer in the study, to date we have only recruited dyads. Given that carers have been crucial in supporting people with dementia to participate in our research, we are keen to explore the efficacy of our capacity judgements with a person without a main carer participating.

### *Judging assent and dissent*

When a person is unable to self-consent, the researcher should still seek assent and respect dissent (to participating in research related activities), where the researcher judges that the person is indeed able to indicate these opinions and exclude those who dissent from the research (Black et al., 2010). To do this, the researcher has to judge whether the person can express or indicate a meaningful choice. This adds another dimension to the complex decisions researchers must make, contributing to the overall ongoing, evolving process of judging capacity. Sugarman et al. (2007) observed that people with dementia are more likely to respond positively (verbally and non-verbally acquiescing) to research involvement than carers, thus highlighting the need for careful judgement.

Assent is defined by Black et al. (2010, p. 4) as '*an affirmative agreement to participate as expressed verbally (i.e. orally) or a non-verbal indication of willingness to cooperate with study procedures*' and ensures that the views and wishes of all participants, including those judged to lack capacity, remain at the forefront of decisions around research participation. However interpreting people with dementia's verbal and/or non-verbal behaviour can be challenging and judging assent or dissent demands similarly careful judgement as the consent capacity procedure itself. Black et al. (2010) provide further guidance regarding what might constitute assent, suggesting it can be

#### **Box 5.** Case scenario.

Minnie's dissent required careful discussion with her husband Chen, who could be described as her partner and primary carer. Carers are often described as being gatekeepers to research involvement, and may protectively inhibit their loved ones' involvement in research (e.g. Hellstrom et al., 2007), but in this situation, Chen was keen to participate in the study in the hope of accessing much-needed support. Through the course of the meeting, we came to the conclusion that Minnie did not have capacity to consent and were pursuing the consultee route. Early in the visit, Minnie presented as reserved, sitting quietly and responding to direct conversation. However, when one researcher was going through the consultee document with Chen, Minnie was chatting with the other researcher about meeting a Dementia Support Worker, and at this point she clearly indicated she would not like this. Chen was still keen to participate, but we discussed the importance of assent, Chen acknowledged Minnie's dissent, and we agreed we should not progress, to Chen's great disappointment. We felt really disappointed for Chen, but at the same time, sure that we had followed all available guidance and acted ethically.



conveyed verbally, behaviourally or emotionally (e.g. through facial expression). In line with this advice, we were mindful of the range of responses to our communications, including non-verbal response cues. We experienced a wide range of ability to assent or dissent during meetings with potential participants. In the early stages of implementing the capacity judgement procedure, a couple of people were unable to self-consent, but could give clear verbal assent. This later made us wonder whether they could have self-consented with a less time-constrained approach that did not require recall of key study details on the spot.

In other cases, people's verbal and non-verbal communications could be more difficult to interpret. Reviewing levels of assent/dissent was continual throughout our meetings. We were aware signs of disengagement could occur for a myriad of reasons including unmet needs, fatigue or attention difficulties. In our case, these kinds of disengagement signals might occur at any stage of the interaction, when discussing aspects of the project, or during times of general conversation (see example in Box 5).

In some circumstances, where there was minimal or inconsistent engagement throughout the meeting, assent or dissent could be difficult to assess. In these situations, we would consult with the carer, drawing on their knowledge and experience of the person with dementia's behaviours to help interpret responses. However, we found it particularly challenging to try to disentangle the cause of any signs of distress with people with more advanced dementia. In these situations, we looked more for an absence of distress, (for example, was our presence in their home accepted by them?) and would respond to any signs of distress conservatively, by not recruiting them. We kept records of the reasons for our decisions and reflected on these together, especially where cases had not seemed clear cut. This helped us to feel more certain about our decisions.

### *Researcher related factors*

While we enjoyed meeting and working with all participants, we found even the most straightforward sessions tiring and were often left feeling uncertain and emotionally drained by some of the more complex capacity judgements. To return to the title of this paper, we questioned our '*capacity to make capacity judgements*' in two ways: (1) Capacity in terms of our abilities to make these judgements. We questioned our skills, but with experience became more confident in applying our standard procedure flexibly, and (2) Capacity in terms of time. Spending time building relationships with potential participants is critical but not always easy when there are competing demands on both a researcher's and potential participant's time.

Two researchers attending each meeting is resource-intensive, however we observed many benefits. We could spend time individually with each member of a dyad and two perspectives were invaluable in arriving at a capacity decision in a relatively short space of time. Working in pairs meant researchers developed an understanding of each other's practice, resulting in a trust which enabled a smooth flow of topics and tasks to be addressed in meetings. Each took the lead on different aspects of the meeting, one focussing primarily on information sharing and discussion; the other being particularly attentive to response cues and forming a capacity judgement. Familiarity with each other's verbal and non-verbal cues meant we could negotiate conversations regarding the appropriateness of self-consent or consultee route more fluidly.

Although not all of us had prior dementia experience, our mix of transferable skills allowed us to prioritise a person-centred approach and draw on existing skills, whilst gaining valuable experience. Over time, other researchers became involved in conducting meetings. We found that pairing more experienced researchers with new team members facilitated skills exchange and learning.

Due to peer working, we usually had opportunities for informal debriefs (e.g. in the car). We would raise particularly challenging cases with the wider team, leading to discussions around changes in practice and sometimes changes in study protocol. However, our experiences highlight the need for researchers to have access to ongoing training, supervision and peer support when engaged in this often challenging, emotionally and cognitively demanding process of judging capacity in research with people with dementia.

## Conclusion

We have presented researcher reflections on using a standard procedure to guide capacity judgements, learning how to increase flexibility as we gained experience and confidence. We are aware that some of the learning points highlighted may be limited to our context, of a large study based in primary care, but we hope they are adaptable and beneficial to other researchers. Our reflective approach was also limited to understanding the experiences of researchers. We are currently gathering qualitative data on remote recruitment, including participant experiences of interactions around capacity judgement. Findings will be reported in a separate paper.

We experienced tensions between the assumed requirements of the ethics panel and the need to ensure that study information was presented accessibly, to allow those with dementia to engage with the information as much as possible, demonstrate their level of understanding and thereby inform our capacity judgements. We would in future start an open discussion with the REC at the earliest stages of project planning, before preparing documents, and involving PPI contributors, to agree the minimum information required and how that can be conveyed in as dementia-friendly way as possible. There is a wealth of information on accessible information for people with aphasia (e.g. [Herbert & Scales, 2019](#)) which is perhaps not drawn on often enough in dementia research. The Dementia Empowerment and Engagement Project (DEEP) and work from the speech and language therapy field (e.g. [Jays, 2016](#); [Volkmer et al., 2019](#)) provide advice on producing dementia-friendly information. Researchers need to feel empowered to argue the case for accessibility and explore what information is essential to convey and how.

Building in flexibility and person-centredness around a standard procedure is difficult and complex. We would now argue that the many ways in which a researcher can be flexible needs to be more carefully defined, with explicit acknowledgement of the time needed to build relationships with potential participants prior to, and during consent meetings. Capacity judgements start to form from the very first contact and are ongoing/built on throughout the recruitment process. A crucial consideration for funders is how this time-intensive work, supporting informed consent best practice for people with potential capacity issues (and hence their participation), should be factored into bid application templates and funding grants and subsequently reviewed in submitted applications.

Despite the combined skills and experiences of our team and the efforts to train and support each other, in future we would enhance the researcher training and support element of delivering this highly skilled work. There needs to be emphasis in training on communication strategies including for the triadic nature of the consent interaction (researcher, person with dementia and carer). With training and support, researchers could develop the ability to apply a standard procedure flexibly and become empowered to use their own judgements (developing an implicit approach as we have described in this paper). In time, it could be that researchers can become completely flexible in approach without need for a standard procedure. Instead, a broad set of principles might support decision-making, with guidance on their implementation.

The flexible approach we are championing has much in common with the person-centred 'Supported Decision-Making Model' (e.g. [Keeley, 2016](#)) which recognises that capacity is not

a binary concept but is situational and often fluctuating. With the right support from a chosen, trusted and skilled advocate, people with dementia can be empowered to make their own decisions. SDM advocates argue that outcomes depend on the quality of communication facilitation used to scaffold the decision-making process, which resonates with the experiences we have reflected on in this paper. In future, it may be beneficial to explore further how the SDM model can be integrated into capacity judgement research procedures. In addition, [Dewing \(2007\)](#) highlights that getting consent right at the beginning can set the tone for an ongoing person-centred participant-researcher relationship in which capacity is informed by understanding the person's wider context and monitored by paying close attention to behaviour and non-verbal communication. Dewing's approach to capacity judgement is inclusionary, rather than competency-based; capacity can even be strengthened by supportive enabling relationships. We wholeheartedly subscribe to Dewing's principles and the reflections we set out here show some ways in which they might be operationalised. We hope that this leads to further discussion amongst researchers about how to 'do' capacity judgements.

A 'Consent Support Tool' recently developed for those with communication disorders ([Palmer & Jayes, 2020](#)) screens for receptive and expressive language abilities, to determine a person's capacity to consent to take part in research. This offers potential; however, we learned early on the importance of minimising the amount people with dementia feel tested. In a project where there are already several outcome measures, adding an additional assessment may not be appropriate. There is also the problem of obtaining consent to carry out the screening assessment. We would advocate development of more naturalistic methods: carefully set up but unobtrusive observational and conversational methods of judging capacity. There is potential for future use of conversation analytic methods in researching this area, using video/audio recordings of consent interactions to develop an understanding of how judgements are made in real time, uncovering supportive strategies and informing training and guidance. Future development of training resources would have applicability in other adult populations where capacity is an issue. Such resources could also be adapted to improve support and guidance for consultees, funders, reviewers and ethics committees.

Since COVID-19, we have developed remote methods of judging capacity and obtaining consent which will be presented in a separate paper. The learning from our F2F work informed this next development. In the future, we envisage that a flexible approach will be needed, incorporating both F2F and remote methods.

### **Author contributions**

SG: Took an overall lead on the co-reflective process and writing the paper. First draft of methods and conclusions. Final drafts of the remainder of the article

AG: Contributed to co-reflection process. Took a lead on writing first draft of findings.

LG: First draft of Introduction. Contributed to co-reflection process. Overview of paper.

LW: Contributed to co-reflection process. Collaborated on writing the findings.

CS and HW: Contributed to co-reflection process. Sense-checking and overview of article. Contributed to final draft of all sections.

TO and RB: Sense-checking and overview of article. Contributed to final draft of all sections.

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## Disclaimer

The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.

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## Supplemental material

Supplemental material for this article is available online.

## Note

1. During COVID-19 D-PACT study recruitment was temporarily paused, and remote recruitment methods developed. These are currently being implemented and will be reported on in a separate paper. Post-COVID-19 there will be a need for a flexible approach, including both face-to-face and remote methods.

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