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Making an Advance Research Directive: An Interview Study with Adults Aged 55 and Older with Interests in Dementia Research

ABSTRACT

Many people with dementia are interested in taking part in research, including when they no longer have capacity to consent. Advance research directives (ARD) enable people to document their wishes about research participation prior to incapacity, however, there are few available ARD resources. This Australian interview study elicited the views of people aged 55 years and older on: the content of an ARD form and guidance booklet; and processes to support research planning. Participants (n=25, 55 to 83 years) had interests in dementia research. All participants described the ARD materials as easy to understand. All participants expressed willingness to take part in future research. Nearly half believed an ARD should be legally enforceable, while others saw it as a non-binding document to guide decisions about their participation in research. Close family members were preferred as proxy decision-makers. The ARD form and guidance booklet may be adapted for use elsewhere.

Key words: advance research directive, dementia research, capacity to consent, incapacity, proxy decision-making, surrogate decision-making

INTRODUCTION

Many people living with or at risk for dementia are interested in taking part in research, including when they no longer have capacity to make their own consent decisions.[1] There is increasing attention to innovative strategies to support recruitment and participation for people at all stages of dementia, including improvements to consent processes.[2] Ethically and

legally, the agreement of a proxy decision-maker is commonly required when a person with dementia is unable to give their own consent.[3] Challenges arise, however, if a personal proxy cannot be identified or, if available, is poorly prepared to make research decisions. A growing number of older people do not have a trusted person to appoint as a proxy decision-maker[4] and up to half of people with dementia who live in the community may not have a study partner to support their participation in research.[5] People who have family members or kin-like friends available to serve in proxy decision-making roles have often not discussed their values and wishes in relation to research participation.[6] Studies show discrepancies between the research preferences of people with dementia and their carers/proxies.[7]

Advance planning for research is advocated as a strategy to overcome some of the barriers to research participation, especially for people with dementia.[8] Advance research planning is a process that involves thinking about, discussing and expressing preferences for taking part in research during future periods of incapacity. It may include making an advance research directive (ARD) to document one's wishes as well as choosing a suitable proxy. Future decisions about research participation for a person who lacks capacity can then be "orientat[ed] towards considering the person's own views and preferences",[9] thereby fostering authenticity in decision-making, where a decision is "informed by knowledge of the person's values and is motivated by respect for the person."[10]

The limited empirical research on advance planning for research has found strong interest among older people. A Canadian trial of an advance research planning intervention among people aged 70 and older resulted in high uptake; 80% of participants chose to complete an advance planning booklet that included a section on preferences for research participation.[11] An Australian survey elicited the views of 174 people aged sixty and over about research participation if they had dementia-related cognitive impairment; 79% reported interest in

making an ARD.[12] In Germany, an interview study with 24 people with self-perceived or mild cognitive impairment found that participants had positive attitudes toward ARDs and preferred a standardised template they could complete.[13] However, there is a dearth of ARD materials available for people who wish to plan ahead for potential incapacity. Suitable resources are needed to move ARDs from a promising concept into practice.

The present study aimed to elicit the views of people aged 55 years and older on: (1) the content of an ARD form and an accompanying guidance booklet; and (2) processes to support advance planning for research. This study focused on ARDs in the context of research involving people with dementia.

METHOD

Our methodological description is guided by the Consolidated Criteria for Reporting Qualitative Studies.[14]

Study design

This study used a qualitative descriptive design, an appropriate method when researchers aim to present "straightforward descriptions of experiences and perceptions, particularly in areas where little is known about the topic under investigation"[15] and to gain knowledge to inform interventions.[16] In this case, the interventions are an ARD form to document one's values and preferences about being involved in future research, as well as strategies to support advance research planning.

Participants

Eligible participants were community-dwelling people aged 55 and older with one or more of the following characteristics: concerns about their memory; family history of dementia or related conditions; a diagnosis of mild cognitive impairment or dementia; and/or other chronic health condition. Participants were invited to involve a support person to take part in

the study with them. The study was advertised through the Step Up for Dementia Research registry[17] and through two geriatrician clinics. Individuals who expressed interest were contacted via phone or email by a member of the research team to discuss further details about the study and decide whether or not they wished to participate. Eight participants declined to participate, citing lack of time or low interest in the study, and five participants did not return contact with the research team. The principle of information power[18] was adopted rather than data saturation to inform the point at which data collection would cease. The focused aim of the study, the quality of dialogue with participants, and the analysis strategy assisted the research team in evaluating when information power was reached.

ARD form and guidance booklet

These documents were developed as part of earlier work with input from dementia researchers on a prototype form.[19]

Data collection

Study packs were prepared and sent to participants by post. Each pack included: an information sheet and consent form; instruction letter on how to prepare for the interview; an ARD form; and an accompanying guidance booklet (see Table 1 for an overview of the form and booklet). The letter asked participants to review the materials and fill out most sections of the ARD as if they were actually intending to document their preferences.

Interviews were conducted by co-author BJ, a PhD candidate and research assistant experienced in qualitative interviewing. Interviews were completed between June and November 2021 and took place by telephone or webconference, meaning participants could take part from their home or other familiar place. The interviewer reviewed the consent form with each participant and verbal consent to participate was confirmed. Interviews averaged just over one hour (63 minutes), were audio-recorded with consent and transcribed verbatim. The interviews proceeded in three parts. First, participants were asked structured questions

from a seven-item Research Attitudes Questionnaire,[20] about their prior or current participation in health-related research, and whether they had prepared other advance planning documents: will; advance care directive; appointment of a proxy health care decision-maker; and appointment of a proxy financial decision-maker (e.g., enduring power of attorney). Demographic details were also collected. Second, the interviewer went through each section of the ARD form with participants to discuss the responses they had recorded, their views on the content, ease of comprehension and completion, and any suggestions for changes. Third, participants were asked for their views on strategies to raise awareness of advance research planning, the legal status of ARDs, storage of ARDs, and whether research planning would support inclusion in research. If a support person was present in a dyad interview, they were asked for their comments or suggestions relating to the content of the ARD documents and the future use of an ARD. The initial interviews enabled pilot testing of the interview guide and no changes to the guide were needed. The interviewer took notes during each interview and recorded post-interview reflections. Transcripts were not returned to participants for comment, but a summary of results was sent to all interested participants, providing an opportunity for follow up comments if desired.

Data analysis

The two authors independently read each transcript to identify and summarise participants' responses to the main topics explored in the interviews. This initial analysis was then compared and discussed, and an iterative writing process was used to prepare a descriptive account of the findings. Exemplar quotations were selected to illustrate key points from the interviews. The data analysis stays close to the participants' own words, consistent with our

qualitative method and is not abstracted to higher level themes.[21] Word processing software was used to manage the data.

RESULTS

Interviews were conducted with 25 participants, aged 55 to 83 years. Three participants were support persons for a principal interviewee in a dyad interview. Demographic characteristics are summarized in Table 2. Most participants (16 of 22 principal interviewees) reported living with chronic illness, such as heart disease, cancer or diabetes. Of these participants, two reported a dementia diagnosis and a third interviewee was awaiting confirmation of a diagnosis. Thirteen interviewees had dementia carer experience. All but one of the principal interviewees had completed one or more advance planning instruments, such as a will or appointment of a proxy decision-maker for health or financial matters, which is in line with the uptake reported in community surveys of older Australians.[22] All participants reported generally positive attitudes towards research. Selected quotations from the interviews are included in the results that follow and are supplemented by additional quotations in Table 3.

Overall assessment of the ARD form and guidance booklet

All participants described the ARD form and guidance booklet as easy to understand and suitable in the amount of information and level of detail provided. One participant, who had taken part in over 20 previous studies, commented: "I think it's excellent and very practical. … When it comes to explanation [about research] … it's addressed all the likely questions" (P1, male, 83). A participant who lives with dementia commented that the documentation "was clear and it seemed to be sensible" (P14, male, 78). His spouse, as a support person, agreed: "We just read the form, we understood it, and it was clear. There's enough information and not too much information" (SP14, female, 73).

In the guidance booklet, participants appreciated the brief examples of research studies and a dementia-related case study that depicted how people would make and use an ARD. All but one participant completed the self-quiz at the end of the booklet and described it as "very helpful" (SP14, female, 73) and "clever [in] assisting somebody to understand, to be informed" about the key points (P21, male, 61). Participants were reassured to know they can review and update the form if their wishes change: "I think it's also important to have the mention in there that as long as you're in a good state of mind, you can change your mind later" (P5, male, 66). "I think it's good that all the way through to make it clear that you can change your mind … that adds a level of comfort for some people who might be a bit nervous" (P13, female, 55). Table 1 summarises several changes to the ARD form and guidance booklet based on participant feedback.

Willingness to take part in research during future incapacity

All participants would use the directive to document their willingness to take part in future research. Doing so was seen as benefiting others by advancing knowledge: "We're here for a purpose and we can do things to help others, or we can just be totally selfish and just do our own thing. … if we contribute as we can, we can help others, and research has helped many people" (P3, male, 69). Participants understood the function of the directive as a future-oriented document to convey their wishes about taking part in research when they are unable to give their own consent. One participant described imagining himself in the future: "I've lost the plot completely. I'm laying in bed, I'm a vegetable. Now, I personally would still be willing … to being part of the research" (P1, male, 83). Another participant commented: "I figure if I'm going to fill out a document like this advance research directive form, then I will be at the stage, when research is undertaken on me that I won't know what's going on" (P15, female, 62).

Specific research activities

All participants completed an optional section of the ARD form to indicate their preferences in relation to specific research activities, including observations of behaviour, cognitive testing, taking blood samples and drug studies. Participants appreciated the brief descriptions and examples of research activities:

> "It was very clear, easy to understand. It didn't feel like I was trying to make sense of a medical document, or a legal document, which can just turn you off. So I looked at those and went, oh, yes, that's easy. I understand what they're asking, without it feeling like it was talking to me like a child. No, it was good. It was easy to do, easy to understand." (P13, female, 55)

Nearly all participants indicated they would be agreeable to all the research activities listed in the ARD. One person explained: "I see nothing that alarms me. … [Any future research] it's obviously going to be controlled for ethics and privacy and all those things. It's not going to be harmful. But basically, the [option to select the] whole scope of research activities, that suits me" (P21, male, 61).

Half of the participants (11 of the 22 principal interviewees) said they gave extra thought to research involving experimental medicines, mainly due to perceptions of increased risk (see Table 3). All but one decided they would be willing to be involved in drug studies. In regard to genetic research, one participant reflected on the potential implications for her family members: "I'm quite happy that blood samples are taken, or other bodily fluids [for genetic studies], but yes, I have no idea what my family would want to do" (P15, female, 62). One participant mentioned a dislike of needles but nonetheless indicated willingness to take part in research activities involving taking blood samples: "the blood bit I had to read carefully to make sure I was comfortable with that" (P11, female, 73).

Motivations to take part in research

The ARD form asked participants to select between two options to identify what motivates them to take part in research: either "I am willing to be part of research that may not help me directly, but might help others"; or "I am mainly interested in research that might help me directly." The first option was overwhelmingly preferred:

> "I recognise that research is mostly for other people and the future." (P11, female, 73)
>
> "Some people I know have dementia … that's why I'm [interested in research]. I may not get help for me, but it might help somebody else down the track." (P15, female, 62)

Several participants said they would have preferred the option to select both reasons. One commented: "I felt a bit guilty about disguising my desire to help myself at the same time" (P1, male, 83). For others, demonstrating altruism was personally beneficial: "Obviously, it's going to help you if it helps others … we'd be pretty selfish if we said, no, you can help me, but don't help others" (P5, male, 66).

Wishes and worries about research

The ARD form provided space for participants to elaborate on any particular wishes or worries about research. Over half of the participants (13 of 22 principal interviewees) noted areas of interest for future research participation, mainly to help advance knowledge on conditions that have affected themselves or their loved ones. These included: dementia, cancers, heart disease, stroke, arthritis, diabetes, allergies, macular degeneration, sleep apnoea, depression and anxiety. Participants also noted broader areas of interest, including research into brain function, healthy ageing, women's health, chronic illness and quality of life, and understanding life course factors that influence disease risks. Six participants mentioned an interest in donating their bodies for research after death and several said they had already made arrangements to do so.

Just two participants used this section of the form to note types of research activities they would not want to take part in. One participant noted procedures she would not find acceptable: “spinal taps, anything with a cannula. I recognise the value of it, but I'm afraid I can't cope with it emotionally” (P11, female, 73). Another participant expressed concern about research that could cause stress for family carers in the future:

> “These are things that I would not want to take part in – anything that may make life for my carer, probably my husband, more difficult. For example, research that would lead to a major physical or psychological change, because he has to deal with the result at home. But if he agrees to the research, knowing that there may be a major physical or psychological change, then fine.” (P15, female, 62)

Using the directive in the future

The ARD form asked participants to consider the use of their ARD in future situations when they are no longer able to make their own consent decisions and there is ambiguity about whether they assent or dissent to a research activity. A majority (15 of 22 principal interviewees) wanted their wishes as set out in the ARD to be followed as much as possible. For them, the directive reflected careful decisions made prior to cognitive changes: “I’ve seen the way that things like dementia can impact your emotional decision-making capacity. I’m pretty clear at the moment, I know what I want. I’ve thought about it a great deal … I want … the decisions [to be] made on that basis” of the ARD (P13, female, 55). Another participant, who had been an allied health professional, said “very definitely, the directive” should be followed. She explained: “I’ve done a lot of work with people with dementia and with various brain impairments, so I think that if you have already set down [in a directive] something that you, as a person, your particular identity wants, I think that” should be respected (P7, female, 79).

Participants also described the importance of responding to the current tolerances and needs of a person living with dementia, while still aiming to respect their wishes in the ARD:

> "I would like my wishes to be followed as much as possible. But of course, if I'm having a total flip-out about something … then of course, you wouldn't want it [a research activity] to be pushed too hard. … I would like it if somehow somebody who was responsible could work around … my [dementia symptoms such as] anxiety or paranoia, and find ways of getting me involved with it [the research], without triggering it off too much. You know … gentleness around those cases …to actually put in the time to work around those to get back to my wishes in the directive." (P20, female, 65)

Strategies to minimise burdens for participants with dementia were also suggested, such as home visits to collect data or blood samples, rather than requiring travel to a research clinic (see Table 3).

Several participants placed less emphasis on adhering to a person's ARD due to the unpredictability of dementia: "… my feelings may change so that complicates research. Because as much as I want to help at this stage in my life, if my dementia involved a lot of fear about what was happening around me, I would get too agitated, I imagine, to be part of any research. It would have to be dealt with as it came along, you know?" (P11, female, 73).

Choosing a supporter / decision-maker and discussing wishes

Most interviewees would choose close family members to be involved in decisions about research participation, both to support them to make their own decisions to the extent possible, or to be a proxy decision-maker if necessary. If they had already made legal instruments to appoint decision-makers for health or financial matters, they typically would choose the same trusted people to be involved in research decisions. For some, the process of working through the ARD documentation was a catalyst for having discussions with family

members about research that they had not previously had. Participants stressed the importance of having conversations to ensure their wishes as expressed in the ARD are known:

> There is “no point doing it [making the ARD] and not telling people. You've got to talk to your family.” (P13, female, 55)
>
> “I think it needs to be emphasised that people who sign a form, set up a form like this, need to discuss it with their children, the way that, well, you don't have to with a Will, but this is more something that's going to happen while you're alive. So you need to feel confident that your own children or support people are on the same page.” (P11, female, 73)

These conversations are an opportunity to consider the responsibilities of being a study partner who facilitates a person’s participation in research activities:

> “… it's easy for me to sit back and say I'm willing to be involved [in research]. But I think it's quite onerous should my condition deteriorate to put that on … my family member, next of kin, to keep me involved. It's fair enough for me to decide for myself that I'm keen to be involved but … where someone else had to help [in the future] you're not really getting their permission at this stage or knowing whether they would be as interested to be involved.” (P4, female, 67).

Raising awareness of advance research planning

Many participants – nearly three quarters – thought advance research planning could be promoted to adults of any age. They considered it worthwhile to encourage younger people to think about being involved in research, since people at all ages can experience illness or injury that affects cognitive abilities. Other participants recommended targeting research planning to groups that are more likely to engage with the process, such as people with a diagnosis involving cognitive decline and people who sign up for a research registry. One

participant commented: “I would say everyone should be involved [in research planning], but it's probably the sort of thing you'd only get involved with because you had something happen … usually you need something to spark you” (P13, female, 55). Her father being assessed for dementia was a prompt for her to consider taking part in research.

When asked who should raise awareness of research planning, a majority of participants suggested information could be disseminated through family doctors, specialists such as geriatricians, and other healthcare providers. Several participants suggested aged care facilities and retirement villages could promote research planning to their residents. Other participants recommended multi-sector efforts to promote research planning: “if a broad range of people, or organisations … recommended [it], then people would hopefully think, well, it must be a worthwhile thing, because lots of people, or organisations are encouraging you to do it” (P16, female, 59). Several participants mentioned legal professionals could help to raise awareness: “I think it should be part of the list of things that a lawyer would tell you” (P20, female, 65). Other suggestions were to raise awareness through university-based research institutes and national dementia organisations. Government bodies could raise awareness, such as when they send mail-outs on health or ageing topics, or when people qualify for seniors’ services.

All but two participants agreed that research planning could be raised alongside advance care planning. One participant reflected on her mother’s care planning process: “there was nothing in the advance care directive for Mum, to answer questions like that. She didn’t have the opportunity to say yes to that [taking part in research]” (P2, female, 65). Those who hesitated expressed concern about overwhelming people: “it could be too much for many people doing it all at the same time” (P5, male, 66). It is also important to ensure that people understand the difference between research and health care: “One would have to be very careful that people could understand … that there's a difference between one thing and the other. One is

research and the other is what's going to actually happen to you, with your health care" (P7, female, 79).

Status of ARDs

Participants considered the legal status of ARDs, with a general view that the point of making an ARD is that it should be respected (see Table 3). Nearly half were agreeable to a legal obligation to follow the wishes recorded in an ARD, especially for lower risk research activities.

> "Otherwise, what, at the end of the day, … what's the use in doing it all if there's not going to be some compulsion to follow it?" (P5, male, 66)
>
> "I think if it's treated as a legal document, then there is a requirement that they follow it. If we're not going to treat it as a legal document, then … it sort of makes a mockery of having the document in the first place. … I would be pretty annoyed if I created a document and then somebody overruled it." (P17, female, 61)

Several participants felt that the ARD should guide future decisions but not be formally binding: "The bottom line should be, as much as possible, the person who's written the directive, their wishes should be carried out. … [But] the family has the last decision, because they've got to cope with the result," referring to impacts that study participation might have on them as carers (P15, female, 62). Another participant observed that, at the time of making the ARD, it can be difficult to forecast your future "level of disease" or how you will "deteriorate"; "I'd probably say it will be wise to include the person I've named" as a proxy decision-maker (P12, male, 62).

Other participants had mixed feelings about an ARD having binding legal effect. They were inclined to want their chosen proxy or family members involved in research decisions, but were concerned about their ARD being disregarded. One person described this as a "doozy" of a question and explained: "my feelings about the whole of the medical research thing, is

that it has to be in consultation [with family] … by the same token, if you had one of those sorts of families who wanted to interfere, maybe say no to research when you'd said yes, then maybe you would want it [the ARD]" to have legal effect (P20, female, 65). Another participant had similar concerns: "It's a bit like when a [person] wants to donate their organs and their body to science, and the family steps in and says, 'No, no, no, no. We don't want that'" (P3, male, 69).

Accessibility of ARDs

Participants stressed that their ARD must be accessible to those who might need to use it in the future: "I think after you've gone to all the trouble of doing it … If you go through all the trouble of saying what you want to happen, you want it to actually happen. Not just to disappear into the woodwork" (P7, female, 79). To ensure that an ARD is "not going to sit there and lie dormant" (P13, female, 55), participants recommended storing it in a known location at home with other advance planning documents. Participants also suggested providing copies to key people, including proxy decision-makers, healthcare providers and lawyers. Online storage was also recommended, either in existing e-health record systems or research-focused systems to enable researchers to connect with potential participants who have completed ARDs. The cost of maintaining such systems was noted, with a concern about individuals being charged fees.

ARDs and inclusion in research

Participants considered that ARDs would enable opportunities for research participation in line with individuals' wishes: "it means you'd have that conversation, instead of getting to the time when you need to make that decision and you don't know what the person was thinking when they were able to think clearly and normally. So this means you'd had that conversation … so I think it would help" (P22, male, 56). ARDs could also help to link researchers with people who are interested in research: "I think it would help and that's part

of the reason why I think this is a good thing to do, because it allows researchers an avenue to gather people … look at … their information and see if there's anything that the research is doing that applies to a specific group of people, it gets them involved" (P9, female, 66).

DISCUSSION

Public perspectives on advance research planning

This project adds to the few studies that have engaged with members of the public, patients and proxies to investigate advance research planning. It provides insights into the views of "research-engaged" individuals, mostly recruited through a dementia research registry, who reported positive attitudes to research and a majority had taken part in previous studies. Such characteristics are associated with willingness to participate in dementia research[23] and research-engaged people are a principal group to whom advance research planning initiatives should be directed. Our study contributes insights on the preferences they would express in an ARD and how they would want their ARD used during future periods of decisional incapacity.

All participants used the ARD to document their willingness to take part in a range of research activities. They described altruistic motivations to help others, consistent with other studies.[24] The process of making an ARD was valuable in stimulating conversations with family members about research participation during periods of incapacity. Such discussions are unlikely to occur without a prompt to do so,[25] but are important to foster "relationality and knowing the person", which are key to authentic proxy decision-making.[26]

The present study contributes new perspectives on the legal status of ARDs and the thorny issue of proxy leeway. In general, our participants put priority on respecting their ARD during future periods of incapacity and nearly half were comfortable with a legally binding status. Giving weight to an ARD acknowledged the effort people put into thinking about and

documenting their wishes in anticipation of a time when they would not be able to make such decisions. The desire for self-determination resonates with the findings of a German study where participants with cognitive impairment considered an ARD valuable to plan for the future and ensure their wishes are known.[27]

The need for leeway was acknowledged, meaning that future decisions take account of changes in the person's condition and tolerances for research activities. However, participants preferred that in exercising leeway, the aim should be to support the person's involvement in research as expressed in their ARD. Prior studies have found variation in the degree of leeway people would give to proxy decision-makers and recommended that advance planning conversations should include discussion of acceptable degrees of leeway.[28] Similarly, our participants underscored the importance of conversations with potential proxies to ensure they know, understand and will advocate for the person's wishes. For some participants, the willingness to grant leeway reflected an awareness that proxy decision-makers are often study partners who must consider their own ability to manage the practical demands of facilitating participation in research activities.[29]

The views of people making an ARD as elicited in this study complement research that has investigated proxies' experiences of research decision-making. The proxy role often involves "balancing a number of factors during the decision-making process, which seeks to honor the person's wishes while assessing the risks and benefits for the patient."[30] Our participants also avowed that living with cognitive impairment does not mean a person is unable to express preferences. To the extent possible, they would want to be involved in decisions and for their proxy to support that involvement. From the proxy perspective, Benson et al describe how proxies seek to involve a person with dementia in research decisions and activities:

> Caregivers felt the person with ADRD [Alzheimer's disease and related dementia] should be involved in research, and that the caregivers' role in the process should be

> largely determined by the person with ADRD's needs and preferences. The majority of caregivers emphasized that their family member with ADRD retained the ability to invite or deny conversation, and that this could be extended to engagement with researchers.[31]

Our study also adds perspectives on how to manage situations of ambiguity where assent or dissent to a research activity is difficult to determine. A previous study in the United States found that half of people who made an ARD "stated that their research participation should not be stopped if, once impaired, they say they want it stopped."[32] Our participants indicated that clear signs of dissent – "if I'm having a total flip-out" – should be respected. At the same time, participants would prefer attentive efforts to address their anxiety or distraction and support their participation rather than excluding them. These views echo the reflections of Griffiths et al on judging asset and dissent among participants with dementia; they noted that "signs of disengagement could occur for a myriad of reasons including unmet needs, fatigue or attention difficulties."[33] Appropriate responses include taking a break, addressing other factors that may be causing discomfort and attempting to re-engage the person in the research activity.[34] For our participants, such efforts would maximise respect for a person who had made an ARD in order to document their wish to be included in studies.

Advance research planning – promotion, documentation and regulation

Multiple strategies are needed to ameliorate the under-inclusion in research of people who lack capacity to give their own consent.[35] Prospective planning for research participation is recommended, including making an ARD and choosing a trusted proxy decision-maker.[36] The findings from the present study contribute new perspectives on promotion and documentation of advance research planning. Our participants advocated multi-faceted measures to raise awareness of advance research planning by reaching people through their interactions with health, aged care, legal and government entities, similar to strategies

endorsed by dementia researchers.[37] Promotion of advance research planning could also be integrated into initiatives that connect prospective participants and researchers, such as dementia or other research registries[38] and outreach by community health workers.[39]

Participants in this study received an ARD form and an accompanying guidance booklet designed to assist their understanding of health-related research, with a focus on dementia research. These materials were sufficient for this group of participants, however additional resources may be useful for people with lower health research literacy or who would like more information on particular types of research. For example, our participants expressed some hesitation about participation in research involving experimental medication. Prior studies have reported lower interest in pharmacological trials among older people[40] and people with dementia.[41] People considering advance research planning may benefit from additional resources on drug studies – and other research that may be perceived as riskier – to inform their choices. This is important to ensure people are aware of safety and ethical protections and also understand the differences between clinical care and research to avoid therapeutic misconception.[42]

This study responds to call for templates that can assist people to consider and document their wishes in relation to research participation. However, people may have reservations about ARDs if they perceive they cannot change the document once made or that it is tantamount to conscription into research.[43] It is vital to ensure that advance research planning is communicated and understood as a voluntary activity and that people who engage in the process are aware they can amend an ARD as long as they have capacity to do so. They must also be aware that any future participation in research will be subject to ethical and legal safeguards.

Participants in this study considered that advance research planning would help to support inclusion in research for people with decisional incapacity. However, achieving this outcome

requires legislation and ethics guidelines that provide clear provisions for advance research directives and research proxies. Commentators have argued that people with dementia who want "to determine the best path for their … life's agenda must have the legal tools needed to make sound plans for their future", including ARDs.[44] Unduly restrictive or complex legal and ethical requirements are barriers to including people with cognitive impairment in research.[45] Researchers and healthcare professionals support "[c]hanges to the legal frameworks governing advance planning for research, and the development of interventions to support people to prospectively express their wishes about research in the event of losing capacity" especially for people diagnosed with dementia.[46]

Areas for further research

Implementation studies are needed for broader testing of ARD documentation and to determine what kinds of interventions work to support advance research planning across different populations. Passive approaches, such as simply making forms available to people, have minimal impact and facilitated interventions have resulted in high uptake of ARDs.[47] Research is needed to investigate the acceptability of ARDs for minoritized groups who experience multiple barriers to research participation.[48] Further research is also needed to investigate whether research planning processes and ARDs help proxy decision-makers in terms of improving their readiness to make decisions and their actual decision-making. Additional resources may be needed to guide proxies in understanding their role, factors to consider in decisions and how to interpret and apply the wishes expressed in an ARD. Promising examples include a decision support tool developed in the UK to guide family members in research decisions.[49] Lessons on proxy preparedness can also be adapted from interventions developed to assist people in making healthcare decisions for relatives who lack capacity.[50] Measures are also needed to evaluate proxy decisions for research. Shepherd et al

have proposed a core set of outcomes[51] and make a strong case for focusing on authenticity, rather than accuracy, of decision-making to account for the nuanced exercise of leeway.[52]

Strengths and limitations

A strength of this study is that the ARD documents were developed from a research base that included several examples of ARDs identified internationally and feedback from dementia researchers on a prototype ARD.[53] The documents followed national guidelines for respectful language when writing about dementia and people living with dementia.[54] As discussed earlier, the participants for this study were a research-engaged group, which is both a strength and limitation. They represent a group for whom advance research planning interventions should be targeted, therefore their views are central to advancing knowledge in this area. Since all participants used the ARD to express their willingness to take part in research, this study does not shed light on the reasons why some people would decline to make an ARD or use the document to record a refusal to participate in future research. On the latter point, a Canadian trial found that a small proportion (15 per cent) of people who made an ARD indicated they would not want to be involved in research in the event of incapacity.[55] More research into individuals' motivations and concerns would be informative.

The COVID-19 pandemic caused some disruptions to our original study plans. In addition to community-dwelling participants, we intended to recruit residents living in aged care facilities, however public health restrictions prevented access to this latter group. We were unable to conduct in-person interviews, but were satisfied with the ability to establish rapport with participants and engage in effective interviews by telephone and webconference. Three interviews involved dyads of a person with dementia or other chronic illness and a support person. Further investigation is warranted to explore dyad perspectives on advance research planning and build on the developing evidence base in this area. All participants described having family members who could be a proxy decision-maker. Future research would be

beneficial to gain insights from people who do not have suitable relatives or friends to act as a decision-maker and/or study partner.

CONCLUSION

Advance research planning deserves further attention as a strategy for people to consider, discuss and express their preferences for taking part in studies during future periods of incapacity. User-friendly ARD documentation is essential to support this process and the ARD form and guidance booklet from this study provide a model that may be adapted for use elsewhere. While this article focuses on dementia, advance planning approaches could address barriers to research participation in other contexts, such as stroke, cancer and palliative care.[56] Across different jurisdictions, the legal rules vary as to the permissible inclusion in research of people who lack capacity to consent, the status of ARDs and the role of proxy decision-makers in research contexts.[57] In light of this variability, the ARD produced from this study is presented as a document to guide and inform decisions about research participation, but not as a legally binding instrument. This approach aligns with the principle, grounded in the human rights of people with disability, that proxies should take should take account of the known values and preferences of a person on whose behalf they are making decisions.[58] Further work to develop the evidence base for advance research planning can inform amendments to legal and ethical frameworks, with the goal of enabling practices that support appropriate inclusion in research.

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TABLES

Table 1: Summary of ARD Form and Guidance Booklet

ARD Form	
Content Area	**Summary**
Part 1: 'Let's Start to Think about Research'	• Provides an overview of health research, the benefits and possible risks of participation, and ethical review processes • Defines an ARD, its purpose, and how it may be used in future
Part 2: 'My Wishes about Taking Part in Research'	• Prompts the person to state a general preference about whether they would or would not be willing to take part in research if they lose the ability to make their own decisions in future • Provides the option to indicate willingness to take part in different types of research activities, with varying burdens or risks (e.g., observations of behaviour, testing memory or thinking, taking experimental medicine) • Prompts the person to indicate what motivates their willingness to take part in research (e.g., mainly interested in research with chance of direct benefit, or interested in research to help others) • Provides a text box for the person to note any particular wishes or worries about research (e.g., types of research projects or activities they would, or would not, want to be involved in in future) • Elicits how the person would like their ARD to be used in the future, i.e., whether they would prefer the ARD or their feelings, as they are able to express them in future, to be followed as much as possible
Part 3: 'Choosing a Supporter and Decision-Maker'	• Prompts the person to think about people they trust who could be involved in decisions about their participation in research studies in future • Allows the person to write the details of chosen supporters / decision-makers
Part 4: 'Signatures'	• Allows the person to confirm they made the ARD freely, understood the information and choices set out in the document, and how it could be used in future • Reinforces that the person is able to review and update their ARD at any time, as long as they are able to make their own choices • Provides an opportunity for the document to be witnessed by another person • Provides a section for completion by a person who provided assistance in the preparation of the ARD, if required
Guidance Booklet	
Content Area	**Summary**
Section 1: 'Health-Related Research'	• Provides a summary of the goals of research, how health research is different from health care, possible reasons for taking part in health research, and ethical requirements for research studies
Section 2: 'Examples of Research Studies'	• Provides a summary of what research studies might involve and types of health research activities, including clinical trials

	• Lists examples of questions that researchers can answer using different types of research methods • Provides links to websites if readers would like to learn more about dementia or cancer research studies
Section 3: 'Making and Using an Advance Research Directive'	• Provides a summary of advance planning for research, the purpose of an advance research directive (ARD), the role of supporters or decision-makers, the relevance of other advance planning documents (e.g., enduring power of attorney), the difference between an ARD and an advance care directive, and whether an ARD can be changed after it is made • Includes a fictional case study of a person who made an ARD following a dementia diagnosis and illustrates how an ARD might be used in future • Includes a six-question quiz with answers for readers to self-assess their understanding of the information in the booklet
Changes to Documents Based on Participants' Feedback	
Summary of Change	**Rationale for Change**
Clarification about legal status of ARD	• New text was added to clarify that the legal status of an ARD varies depending on local law, but as a general principle, an ARD should guide and inform future decisions about research participation.
Clarification about role of supporter and/or decision-maker	• A list of questions was added to the guidance booklet to help people decide who would be suitable to name as a supporter and/or decision-maker. • The ARD form was updated with space for named supporters and/or decision-makers to sign to acknowledge that they understand their role and the wishes set out in the form.
Removal of question that asked about motivations for taking part in research	• All participants in our study expressed willingness to participate in research to help others. The opportunity to contribute to the advancement of knowledge was perceived as personally beneficial, so the distinction between benefiting self and benefiting others was not seen as meaningful. Removing the question also helps to avoid therapeutic misconception.
Guidance added on storage and sharing copies of ARD	• In response to participant questions about what they should do with a completed ARD, text was added to provide guidance on storing the form and sharing copies with relevant people.
Clarification that ARD does not cover post-mortem research	• An explanatory note was added to the ARD form to state that it "applies to research that occurs while you are still alive – it does not extend to research after death." This was added in response to comments from several participants about post-mortem body donation for research.

Table 2: Participant Characteristics

Characteristic	Number
Age	
50-59	4
60-69	11
70-79	8
80-89	2
Gender	
Female	16
Male	9
Marital Status	
Married or living with partner	19
Divorced/separated, widowed or single	6
Highest Level of Education Completed*	
High school	4
Trade or vocational training	3

University	15
State / Territory of Residence	
Australian Capital Territory	2
New South Wales	8
Queensland	5
Victoria	4
Western Australia	6
Advance Planning Instruments*^	
Will	17
Appointment of proxy financial decision-maker	9
Appointment of proxy healthcare decision-maker	8
Advance care directive	2
Previous Study Participation	
0	7
1-3 research studies	12
4-10 research studies	4
More than 10 research studies	2

*Principal interviewees only; ^ some interviewees reported more than one instrument

Table 3: Interview quotations

Overall assessment of ARD form and guidance booklet
▪ "It's simple, the stuff you need to know. I think if you put too much more in there, it starts to get too complex." (P5, male, 66) ▪ "The way it's presented, you feel very comfortable and safe with what's being said." (P11, female, 73) ▪ "It's very easy to understand. It was so much simpler than I expected." (P13, female, 55) ▪ "I think there's a lot of information there that will put people's minds at rest and I think more people will go further with that much information, it's presented in a way that's easy to understand." (P22, male, 56)
Specific research activities
Hesitance about drug studies: ▪ "Can you say in this [ARD], I don't want to be in ones [drug studies] that are risky?" (P5, male, 66) ▪ A participant with chronic health conditions expressed concern about adverse reactions to experimental drugs: "I don't want to put myself in a worse situation than what I'm already in." (P16, female, 59) ▪ One participant described her hesitation about drug studies as "foolish" because she had recently watched a fictional television show "where somebody was given experimental medication and this person suffered. So it's only because that was fresh in my mind…" (P9, female, 66)
Using the directive in the future
▪ "When you're looking at a research situation, and the directive says, 'Yes … I want it to be followed as much as possible.' Say [my husband] had picked that one, and it [being part of a study] was distressing in any way… maybe transportation to a place for a blood test, or just moving into an unfamiliar environment stresses that person, then that might cause some concern. I might want to adjust something, or say, 'Look, yes, let's continue with the… medical trial, a medicine trial, yes, do that. But let's do the blood sampling at home … like little, minor things like that, I might find, as a support person, I'd want [him] to be comfortable all the time and not stressed." (SP14, female, 73) ▪ "He [my father] felt strongly about research and donating your organs and all that kind of stuff. He actually participated in a research program for macular degeneration, so I know that he felt strongly about it, because he actually did participate in something. … But as his dementia progressed, just doing normal, everyday things like, say, giving him his medication, sometimes he would refuse. So it's a hard thing to say … your wishes in this Directive are followed as much as possible … because he would have felt very strongly about it, when we filled it out originally, but then down the track, with the dementia, it could have appeared in some cases, that he felt very strongly against it. Whereas, he wasn't strongly against it. That was just the dementia coming out. So, yes, there's a fine line in that sort of situation, but I suppose with dementia, that's just, you have to deal with it as it comes." (P16, female, 59) ▪ "I've acknowledged that I'd like to be a participant in research… so go ahead, go right ahead … You're not going to hurt me. It's ethically constrained and I might get upset, because [that can happen with] people

with dementia … But that was the whole point; in anticipation of that, I've said, go ahead and do the research. Obviously, if I start to scream my lungs out, you're not going to want to stay doing the research. You're going to go, 'We just can't deal with him. So we can try again [another time]'. … So I think it's implicit in the agreement that there will be a time, there may, or this is an advance directive, so we are talking about a time when you can't make decisions for yourself. And I think it goes with the territory, that there are times when you might not be happy with people around you, because of your condition. But that doesn't mean you shouldn't follow the earlier instructions." (P21, male, 61)

Status of ARDs

- "I don't see a problem with it [the ARD being legally binding]… it's my wishes." (P6, female, 66)
- "It should carry weight on its own. This is a directive. I've said, this is what I want to happen to me when I'm not able to make the decision anymore myself." (P7, female, 79)
- "If you've made the decisions, everyone should stick to it … if you've made the decision at a time when you were able, then just respect it. " (P13, female 55)
- "I think if you decide that you're going to put an Advance Research Directive in place, and you're comfortable with that, it's got nothing to do with anybody else. It's personal choice." (P17, female, 61)
- "This is now five, ten years down the track, and things have changed dramatically. [The status of the ARD] shouldn't be just black and white, well, that was written, and that's how it stays. I don't think that's appropriate. … they [person who made ARD] might be in a completely different medical situation … Things change. We're human beings, we change." (P9, female, 66)