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Older persons' and their caregivers' perspectives and experiences of research participation with impaired decision-making capacity: A scoping review

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Older Persons' and Their Caregivers' Perspectives and Experiences of Research Participation With Impaired Decision-Making Capacity: A Scoping Review

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Conflicts of Interest

None to declare.

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ABSTRACT

Background and Objectives: Human research ethics statements support equitable inclusion of diverse groups. Yet older people are under-represented in clinical research, especially those with impaired decision-making capacity. The aim of this study was to identify perspectives and experiences of older persons and their caregivers of research participation with impaired decision-making capacity.

Research Design and Methods: Scoping review of literature and online sources in January-February 2019 (updated June 2020) according to Joanna Briggs Institute methodology and PRISMA Extension for Scoping Reviews. English-language peer-reviewed research articles and Australian online narratives were included. Data were tabulated and narratively synthesized.

Results: From 4171 database records and 93 online resources, 22 articles (2000-2019, 82% United States, 16 first authors) and one YouTube webinar (2018) were initially included; updated searches yielded an additional article (2020) and YouTube webinar (2020). Studies were heterogeneous in terminology, methods and foci, with hypothetical scenarios, quantitative analyses and examination of proxy consent predominating. Participants (n=7331) were older persons (71%), caregivers of older persons with dementia/cognitive impairment (23%) and older persons with dementia/cognitive impairment (6%). Synthesis identified two themes: willingness to participate and decision-making approaches.

Discussion and Implications: Research participation by older persons with dementia may be optimized through reducing risks and burdens and increasing benefits for participants, greater consumer input into study development, and shared and supported decision-making. Older persons' and caregivers' perspectives and experiences of research participation with impaired decision-making capacity require investigation in a greater range of countries and conditions other than dementia, and dissemination through more varied media.

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Keywords: Decision Making, Ethics (research, practice, policy, individual choices), Analysis – Scoping Review

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Background and objectives

Research seeking to improve health, function and quality of life requires representative samples. Yet older persons are under-represented in research relevant to their needs, especially those with impaired decision-making capacity (Ridda, MacIntyre, Lindley, & Tan, 2010). Research exclusion of this group of older persons impairs external validity of many clinical studies, reducing opportunities to equitably build evidence for the benefits and harms of healthcare interventions (Ries, Thompson, & Lowe, 2017).

This selection bias is multi-factorial. Informed consent and valid outcome measurement are more challenging when cognitive or communication impairments are present (Ridda et al., 2010). Researchers may lack pre-requisites to tailor methods and measures and instead use exclusion criteria to circumvent the challenges. Older people are often stigmatized, even more so when cognitive impairment is present (Evans, 2018), or considered too vulnerable for research participation (Bracken-Roche, Bell, Macdonald, & Racine, 2017). When proxy consent is used, proxy decision-makers (i.e. the person permitted by law to make decisions on behalf of another) may be uncertain of or disagree with the other's preferences (Reamy, Kim, Zarit, & Whitlatch, 2013). International and national human research guidance supports equitable inclusion of diverse groups, yet varies in explanation and categorization of relevant ethical principles and processes (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, & Social Sciences and Humanities Research Council of Canada, 2014; Dobson, 2008; "International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition," 2016; National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978; The National Health and Medical Research Council, Australian Research Council, & Universities Australia, 2007 (Updated 2018)). Jurisdictional statutes and research ethics committees use different terms, definitions, degrees of inclusiveness and permissible consent processes, with some more

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restrictive than the overarching guidance (Ries et al., 2017). Individual reviewers, researchers, ethics committee members and clinicians also vary in attitudes, knowledge and practice regarding research inclusion of people with impaired decision-making capacity (Prusaczyk, Cherney, Carpenter, & DuBois, 2017; Ridda et al., 2010).

Given this complex landscape, the aim of this study was to identify what is known about older persons' and their caregivers' perspectives and experiences of research participation for those with impaired decision-making capacity. The primary objective was to review relevant international peer-reviewed research literature on the topic. To inform future local initiatives to improve research participation by older people with conditions impacting decisional capacity, the second objective was to review relevant online contemporary accounts by older Australians.

Methods

A scoping review of published literature and online sources, according to Joanna Briggs Institute methodology (The Joanna Briggs Institute) and PRISMA Extension for Scoping Reviews (PRISMA-ScR). (Tricco et al., 2018).

Search strategy

We performed a database search of international literature in January 2019 in Medline, CINAHL, Cochrane, EMBASE, Web of Science and PsycInfo, using relevant terms for the participants (older people and caregivers) and concepts of interest (conditions affecting cognition; research participation; perspectives and experiences), with a lateral search of references of identified relevant articles. In February 2019, we searched websites of 30 pertinent Australian health advocacy organisations (nominated by investigators) for relevant narratives. Lastly, a Google search on February 11, 2019 for additional relevant webpages with eligible narratives, with the limit set to Australia and browsing history cleared before

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each new search. Reviewers appraised Web pages of each Google search against eligibility criteria and followed potentially relevant links until 10 consecutive ineligible ones were found. YouTube video lists were systematically scrolled, potentially eligible videos identified and further relevant links pursued, for a maximum of one hour per search term (Luckett et al., 2016). All searches were repeated in June 2020.

Full details of the search terms and websites are reported in Supplementary file 1.

Selection criteria

Included data sources were: i) research articles reporting perspectives and/or experiences of older persons (including those with and without cognitive impairment) and their caregivers of participating in research with impaired decision-making capacity, published in international English-language peer-reviewed journals with no date limitations; and ii) relevant online narratives (e.g. blogs, chats and/or commentaries, spoken or written) by older persons or their caregivers on Australian websites. Sources primarily reporting professional advocates', health carers' or researchers' perspectives of the topic, or not reporting a majority (i.e. <50%) of older participants and/or caregivers or age of the sample, were excluded.

Data charting and synthesis

Database search results were imported into Endnote X7 then Covidence (www.covidence.org, Veritas Health Innovation Ltd.) One reviewer [AG] applied eligibility criteria to all titles and abstracts with others performing the second independent screen [AH, SK, CS, AC, IAD, LX]. Two reviewers [AH, SK, IAD, LE] independently appraised each full text, compared decisions and resolved discrepancies through discussion [AH, LE, SK, CS, AG]. LE extracted data relevant to study authors, country of origin, aims, design, sample, methods and results into an Excel V15.28 spreadsheet, AH undertook independent checking, and discrepancies were resolved by discussion [LE, AH, SK].

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Four reviewers [AG, AH, AC, MV] extracted online narrative data relevant to the organisation, URL, focal health condition, target audience, country, date, type of commentary and its URL, title, author and content into a second Excel V15.28 spreadsheet.

LE, AH and SK presented extracted and tabulated data to the full investigator team, consumers (i.e. people with lived experience of relevant health issues) (NHMRC, 2018) and researchers with topic expertise in a face-to-face/Zoom workshop in October 2019 to obtain ranging perspectives in interpretation. Of note, while no consumer who contributed to the study as an investigator [IG] or workshop participant had a condition that impaired their decision-making capacity, all were aged over 65 years and had experience of serious or chronic illness and/or caring for a family member with dementia or other life-limiting conditions.

Ultimate reporting of results was via summation of source and participant characteristics, summary tables, and narrative synthesis of all findings (Popay et al., 2006), using source terminologies and rounding of quantitative results to whole numbers.

In keeping with scoping review methodology, we did not assess included studies for risk of bias (The Joanna Briggs Institute; Tricco et al., 2018).

Results

From 4171 identified database records, we initially included 22 research articles by 16 first authors. Four first authors contributed to eleven articles (50%), one to seven (32%) and another was an investigator of this review [NR]. The first search of Australian websites identified 93 potentially relevant online resources, of which we included one: a 2018 YouTube webinar on dementia research Updated searches in June 2020 yielded one additional article (2020) and another YouTube webinar (2020). Overall, 23 research articles and two online sources were included (Figure 1).

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Characteristics of included sources

Research articles

Studies were conducted in the United States (US) (n=19), Canada (n=2), Australia (n=1) and Israel (n=1), published during 2000-2020. Sixteen (70%) included caregivers, 14 (61%) included participants experienced in proxy decision-making for an older person with dementia and nine (39%) included participants with dementia and/or cognitive impairment.

Of 7331 total participants, 5189 (71%) were older persons with no diagnostic information reported (mean age 76); 1685 (23%) caregivers of older persons with dementia/cognitive impairment (mean age 63); and 457 (6%) older persons with dementia/cognitive impairment (mean age 76). Dementia/cognitive impairment was variously ascertained and ranged in severity from mild to severe. Terminology for participants varied, with some articles using terms for persons with dementia that were seemingly contrary to more recent recommendations for "accurate, respectful, inclusive, empowering and non-stigmatizing" language ("Dementia Language Guidelines," 2018); for example, "demented patients" and "noncompetent" (Table 1).

Studies were also heterogeneous in methodology and foci. Methods included:

1. Structured interviews/questionnaires (n=11, 50%), with 1634 participants overall (901 older adults [262 with dementia or cognitive impairment] and 733 caregivers; mean sample 149 [range 29-538]. Eight of these studies used structured tools to measure participants' understanding, attitudes, illness severity and/or function (Table 2). All 11 were quantitative, with two incorporating qualitative analyses.
2. Surveys (n=8, 36%), with 5486 participants overall (818 caregivers, 229 older persons at risk of dementia and 141 older persons with cognitive impairment; mean sample 686 [range 67-1515]).

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3. Focus groups (n=2, 9%), with a combined total of 80 caregiver participants; mean sample 40 [range 30-50]).

4. Semi-structured interviews (n=2, 9%) with a total of 54 persons with dementia/cognitive impairment, 54 caregivers and 23 other older persons; mean sample 66 [range 33-98]

Overall, fifteen articles (68%) reported perspectives of older persons towards consent and/or participation in hypothetical research with varying risk/burden and benefit, including trials of drugs, exercise and other interventions to treat dementia, genetic studies and brain donation after death. Ten studies (43%) were situated within 'parent' studies, mostly drug trials and population-based surveys.

A summary of the included studies is presented in Supplementary file 2.

Online sources

The two online sources were webinar discussions. The first included a woman with Alzheimer's disease, her husband and carer, researchers, clinicians and pharmaceutical industry persons (total n=7), entitled "Let's Talk Dementia Research Webinar 1: Demystifying Trials, Access and Understanding" (Alzheimer's Disease International, 2018). The second, "Consumer perspectives in dementia research" included a woman with frontotemporal dementia, a man with Lewy Body dementia, and the wife of a man with Alzheimer's disease, along with three dementia researchers (total n=6) (NHMRC National Institute for Dementia Research, 2020).

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Narrative synthesis

Synthesis of findings across sources is presented as two themes: willingness to participate and decision-making approaches.

Willingness to participate

Varying majorities were willing to support, participate, enrol another and/or agree to dementia-related research with impaired decision-making capacity, and for consent to be provided by a proxy (most often a family member) (Ayalon, 2009; Bardach, Parsons, Gibson, & Jicha, 2020; Bravo, Paquet, & Dubois, 2003; Calamia, Bernstein, & Keller, 2016; Kim et al., 2009; Kim, Kim, McCallum, & Tariot, 2005; Ries, Mansfield, & Sanson-Fisher, 2019). Willingness to participate was positively associated with lower study risks and burdens (including less travel to study centers), perceived potential for benefit (direct and indirect), and positive research attitudes (Ayalon, 2009; Bardach et al., 2020; Bravo et al., 2003; Calamia et al., 2016; Dunn, Hoop, Misra, Fisher, & Roberts, 2011; Jefferson et al., 2011; Karlawish, Cary, Rubright, & Tenhave, 2008; Karlawish et al., 2009; Kim et al., 2009; Kim et al., 2005; Ries et al., 2019). Feeling valued, more closely monitored, supported and/or mentally stimulated by the research team/process were reported as motivators or re-enforcers in all of the four qualitative studies (Austrom et al., 2011; Bardach et al., 2020; Connell, Shaw, Holmes, & Foster, 2001; Sugarman, Cain, Wallace, & Welsh-Bohmer, 2001); with one further reporting that participants valued the "positive and enjoyable" environment of the research center (Bardach et al., 2020).

Positive research attitudes almost always overcame the effect of other individual variables; including minority ethnicity of US participants (Ayalon, 2009; Kim et al., 2009; Kim et al., 2005), which without multivariate analyses was a significant variable or thought to require a tailored approach to recruitment (Connell et al., 2001; Jefferson et al., 2011; Stocking et al., 2006). Common motivations to participate were altruism, potential benefit for the person with

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dementia, and improved scientific knowledge (Alzheimer's Disease International, 2018; Austrom et al., 2011; Bardach et al., 2020; Bravo et al., 2013; Bravo et al., 2003; Calamia et al., 2016; Connell et al., 2001; Dunn et al., 2011; Jefferson et al., 2011; Ries et al., 2019; Sugarman et al., 2001). A greater range of influential circumstantial and relational factors was reported when decision-making was actual rather than hypothetical (Black, Wechsler, & Fogarty, 2013; Elad et al., 2000; Karlawish, Casarett, & James, 2002; Kim et al., 2009). Hope, desperation with regard to cure, and lack of other options also influenced decisions (Alzheimer's Disease International, 2018; Bardach et al., 2020; Elad et al., 2000; Sugarman et al., 2001).

The online narratives by persons actively involved in dementia research (Alzheimer's Disease International, 2018; NHMRC National Institute for Dementia Research, 2020) revealed their willingness to participate was motivated by family history and legacy; hope; direct (e.g. improved physical and cognitive abilities during and after participating in a study of high intensity weight training: "*One of the best things that has happened to me, by the way*") and indirect benefits (e.g. increased networks and opportunities to advocate for people with dementia); contributing to knowledge; and addressing unmet needs for people with dementia. For example:

> "*Hope was important as I was concerned for my sons and grandchildren and future generations, especially since I had a genetic link. I also saw it as a worthwhile exercise as I had an interest in research methods*."

One woman described how she became involved in research because she was mindful of her potential future experiences in residential aged care. Another stated she did so after her husband, a retired surgeon with Alzheimer's disease, requested that she take him home so that he could resume watching a Stephen Hawking's series about the universe instead of an organised activity that involved rolling balls down a slope. Two other narrators highlighted

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that many people with dementia require more than "*balloon games and bingo*" to maintain their abilities and quality of life. With regard to advocacy for others, one man recounted how his involvement in research led him to state in a presentation to a large group of stakeholders, "*We have to remember that this is all about me, and 459,000 people living with dementia in Australia*".

The narrators' willingness to participate in research appeared resilient and yet, as in the included studies, was not absolute, as some outlined how researchers could improve the experience of participation by persons with dementia and their caregivers. They recommended using respectful language (with one narrator explicitly referring to an Australian guideline) ("Dementia Language Guidelines," 2018); person-centeredness; adopting a fighting rather than nihilistic attitude towards dementia; actively collaborating with people living with dementia in all stages of the study process; and providing appropriate information and support throughout studies, including at cessation (Alzheimer's Disease International, 2018; NHMRC National Institute for Dementia Research, 2020).

Decision-making approaches

While proxy research consent was the predominant focus, decision-making was also found to be highly diverse and multi-factorial (Black et al., 2013; Elad et al., 2000; Karlawish et al., 2002; Karlawish, Kim, et al., 2008; Stocking et al., 2006). It generally involved discussions between many persons, including the person with dementia, their proxy, other family members, clinicians and researchers, and it was not always clear who made (or should make) the ultimate decision (Austrom et al., 2011; Sugarman et al., 2001). There was imperfect congruence between older persons' and proxies' choices, with rates of agreement higher for those with supportive relationships and prior communication about research preferences (Black et al., 2013; Karlawish et al., 2002; Karlawish, Kim, et al., 2008). Hypothetical advance research directives were of interest to two cohorts, especially for lower risk studies

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(Karlawish et al., 2009; Ries et al., 2019). However, elsewhere advance documented preferences were also found no more congruent with current preferences than with surrogate predictions (Herault, Bravo, & Trottier, 2018).

Informal caregivers who made health-care decisions for an older person with dementia were commonly the presumed (Ayalon, 2009; Kim et al., 2009) or preferred (Bravo et al., 2003; Ries et al., 2019) future research proxies. Five studies reported participants gave proxies complete or partial leeway to override their current stated preferences in the future (Ayalon, 2009; Bravo et al., 2003; Karlawish et al., 2009; Kim et al., 2009; Stocking et al., 2006). Being willing to participate in research was positively associated with willingness to give proxies this future leeway (Ayalon, 2009; Bravo et al., 2003; Kim et al., 2009). Another four studies examined ethical standards guiding decision-making, including best interests (seeking to maximise a person's current well-being) and substituted judgement (making a decision that reflects what the person would choose if able to do so) (Dunn et al., 2013; Dunn et al., 2011; Karlawish, Kim, et al., 2008; Stocking et al., 2006). In these studies, more participants endorsed best interests, or best interest combined with substituted judgement, than substituted judgement alone. Proxies considered both past and present wishes of the person with dementia, often integrated best interests and substitute judgment considerations, and frequently prioritised what they thought matched the person's current preferences and tolerances. Proxy decision-making operated and impacted upon spouses differently to children of older people with dementia (Bravo et al., 2013; Cary, Rubright, Grill, & Karlawish, 2015; Elad et al., 2000; Karlawish et al., 2009; Kim et al., 2009), and for those making decisions for persons with earlier stage dementia compared to later (Austrom et al., 2011; Sugarman et al., 2001).

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Discussion

This scoping review identified that older persons' and caregivers' perspectives and experiences of research participation with impaired decision-making capacity have been predominantly studied in the US by a discrete group of researchers, focused on investigating dementia pathophysiology, prevention and cure and proxy decision-making via hypothetical scenarios and quantitative methods. Most of the overall sample were not reported to have impaired decision-making capacity, and an extensive online search of relevant Australian websites contained only two sources containing consumer perspectives on the topic. With these caveats, key findings were as follows. Most, but not all, persons in the included studies supported research participation with impaired decision-making capacity, especially if the study presented lower risk/burden and greater reward and if they themselves had a positive attitude to research. Preferences and decision-making were highly diverse, fluid and circumstantial. Proxy decision-making was often informally shared, and proxies sought to integrate best interests and substitute judgement considerations. Altruistic motivations by older people and proxies to advance knowledge, care, support and advocacy with regards to neurocognitive disorders suggested that affinity with a 'community of illness' (Barnbaum, 2019) was another consideration in their research decision-making. The Australian online narratives by persons with dementia and their spouses added contemporary local perspectives that were congruent with findings of the included studies, as well as lending support to other calls to increase the involvement of persons living with dementia in research design, nomenclature and process (Bethell et al., 2018; "Dementia Language Guidelines," 2018). In

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the context of dementia, a progressive, life-limiting condition with no effective curative treatment, the finding that desperation also influenced decision-making about research participation further highlights the need for consumer contribution to study design and process, as well as circumspect presentation of potential benefits to prospective participants.

Overall, factors influencing willingness to participate in clinical research were similar to studies pertaining to other life-limiting illnesses. A qualitative meta-synthesis of what influenced cancer patients to participate in drug trials reported similar factors: trust in physicians, attitudes of and consequences for family, hope of benefit, altruism, cost- benefit considerations, availability of other options, attitudes towards living with cancer and as a way of coping with its psychological impacts (Nielsen & Berthelsen, 2019). A systematic review of perceptions of people receiving palliative care of research participation reported motivations were potential for personal benefit, altruism and desire to retain autonomy, and preferences were for lower risk and burden studies (White & Hardy, 2010). Most recently, a 2019 international survey of 12,451 respondents (26% aged 65 or older) reported motivations to participate in clinical research were to help advance science and treatments and others with the disease, obtain better treatment or treatment education, and receive money; with older respondents more motivated by advancing science and helping others ("Perceptions and Insights Study: Deciding to participate," 2019). The commonality of findings about altruism, desire to contribute to knowledge, hope for benefit, and preference for safe and feasible studies is congruent with key human research advocacy for ethical inclusion of groups of persons who potentially are at increased risk of harm (Canadian Institutes of Health Research et al., 2014; Dobson, 2008; "International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition," 2016; National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978; The National Health and Medical Research Council et al., 2007 (Updated 2018)).

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Relevant to findings on approaches to consent for research participation is the movement from *proxy* decision-making to *shared* and *supported* decision-making approaches for people with disability (Australian Law Reform Commission, 2014; Sinclair, Field, & Blake, 2018). Shared decision-making refers to the joint involvement of the person concerned and others involved in their life to reflect, respect and accommodate that person's preferences, priorities and goals (Bunn et al., 2018). This includes situations where the person may require additional means to support their decision-making. Shared decision-making incorporates the provision of evidence-based information, including via decision aids, with personal interaction and continuity of relationship (Bunn et al., 2018). In this approach, the question of who actually makes the decision is secondary to key persons engaging in the process together. In the clinical context, shared decision-making has resulted in better care and outcomes, including greater satisfaction and less conflict (Stacey et al., 2017). Development and testing of shared decision-making as an explicit research consent approach for older persons with impaired decision-making holds potential for better tailoring of information, consideration of the person's preferences and values, reduction of decision-making burden on proxies, and guidance for researchers (Bunn et al., 2018; Clayman, Kumar, Murray, Mok, & Sharpe, 2019).

A distinction of supported decision-making is that it privileges the person with disability as the decision-maker (Sinclair et al., 2018). This approach arose in Canada in the 1990s and has gained prominence in the context of the 2006 United Nations (UN) Convention on the Rights of Persons with Disabilities, which asserts that people with a disability can be enabled to make and communicate decisions affecting their lives (Sinclair et al., 2018). Recommendations of the Convention have been ratified and variously implemented by most UN Member States (Department of Economic and Social Affairs Division for Inclusive Social Development, n.d.). For example, in 2014 the Australian Law Reform Commission

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(ALRC) developed National Decision-Making Principles to inform Commonwealth, state and territory laws and frameworks relevant to legal capacity (Australian Law Reform Commission, 2014). These are, in brief: equal right to decision-making and respect; obligation to provide necessary support for decision-making; person's will, preferences and rights must direct decisions; and need for legal safeguards to prevent abuse and undue influence (Australian Law Reform Commission, 2014; Sinclair et al., 2018). No studies in the present review focused on supported decision-making. The absence of any findings regarding preferences for supported decision-making in research participation in this review may reflect the fact that this approach is relatively new, and has only recently begun to be explored in the context of people with age-related cognitive impairments. We suggest that further research should more directly explore the potential role of supported decision-making in the process of consent for research participation (Haberstroh, Oswald, & Pantel, 2017).

The ALRC considers decision-making solely by a proxy as last resort and proxy decisions should, to the extent possible, reflect the will and preferences of the person with disability (Australian Law Reform Commission, 2014; Sinclair et al., 2018). Current research guidance establishes various standards for proxies, referring to decisions that are in, or not contrary to, the person's best interests (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978), substitute judgment (Canadian Institutes of Health Research et al., 2014; Dobson, 2008; "International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition," 2016), or an integrated approach. An example of the latter is within the Australian National Statement on Ethical Conduct in Human Research, which states a person with cognitive impairment, intellectual disability or mental illness unable to provide consent should have their wishes followed: *"…unless changed circumstances mean that acting in accordance with those wishes would be contrary*

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to the participant's best interests." (The National Health and Medical Research Council et al., 2007 (Updated 2018)).

Findings of this review indicate that participants positioned respecting previous preferences of the older person with dementia as simply one or even a subordinate consideration among many others when actually making a research decision. This highlights how proxies' likely intimate knowledge of the person uniquely positions them to communicate present wishes when that person can no longer do so independently. It also raises the question whether it is reasonable to expect proxies to make decisions based on a person's prior expressed wishes without being influenced by actual research risks, burdens and benefits (for both the person and themselves), as the details and implications of the study under consideration would not have been known when the wishes were previously expressed. This finding also reflects the wider understanding of advance care planning as primarily "*an ongoing process of reflection and communication with key others"*, rather than a static directive (Ries, Mansfield, & Sanson-Fisher, 2020).

Advance planning for research participation is yet to be fully implemented into practice. Of note, no standard advanced research directive (ARD) template or process currently exists. There is also evidence of researchers' uncertainty and inexperience in aligning a person's previously expressed research preferences, current wishes and circumstances, and proxy decision-making. For example, a recent survey of dementia researchers' views on ARDs found that while the majority supported their use and almost all agreed that later dissent by the person overrode prior stated wishes, very few had actually used an ARD, and there was equipoise as to whether prior documented preferences could be overridden by proxies. These researchers also expressed uncertainty about whether ethics committees/institutional review boards (IRBs) would accept an ARD as a valid expression of a person's willingness to participate in research; and, conversely, some feared IRBs making them mandatory (Ries et

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al., 2020). Development of evidence, standards and practice for advance research decision-making is therefore required to inform IRBs, research teams and their interactions to best operationalize the practice. In these translation endeavors, older persons' frequent prioritization of current preferences, circumstances and willingness to grant their proxies leeway will be important to consider. Where persons do not have anyone available or willing to be their proxy, ARDs, to the extent that these may be acceptable evidence of willingness to participate (e.g. for low risk activities), may help to overcome this particular barrier to research participation during decisional incapacity.

Limitations

Inclusion of only English-language research articles and Australian online narratives limits findings to high-income countries, particularly the US, which is a significant limitation given the majority of people with dementia live in lower and middle income countries (Prince et al., 2013). Risk of bias of included studies was not assessed, precluding systematic critique of overall strength of evidence. An inherent selection bias is possible due to sources representing mainly white persons, and likely those with more positive research attitudes (Hughes, Varma, Pettigrew, & Albert, 2015). Findings may not be generalizable to older people with non-dementia-related causes of impaired decision-making capacity, such as delirium or coma, or studies of other conditions.

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Conclusion

This scoping review of international research literature and Australian online resources to identify older persons' and caregivers' perspectives and experiences of research participation with impaired decision-making capacity included 23 methodologically heterogeneous studies and two sources of online narratives. Predominant foci of included sources were dementia, proxy decision-making, hypothetical scenarios and quantitative methods. Findings highlight that research participation by older persons with dementia may be optimized through reducing risks and burdens and increasing benefits for participants, greater consumer input into study development, and investigation of shared and supported decision-making approaches. Older persons' and caregivers' perspectives and experiences of research participation with impaired decision-making capacity requires empirical investigation in a greater range of countries and conditions other than dementia, and dissemination through more varied media.

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Table 1: Terms used for participants in included articles

Participants	Terms
Older persons with no diagnostic information reported	Older adults/older people/older Americans (n=7)
Persons with dementia/cognitive impairment	Older adults/persons/relatives*/family members* (with condition of interest) (n=7)
	Patients with (condition of interest) (n=5)
	Subjects (n=4)
	Decisionally incapacitated close relatives* (n=1)
	Noncompetent (n=1)
	Demented patients (n=1)
Decision-makers for older persons with dementia/cognitive impairment	Caregivers (n=7)
	Relatives (n=7)
	Proxies (n=6)
	Surrogates (n=5)
	Family members (n=4)
	Carers (n=1)
	Substitute health-care decision-makers (n=1)
	Legal guardians (n=1)

* of the caregiver/proxy participant

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Table 2: Structured measures used in included studies

Structured measures	Included studies
Understanding of proposed study	
MacArthur Competency Assessment Tool for Clinical Research (MacCAT-CR)	Dunn et al., 2013; Dunn et al., 2011; Karlawish et al. 2008; Karlawish, Kim, et al., 2008; Karlawish et al., 2002; Karlawish et al., 2009
Attitudes	
Research Attitudes Questionnaire (RAQ)*	Cary et al., 2015; Karlawish et al., 2009
Social Responsibility Scale (SRS)	Karlawish et al., 2009
Health Care System Distrust Scale (HCSDC)	Karlawish et al., 2009
Intrinsic Religiousness Motivation Scale (IRMS)	Karlawish et al., 2009
Perceived Threat of Alzheimer's Disease Scale (PTADS)	Karlawish et al., 2009
Function	
Activities of daily living (ADLs)	Cary et al., 2015; Karlawish et al., 2008
Instrumental Activities of Daily Living (IADLs)	Karlawish et al., 2008
Folstein Mini-mental State Examination (MMSE)	Black et al., 2013
Neuropsychiatric aspects	
Neuropsychiatric Inventory Severity subscale (NIS)	Cary et al., 2015; Karlawish, Cary, et al., 2008
Neuropsychiatric Inventory Distress subscale (NID)	Karlawish, et al., 2008

* Original RAQ was developed by Kim, and with further psychometric testing by Kim and two other first authors of included articles, Cary and Karlawish, subsequent to included studies *(Rubright, Cary, Karlawish, & Kim, 2011)*.

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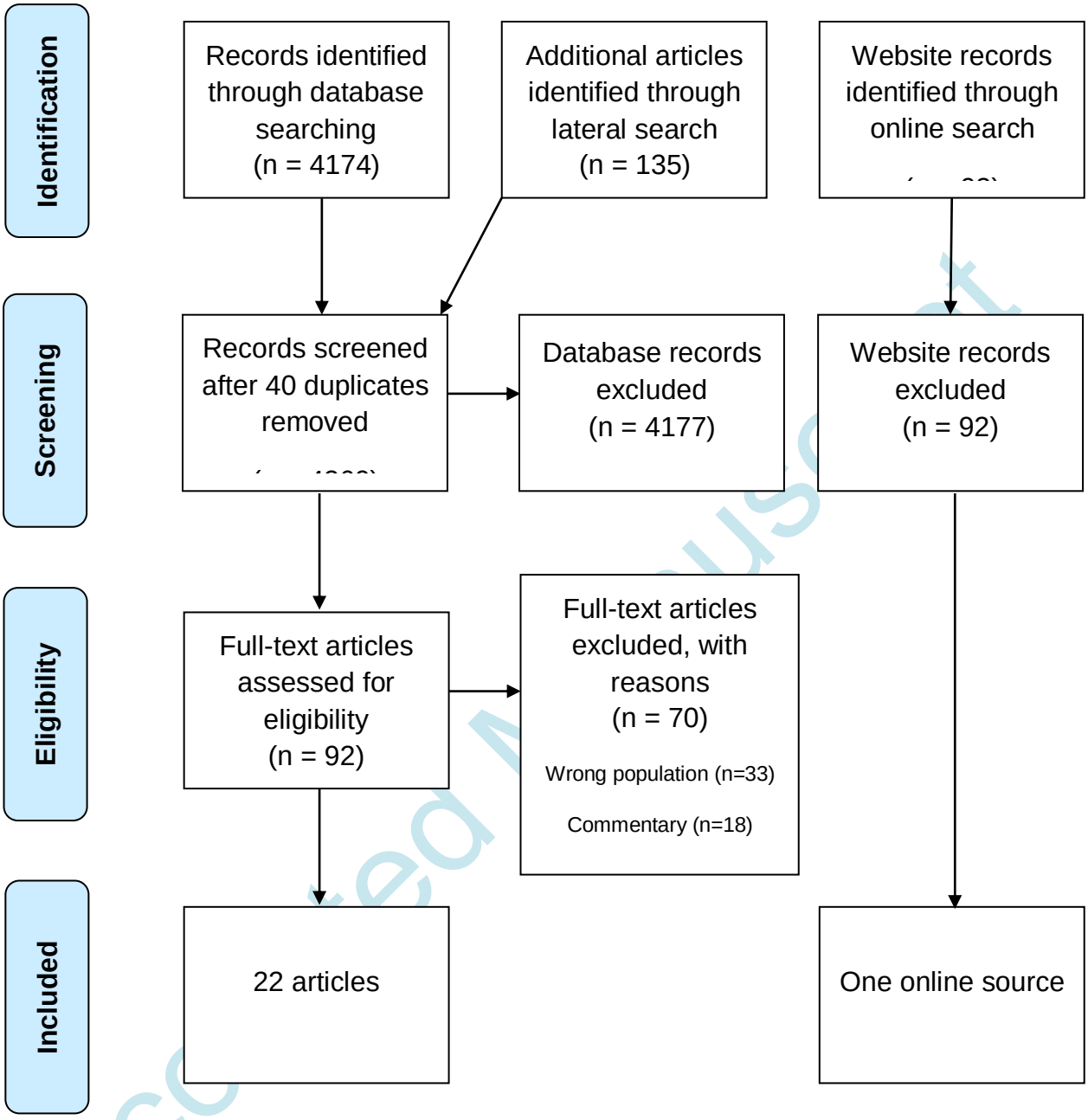

Figure 1: Flow chart of initial searches and inclusion Jan-Feb 2019

Note: The updated searches in June 2020 yielded one additional article and one additional online source

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