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Citation for final published version:

Shepherd, Victoria 2021. How nurses can support the inclusion in research of older people who lack capacity to consent. *Nursing Older People* 33 (2) , pp. 26-31. 10.7748/nop.2020.e1267

Publishers page: <http://dx.doi.org/10.7748/nop.2020.e1267>

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How nurses can support the inclusion of older people who lack capacity to consent in research

Nursing Older People

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Abstract

This article reports recent research exploring some of the challenges around the inclusion of older people who lack capacity in research, including how families and others are involved in making decisions about research participation on their behalf. Research is important as it underpins the provision of evidence-based care and treatment. However, people with conditions such as dementia may have impaired capacity to provide informed consent to take part in research. People who lack capacity to consent, which includes around 70% of older people living in care homes, are often excluded from research. This contributes to less research being carried out in care homes than in the NHS, despite there being more beds in care homes. This exclusion is partly due to ethical concerns about including 'vulnerable' populations in research, but also because there is a lack of awareness about the alternative legal arrangements for including adults lacking capacity. The importance of including older people with cognitive impairment in research has been particularly highlighted during the COVID-19 pandemic as it disproportionately affects older people and has had a profound impact on those living in care homes. Nurses play a key role in supporting older people living in care homes to participate in research, and facilitating relationships between residents, their families, and researchers. However, nurses' lack of familiarity with the ethical and legal arrangements around capacity and consent to research can act as a barrier to the inclusion of older people. This paper outlines the implications for nursing and research practice involving older people and presents practical information and resources for nurses caring for older people.

Main text

Care homes have traditionally not been seen as places where research is conducted, with less research carried out in care homes than in the NHS, despite there being more beds in care homes (NIHR, 2017). This is due in part to the ethical concerns and practical challenges of including older people who may lack capacity to provide consent to take part, and a lack of awareness about the legal arrangements that enable people lacking capacity to be ethically included in research. Given that COVID-19 disproportionately affects frail older people, it is more important than ever that older people with cognitive impairment and those living in care homes are included in research (Richardson et al., 2020). The aim of this article is to highlight this issue and outline recent research and practical resources that may support nurses caring for older people to increase the opportunities for older people to participate in research.

Research is vital in order for us to improve care for older people, including those living with conditions linked to ageing such as dementia and Parkinson's disease. Research takes many forms,

including helping us to understand more about health conditions, find effective treatments and ways of delivering care, as well as understanding people's experiences of living with these conditions. However, conditions commonly associated with ageing such as stroke, dementia, and Parkinson's disease may also be associated with impaired cognition, with 75% of care home residents experiencing cognitive impairment (Gordon et al., 2014). While the latest NICE dementia guidelines recommend that opportunities to participate in research should be available to people living with dementia at all stages of the condition (NICE, 2018), people with conditions such as dementia are often excluded from taking part in research, particularly in the later stages of the condition (Taylor et al., 2012). This can be due to concerns about safeguarding and that including people who are unable to provide their own consent to participate in research is 'unethical' (West et al., 2017).

This lack of inclusion in research means that groups such as care home residents have less evidence-base for their care than other groups who can consent (NIHR, 2017), leading to older people living in what Age UK has described as a 'knowledge shadow' (Age UK, 2013). It also means that dementia research studies have mainly people with early dementia taking part, and there is a lack of research on issues of relevance to people in the more advanced stages of dementia and other impairing conditions.

Inclusion in research matters

There are a number of ethical arguments around the inclusion of people who cannot give their own consent to take part in research (Nuffield Council on Bioethics, 2009). On the one hand it is argued that people who are unable to provide consent and so cannot protect their own interests shouldn't be 'made' to participate in research when it isn't known whether they would wish to do so or not. Others argue that it is unethical to exclude people from the benefits that research may bring, with concerns that this may lead to them receiving poorer quality care. There are also arguments around the inequality of excluding people with cognitive disabilities from research. Parkinson's UK policy statement on mental capacity reminds us that 'It is important not to exclude people who lack capacity from taking part in research, in the same way that they should not be excluded from services and medical treatment' (Parkinson's UK, 2017). A number of safeguards are in place to ensure that the research is ethical (HMSO, London, 2005). Including that prior to including adults lacking capacity in research, the study must be reviewed by an independent research ethics committee who consider the potential risks and benefits and whether the research would be less effective if only people with capacity were involved (HMSO, London, 2005.). The committee must provide a favourable opinion before the research can go ahead.

Due to the increasing prevalence of conditions like as dementia and multimorbidity, care homes are increasingly providing care to older people with complex needs. There is an urgent need for more research to be carried out in care home settings, however the issue of consent is particularly important in care home research (Luff et al., 2015). One of the challenges is that around 70% of residents will lack capacity to provide consent to take part in a study (Butler et al., 2020; Hood et al., 2014; Wade, 2019). Care home residents who lack capacity are likely to be more frail than those with capacity and, for example, have an increased vulnerability to infection (Hood et al., 2014). This has led to those of us who want to include older people with impaired capacity in research to seek a more inclusive and person-centred approach whilst ensuring the research is conducted ethically.

As a nurse with a background in both caring for and conducting research with people with impaired capacity, the focus of my research has been exploring how to reduce some of the barriers to the inclusion of people with impaired capacity, including care home residents, to ensure that research is both ethical and inclusive. The aim of my research is to develop new ways of ensuring that people

who lack capacity to consent have equal opportunities to take part in research. In this article I describe some of the research I have carried out and outline how it links to nursing practice involving older people.

The role of the older people's nurse

As key gatekeepers in the process, healthcare professionals can either facilitate or impede access to research opportunities. Nurses can play a key role in ensuring that older people with conditions associated with cognitive impairment such as dementia can contribute to, and benefit from, research (**see Box 1**). They can help ensure that the experiences of older people are recognised and valued and help give a voice to this group who are often under-represented in research. For example, providing accessible information about research studies that takes account of dementia-related cognitive and communication needs, and ensuring support is available to make decisions about participation is available, is essential. There is a growing focus on 'inclusionary consent' in research, where people are enabled to participate in meaningful ways to the level of their capacity, which draws on the principles of person-centred care (Dewing, 2008). Nurses are often best placed to advise researchers about the communication needs of those in their care, how they can best be supported to access information about a study and maximise their capacity to decide whether they wish to take part. For some studies in care homes, nurses who know the residents well may also help identify which residents are eligible to take part in a study (Shepherd and Davies, 2020). This includes trials investigating COVID-19 treatments for older people, including those living in care homes for whom COVID-19 has had a profound impact (Richardson et al., 2020).

For people who lack capacity to consent, nurses can also advise researchers about who is closest to that person and so who can be approached to be involved in the decision about whether they should participate or not, and so play a key role in facilitating their inclusion (Shepherd and Davies, 2020). However, some of my research, which looked at what healthcare professionals knew about the legal aspects of involving people lacking capacity in research, found that there was a lack of knowledge and understanding about who legally should be involved in making a decision on behalf of someone lacking capacity (Shepherd et al., 2018). This meant that health and social care professionals, including care home nurses, didn't feel confident about including people who lacked capacity in research. Following on from this I developed some information resources for care home staff and other health and social care professionals (**summarised in Box 2**).

Involving family members

One of the other challenges is the involvement of family members or close friends when someone lacks capacity to consent. When someone lacks capacity to consent to take part in research, relatives or close friends are usually approached to be involved in the decision about their participation as their consultee (HMSO, London, 2005) or legal representative if it is a trial involving medicines (The Medicines for Human Use (Clinical Trials) Regulations 2004 SI No.1031, 2004). This decision should be based on what the person's preferences and wishes would be about taking part if they had capacity to decide. Making decisions on behalf of someone else can be hard, and although previous research had looked at how families make other types of decisions like moving into a care home (Lord et al., 2016), decisions about research had not previously been explored.

In one of my studies (called the DECISION Study), I wanted to find out how family members make decisions about research on behalf of someone living with a condition such as dementia. I interviewed family members of people who lacked capacity to consent, including families of care

home residents, who had been involved in deciding whether they should or should not participate in a research study (Shepherd et al., 2019).

I interviewed 17 family members who had made decisions about research on behalf of a family member (parent or spouse) who lacked capacity to provide their own consent. I used thematic analysis to explore their experiences and identify the key themes (Braun and Clarke, 2006). I found that family members had rarely discussed future preferences about research with the person they cared for. Instead, family members made a decision they thought was authentic to the person they represented and the values that were important to them. This might include knowing that their family member supported organ donation or had been a blood donor, had an interest in helping science or medicine, or would be keen to help others with similar conditions in the future as they were altruistic.

However, for some family members it was a difficult decision to make, and some experienced an emotional and decisional burden as a result. Families thought that support for family members making decisions about research on behalf of someone living with dementia might benefit families in the future. In another study I also found that information about research studies given to families making decisions rarely provides enough information about how they should approach making such decisions, or their role in the process (Victoria Shepherd, Wood, et al., 2019b). Together, this highlighted the need for developing new ways to support families to make informed decisions about research.

New ways of supporting families

Supporting families to make a decision could reduce the impact felt by family members and make their decisions more informed and representative of the wishes and preferences of the person they care for, and so continue to provide an opportunity to participate in research in the later stages of dementia. Improving decision-making, including the use of shared decision-making, has been increasingly seen as important in both clinical practice (Madsen and Fraser, 2015) and decisions about research participation (Gillies and Campbell, 2019). To help improve decision-making, decision support tools (or 'decision aids') are frequently being developed. Decision support tools can improve key decision outcomes such as increase knowledge and reduce decision conflict, leading to decisions which are more informed and consistent with the person's values (Gillies et al., 2015). In order to help families who are approached to be involved in making decisions as a consultee or legal representative, I developed a decision support tool called 'Making decisions about research for others' (V Shepherd et al., 2019).

The decision support tool is in the form of a booklet which provides a structured way for families to understand what role they are being asked to play, what the potential advantages and disadvantages of taking part in a particular study might be, and explore what the person with impaired capacity's wishes and preferences might be about taking part. This could be used during a consultation with a researcher or research nurse and allows the family member to write down any further questions they might have. It has been preliminary tested with family members and research nurses, and further research is underway using cognitive interviewing techniques to explore the acceptability, comprehension, and interpretation of the tool ([DECISION 2 Study](#)). The next stage is to test whether this new tool is an effective form of support. This will be done through a trial where family members acting as a consultee or legal representative will be randomly allocated to either receive the decision tool intervention together with information about the study, or to receive the standard information alone.

Nurses hold the key

Other recommendations from my research includes encouraging people living with dementia and similar conditions to have early conversations about their future research (as well as care) preferences. While there is a growing focus on advance care planning to ensure that future decisions reflect older peoples' preferences and wishes (Lyne and Mucci, 2018) there has been little attention paid to discussions about research preferences in the event that capacity is lost. Family members in the DECISION Study spoke about the importance of discussions about future research preferences, and supported extending current Power of Attorney arrangements to include prospectively appointing who should act as consultee or legal representative, rather than this being chosen by others once capacity is lost (Shepherd et al., 2019). Nurses caring for people living with dementia are well placed to help them express their wishes about taking part in research studies and who should be involved, and to discuss this with their families and friends.

In circumstances where there is no family member or close friend to act as a consultee or legal representative, in England and Wales someone acting in a professional capacity can be involved as a Nominated Consultee or Professional Legal Representative (HMSO, London, 2005; The Medicines for Human Use (Clinical Trials) Regulations 2004 SI No.1031, 2004). This could include a member of care home staff who knows the person well, provided they are not involved in the research study (Department of Constitutional Affairs, 2007) and is an approach often needed for care home residents (Victoria Shepherd, Wood, et al., 2019a). Care home staff may also be asked to complete questionnaires on behalf of residents they care for who, even with additional support or alternative formats, are unable to answer for themselves. This might include their views about the resident's health and well-being or their quality of life which is used as a 'proxy' for the resident's own views (Griffiths et al., 2020).

My research also suggests that health and social care professionals caring for older people might benefit from greater training in involving populations who lack capacity to consent in research in order to provide opportunities to include them in research at all stages of the condition (Shepherd et al., 2018). As nurses are also increasingly leading research into the care of older people, it is important that they have access to information and training when designing and conducting their research. There are a range of resources available for nurses to help when designing their research, when involved in conducting research, and to help them ensure that research is inclusive for people with cognitive impairment in their care (see Box 3).

Conclusion

The aim of this article was to highlight the importance of including older people with dementia and other cognitive problems in research. Although it raises a number of ethical and practical issues, excluding people with cognitive disabilities from research may in itself be unethical and lead to them receiving less evidence-based care than other populations who are included in research. Improving the evidence-base for the care of older people through research will need researchers, health and social care staff, and older people and their families to come together. The research findings and resources described here may support nurses to ensure that older people in their care have the opportunity to participate. It will also need a shift in our perception that we as a society need to protect 'vulnerable' groups *through* research not *from* research. Inclusion in research matters, and nurses have a key role to play in facilitating the inclusion of older people with cognitive impairment.

<2694 words>

Box 1. The role of nurses in supporting older people with impaired capacity to consent

Communication support – advising researchers about communication needs or aids used (including glasses, hearing aids, assistive communication devices)

Maximising capacity to consent – providing a quiet environment, advising researchers about the best time/method when providing information, awareness of any fluctuations in capacity

Supporting decision-making – ensuring tailored information (large print, pictorial versions, audio/visual formats), supporting person when asking questions, reinforcing and clarifying information provided

Identifying an alternative decision-maker – use their knowledge of the person’s family relationships to help identify who can be involved in making a decision on the person’s behalf

Representing the person lacking capacity – acting as a Nominated Consultee or Professional Legal Representative (if no-one is able or willing to act in a personal capacity) and making a decision about whether in their view the person would have wanted to take part

Box 2. Legal aspects of including people lacking capacity in research (in England and Wales)

Under the Mental Capacity Act 2005 (MCA) it is presumed that an adult has capacity, unless assessed as lacking the capacity to make the particular decision at the time the decision is needed

The MCA applies to decisions about research (s30-34) as well decisions about care and treatment

When an adult lacks capacity to consent to research, under the MCA the researcher can identify someone who is involved with the person, usually a family member or friend, to act as their Personal Consultee. This doesn’t need to be their ‘next of kin’ or have Power of Attorney

If no-one is willing or able to act as a Personal Consultee, a professional who is involved in caring for the person (but not involved in the research project) may act as their Nominated Consultee. For example, this can be any member of the care home staff who knows them well

The consultee is given information about the study and asked to give their advice about whether the person who lacks capacity should take part in the project, and what they think the person’s feelings and wishes would be, if they had capacity to decide

For clinical trials involving medicines, the family member or professional (usually their doctor provided they are not involved in the research) acts as a Legal Representative and provides informed consent on the person’s behalf based on their ‘presumed will’

The decision about whether they take part in the research or not is not based on their ‘best interests’ as decisions about research are excluded from the best interests requirement of the MCA

The person who lacks capacity should be informed about the study and involved in the decision to the extent that they are able. Consent is an ongoing process, and capacity is re-assessed as appropriate during the study

Box 3. Further resources

Enabling Research in Care Homes (ENRICH) is an online toolkit which contains lots of information and advice about conducting research in care homes <https://enrich.nihr.ac.uk/>

ENRICH Cymru is the care home research network in Wales and has more information about involving care home residents with limited capacity in research <https://www.swansea.ac.uk/enrich-cymru/enrich-cymru-for-care-home-staff/involving-residents-with-limited-capacity/>

Research and Impaired Mental Capacity in Adults: Guidance for Researchers contains introductory guidance to involving people with impaired capacity in research and how the Mental Capacity Act applies https://www.healthandcareresearch.gov.wales/uploads/News/research_and_impaired_mental_capacity_in_adults-guidance_for_researchers.pdf

Advancing Care: research with care homes is a roundup of recent research on improving the health and care of care home residents in themes such as living well, ageing well and dying well
<https://content.nihr.ac.uk/nihrdc/themedreview-001931-AC/Advancing-Care-Final.pdf>

NIHR School for Social Care Research Methods Review: Care Homes is an evidence-based guide to designing and undertaking qualitative, quantitative, and participatory research in care homes
http://eprints.lse.ac.uk/41191/1/SSCR_Methods_Review_8_web.pdf

For more information about the DECISION Study, including an animation of the findings, visit:
<https://www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/decision>

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