

Conference presentation

Process consent and research with older persons living with dementia

JAN DEWING

Independent Consultant Nurse (Jan Dewing Consultancy); Honorary Research Fellow Institute of Nursing Research University of Ulster; Visiting Fellow Northumbria University; Professorial Fellow University of Wollongong NSW Australia.

Email: Jan.dewing@btinternet.com

There is always a debate around consent in the context of research. Given the expansion of different approaches to qualitative research within dementia care, there is increasing consideration around consent in this context; particularly in research concerning the experiences of living with dementia and the care of persons with dementia. Specifically there is a drive to directly involve persons with dementia as they offer specific expertise concerning living with dementia. Additionally, capacity legislation strengthens the case for ensuring that persons with dementia are actively enabled to make their own decisions for as long as possible. This paper discusses an approach and method that can enable more persons who are living with dementia to participate in some types of research should they want to. Currently, most researchers rely on an extension of the traditional competency-based informed consent method and/or proxy consent or assent. However, related to the development of so-called person-centred and participatory research in dementia, there are now a number of academic publications on approaches and practical methods of 'inclusionary' consent. This paper considers the broader contextual influences on inclusionary consent and outlines the key aspects of such approaches based on the development of one specific method for including persons with dementia in consent processes. The method is based on the premise that, for persons with a dementia, informed consent becomes increasingly redundant and consequently exclusionary to them as persons. And even where capacity is said to no longer exist, persons with dementia are often able to make choices and make known their preferences about participating in research where the consent process is made specifically dementia-sensitive. Ethics committees can facilitate researchers both by supporting them when they need to and want to include persons with dementia in gerontological research and by challenging them to ensure that participation is genuine and starts with process consent.

Introduction

Although a sizable and growing group in our society, it is still common for persons with dementia, in keeping with the wider social and cultural exclusion they experience, to be excluded from a range of qualitative research. This is for a number of reasons that may include a lack of academic development around how consent can rigorously and practically be addressed in this area [1-2]; researchers feeling they do not have the expertise or time to include persons with dementia; a perceived lack of dementia-friendly research methods; some researcher's beliefs that ethics committees will automatically reject submissions that include persons with dementia [3]; ethics committees feeling that particular research does not require persons with dementia to be included; and being unconvinced about the rigour of the ethics submission where persons with dementia are included. There is an increasing recognition amongst researchers, particularly within social gerontology and nursing, that persons with dementia should not only be included in research (as subjects) but also be given opportunities to participate in research as participants [4-8].

With this comes the accompanying debate around what inclusion in research means and the level to which it can be achieved without being too cognitively and emotionally demanding for persons with dementia. Where capacity is queried, proxy consent has often been preferred; deemed preferable by some, even where residual capacity for non-cognitively based consent remains [9-10], and despite evidence suggesting conflict exists between persons with dementia and their proxies (see for example [11-12]). Additionally, Dewing [7] has said that persons with dementia often object to a carer providing proxy consent. Although some protection needs to be available, continued adherence in social gerontology to a traditional approach based on a universal system of ethics grounded in responsibilities and rights is not always consistent with core principles of social gerontology. Traditional moral theories in their effort to be universal are often inadequate in that they fail to account for different voices [13, 14]. They also place high value on the traditional model of autonomy and beneficence which is not helpful for older persons with dementia [15]. Capacity legislation may go some way

to helping readdress the balance depending on how it is interpreted [16].

This paper will focus on one significant area of inclusion in research; that of consent. Specifically, process consent is the approach and methods taken both informally and formally to making consent a real and meaningful activity in research where the person with dementia is enabled to participate in meaningful ways to the level of their capacity and other abilities regardless of legal capacity. This is both relevant and significant because the form of the ‘moral space’ [17] around the research (which includes consent) helps set the foundations for the relationship between the researcher and the person with dementia throughout the research process. The paper begins by offering some background and then moves on to describe the principles underpinning process consent and outlines the key aspects that need attending to in order to enable greater participation by those living with dementia and on the threshold of capacity and by some of those without capacity.

Personhood and consent

There are a number of fundamental principles about those of us who are living with dementia that form a values base for process consent. Firstly, persons with dementia are entitled to be regarded and treated as persons [18] regardless of their cognitive state. Being able or enabled to make choices is one of the core attributes of being a person and a demonstration of whether or not others respect us as persons. In terms of consent this is legally enshrined by the assumption that capacity must be presumed to exist unless it is proved otherwise. Where found to be on the threshold or not to exist, it is still necessary to enable persons with dementia to be as capable as possible in terms of making choices. Given there are still many negative images of dementia and negative consequences of late diagnosis and poor care, it is vital that wider cultural stereotypes and even personal experiences do not impose stereotypical decision making and a blanket view about dementia and its ‘inevitable consequences’. Wilson [19] theorizes that later life must be seen in terms of difference and diversity. It follows that persons with dementia are diverse and different. In the context of consent, the ability to make decisions and then choices is also diverse. Thus, blanket exclusion or inclusion from research is not an acceptable solution. Accepting that older persons with dementia can be involved in research means everyone in the research ‘business’ must collaborate to find creative ways of enabling persons with dementia to be included and participate in research.

Informed and proxy consent

Often resulting from a desire or perceived duty to protect, exclusion and its consequences for the per-

son with dementia have generally not been the main concern in informed consent. The main issues for persons with dementia with consent obtained via proxies are twofold. Firstly, the person with dementia has generally not been included in any meaningful way. Informed consent does not necessarily require contact with the person with dementia until after proxy consent for the research has been given; a practice which may amount to ‘exclusionary ethics’ [20]. Kitwood [17] summarizes this; although, the original intention of proxies is to protect the person from harm, the emphasis on ‘right doing’ and duty has in consequence, a direct focus on the researcher and proxy and not the person with dementia. Gilligan [21] contends that such rights based approaches are a simplistic way to deal with competing needs within a situation or relationship.

Secondly, if they are included, the almost ritualistic and cognitive-competency-based approach of informed consent can make the experience daunting. The person with altered abilities in communication, memory, language and perception does not experience the ritual of informed consent from the perspective of a cognitively competent subject/participant. Thus something more dementia-friendly needs to be used. It could be conversely argued of course, that proxy consent at its best (for example with skilled advocates) means that although invisible, the person’s voice is heard in the process [22]. However, not all persons with dementia are in the position of having skilled advocates. This can be addressed by ethics committees asking for evidence about when and how the person with dementia is going to be included. Where the principle of best interests has been followed based on last known preferences and wishes, a person with dementia may in the present demonstrate objection to participating. Thus ethics committees need to ensure that researchers are able to respond to the ethical dilemma of last known wishes versus here and now responses. For persons with dementia there are specific issues around the ‘then’ and the ‘now’ self [11, 20, 23] and with precedent autonomy [24]. This is something that may need to be more of a focus in ethics submissions. The overall principle must be about how to promote inclusion in meaningful ways. The challenge for ethics committees and researchers is therefore to ensure that the traditional invisibility and silence of persons with dementia is corrected and that decision-making based on best interests (rooted in the past) does not exclude here-and-now preferences and choices that emerge from lived experience.

Exclusion through valuing the then or past person more is as good as saying that persons with dementia are now inferior beings. Ultimately, Post [13] warns, there are strong tendencies in our hyper-cognitive culture to exclude those of us who are deeply forgetful by

reducing moral status or by neglecting the emotional, relational, aesthetic and spiritual abilities that remain in the here and now. Exclusion also limits the opportunity persons with dementia have for engaging in what they might feel and experience as a meaningful social encounter or a therapeutic process [25-27]. As with many people, participating – being useful and making a contribution – may be highly significant in terms of therapeutic potential as a broader sense of meaning and purpose can be found through voluntarily contributing to research for persons with dementia [28].

Inclusion

Here the focus is with relationship and connecting or engaging with the other person, using residual capacity and other abilities, with a view to working out consent issues as an on-going process through their relationship. Consequently this will mean that both the continuous thread between the person's past and future self, and the person in the here and now as a perceiving feeling being, will be a focus for the researcher. Inclusionary consent processes need not be problematic if they are perceived as a part of the person's lived experiences of dementia, and to be negotiated as part of a particularistic ethical discourse [13, 26]. However, process consent with persons with dementia should not be an informal activity with no audit trail or be unreplicable. Some persons with dementia can be reasonably expected to participate in full informed consent with alterations made for the consequences of the early changes in cognition and have a meaningful, informed and engaged experience for both parties. Offering simplified information and consent forms is however only one way forward and can be a source of anxiety for some [25]. As cognition fails more, many persons with dementia require a more radical way forward.

In many situations, older persons with dementia do become excluded from being involved in research as active participants by default. Ethics committees may feel it is practically too difficult to do, the risks are too great and where informed consent is not applicable there have been no other detailed options set out for them [29]. Whilst ethics committees have some responsibility for this situation, gerontological researchers have perhaps been too ready to accept the so called gold standard of informed consent and thus slow to develop viable alternative methods acceptable to ethics committees and take risks with presenting ethics committees with alternative methodologies and methods: there are already some accounts of alternative methods available (for example [30-32]). If ethics are based on inclusion then it has to be based on capacity and competencies that persons with dementia retain. Advance directives about inclusion in future research as suggested by Post [33], can go some way to dealing with exclusion, although there

are acknowledged problems with a system based on precedent autonomy [20, 34]. For example, changes in decisions, whether seemingly deviating from the person's overall life plan or on smaller day-to-day issues, can be greatly influenced by the values and beliefs of others, the environment and the culture of care amongst other reasons. Non-cognitive ways of knowing, and remaining cognition within the person, must inform and guide the researcher. There can therefore be no one method for inclusionary consent for all although the principles or methodology on which the methods are grounded can be common.

Process consent method

The overall purpose of this final part of the paper is to outline the key aspects of the process consent method. These have been drawn from a specific model of process consent which has been developed, tested and refined over the last ten years in the UK and elsewhere (for example: [7, 29, 35-39]). At this point, the model has been successfully submitted to numerous research ethics committees around the UK, Republic of Ireland and also adapted for use in Australia in different types of qualitative research and practice development. The method is designed for use with older persons who have a cognitive impairment (usually through a dementia) and changes in their capacity that would be expected to exclude them from giving informed consent. The values behind process consent are those of a revisionist notion of person-centredness and inclusionary ethics that values the interests of all parties involved, including above all the person with dementia. It also recognizes that ethical decisions and actions are context-specific, and centred on interdependence within a caring relationship, and acknowledges that capacity is situational, that residual capacity can be present even after the legal threshold has been crossed and that it is often strengthened or even reinvigorated within an enabling and caring relationship. Thus it allows for a particular rather than a universal approach to consent. It incorporates principles of personhood, direct representation of interests, equality and social justice [21, 40-46]. Consequently, this enables recognition of persons with dementia as active persons capable of engaging in co-operative participation. Although it contains elements of negotiated or tripartite methods as described by Grout [32] Barr et al [31] and Moody [28], this method moves beyond negotiated or tri-partite methods of consent because the person with dementia is the centre of the process.

An outline of the method

The method comprises five aspects (see box). They are not necessarily linear, with the relationship between each being fluid, according to context and

people involved. Whilst the method offers a pathway for researchers, the process very much relies on the researcher's expertise in being able to engage with persons who have dementia, and to value and see the meaning in all types of communication made by the person and on their own critical reflection skills. There are three fundamental questions that researchers need to be concerned with:

- How do I know this person is consenting?
- What type of appreciation does this person have of their consent?
- How would this person demonstrate reluctance and/or objection?

The process consent method

- (1) Background and preparation
- (2) Establishing a basis for capacity and other abilities
- (3) Initial consent
- (4) On-going consent monitoring
- (5) Feedback and support

Preparation work in knowing the person's residual capacity and other abilities enables the researcher to set the complexity of information and questions to a level that the person finds meaningful. Throughout, the researcher is looking for: (1) verbal, non-verbal and behavioural indicators that suggest that the person is wanting to consider the research and their participation, or not; (2) constant building up of a picture that enables them to know when 'yes' means yes and 'no' means no; (3) opportunities to look for the implied meaning in what is being said rather than looking for intellectually correct language [47]. Although clearly there is still a cut-off point in this method in those occasions where some persons with dementia may lack abilities to make even small choices and decisions, or where their ability to communicate is severely reduced, and thus researchers may decide that it is in the best interests of the person that they are not included.

One: Background and preparation

This aspect of the model requires researchers clarify that permission to access the person with dementia has been gained from staff, relatives or another named person. It is important to note that this permission for access does not equal proxy consent. This recognizes the role of various gate-keepers [48] although it may not always be necessary to do this before approaching the person with dementia. However, it does enable persons deemed meaningful by the person with dementia and/or authorized representatives to be included in the process. The principle to be observed here is that researchers should be transparent about their negotiations. Seeking permission also acts to remind those in gate-keeping roles

that they have a legal and professional duty of care towards persons with dementia in their care and must act based on best interests.

Researchers need to establish basic biographical knowledge of the person. It is suggested that as a minimum, the researcher has some clues about how the person usually presents themselves when in a relative state of well-being. The person's usual level of well being needs to be assessed through generating descriptions of how the level of well being is recognized by an observer and where the usual level is situated. Alternatively, generating a description of facial expressions for different levels of well-being can be a helpful tool. A state of well-being with positive emotions can positively influence cognitive and emotional processing [49]. Approaching the person in a state of well-being means intrapersonal and environmental conditions are favouring the building up of trust between the person with dementia and the researcher.

Two: Establishing the basis for consent

Here the researcher is primarily concerned with establishing the basis for consent beginning with whether legal capacity exists or not. The researcher must consider existing assessments or opinions on capacity [50]. Where scores are used, and show significant cognitive deficit, this does not mean the researcher can assume that the person lacks capacity and should be excluded. Instead it challenges the researcher to find a way of trying to include the person. The poorer the score the more the researcher needs to sensitize their approach to the person's level of ability. It may be that in the presence of capacity an adapted informed consent process can be used. Using the process consent method will add credibility to any informed consent and help researchers respond to any challenges about their decision making processes. Should capacity not exist, the researcher needs to establish to what degree the person can make choices for themselves. Here there is significantly less emphasis on the person's ability to retain information and appreciate consequences and more on how it feels to the person in broad terms. Thus it is still possible that consent can be established in an on-going process, it is however not informed consent. Once in this domain, the consent must be revisited continuously, hence it is an ongoing process. Throughout the process, the researcher needs to note any significant conversation or behaviour that might be indicative of a deeper psychotherapeutic need and possible courses of action

Three: Initial consent

The consent process moves from what is known about consent and assent in general terms to its translation into the specific context. The exact way of achieving this will vary. It will generally involve pro-

viding information. However, researchers need to assess the person's abilities and preferred ways of receiving information. For example; adapted written information may work well; for others it may need to be highly modified or simplified down to single key words with or without pictures. For some, pictorial information or the handling of objects or 'props' relevant to the research may be more helpful. Whilst others can have residual capacity enabled through use of web-based information which they can work through. Several doctoral studies have used these methods; Dewing [37] in a study on wandering which included videoing, used pictures of the video camera and the actual camera in the discussions with participants who were then able to handle the props to help them contextualise the discussion. Knight [51] used a video specifically about process consent whilst Donnelly [37] used a heel boot which was the research intervention. With some, it may be possible to judge consent based on a very slow gradually introduction of the research and consent is judged on how the person responds and what feelings they express. This in effect is what the process consent method advocates in all situations, however here it is drawn out to a pace that may better respond to remaining abilities.

Four: On-going consent monitoring

The principle here is to ensure initial consent is revisited and re-established on every occasion and even within the same occasion thus highlighting the notion of consent as a process. Here, researchers assess that the way in which on-going consent is provided is consistent to the initial consent. The level of transparency can be increased by asking someone else known to the person to validate the process. The method thus allows for an independent observer to track the well-being of the person with dementia at any point, should the context support this. Tracking or assessment can be informal and unstructured or it may be highly structured using a specific method or tool.

Five: Feedback and support

In some situations it may be necessary for researchers to consider providing staff, principal researchers and/or supervisors with feedback about the person's well-being or on a particular concern. Feedback needs to be thought about carefully in relation to confidentiality. Where possible, feedback to be given to others should be agreed with the person with dementia beforehand so that they are included or taking the lead if they choose. Researchers must also consider if the person with dementia needs support to make the transition back from the research context into another context such as their day-to-day environment. The researcher notes any interactions or interventions made with the person in order to achieve a transition/return back into another social relationship or their environment of care.

Summary

Working towards inclusion rather than exclusion is the way forward for qualitative research about dementia and persons with dementia. The principles of process consent are meant for use with persons who have an extremely limited capacity, who would generally be thought to be incapable of legally informed consent by others, but on observation can communicate and express their wishes in other ways. Process consent can add to formal and informal or proxy-based consent methods and can also constitute a formal consent method on its own. In this regard, it can offer society at large and persons with dementia opportunities for involvement and inclusion in research that otherwise would have not been possible.

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