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DESIGNING WITH AND FOR PEOPLE WITH DEMENTIA
Wellbeing, Empowerment and Happiness

What is needed to obtain informed consent and monitor capacity for a successful study involving People with Mild Dementia?

Our experience in a multi-centre study

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ABSTRACT Strategies on informed consent process and capacity monitoring for mild dementia research are at developing state. We reflected on our experience and found that the successful collection of informed consent and full participation of PwD required the involvement of familiar healthcare professionals/care workers/staff at the recruitment and data collection stages and this needs to occur in an active support environment. Time is another important factor affecting the success of the study.

Keywords: mild dementia, informed consent process, capacity monitoring, multicentre study

Background

Informed consent in research is a process whereby individuals have the opportunity to freely determine whether or not to participate in a study; and this decision requires that individuals receive appropriate explanation, full understanding and the opportunity to ask questions before giving consent. The potential participant must be treated as an autonomous agent who is considered to be capable and free to decide, and, therefore, the person has the capacity to understand, evaluate, and use the information; and thus is choosing without external controls or pressures. For people with dementia, the ability to provide informed consent may be an issue when these individuals are experiencing altered abilities in communication, memory, language and perception.

The issues related to informed consent focus on capacity to decide, disclosure of information, assessment of understanding and voluntariness. Having the capacity to decide is a necessary prerequisite to giving informed consent; whereas disclosure of information, assessment of understanding, and voluntariness are usually considered to be the common elements of informed consent. For people with mild dementia - who are deemed to have capacity after an evaluation - support, care and time are crucial to help them understand and decide to consent to participation (Helstrom et al, 2007; Beattie et al, 2018; Sherratt et al., 2007).

Researchers require approval from ethics committees and/or institutional review board before their study can commence. The responsibility of the ethics committee/institutional review board is to ensure that individuals' rights are protected; that individuals demonstrate the capacity to consent; the possible risks to participation are identified and minimised; and that the consent document is clear, concise, and accurately represents the study. However, there is limited guidance to assist ethics committee/IRB in considering the capacity to give consent in dementia research. The *Declaration of Helsinki* (World Medical Association, 2013), the *EU's Ethics for Researchers* document (European Commission and Human Services, 2009), or the *England NHS HRA's Consent and Participant Information Sheet Preparation Guidance* (HRA, 2018) do not prescribe specific procedures to determine capacity for dementia research. There are the existing standard procedures for obtaining informed consent, grounded in responsibilities and rights (Bjørnby et al, 2004). This set of procedures, however, is not consistent with research claiming to be person-centred and which values personhood (Gerritsen et al., 2018; Thorogood et al., 2018).

The current ethical application procedure emphasises the *product* - namely the completion of a set of documents and adherence to ethical policies that place high value on the traditional model of autonomy, beneficence and legal rights - rather than the *process* of informed consent to participation. This process consists of how the information is presented; who describes the study protocol (and how it is described); the psychological state of individuals;

and where (what environment) and by whom (companions, relatives) should informed consent be given. Attending to the process - rather than the product - can influence the decision-making and increase the likelihood of participation in research.

Strategies to facilitate the process to obtain informed consent for dementia research have been proposed (Dewing, 2008; Erlen, 2010, Murphy et al, 2015). Dewing (2002) provided a framework to obtain informed consent for research that is underpinned by a particularist approach. This framework considers informed consent as a continuing activity (Figure 1). A particularist approach recognises the personhood, identity and value of person with dementia (PwD); and its continuous informed consent monitoring approach assesses capacity throughout the study (because it acknowledges the 'then' and 'now' self of research participants). Dewing also emphasises that researchers need the necessary skills to communicate with individuals/participants with capacity issues.

1. Background and preparation
    a. clarify permission to access the person with dementia
    b. establish basic biographical knowledge of the person with dementia
    c. assess the person's usual level of wellbeing
2. Establishing a basis for capacity
    a. establish whether capacity exists or not
    b. if capacity does not exist, the researcher needs to establish to what degree the person usually consents to activities in day-to-day life
3. Initial consent
    a. initial consent for the study. Information about the study given in a way that will help the person understand
4. Ongoing consent monitoring
    a. initial consent on every occasion
5. Feedback and support
    a. feedback to staff on the person's wellbeing or concerns

Figure 1: Five aspects of the process consent method (Dewing, 2002)

Apart from sharing Dewing's strategies (training researcher to collect informed consent, regular monitoring of the consent process), Erlen (2010) also suggests a need to develop quality informed consent documents written at a literacy level fitting those of the target population and with the involvement of users. Murphy and colleagues (2014) reviewed strategies within dementia research literature and synthesized the findings to develop the CORTE guide. CORTE stands for 'gaining COnsent, maximizing Responses, Telling the story, and

Ending on a high', and is used at the data collection stage. The CORTE guideline was used as an analytical tool for relevant research reports; to maximize the meaningful involvement of PwD; and act as a learning tool between researchers (Murphy et al., 2014).

In this paper, we will reflect on our experience of obtaining informed consent and capacity monitoring in a multicentre study, with the aim of determining the conditions needed for full participation in the study.

The MinD project

The "MinD – Designing for People with Dementia: designing for mindful self-empowerment and social engagement" – project is a 4-year project, funded by European Union's Horizon 2020 research and innovation programme, which began in 2016. The project aims to help people with mild dementia engage in social contexts to improve psychosocial wellbeing and self-empowerment. The project combines expertise from 17 organisations from 8 countries (United Kingdom, The Netherlands, Germany, Luxemburg, Spain, Italy, Australia and Russia), including eight universities, one healthcare policy partner, four healthcare partners, and four design/ICT partners.

The project comprises three phases with involvement from persons with dementia (PwD) at all phases. Phase 1 involves a qualitative data collection, aiming to identify the most relevant areas of need for assistance with regard to activities of daily living, social engagement, decision-making and subjective wellbeing. The findings of this phase inform Phase 2 – a co-creation phase formulating the type and development of designs; and, in Phase 3, the designs are evaluated with people with dementia. Ethical approval was obtained from institutional review boards and regional ethic committees in all the partner countries before the project commenced in 2016.

Phase 1: Qualitative data collection

Qualitative data were collected using both individual interviews and focus group discussions in Germany, Spain and the Netherlands. In Germany, participants were recruited at the Alzheimer's Gesellschaft, the Department of Old Psychiatry at the St. Hedwig Hospital, Berlin – then interviewed at their homes – while focus group discussions (FCGs) were carried out at an occupational therapy practice in Dresden. Participants in Spain were recruited and interviewed at the INTRAS' Memory Clinic in Valladolid - a social and health resource designed to offer (on an ambulatory basis) treatments for the prevention of cognitive impairment, evaluation and neuropsychological rehabilitation. In the Netherlands, participants were recruited and interviewed at Zorggroep Sint Maarten – a nursing home care which also provides ambulatory services.

A topic guide was developed based on a priori knowledge from a literature review, and covered 4 areas: activities of daily living/managing and coping with daily life; social engagement;

supporting psychosocial well-being; and potential for use of technological devices (and attitudes towards them).

Interviews and FCGs were conducted by researchers who had experience working with PwD (or received training prior to the interviews). A note-taker was also present. The interviews lasted up to 60 minutes on average, while focus group discussions took up to two hours. All interviews and FCGs were audio-recorded with consent from the participants. Design probes were used to facilitate and seek meaningful answers from the participants. A total of 104 people with mild dementia and their care-givers participated in the study. Data management was performed using MaxDA and analysed using Thematic Analysis approach. The findings were used to inform the development of designs in Phase 2.

Phase 2 – Deciding and Developing the Designs

The findings from Phase 1 were shared with healthcare professionals, PwD and/or PPI (Patient and Public Involvement) groups in the co-design Phase 2. PPI group workshops - to identify and develop the design concept - were organised in Berlin (September 2017: carers and healthcare professionals), Barcelona (September 2017: carers and healthcare professionals), and in the UK at the Nottinghamshire Healthcare Trust (October 2017: carers and people with various memory issues). Another co-design workshop was organised with PwD in an Alzheimer's day care group by the Alzheimer's Society Research Partnership scheme. The final design, The Good Life Kit, consists of 3 components, aiming to fulfil the needs of PwD as initially identified in Phase 1.

Phase 3 – Evaluating the Good Life Kit Design

The evaluation phase started in the Netherlands, Spain and Germany at the beginning of 2019, with the UK to follow in March 2019. The evaluation questionnaire was developed using user-friendly language. It covers aspects required to assess user experience of the new product. It was piloted with the PPI group in Nottingham, UK, and additional documents were produced to aid the delivery of the evaluation – specifically a user-friendly participant information sheet and questionnaires adapted to local context (language and presentation).

Reflection on the process of obtaining informed consent and capacity monitoring

All the four healthcare centres/clinic and universities completed local institutional application forms – and received ethics approval as required – at recruitment and data collection stages. We followed institutional ethical procedures to collect informed consent; used experienced researchers (or researchers who had received training) and data collection tools that were developed to meet the needs of the target population; and included members of staff (with wide experience of working and caring for people with dementia) and caregivers during data collection and evaluation of designs.

Process to obtain informed consent and monitoring capacity

Access to PwD determined the approach that we used to recruit participants into the study. Researchers based in healthcare provider organisations - such as clinics or care/nursing homes - had direct access to recruit PwD into the study; whereas university-based researchers did not have direct access, and thus required assistance and collaboration from case workers/managers who worked with PwD. Regardless of the recruitment approach, at all stages of the study we involved healthcare professionals familiar to PwD to support and monitor capacity.

Germany:

The clinician/researcher and her team approached all patients with mild dementia who visited the clinic for treatment. These were PwD who they thought were able to give consent and seemed sufficiently active to talk/participate in activities. The procedure used to ensure that PwD have the capacity to consent is as follows:

- Explain the study in short sentences using few words with no time pressure.
- Focus on the PwD without interruption from accompanying relative.
- Enquire if the PwD had any questions.
- Ask the PwD to repeat what was just explained in their own words – to test their understanding of the study and activities.
- Ask the PwD what would happen if they did not give consent. This is to ensure that the PwD understands that the choice of participation is voluntary and the care they receive will not be affected if they decide to stop before completing the study.
- Emphasise and clearly state that refusal to participate would not affect their treatment or further treatment.
- Allow time (1–2 days) to provide consent. Give out the consent form and ask the PwD to think about their willingness to participate. PwD are asked to return with the consent form – or ask any questions – within 1–2 days.

Consent was not monitored during the study in Germany. However, before the commencement of the study, the researchers (who are also staff of the clinic) reiterated that participation is voluntary and that the participants could stop whenever they want to without giving any reason. They also repeated that if a PwD stops participation, any information or data provided will be destroyed. On recruitment, many PwD agreed to participate in the study because they feel that it is important to the relative/caregiver and/or the treating therapist. The patients are mostly accompanied by the caregiver or a close person.

Spain:

Researchers who are also healthcare professionals specialising in dementia care at INTRAS recruited eligible PwD among those attending the INTRAS Memory Clinic services, and evaluated their capacity to consent. In simple language, researchers explained the study to the

PwD and caregivers (relatives, children, spouse), and then handed them the participant information sheet, an invitation letter, and consent form written to fit PwD's literacy needs. Potential participants also received a newsletter specially produced to inform PwD and carers about past and current work/activities in INTRAS.

Upon expression of interest, researchers took time to communicate the information with participants, and ensured that PwD were able to understand the information and ask questions. In all the interviews/discussions, we involved the dementia expert/healthcare staff familiar with the participants, to monitor capacity and voluntary participation. Researchers also paid particular attention to participants' feelings and expectations - and verbal and non-verbal language - during the study.

The Netherlands:
Case managers who frequented the nursing home, Zorggroep St Maarten, asked residents with mild dementia if they would be willing to participate in the study. They identified PwDs who expressed an interest and evaluated their capacity for participation. Case managers subsequently organised the meetings between the potential participants and the University of Twente's researchers. Researchers visited the nursing home, explained the study, collected informed consent and conducted the study. Case managers are regular visitors and are known to the participants. They were present throughout the study to monitor capacity and, being known to the participants, it would be easy for them to identify behavioural change or distress during the study. Participants understood that participation was voluntary and they could stop at any time, without their rights and care being affected. One participant left the study after consenting, because she did not feel like talking about herself or did not like using the Good Life Kit.

United Kingdom:
The UK researchers (from the University of Wolverhampton and Manchester Metropolitan University) were granted permission by the Alzheimer's society to run the evaluation of the Good Life Kit (This is Me) design with the dementia day group based in Solihull, West Midlands. PwD attending the weekly day group were informed about the study by their care manager and worker. They were also handed information about the study and a consent form and were told to discuss the study with their carers at home. PwD were given a week to decide on participation and to return to the day group on the following week for the study. On the day of the evaluation, care workers assessed the capacity of the PwD who came to the meeting, and only those who were willing to participate were included. Before informed consent was sought, the researchers explained the study and handed out additional information about the study. The participants were divided into 3 groups with 4 in each group. The researcher further explained the study and went through each of the items in the consent form. All except two PwD consented to participation; two PwD worried about disclosing their names and signatures because they said that their spouses told them

strictly not to provide name or sign any document. During the evaluation, capacity was monitored at all time by three care workers who constantly observed participants' behaviour to assess their willingness to continue with the activity. Participants understood that their participation was voluntary and they could stop at any time.

Challenges faced to obtain informed consent and capacity monitoring

We encountered similar challenges across the four study sites:

- Using appropriate way of communicating/describing the study with short sentences, yet precise enough to make the aim of the study and questionnaires understandable to PwD.
- Finding the appropriate pace while explaining the study and to not overwhelm PwD with information. Studies with PwD therefore cannot be rushed and sufficient time needs to be included to complete the study satisfactorily.
- Being attentive and showing understanding at all time; as well as being observant about verbal and non-verbal language which might indicate capacity issues and diminished interest in participation.
- Observing the interaction between caregiver and PwD to make sure that the PwD is not pressurised to participate by their caregiver. However, the presence of caregiver could be positive because PwD felt safe to consent and this encouraged their contribution.
- Needing time to gain trust for PwD to provide personal data such as name (first name only was requested) and signature; and to ensure participation. PwD were wary when asked to provide personal information, as they had been told not to disclose this information by their carer givers and care workers. In future, consideration may be given to involving caregivers in order to secure participation of PwD. Also, in order to gain trust, a longer period of time might be needed for researchers to familiarise themselves with participants before the study.
- Recognising the many logistical aspects key to ensuring participation and long-term motivation to stay with the 3-year project; e.g. when and where to meet being determined by the participants.
- Realizing the standard institutional consent form has overly long sentences and technical terms which were hard for PwD to read and understand; simple and short sentences and font size appropriate to PwD should be used in future.

Our approach to seek informed consent, and monitoring capacity with sensitivity to needs, is grounded in the expertise and knowledge of experienced healthcare staff working with PwD. The same approach was recommended by Dewing (2002). Healthcare teams sought access to PwD and collected the relevant information about their condition and wellbeing in order to assess capacity for recruitment. Potential participants were handed a Participant

Information Sheet – consisting of the usual topics: i.e. the purpose of the research; who is involved; how to participate; potential risk and harm; voluntary participation; withdrawal and standard of care; data management and confidentiality; and contact details of researchers and complaint contact details. PwD were allowed time to consider participation. Care was taken to present the information, both in simple written and oral formats. The speech was adapted in order to ensure PwD were able to clearly understand the information provided in the PIS. We took time and care to explain the study and participation, and provided PwD with ample time and opportunity to ask questions. Research activities took place in environments familiar to the PwD – either in the care organizations facilities or the PwD's home. During all research activities involving PwD, case managers/workers known to the PwD accompanied university researchers, and were present to assess capacity and monitor behaviour.

In our interactions with PwD, we showed consideration, sensitivity and sensibility, support and care. We continued to assess capacity and wellbeing throughout the study with the presence of healthcare staff familiar to the participants. We also ensured that we raised awareness among ourselves and the participants of their needs and comfort - with the aim of establishing an environment for participation that was secure, created a feeling of confidence and motivation, and fostered meaningful participation. Our practice in all the institutions showed that we valued 'personhood' and placed the needs of our participants first. We also created an environment of mutual respect, kindness, and mutual support between the research team and participants in all the institutions involved.

Discussions

Current ethics procedures are based on traditional moral theory that bridges philosophical and legal approaches to informed consent – i. e. grounded in autonomy, and the role and responsibility of researchers to minimise harm and risk. These guidelines place priority on the legal rights and the product/outcome (informed consent), rather than the processes of delivering and obtaining informed consent, and monitoring capacity and voluntary participation in dementia research. For dementia research with people with mild dementia, our experience showed that both product and process are essential to protect PwD from harm and risk.

The lack of ethics guidelines for mild dementia research – particularly focusing on the process to determine, and monitor capacity and voluntary participation – has created problems within partner countries as we have to rely on our experience and knowledge to deliver an ethical study; the problem was further compounded by the differences in setting and context between partners. Using experienced healthcare professionals (clinicians and case managers/workers) working with PwD, we were able to successfully recruit participants, while facing challenges through the journey arising from our differences.

It is widely recognised that dementia research demands a particularist approach which values personhood and a continuous monitoring of the capacity to consent process; and which acknowledges altered abilities in communication, memory, language and perception of PwD. Our steps are similar to Dewing's 5-step informed consent framework, and we developed and implemented quality protocol and data collection tools including interview probes with PwD involvement. We were also supported by care workers/staff members at all the stages of the study. This strategy ensured that PwD's autonomy was protected and enhanced at all time.

Additionally, the successful recruitment and completion of our study is due largely to the actively supported, mindful and friendly environment we created: underpinned by the following principles:

— Place needs of PwD first –
acknowledging personhood; showing sensitivity to their needs;
addressing cognitive abilities and functions at different times
with simple language, using prompts/cue cards/photos and
carefully constructed statements to communicate.
— Create autonomy –
providing PwD with relevant information to make decisions.
— Enable autonomy –
providing active support to PwD so that they can
be encouraged to retain and express their sense of self,
rather than simply being protected from harm or risk.
— Preserve dignity and uphold well-being of PwD. Treating a person in a way which maintains and upholds their values as a human being creates dignity.
— Promote trust and mutual respect between researchers,
participants and caregivers.
— Facilitate the diversity within research team through training and
developing documents to promote understanding and appreciation.
— Use communication skills appropriate to PwD.
— Adopt autonomy monitoring by staff/care workers familiar to the PwD.

Conclusion

Treating informed consent as a process and adopting a continuous monitoring of capacity to consent and participation in dementia research, are two pertinent elements of valuing personhood. However, the success of obtaining informed consent and participation from PwD in a multi-centre dementia study hinges on the involvement and presence of healthcare professionals or care workers/managers whom are familiar to the PwD at both recruitment and data collection stages. In addition, the study needs to be conducted in an active support environment that places PwD first, where autonomy is created, enabled and

maintained; dignity preserved and well-being upheld; and mutual respect promoted. Researchers also need to have the skill to communicate with PwD and allow sufficient time for implementation of study.

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