# Methodology - Ethical issues and consent

***“Ethical issues are not just something that needs to be taken into account in completing application forms for ethics committees. Consideration of ethical issues should be a feature of each stage of focus group research ….” (Barbour, 2009, p.100)***

SMART4MD is an app and platform developed under European Commission, H2020 Project 643399 for people living with dementia to manage their health and improve their quality of life.

The project used focus groups, design guidelines based on COGA research, and userability testing to help adapt the platform for people living with dementia. The following is a summary of the methodology used for ethical considerations such as informed consent.

## Respecting autonomy

### Informed consent process

A key condition for the conduct of ethical research is that participants have been informed of and understand the purpose of the study and of possible harm which might arise as a result of participation, that they have given informed consent and that appropriate measures have been taken to minimise the likelihood of harm occurring. Article 1 of the Declaration of Helsinki (World Medical Association, 2000) covers respect for the autonomy of research participants. Respect for autonomy is traditionally described as the “the norm of respecting the decision-making capacities of autonomous individuals” (Beauchamp and Childress, 2008, p.12). Where autonomy may be diminished, participants must be protected from exploitation of their vulnerability and their dignity must be respected (Belmont report, 1979, quoted by Mack et al., 2005).

Whilst these documents and definitions were developed in the context of biomedical research, non-medical research involving humans, especially those who are vulnerable, also typically requires ethical approval, involving obtained informed consent. The two main values governing the need to obtain informed consent are: 1. to promote and protect the person’s wellbeing, 2. to respect the person’s self-determination (Buchanan and Brock, 1990). If the planned focus groups are considered as consultations (e.g. in the context of patient and participant involvement) rather than research, it is likely that in most countries, ethical approval and a formal consent process involving the assessment of capacity would not be needed. This should be verified. However, the consultations/focus groups are being conducted in the context of a research project. Consequently, although a formal informed consent procedure may not be an ethical or legal requirement, we could still consider obtaining such consent.

Consent can be considered valid if it has been given by a person with the necessary capacity and provided voluntarily (not obtained under duress), based on the provision of relevant information (e.g. full details of what is involved, including possible risks and benefits). It is therefore important to provide participants with the information they need to make an informed decision and this can be achieved either verbally or in writing and either before the consultation or on the day. Both are possible i.e. a participant information sheet given to participants before the event and a brief presentation at the start of the consultation.

The participant information sheet could perhaps cover the following:

* The aim of the project
* The aim of the consultation
* Who is in charge of the project and introduction of the group moderators
* The fact that it is voluntary and that people can leave at any time without having to explain why
* Issues surrounding the use of the data that will be collected
* Ground rules and expression of gratitude to the participants

### Capacity and consent

Capacity is task specific in that it relates to the ability to perform a particular task, at a particular moment in time and under specified conditions (Buchanan and Brock, 1990). The capacity for a particular task may, with people with dementia, sometimes fluctuate, not only because of the dementia but also owing to a range of factors (e.g. psychosocial, situational, medical, etc.) (Holzer et al., 1997). However, a person either has or does not have the capacity to consent to a particular consultation at a particular time.

If people turn up to the focus group discussion, having read and understood the participant information sheet and having been given the opportunity to clarify any questions about the consultation, this could be taken as implicit consent. Such consent could be complemented by explicit consent at the start of the consultation when the focus group moderator runs through the information about the consultation, explains the “house rules” and asks whether everyone agrees to the recording and use of their data. Oral consent is often considered acceptable for research with minimal risk or where a loss of confidentiality is the primary risk (Mack et al., 2005). Sometimes, a written, signed consent form is the actual threat to the confidentiality of data (Dubois (2008).

A problem may arise if the moderator suspects that a person who has agreed to participate does not fully understand the purpose of the consultation, does not fully understand that the data (although anonymised) will be used for the purpose of the study and/or that the discussion is being recorded. On the other hand, it should not be assumed that a diagnosis of dementia or difficulty communicating without the assistance of a carer means that a person lacks such understanding. It may nevertheless be a justifiable reason to check whether the person does have the capacity to decide whether to participate. This raises a few questions, namely: Will moderators rely on information from the participant that they have dementia (i.e. if having dementia is an inclusion criterion)? Should a person with dementia be included if s/he seems to lack a full understanding of what is involved (e.g. s/he may lack the capacity to consent, not understand that participation is voluntary, not understand how the information will be used etc.)? Are moderators qualified to assess capacity?

*Action points:*

* Agree within the team whether this is a consultation and whether ethical approval and/or formal consent is required.
* If the answers to the above are “yes” and “no” respectively, but the group agrees that informed consent should nevertheless be sought….
  + draw up a common participant information sheet
  + adapt this to the cultural context of the country in which the consultation is being carried out
  + check at the start of the session that everyone consents to the consultation (participation, use of data and recording).
  + decide within the group what to in the case of a person possibly lacking capacity to participate turning up for the consultation.
  + remind participants that they are free to leave at any time without having to justify their decision.
  + make it clear that participants do not have to answer any questions they would prefer not to.

**Confidentiality and privacy**

Confidentiality refers to “the interest people have in controlling access to information or data about them” whereas privacy refers to “the interest people have in restricting the access of others to themselves” (DuBois, 2008, p. 154). One of the aims of a focus group is to promote self-disclosure and this is more likely when the participants feel respected and free to give their opinions without being judged (Krueger and Casey, 2009). This involves sharing information with the moderator as well as with other members of the group. Participants, researchers involved and those in the wider research group should all respect the principle of confidentiality and take measures to protect the privacy of participants.

Participants should all be encouraged to contribute to the discussion and the moderator should try to involve those who are less vocal, whilst ensuring that the more vocal participants do not dominate the discussion at the expense of the former. The moderator should also ensure that both the line of questioning and the course that the discussion takes is kept well within proper boundaries. At the same time, sensitivity is needed from the moderator to ensure that people do not feel obliged to divulge personal information about their lives or condition which they would prefer not to share. Small focus groups often take the form of a fairly intimate and open discussion which may sometimes lead to over-disclosure whereby participants go beyond their usual boundaries and disclose information which they later regret having shared (Kvale and Brinkmann, 2009).

*Action points:*

* Explain in the participant information sheet and on the day that the consultation is a group activity and that consequently, information will be shared within the group and not only with the moderator, concluding with the request that everyone treat what they see and hear with utmost confidentiality.
* Take necessary measures to ensure that the data is treated with confidentiality (i.e. that information we have learned in confidence is kept secure and private, and is not divulged to other people without permission).
* Hold the consultation in a place where the participants will not be observed or overheard by passers-by.
* (Pseud-)anonymise the data from the consultation and remind participants that this will be done.
* Keep the list of names and pseudonyms in a secure location so that people other than the researchers do not have access to it.
* Encourage all participants to contribute to the discussion, whilst taking take to respect their personal boundaries in relation to self-disclosure.
* Ensure that participants have the opportunity to check the transcript or summary of the discussion (and to ask for something they said and wished they hadn’t to be taken out – unlikely to occur)

## Protection from harm (non-maleficence)

Participants involved in a research project must be protected from potential harm (World Medical Association, 2000). The biomedical ethical principle of non-maleficence is therefore relevant, namely avoiding the causation of harm (Beauchamp and Childress, 2008). This is a fundamental requirement for the conduct of ethical research and should ideally apply to this consultation which is part of a more global research project. Different types of harm are possible (e.g. physical, emotional, psychological and financial). The potential vulnerability of people with dementia should be recognised but this should not lead to over-protection and paternalism. Avoiding harm should be combined with promoting wellbeing (similar to the principle of beneficence).

Avoiding harm and promoting the wellbeing of participants also involves paying attention to the concepts of respect, integrity, singularity/personhood, relationality and historicity (Alzheimer Europe, 2014). Virtues such as compassion, discernment, integrity, trustworthiness, conscience and conscientiousness are also important in the healthcare domain, as highlighted by Beauchamp and Childress (2008), who also suggest that some virtues (e.g. loyalty, courage, kindness and benevolence) may at times lead to inappropriate and unacceptable behaviour.

Whilst the topic of this consultation is perhaps not sensitive *per se*, participants may nevertheless touch on personal and health-related issues linked to their private lives and relationships with other people. The group discussion may result in issues arising (e.g. about certain symptoms of dementia and the impact of loss of capacity) which might lead to reflection and emotional or psychological responses (e.g. frustration, embarrassment, shame or fear). Whilst such reactions might be expressed during the consultation, for some participants they may be experienced later. Barbour (2009) suggests the need to have relevant contact numbers at hand so that researchers do not “simply grab the data and run” (p.92). Ideally, participants should leave the consultation not only “unharmed” but also feeling good about have been heard and having contributed towards something important.

Participants may also disclose information which has ethical implications such as possible abuse (Smith, 1995). Moderators will need to consider beforehand how to deal with such information, should this situation arise.

*Action points:*

* Go through the “ground rules” at the beginning of the consultation and have them on a flip chart or printout to remind participants.
* Avoid the use of derogatory terms such as “demented” when interacting with people with dementia and reporting findings;
* Do your best to handle emotional and psychological reactions, recognising the potential vulnerability of some of the participants
* Be careful not to adopt a psychotherapeutic role for which you are not equipped. A sensitive and compassionate approach is needed, however, to avoid appearing cold and aloof (Kvale and Brinkmann, 2009).
* Reflect on your understanding and perception of dementia (see Alzheimer Europe’s 2013 report on the ethical issues linked to the perceptions and portrayal of dementia)
* Consider each person in their entirety, recognising that they have a past and a current life and that this might not be immediately apparent but it is part of who and what they are.
* Avoid reducing people with dementia solely to their condition. People with dementia *have* dementia but each person is more than their dementia.
* Try to ensure that participants’ rights, needs and dignity are respected but avoid being over-protective.
* Make time for a debriefing with the participants including the provision of contact details of a person or organisation (e.g. local Alzheimer association) in a position either directly or indirectly to offer support. Bring along leaflets and/or your own business card to facilitate future contact from participants.
* Send a summary/feedback to participants once the consultation is finished, preferably in the form of a written report.

## References

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