Enhancing the Informed Consent Process: Supported decision-making and capacity assessment in clinical dementia research, (Ensure)

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As a result of an ageing population, the already high number of people suffering from dementia will significantly increase in European countries and beyond in the coming decades. No treatments are currently available that can reverse or even halt the neurodegenerative process, and dementia leads to a considerable burden on patients and caregivers, as well as societies as a whole. For this reason, there is a substantial need for further medical dementia research. People with dementia have the right to decide whether or not they want to participate in clinical research and to give their free, prior and informed consent. However, as dementia progresses, they can lose their ability to give informed consent to complex medical research because of an increasing loss of cognitive functions. At first sight, it seems ethically problematic to involve dementia patients in research, as people with impaired mental capacity must be protected against the risks of research participation, not least because of various conflicts of interests involving the researcher and the pharmaceutical industry. Furthermore, in contrast to informed consent to medical treatment, an individual benefit from participation in research largely depends on the research design and can rarely be taken for granted. However, people with dementia also have a right to benefit particularly from neuroscientific and medical research, so their categorical exclusion would appear to be ethically problematic too. From an ethico-legal point of view, high standards for the informed consent process and a thorough assessment of mental capacity are therefore regarded as important measures to protect research participants. This project aims to provide recommendations for clinical researchers on how to a) enhance the capacity to consent of people with dementia, b) improve the assessment of decision-making capacity, c) protect those who do not have the capacity to consent, and d) ensure the inclusion of people with dementia in neuroscientific and medical research is ethically justifiable. The results of this project will contribute towards achieving an adequate balance between autonomy and protection of dementia patients in clinical research.