Project ESDA:
Evaluation of Supported Decision-Making Strategies for Monoclonal Anti-Beta-Amyloid Antibodies

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BACKGROUND

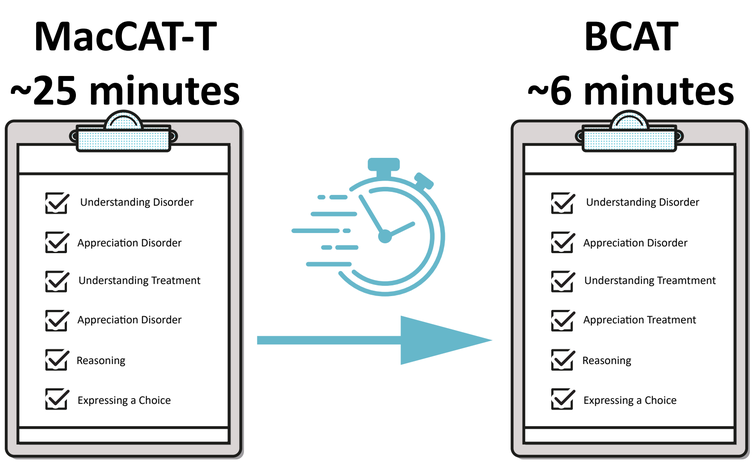
- Introduction of monoclonal anti-beta-amyloid antibodies (mABAA) requires re-evaluating clinical decision-making practices (Largent et al., 2023).
- Complexities of mABAA, including potential risks like ARIAs, challenge the decision-making process (van Dyck et al., 2023; Cummings et al., 2023; Largent et al., 2023).
- Cognitive impairments in AD patients often compromise their capacity to consent to treatments (Parmigiani et al., 2022; Karlawish et al., 2005).
- Existing tools for assessing capacity to consent are time-consuming or lack validation, highlighting the need for brief, validated tools in mABAA contexts (e.g. Grisso & Appelbaum, 1998; Carney et al., 2018).
- Supported decision-making tools help empowering MCI or early dementia patients' capacity to consent. Consensus exists, but evidence is mixed due to small samples (Wied et al., 2021; DGN e. V. & DGPPN e. V., 2023).
- Ethical mABAA treatment needs supported decision-making, with tailored interventions. A patient-centered approach ensures informed, autonomous decisions (Scholten et al., 2022) in mABAA treatment.

To address these challenges, the ESDA project comprises the following three sub-studies.

PART I: STATEMENT

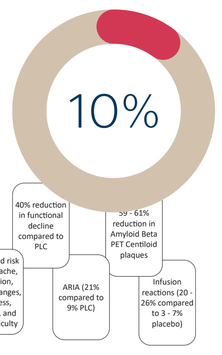
- Highlighting the importance of autonomy decisions in mABAA treatment and the need for larger sample sizes for valid results.
- Emphasizing challenges in assessing capacity to consent (CTC) in mABAA therapies and the role of supported decision-making.
- The aim is to develop practical recommendations to improve informed consent and CTC assessment.
- This publication seeks to engage clinics in the evaluation of supported decision-making methods and to recruit larger samples.

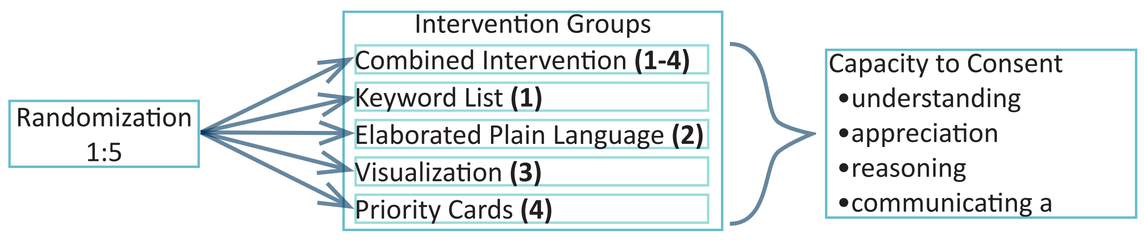
PART II: CAPACITY ASSESSMENT



- **Objective:** To establish a standardized, clinically appropriate assessment tool for evaluating CTC. Evaluation of the non-inferiority of the Bedside Capacity Assessment Tool (BCAT) (Carney et al., 2018) versus the MacArthur Competence Assessment Tool - Treatment (MacCAT-T) (Grisso & Appelbaum, 1998) in assessing CTC in patients with cognitive impairment.
- **Sample:** Aimed sample size of *N* = 69; participants include professionals from neurology, neuropsychology, and psychiatry.
- **Materials:** Video simulation (see Figure above) of a medical consultation based on the vignette of a treatment with common anti-dementia drugs; adaptation and translation of the MacCAT-T (Haberstroh et al., 2012) and the BCAT.

PART III: DECISIONAL SUPPORT



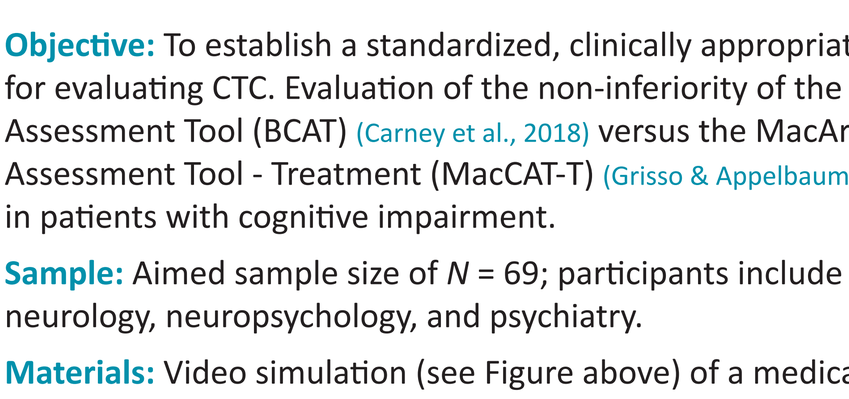


Due to a recent decision by the EMA, the evaluation will be conducted with common anti-dementia drugs and not with mABAA and thus represents a timely preparation for a possible introduction of mABAA in Europe.

- **Objective:** To investigate the effects of different supported decision-making-Tools on capacity to consent in patients with mild cognitive impairment (MCI) or mild Alzheimer's disease (AD).
- **Design:** A multi-arm randomized controlled trial through a dismantling approach, see figure above.
- **Sample:** A target sample size of *N* = 590 participants is calculated, focusing on individuals with MCI or mild AD, recruited from memory clinics across Europe.
- **Materials:** BCAT as adapted before (Carney et al. 2018); Supported-Decision-Making Tools promoting Understanding: Keyword lists, Elaborated Plain Language, Visualization and promoting Reasoning: Priority Cards (Poth et al., 2022), see figure above).

CALL FOR PARTICIPATION

CONTRIBUTE TO NATIONAL GUIDELINES: SHAPE THE FUTURE OF ALZHEIMER'S CARE



Join our European study to apply and evaluate supported decision-making tools and provide critical evidence that will influence national healthcare guidelines.

CONTACT

LITERATURE

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