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Statistical Analysis Plan

Decision-making, Ethical Consent, and Interactive Dialogue in Ongoing Neurocognitive Decline (DECISION)

Version 1.0 – As of 10th October 2025

Statistical Analysis Plan

Project Title: DECISION – Decision-making, Ethical Consent, and Interactive Dialogue in Ongoing Neurocognitive Decline
Ethics Approval No.: 25-0177
Version: 1.0
Date: 10th October 2025
Study Period: Oktober 2025 – October 2026

Institution: Department of Psychiatry and Psychotherapy, LMU University Hospital Munich, Nußbaumstr. 7, 80336 Munich, Germany

Objectives of Statistical Analysis

The statistical analysis aims to evaluate the psychometric validity, reliability, and diagnostic accuracy of the DECISION test battery for assessing decisional capacity in individuals with neurocognitive disorders.

Specific goals include:

1. Verification of criterion validity against the *MacArthur Competence Assessment Tool for Treatment (MacCAT-T)* as the gold standard.
2. Analysis of construct and convergent validity through associations with established neuropsychological tests.
3. Assessment of discriminative power between diagnostic groups (e.g., Alzheimer's disease vs. controls).
4. Evaluation of internal structure and reliability (internal consistency, test–retest stability).
5. Exploration of correlations between cognitive performance, biomarker levels, and imaging parameters (external validation).

Data Sets and Sample Description

- Planned sample size: 100–150 participants (aged ≥50 years)
- Groups:
    - *Neurocognitive disorder group* (Alzheimer's, vascular, or mixed dementia forms)
    - *Cognitively unimpaired control group*
- Data collection: two sessions per participant (baseline and retest, approx. 4–6 weeks apart).

- Covariates: age, sex, education, MMSE score, disease duration, biomarker levels, and MRI/OCT indices.

Data Preparation

- Data pseudonymization according to LMU data protection standards.
- Quality control: completeness, plausibility checks, outlier screening (>3 SD from group mean).
- Handling of missing data:
  - <5% missing: mean substitution or expectation–maximization method.
  - 5% missing: multiple imputation (MICE) procedure.
- Software: IBM SPSS (v29), R (v4.3), and JASP for psychometrics.

Descriptive Statistics

- Continuous variables: mean ± SD, median, range.
- Categorical variables: frequencies and percentages.
- Between-group comparisons:
  - *t-tests* or *Mann–Whitney U tests* (depending on distribution).
  - *Chi² tests* for categorical data.
- Significance threshold: p < .05 (two-sided).

Timeline

Type of Validity	Objective	Comparator	Statistical Method	Expected Outcome
Criterion Validity	Agreement with gold standard	MacCAT-T total and subscale scores	Pearson/Spearman Correlations linear regression	r > .5, p < .05
Construct Validity	Theoretical coherence with cognitive domains	TMT A/B, AAT, DOSPERT, CFQ, PCRS	Correlations Exploratory factor analysis	r > .3, theoretically c
Convergent Validity	Similarity with established judgment/insight measures	Comparable scales from literature	Correlations, regression m	r > .4, p < .05
Discriminant Validity	Distinction between unrelated constructs	Mood/affect measures	Correlation	Non-significant correlation

Reliability Analyses

- Internal consistency: Cronbach's α and McDonald's ω (target ≥0.80).
- Test–retest reliability: Intraclass correlation coefficient (ICC, two-way mixed model; target ≥0.75).

- Inter-rater reliability: Cohen's κ for categorical ratings (subset of 20% of cases).

Structural Validation

- Exploratory factor analysis (EFA): Principal axis factoring with varimax rotation to explore subscale structure.
- Confirmatory factor analysis (CFA): Fit indices – CFI ≥ .90, RMSEA ≤ .08, SRMR ≤ .08.
- Item analysis: item–total correlations (rit > .30), redundancy screening (r > .80 between items).

Diagnostic Accuracy

- ROC analyses (Receiver Operating Characteristic):
  - Target variable: *presence of decisional impairment* (defined by MacCAT-T thresholds).
  - Output: AUC, sensitivity, specificity, positive/negative predictive values.
  - Criteria for good discrimination: AUC ≥ .80; sensitivity/specificity ≥ 75%.
- Youden Index for determining optimal cut-off scores.
- Logistic regression for prediction of impaired consent capacity from cognitive, language, and biomarker predictors.

Biomarker and Imaging Correlations

- Correlational analyses: Pearson or Spearman (depending on distribution).
- Multivariate linear models to test the association of plasma biomarkers (Aβ1-42/1-40, pTau217, NfL, GFAP) with DECISION composite scores.
- MRI/OCT integration:
  - MRI indices (temporal lobe atrophy, vascular lesions) and OCT parameters (retinal layer thickness, pulsatility).
  - Partial correlations controlling for age, sex, education.
  - Exploratory path models for mediation effects (e.g., atrophy → cognitive domain → decisional capacity).

External Validation

- Validation in an independent cohort (e.g., ActiGlia, AmyClear) using same protocol.
- Metrics: effect size stability (Cohen's d), reliability coefficients, and ROC performance.
- Cross-validation by split-sample (70/30) or bootstrapping.

Sensitivity Analyses

- Excluding outliers (>3 SD) to test robustness.
- Subgroup analyses by diagnosis (AD vs. vascular vs. FTD).
- Gender and education stratification.
- Alternative imputation methods to check impact of missing data.

Data Visualization

- Correlation matrices and heatmaps for construct validity.
- ROC curves for diagnostic discrimination.
- Factor loading plots and scree plots for structural validity.
- Regression coefficient plots for predictor contributions.

Reporting

- All results will be reported following APA 7th and CONSORT guidelines (for observational validation studies).
- Significant and non-significant findings will be fully documented.
- Statistical code will be archived for reproducibility in line with LMU good scientific practice.

Signatures

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