

Appendix

WHO Trial Data Registration Set

Category	Information
Primary registry and trial identifying number	drks.de DRKS00036478
Date of registration in primary registry	17.04.2025
Source(s) of monetary or material support	German Federal Ministry of Research, Technology and Space (BMFTR)
Primary sponsor	Universität Siegen
Secondary sponsor(s)	-
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Title	Project DECIDE-2 Evaluating the efficacy of supported Advance Care Decision Making within routine care in dementia: A randomized controlled trial
Countries of recruitment	Germany
Health condition(s) or problem(s) studied	Lack of effective supported decision-making strategies for people with dementia
Intervention(s)	Intervention 1: supported Advance Care Decision-Making within Dementia Care Management Intervention 2: Dementia Care Management
Key inclusion and exclusion criteria	Inclusion criteria: - confirmed diagnosis of mild to moderate dementia (F00-F03) or mild cognitive disorder (F06.7), diagnosed by a physician specialised in neurology or psychiatry and based on ICD-10 criteria. Exclusion criteria: - Severe dementia (MMSE score < 11)

Category	Information
	- lack of capacity to consent to medical research (and incapacity for supported decision-making with relative or proxy)
Study type	Interventional allocation: randomised controlled study Assignment: parallel group design Masking: single-blind (participants are blinded) Primary purpose: Increase the autonomy of PwD in making advance care and end-of-life decisions and reduce proxy burden
Date of first enrolment	Mai 2025
Target sample size	150
Recruitment status	Recruiting
Primary outcome(s)	- Prevalence and validity of advance healthcare planning documents - Proxy burden - Decisional conflict
Key secondary outcomes	- Patient autonomy - Patient-caregiver congruence in preferences