

Additional File 2: World Health Organization - Trial Registration Data Set

No	Item	Information
1	Primary Registry and Trial Identifying Number	ClinicalTrials.gov; Identifier: NCT04977362
2	Date of Registration in Primary Registry	July 26 th , 2021
3	Secondary Identifying Numbers	Innovationsausschuss in the Gemeinsamer Bundesausschuss; Identifier: 01NVF19028 Ethics Committee of the Medical Association Hamburg; Identifier: 2020-10276-BO-ff
4	Source(s) of Monetary or Material Support	Innovationsausschuss in the Gemeinsamer Bundesausschuss
5	Primary Sponsor	Universitätsklinikum Hamburg-Eppendorf
6	Secondary Sponsor(s)	BARMER University Hospital Augsburg
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9	Public Title	Interdisciplinary Perioperative Care in Minimally-invasive Heart Valve Surgery
10	Scientific Title	Interdisciplinary and Cross-sectoral Perioperative Care Model in the Cardiac Surgery: Implementation in the Setting of Minimally-invasive Heart Valve Surgery (INCREASE)
11	Countries of Recruitment	Germany
12	Health Condition(s) or Problem(s) Studied	Heart Valve Diseases
13	Intervention(s)	Enhanced Recovery After Surgery Enhanced recovery after surgery is a multimodal, transdisciplinary care approach for patients undergoing surgical procedures. It is implemented in various surgical specialties, among others in cardiac surgery. The care approach aims at promotion of recovery of the patients throughout their perioperative process, reduction of complications, and early return to normal activities. Treatment as Usual treatment as usual according to standard care in heart valve surgery
14	Key Inclusion and Exclusion Criteria	Inclusion Criteria: - Indication for elective minimally invasive (open) aortic or mitral valve surgery - Patient's ability to understand the nature and extent of the individual's requirements for participation in the new care setting

		- Classification of the patient as "FIT" or "Pre-FRAIL" using the LUCAS functional index (frailty index) (Dapp et al. 2012) Exclusion Criteria: - Limited life expectancy less than one year (e.g., advanced tumor disease) - Urgent or emergency interventions - Severe comorbidities or psychosocial reasons that militate against participation or do not allow for written informed consent - Lack of a social environment that can provide supportive patient care
15	Study Type	Randomized Controlled Trial
16	Date of First Enrollment	July 1 st , 2021
17	Sample Size	186
18	Recruitment Status	Recruiting
19	Primary Outcome(s)	Hospitalization: number of hospitalized days due to cardiac reasons Six Minute Walk Test: physical capacity expressed with the walking distance in meters
20	Key Secondary Outcomes	Goal Attainment Scale (GAS): level of attainment of individual goal HeartQoL: quality of life; Costs: direct costs in € associated with the operative procedure and the initial hospitalization using diagnosis related groups as classification system, in which diagnoses and treatments are valued according to their necessary economical expenditure
21	Ethics Review	Approved by the Ethics Committee of the Medical Association Hamburg, Germany (June 7 th , 2021)
22	Completion date	Anticipated December 2023
23	Summary Results	Ongoing Study
24	IPD sharing statement	IPD will not be shared