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Prehabilitation to improve outcomes following transcatheter aortic valve implantation

Submission date
15/11/2026

Recruitment status
Not yet recruiting

Registration date
25/11/2026

Overall study status
Ongoing

Last Edited
25/11/2026

Condition category
Circulatory System

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Aortic stenosis is a condition in which the aortic valve, one of the heart's four valves, becomes narrowed. This restricts blood flow out of the heart and can cause symptoms such as breathlessness, chest pain and fainting. If left untreated, severe aortic stenosis can be life-threatening. Transcatheter aortic valve implantation (TAVI) is a minimally invasive procedure in which a new heart valve is inserted within the narrowed valve, usually through a blood vessel in the leg. This avoids the need for open-heart surgery.

Although TAVI is very effective, some patients do not experience the expected improvement in their symptoms or quality of life. This is particularly true for people living with frailty, who may also be more likely to experience complications and have a slower recovery. There is some evidence that frailty may be improved through interventions such as exercise and nutritional support. Prehabilitation is like training for the procedure; it combines gentle exercise, nutritional support, and advice to support your well-being. This preparation is intended to help patients feel stronger and more confident before their procedure, which may lead to better recovery and outcomes afterwards. Although prehabilitation has shown benefits in patients undergoing surgery, it is not yet known whether it is suitable or beneficial for patients awaiting TAVI.

The IDEAL-TAVI Pilot Study aims to investigate whether an eight-week prehabilitation programme can be safely and practically delivered to patients with frailty awaiting TAVI, and whether it is acceptable to patients. The findings will help inform the design of a larger study to determine whether prehabilitation improves recovery and outcomes following TAVI.

Who can participate?
Adults aged 18 years or older with severe symptomatic aortic stenosis who are living with frailty and are awaiting a planned TAVI procedure may be eligible to participate.

What does the study involve?
The study aims to recruit 60 participants, who will be randomly allocated to one of two groups. Approximately two-thirds will receive an eight-week prehabilitation programme in addition to their usual care, while the remaining third will continue to receive usual care alone.

The prehabilitation programme includes three components:
- Exercise: An initial face-to-face assessment with a physiotherapist to develop an individualised exercise programme, followed by weekly supervised virtual exercise sessions and additional home-based exercises.
- Nutritional support: Assessment and advice from a dietitian to optimise nutritional intake, including dietary recommendations and nutritional supplements where required.
- Educational support: Information and resources to help patients understand their condition, prepare for their procedure and manage their recovery.

All participants will undergo assessments at the beginning of the study, immediately before their TAVI procedure and approximately 6 months afterwards. These will include questionnaires about their health and quality of life, walking and balance tests, measurements of muscle strength and body composition, and activity monitoring using a wearable fitness tracker. Some participants receiving prehabilitation may also be invited to take part in an optional interview to share their experiences of the programme.

What are the possible benefits and risks of participating?
Participants receiving prehabilitation may experience improvements in their physical fitness, strength and confidence before TAVI, which could support their recovery afterwards. However, these benefits cannot be guaranteed. All participants will contribute valuable information that may help improve care for future patients undergoing TAVI.

The exercise programme is designed to be gentle and tailored to each participant's abilities. However, physical activity may cause muscle soreness, fatigue or, rarely, minor injury. Due to their underlying heart condition, some participants may experience symptoms such as breathlessness, chest discomfort or dizziness during exercise. A physiotherapist will assess participants before starting the programme to minimise these risks.

Where is the study run from?
Guy's and St. Thomas' NHS Foundation Trust

When is the study starting and how long is it expected to run for?
December 2026 to June 2028

Who is funding the study?
Edwards Lifesciences (UK)

Who is the main contact?
Dr Rea Ganatra, rea.ganatra@nhs.net

Contact information

Type(s)
Principal investigator

Contact name
Dr Tiffany Patterson

ORCID ID
https://orcid.org/0000-0001-7619-9122

Contact details
Guy's and St. Thomas' NHS Foundation Trust
St. Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH
+44 20 7188 7188
tiffany.patterson2@nhs.net

Type(s)
Public, Scientific

Contact name
Dr Rea Ganatra

ORCID ID
https://orcid.org/0000-0001-9697-1837

Contact details
Guy's and St. Thomas' NHS Foundation Trust
St. Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH
+44 20 7188 7188
rea.ganatra@nhs.net

Additional identifiers

Integrated Research Application System (IRAS)
356270

Study information

Scientific Title
A randomised controlled trial of multI-moDal prEhAbiLitation in patients with severe aortic stenosis awaiting Transcatheter Aortic Valve Implantation: The IDEAL-TAVI Study

Acronym
IDEAL-TAVI

Study objectives
Primary objective:
1. To assess the feasibility, acceptability, and safety of multimodal prehabilitation in patients awaiting TAVI

Secondary objectives:
1. To obtain preliminary estimates of the effect of multimodal prehabilitation, compared with

usual care, on:
- Procedural outcomes and length of hospital stay;
- Functional capacity and health-related quality of life
- Cardiac biomarkers
- Nutritional status and sarcopenia assessed using anthropometric, biochemical, functional and bioelectrical impedance analysis
2. To explore the effect of prehabilitation on LV reverse remodelling following TAVI in an exploratory mechanistic sub-study using transthoracic echocardiography
3. To inform the design of a future definitive randomised controlled trial, including refinement of the intervention and trial procedures, estimation of sample-size, and assessment of the feasibility of collecting health-economic data

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/10/2026, Surrey Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8088; surrey.rec@hra.nhs.uk), ref: 26/LO/0744

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Optimisation of outcomes in frail patients with severe aortic stenosis

Interventions
In this initial pilot phase, 60 participants living with frailty and awaiting TAVI will be randomly allocated to either the multimodal prehabilitation intervention group (n=40) or the usual care control group (n=20), in a 2:1 ratio. Randomisation will be performed using an online system and stratified by age and sex.

All participants will undergo research assessments at baseline, immediately prior to TAVI and at 6 months post-TAVI. These will include quality-of-life questionnaires, a 6-minute walk test (6MWT) and the Short Physical Performance Battery (SPPB) test to assess physical function.

Muscle strength (hand-grip strength) and body composition will be assessed using a handheld dynamometer and bioelectrical impedance analysis (BIA), respectively. Participants will also be provided with a wearable activity monitor to record heart rate and physical activity over a 7-day period at each assessment time point.

All participants randomised to intervention will undergo 8-weeks of multimodal prehabilitation prior to TAVI comprising the following:
1. Exercise support: Participants will undergo initial assessment by a physiotherapist/cardiac rehab specialist following which an individualised exercise prescription will be generated (guided by participant's initial 6MWT). Following the initial face-to-face assessment, exercise sessions will be delivered virtually. Participants will be offered one supervised 60-minute virtual exercise session per week alongside individualised home-based exercises to complete approximately twice weekly.
2. Nutritional support: Participants will receive dietetic assessment within 2 weeks of referral, with follow-up scheduled within 6 weeks if indicated and ongoing dietetic care to continue beyond this as required. The dietetic intervention will aim to ensure that participants can meet their nutritional requirements- this may be multimodal and consist of nutritional counselling, food-based strategies or oral nutritional supplement prescription
3. Psychological support: Participants will receive psychoeducational support integrated within the prehabilitation programme. Content will focus on adjustment to changes in health, preparation for TAVI, recovery following the procedure, and confidence in resuming activity. Support will be tailored to individual participant needs

Participants assigned to the control group will receive usual care as per guideline recommendations but will be asked to complete the same research assessments as the prehabilitation arm at baseline, immediately prior to TAVI, and at 6 months after TAVI.

In a sub-group of participants, transthoracic echocardiography will be used to assess for any potential impact prehabilitation may have on left ventricular geometry and function.

Intervention Type
Mixed

Primary outcome(s)
1. Recruitment rate measured using the proportion of eligible patients approached who are randomised at the end of recruitment

2. Attrition rate measured using the proportion of randomised participants who withdraw or are lost to follow-up at the time of TAVI and at 6 months post-TAVI

3. Intervention adherence measured using attendance records and completion of prescribed intervention components at weekly timepoints during the 8-week programme

4. Data completeness measured using the proportion of expected outcome data successfully collected at baseline, pre-TAVI and 6 months post-TAVI

5. Intervention acceptability measured using semi-structured interviews with participants at the end of the 8-week intervention

6. Intervention fidelity measured using independent review of audio-recorded sessions against a standardised checklist at different timepoints during the 8-week intervention

7. Safety measured using the incidence of adverse and serious adverse events in both groups at randomisation to 6 months post-TAVI

Key secondary outcome(s)

1. Procedural success measured using VARC-3 criteria at TAVI

2. Procedural outcomes measured using the incidence of complications defined by VARC-3 criteria at 30 days and 6 months post-TAVI

3. Length of hospital stay measured using the number of days from admission at the time of discharge

4. Exercise capacity measured using six-minute walk test (6MWT) distance in metres at baseline, pre-TAVI and 6 months post-TAVI

5. Physical performance measured using the Short Physical Performance Battery (SPPB) score at baseline, pre-TAVI and 6 months post-TAVI

6. Physical activity measured using daily step count and activity data from a wearable accelerometer at baseline, pre-TAVI and 6 months post-TAVI

7. Health-related quality of life measured using the Kansas City Cardiomyopathy Questionnaire (KCCQ) score at baseline, pre-TAVI and 6 months post-TAVI

8. Health-related quality of life measured using the EQ-5D-5L score at baseline, pre-TAVI and 6 months post-TAVI

9. Anxiety and depression measured using the Generalised Anxiety Disorder-7 (GAD-7)/Patient Health Questionnaire-9 (PHQ-9) score at baseline, pre-TAVI and 6 months post-TAVI

10. Functional status measured using New York Heart Association (NYHA) Functional Classification at baseline, pre-TAVI and 6 months post-TAVI

11. Clinical frailty measured using the Clinical Frailty Scale (CFS) and Essential Frailty Toolset scores at baseline, pre-TAVI and 6 months post-TAVI

12. Hand-grip strength measured using a hand-held dynamometer at baseline, pre-TAVI and 6 months post-TAVI

13. Body composition measured using bioelectrical impedance analysis (BIA) at baseline, pre-TAVI and 6 months post-TAVI

14. Skeletal muscle mass measured using CT-derived skeletal muscle index from routine pre-TAVI CT imaging at baseline

15. Nutritional markers including full blood count (haemoglobin), renal function (creatinine), liver function (albumin) measured using routine blood samples at baseline, pre-TAVI and 6 months post-TAVI

16. Cardiac biomarkers including Nt-proBNP measured using routine blood samples at baseline, pre-TAVI and 6 months post-TAVI

17. Left ventricular geometry and function measured using transthoracic echocardiography (LVEDV, LVESV, LV mass, LVEF, LVIDd, LVIDs, LV diastolic dysfunction, LV GLS) at baseline and post-TAVI

Completion date
01/06/2028

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Symptomatic severe AS and accepted for TAVI by the treating TAVI multidisciplinary team (i.e. echocardiographic findings consistent with severe AS, including an aortic valve area ≤1.0 cm^2, indexed aortic valve area ≤0.6 cm^2/m^2, mean transvalvular gradient ≥40 mmHg and/or peak aortic jet velocity ≥4.0 m/s, or with integrated clinical assessment used where discordant parameters are seen)
3. Clinical Frailty Scale score 3-5
4. Able and willing to provide informed consent and participate in study procedures

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
110 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Critical AS, defined as AVA ≤0.6 cm^2, mean transvalvular gradient ≥60 mmHg or peak aortic jet velocity ≥5.0 m/s;
2. Previous cardiac syncope considered attributable to AS
3. Unstable angina (CCS class III–IV)
4. Severe left ventricular systolic impairment (LVEF <35%)
5. Greater than Stage 2 extra-aortic cardiac damage, according to the prespecified cardiac damage staging system
6. Significant non-cardiac limitation that, in the opinion of the investigator or treating clinical team, would prevent safe participation in the exercise intervention
7. Severe obstructive pulmonary disease
8. Scheduled TAVI date <8 weeks from enrolment
9. Concurrent participation in another research study where participation would require

deviation from the IDEAL-TAVI protocol or otherwise interfere with the intervention or study outcomes

Date of first enrolment
01/12/2026

Date of final enrolment
01/12/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Guy's and St. Thomas' NHS Foundation Trust
St. Thomas' Hospital
Westminster Bridge Road
London
England
SE1 7EH

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust

ROR
https://ror.org/00j161312

Funder(s)

Funder type

Funder Name
Edwards Lifesciences

Alternative Name(s)
Edwards, Edwards Lifesciences Corporation, Edwards Lifesciences Corp., Edwards Lifesciences LLC, E, ELC

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available