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Acceptability testing of a Decision Support Tool for patients and relatives that are deciding about being screened for Thoracic Aortic Disease

Submission date 01/09/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 23/09/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 17/09/2026	**Condition category** Circulatory System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Thoracic aortic disease (TAD) is a silent disease that doesn't show symptoms until it becomes really dangerous. The disease is characterised by a swelling or bulge in the aorta, which is the body's largest artery. This project is looking to prevent the most dangerous thing that can follow, which is a tear in the aorta called an aortic dissection. Preventing aortic disease is a national research priority for the NHS.

TAD can be caused by mutations in DNA and may run in families. If the relatives of people with TAD are checked early, using scans and genetic tests, we might be able to find TAD sooner and save lives. However, there are problems getting in the way of this, like doctors and people not knowing enough about TAD, some groups of people not getting access to the right care, plus worries about the cost and how the tests might affect someone's life.

We think the best way to fix these problems, is to create an interactive tool that provides information to help families make choices about being screened for TAD, based on what's important to them. We believe this will increase the number of people that get screened for TAD and find the disease early. This interactive tool is called a Decision Support Tool (DST).

Work Package (WP) 1 of the DECIDE-TAD Programme is the co-development of the DST and the Implementation Toolkit which will be used to train doctors and other healthcare professionals on how to use the DST. This part of WP1 (WP1.4) is the acceptability testing of the DST and will involve patients with TAD, their close relatives and healthcare professionals, from two UK NHS hospitals taking part in interviews, or completing a questionnaire to give feedback on the DST.

Who can participate?

People aged 16 years and above who are either:

1. A patient with Non-Syndromic TAD diagnoses in the last 24 months
2. A first- or second-degree relative of a patient with TAD, or
3. A healthcare professional involved in shared decision-making consultations regarding screening for TAD

What does the study involve?
The study involves participants looking at the Decision Support Tool and giving their feedback through an interview with a qualitative researcher or by completing a questionnaire.

What are the possible benefits and risks of participating?
There are no direct benefits to taking part, but people who take part will be helping to develop a decision aid for patients and their family members for use in a larger trial. This will help us to understand whether the decision aid is beneficial for patients and their family members to use in the NHS. People who take part might find the experience useful in terms of talking about their experiences in relation to the content of the decision aid. The possible disadvantages and risks of taking part are that talking about their experience with TAD may be upsetting for people.

Where is the study run from?
Leicester Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
October 2024 to August 2026

Who is funding the study?
The National Institute for Health and Care Research (NIHR) Programme Grants for Applied Research (PGfAR) (UK)

Who is the main contact?
Jane Hughes, jane.hughes2@sheffield.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
351644

Central Portfolio Management System (CPMS)
68759

National Institute for Health and Care Research (NIHR)
206798

Study information

Scientific Title
Mixed methods co-design and evaluation of a decision support tool to enable shared decision making for people who are considering cascade screening for thoracic aortic disease: the DECIDE-TAD Programme. Acceptability Testing Work Package 1.4

Acronym
DECIDE-TAD

Study objectives
Primary Objective:
To evaluate the acceptability of a decision support tool (DST) to support shared decision making for patients with thoracic aortic disease (TAD) and their first- and second-degree relatives.

Secondary Objective:
To evaluate the feasibility of implementing a DST in clinical services and explore what training would be required to support delivery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/08/2025, London – Stanmore Research Ethics Committee (2nd Floor, 2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)2071048068, +44 (0)2071048208; stanmore.rec@hra.nhs.uk), ref: 25/PR/0917

Primary study design
Observational

Study design
Observational; Design type: Qualitative

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Thoracic aortic disease

Interventions
For this component of the NIHR programme – Acceptability Testing – we will conduct qualitative interviews with TAD patients and their first and second-degree relatives as well as Health Care Professionals (Aortic Specialist Nurses, Inherited Cardiac Conditions (ICC) Specialist Nurses or other clinical staff involved in shared decision making).

First, we will conduct between 15-36 qualitative interviews with patients and relatives over three rounds of interviews. After each round of interviews, researchers will analyse the

interviews, refine the DST based on the participant feedback, and then conduct further interviews with the refined DST. After three rounds of interviews with patients and relatives and refinement of the DST, a questionnaire will be developed based on interview findings to ascertain how acceptable and useable the DST would be to participants.

Further TAD patients and their relatives (n = 20-25) will be recruited to complete the questionnaire.

Following patient and relative interviews and the survey, and analysis of the results, researchers will conduct qualitative interviews with health care professionals (n = 8-10) to find out how useable and acceptable the DST is for healthcare professionals to support shared decision making and what training would be required to support delivery.

Intervention Type
Other

Primary outcome(s)
The acceptability of DST, assessed through an interview or a questionnaire with patients with TAD and their first- and second-degree relatives at a single timepoint for each participant

Key secondary outcome(s)
The feasibility of implementing a DST in clinical services and what training would be required to support delivery, assessed through interviews with healthcare professionals at a single timepoint for each participant

Completion date
31/08/2026

Eligibility

Key inclusion criteria
1. People with a diagnosis of NS-TAD where this is defined as:
1.1. People with Acute Type A dissection, treated or untreated
1.2. People who have undergone non-emergency treatment (surgical or endovascular) for NS-TAD. This means anyone with NS-TAD who has had treatment at a UK cardiac surgery centre
Or first- or second-degree relative of a patient with TAD
Or healthcare professional involved in shared decision making consultations regarding screening for TAD
2. Aged 16 years and above
3. Diagnosed in the last 24 months from start date of this study when recruiting from Trusts (relevant for the patient with TAD)
4. Ability to understand the languages in which the information is available (Acceptability questionnaire study only)
5. Willingness to provide informed consent

Participant type(s)
Health professional, Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit
200 Years

Sex
All

Total final enrolment
14

Key exclusion criteria
1. Previous diagnosis of syndromic TAD (relevant for the patient with TAD)
2. Inability to understand English written and spoken language (Acceptability questionnaire study only)

Date of first enrolment
12/09/2025

Date of final enrolment
31/08/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

Study participating centre
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
England
B15 2GW

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Jane Hughes (jane.hughes2@sheffield.ac.uk). Participants will consent to information collected about them in this study being shared with other researchers, organisations, and collaborators for the purpose of future ethically approved research.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results			16/09/2026	No	Yes
Protocol file	version 1.1	30/07/2025	04/09/2025	No	No
Protocol file	version 3.1	11/02/2026	16/09/2026	No	No