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

Protocol

PROTOCOL VERSION NUMBER AND DATE

- **V3.1,11-02-2026**

RESEARCH REFERENCE NUMBERS

IRAS Number:	351644
SPONSORS Number:	University of Leicester (Ref: 1081)
FUNDERS ID:	NIHR206798
Study Registration Number	ISRCTN 15536599

FUNDED BY NIHR | National Institute for Health and Care Research

This protocol has regard for the HRA guidance and the University of Leicester Sponsor Standard Operating Procedures (SOPs).

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:	
Name: (please print):	
Signature:	
Date:	
Principal Investigator:	
Site:	
Name: (please print):	
Signature:	
Date:	

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Funding start and end date(s)	Start: 01/10/2024 End: 31/03/2030
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Committees	For all queries aimed at the research team, protocol contributors, steering group or PPIE panel please email decidetad@leicester.ac.uk

NIHR Portfolio Adopted	Yes

STUDY SUMMARY

Full 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
Internal ref. no. (or short title)	DECIDE-TAD Acceptability Testing Work Package 1.4
Study Design	Mixed methods, multi-centre
Study Participants	Thoracic Aortic Disease (TAD) patients and their first- and second-degree relatives Healthcare professionals
Planned Size of Sample (if applicable)	Between 43 - 71 participants in total • Interviews with patients with TAD (6–18) • Interviews with first- and second-degree relatives including relatives of deceased patients with TAD (9-18) • Interviews with healthcare professionals (8-10) • Questionnaire for patients with TAD (5-10) • Questionnaire of first- and second-degree relatives including relatives of deceased patients with TAD (15)
Follow up duration (if applicable)	N/A
Planned Study Period	15/07/25 – 31/08/2026
Research Question/Aim(s)	Aim: Following earlier development stages of the Decision Support Tool (DST) in the overall NIHR Programme, this component of the programme aims to evaluate the acceptability, usability, comprehensibility, and desirability of a DST for patients with TAD, their relatives and healthcare professionals. Research questions: 1) How acceptable and desirable is a DST for patients with TAD and their first- and second-degree relatives? 2) How useable and acceptable is the DST for healthcare professionals to support shared decision making and what training would be required to support delivery?

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
NIHR PGfAR 206798	Financial

ROLES OF STUDY SPONSOR AND FUNDER

The Sponsor, the University of Leicester, take on overall responsibility of the research project.

The University of Leicester is responsible for the design, management and outputs of the research. Participating NHS sites are responsible for the conduct of the study within their organisation.

The Research Governance Office review and approve all iterations of the protocol as part of their initial Sponsor review and amendment review process. Further information is available from our Sponsor Standard Operating Procedures webpage.

The funder is the National Institute for Health and Care Research (NIHR) Programme Grants for Applied Research (PGfAR). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Neither organisation has influence over the data analysis and interpretation, manuscript writing, and dissemination of results. They do not control the final decision regarding any of these aspects of the study.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Management Groups

Programme Management Group (PMG)– Chaired by the Chief Investigator (CI) and Co-Chief Investigator (Co-CI) and composed of all co-applicants who will meet at least monthly to oversee the day-to-day management of the trial. Responsibilities will include ensuring financial and regulatory governance, making staff appointments, approving protocols and amendments to study design, ensuring activity proceeds as expected against milestones, managing risks, producing reports for the funder and governance committees, overseeing completion of all the desired work packages and dissemination of the research results. The PMG will report to the Independent Programme Steering Committee.

Programme Steering Committee (PSC) – Composed of an independent Chair, Statistician, Clinical Geneticists, Genetic Counsellor, and a Lay Member. Additional non-voting representatives from the

PMG, Funder and Sponsor will also attend. The committee will meet every 6 months, or more frequently if desired, and will oversee the Programme and ensure that it is being conducted according to the protocol and the applicable regulations.

Patient and Public Involvement and Engagement (PPIE) Group

The PPIE co-applicants of the overall study are members of the Aortic Dissection Awareness UK and Ireland (ADA-UK&I) charity. They will co-develop strategies for consultation, recruitment, equality, diversity and inclusion (EDI) and dissemination, and participate in these activities along with other PPIE members. They will also participate in workshops and in the development of materials for use in the IRAS submission, recruitment, governance, and participation.

PROTOCOL CONTRIBUTORS

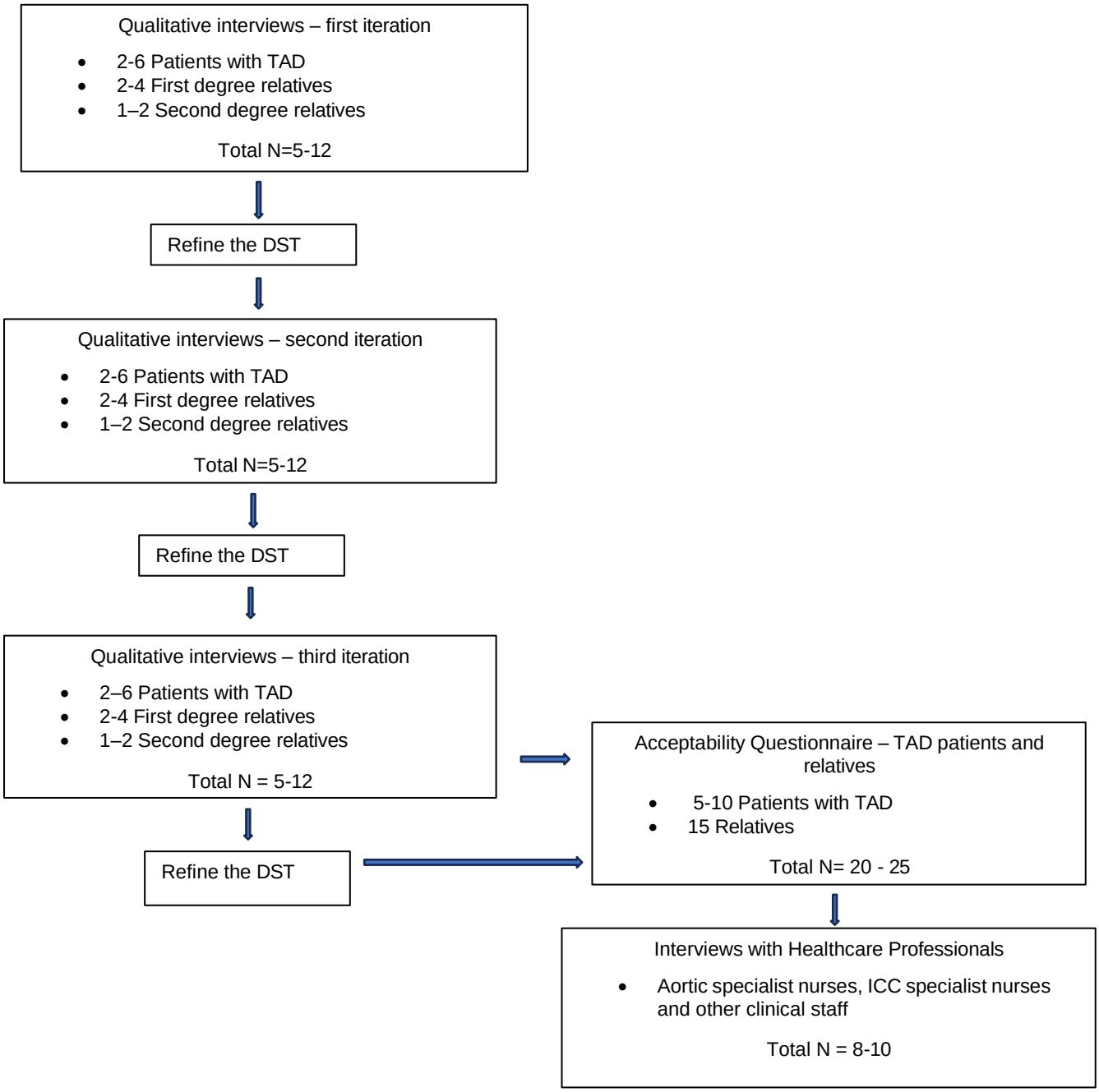
Name	Role	Contributions
Professor Alicia O'Cathain	Mixed Methods Researcher, University of Sheffield	Project Lead for Work Package 1.4
Professor Gavin Murphy	Consultant Cardiac Surgeon, Professor of Cardiac Surgery and Director of Leicester Clinical Trials Unit	Chief Investigator
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Dr Maria Pufulete	Associate Professor of Applied Health Research, University of Bristol	Lead for Work Package 1
Jane Hughes	Mixed Methods Researcher, University of Sheffield	Researcher for Work Package 1.4 – will undertake recruitment, interviews, collect data and analyse results
Lisa Skinner	PPIE Co-Applicant and administration lead for the Aortic Dissection Buddies UK and Ireland Bereaved Family and Friends Group	Liaison to support recruitment of relatives of bereaved patients with TAD
Dr Riccardo Abbasciano	Academic Cardiac Surgeon	Co-Lead of all Work Packages as part of an Advanced Fellowship in Mixed Methods
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LIST OF ABBREVIATIONS:

ADA-UK&I	Aortic Dissection Awareness UK and Ireland charity
CI	Chief Investigator
DST	Decision Support Tool
GCP	Good Clinical Practice
HES	Hospital Episode Statistics
HRA	Health Research Authority
IPDAS	International Patient Decision Aid Standards
IRAS	Integrated Research Application System
NIHR	National Institute of Health and Care Research
NS-TAD	Non-Syndromic Thoracic Aortic Disease
PIC	Participant Identification Centre
PGfAR	Programme Grants for Applied Research
PI	Principal Investigator
PIS	Participant Information Sheet
PMG	Programme Management Group
PPIE	Patient and Public Involvement and Engagement
PSC	Programme Steering Committee
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SOP	Standard Operational Procedure
TAD	Thoracic Aortic Disease

STUDY FLOW CHART



1. BACKGROUND

Thoracic Aortic Disease (TAD) is a condition caused by a swelling or bulging (an aneurysm) at any point along the part of the aorta (the blood vessel that carries blood from the heart to the body) in the chest. TAD can be life threatening when the aneurysm leads to a partial tear between the layers of the aorta's wall (an aortic dissection) and it's not treated immediately. The only treatment is emergency surgery, although less than 50% of people make it to hospital in time, and only 70% of people who make it to surgery survive (1). TAD causes almost 3000 deaths per year in the UK; more than road traffic accidents (2). The prevalence of the disease is increasing (3).

Early detection of TAD and prevention of aortic dissection is critical to reduce mortality. Because TAD with a genetic cause can be inherited, cascade screening of first- or second-degree relatives of people who have been diagnosed with TAD, followed by targeted secondary prevention and interventions to prevent aortic dissection if an aneurysm is present, are needed to reduce mortality. Cascade screening is routine in syndromic (part of a syndrome) forms of TAD such as Marfan and Loeys Dietz. However, for non-syndromic TAD (NS-TAD), which account for 80% of all cases of TAD, only one third of first- and second-degree relatives of people with TAD participate in any screening in the UK, with large variation particularly in underserved populations (4,5).

A 2023 survey of the national patient charity membership of Aortic Dissection Awareness UK and Ireland demonstrated that 47% of aortic dissection survivors who responded had undergone genetic testing, including 45% with a positive family history of TAD Of relatives who responded, 44% and 21% were offered imaging or cascade genetic testing respectively. There was a strong preference to be involved in decisions about screening, however only 27% of probands (defined as the first individual diagnosed with TAD in the family), and 13% of relatives who responded reported that they were involved in shared decisions about their care. These figures are better than suggested by NHS Hospital Episode Statistics (HES) data, where one percent of people admitted to hospital with TAD between 2013 and 2018 who survived to discharge subsequently attended a genomic medicine clinic, with lower rates in women, people from minority ethnic backgrounds and people from areas with high levels of deprivation (6).

The survey suggested there are multiple barriers to the uptake of screening, including limited awareness of the disease and genetic aetiology among clinicians and the public, poor health literacy, concerns about the cost-effectiveness of screening if detection rates are low, the requirements for life-long surveillance and the management of uncertain test results. There are also local, regional and national barriers, such as the potential increase in workload, financial constraints, alignment with existing care pathways and lack of NICE guidance on TAD because of low certainty evidence.

This NIHR Programme therefore aims to develop and evaluate a Decision Support Tool (DST) and Implementation Toolkit to improve shared decision making for people at risk of NS-TAD who are deciding whether to undergo cascade screening (genetic testing and imaging) and secondary prevention.

2. RATIONALE

Researchers propose that implementation of a DST to improve the detection of latent TAD through increased uptake of cascade screening in people at risk of NS-TAD may improve outcomes and reduce

mortality. Cascade screening, where relatives undergo genetic tests and imaging, significantly reduces mortality through detection of latent disease, effective secondary prevention and early treatment.

The rationale for this component of the NIHR programme is that the DST must be assessed so that users find it easy to use and acceptable before roll out to the wider work packages of the feasibility trial and randomised controlled trial (RCT).

3. THEORETICAL FRAMEWORK

We will use the "user-centred design" conceptual framework for decision aids (7) to test acceptability of the DST, which includes understanding the needs and context of users and healthcare professionals and observing users and healthcare professionals interact with the DST prototype. The DST and Implementation Toolkit development is based on guidance from the International Patient Decision Aid Standards (IPDAS) checklist (8). To incorporate perspectives from various stakeholders, we will use the Theories of Planned Behaviour (9) and Implementation Intentions. (10,11). These models will aid in understanding individual beliefs, health literacy, the impact of significant others and the community, and in identifying both barriers and facilitators to implementation of the DST.

4. RESEARCH QUESTION/AIM(S)

Aim

To evaluate acceptability, usability, comprehensibility, and desirability of a DST for patients with TAD, their relatives and healthcare professionals.

Research questions

1. How acceptable and desirable is a DST for patients with TAD and their first- and second-degree relatives?
2. How useable and acceptable is the DST for healthcare professionals to support shared decision making and what training would be required to support delivery?

4.1 Objectives

4.1.1 Primary Objective

To evaluate the acceptability of a DST to support shared decision making for patients with TAD and their first- and second-degree relatives.

4.1.2 Secondary Objective

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

4.2 Outcomes

To determine how acceptable a DST is to patients with TAD and their first- and second-degree relatives. To determine the feasibility of implementing a DST in clinical services and establish what training would be required to support delivery.

5. STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

We will undertake a mixed methods study of qualitative interviews with patients with TAD and first- and second-degree relatives of patients with TAD, followed by an acceptability questionnaire of patients with TAD and first- and second-degree relatives of patients with TAD, followed by qualitative interviews with healthcare professionals. To evaluate acceptability, usability, comprehensibility, and desirability of the DST, we will show people a copy of the DST. We will conduct cognitive interviews using 'think aloud' to capture participant thought processes when engaging with the DST (12). We will conduct qualitative interviews with patients with TAD and first- and second-degree relatives of patients with TAD identified by clinical staff at two hospitals that represent regions with high levels of diversity. We will also recruit first- and second-degree relatives of decease patients with TAD through an Aortic Dissection bereaved support group. We will aim for maximum diversity of participants because sample diversity is more informative than a large sample at this stage. Throughout all qualitative research we will approach and undertake data collection with people with sensitivity, working with our PPIE colleagues to ensure we approach patients and relatives with care.

Data Analysis

All data will be entered into SPSS for analysis (13). We will enter interview transcripts into NVivo for analysis. We will use the framework approach to analyse the interviews (14) because clear research questions have been set, and awareness of some of the issues important to acceptability of DSTs have been ascertained from previous research. Additionally, this approach will allow for emergent themes that could be identified inductively.

6. STUDY SETTING

The study will recruit patients with TAD and their first- and second-degree relatives as well as healthcare professionals from two hospitals based in regions with high levels of population diversity. This will help to recruit a diverse sample. If we struggle to recruit patients and relatives from the two hospitals, we will supplement the sample with patients with TAD and first- and second-degree relatives from the Aortic Dissection Awareness charity membership.

7. SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion criteria

- People with a diagnosis of NS-TAD where this is defined as:
  - (i) People with Acute Type A dissection, treated or untreated
  - (ii) 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.
- Aged 16 and above.
- Diagnosed in the last 24 months from start date of this study when recruiting from Trusts (relevant for the patient with TAD).
- Ability to understand the languages in which the information is available (Acceptability questionnaire study only).
- Willingness to provide informed consent.

7.1.2 Exclusion criteria

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

7.2 Sampling

7.2.1 Size of sample

Interviews with patients with TAD (6–18)

Interviews with first- and second-degree relatives including relatives of deceased patients with TAD (9-18)

Interviews with healthcare professionals (8-10)

Questionnaire for patients with TAD (5-10)

Questionnaire of first- and second-degree relatives including relatives of deceased patients with TAD (15)

7.2.2 Sampling technique

For patient and relative interviews, we will aim for maximum diversity of participants because sample diversity is more informative than a large sample at this stage. We are including first- and second-degree relatives as their risks are different. Maximum diversity will include age, sex, social class, and ethnicity. For healthcare professionals we will use purposive sampling by clinical discipline.

7.3 Recruitment

7.3.1 Sample identification

Patients with TAD

Patients with TAD will be identified by a healthcare professional when they are attending an outpatient appointment at either a research site or a Participant Identification Centre (PIC). Both research sites and PICs will identify and approach potential participants as detailed below. Research sites may also advertise the study in clinical areas using the Participant Flyer, and will be able to facilitate in-person interviews, in clinic, at the participants preference. In person interviews will not be available for individuals who are identified from PICs.

The type of healthcare professional doing this will depend on who has agreed to help with the research. We will discuss with the healthcare professional the need to approach people from underserved groups and we will discuss with them how they might communicate with people who prefer to speak in languages other than English e.g., using the local interpreter services, where NHS resources permit. We will also ask the healthcare professionals to complete a screening log to record all people who are screened for the study. The screening log will collect information including Biological Sex, Age, Ethnicity and IMD quintile (for the patients' home address) for all patients that are screened for the study. This information will be used to monitor specific demographics of patients who are considered for the study and will be used to identify barriers that may be preventing participation of people from underrepresented communities, and will be used to inform the future Work Packages.

The healthcare professional will briefly discuss the study with the patient and give them a Participant Information Flyer. This flyer will be provided in a range of the most common languages spoken at the recruiting sites. If a patient is interested in taking part in an interview, the patient will be invited to talk to a member of the research study team from the University of Sheffield who will be present in the clinic. An interpreter might be needed for this discussion, where NHS resources permit. The researcher will discuss the study in more detail and if the patient is still interested, they will be given a study information pack by the researcher. If the potential participant needs the study information pack interpreted into their language, this will be arranged. The pack will contain information about the study, including a summary Participant Information Sheet (PIS), a full PIS, a Study Reply Form, and a pre-paid (Freepost) envelope. If the patient is interested in taking part, they will complete the reply form with their name and contact details and confirm they consent to a research study member contacting them to discuss taking part in an interview. Once the patient gives their contact details (in the clinic or by returning the reply slip in a prepaid envelope), the researcher will contact them and confirm they would like to take part in an interview. An Informed Consent Form will be posted or emailed to the participant (depending on their preference) along with a paper copy of the DST or a link to an electronic PDF version (depending on their preference) for them to review. A date and time will be arranged for the interview. Interviews could be online, by phone or in person in the clinic (only available at research sites, not PICs). Interviews could also be in evenings or at weekends (phone or online interview only) if that is the preference of the participant. Written informed consent will be given before the interview takes place. Informed consent will be collected by the participant returning the signed consent form to the researcher (via post or email). The researcher will also go through the consent form with the participant before the interview starts. Interviews will be audio recorded.

If a participant wishes to do an in-person interview which involves making an additional visit to the clinic, then we will reimburse reasonable transport costs. The participant will be asked to provide bank details

to enable payment to be made. This information will be stored either in a locked filing cabinet with limited access or on the University of Sheffield restricted drive in a data-encrypted, password-restricted spreadsheet.

First- or second–degree relatives

If a first- or second-degree relative accompanies a patient to their outpatient appointment, the same recruitment process will be used as above, for the patient. Otherwise, the following process will be used. Patients who have agreed to take part in a qualitative interview will be asked if they have any first-degree or second-degree relatives who might be also interested in taking part in an interview. The patient will then be given a study information pack to pass on to their relative. The pack will contain a summary PIS, a full PIS, a reply slip and pre-paid envelope. If the relative is interested, they will complete the reply slip with their name and contact details and confirm they consent to a research study member contacting them to discuss taking part in an interview. This will then be returned to the researcher at the University of Sheffield in the pre-paid envelope.

First- and second-degree relatives of deceased patients with TAD

To ensure that relatives of deceased patients are approached in an inclusive but sensitive and appropriate manner, recruitment will take place through the Aortic Dissection Buddies Bereaved Family & Friends Group. The group lead will present information about the study to members. Those members who might be interested in taking part in an interview will be given a study information pack. Once they have had time to read through and consider the study, if they are still interested, they will complete a study reply slip with their contact details and send this to the researchers at The University of Sheffield in a pre-paid envelope. The researcher will then contact them to arrange a time and date for the interview. Interviews will take place online, by phone or in person. If people do not respond we will seek the advice of the lead of the bereavement group who may feel that it is appropriate to remind people of the study. A highly experienced qualitative researcher will undertake these interviews with sensitivity.

Timing of interviews

We will use three iterations: interview 5-12 participants (2-6 TAD patients, 1-2 first- and 1-2 second-degree relatives); refine the DST; interview a further 5-12 participants and 1-2 first- and 1-2 second-degree relatives, refine the DST; interview final 5-12 participants 1-2 first- and 1-2 second-degree relatives, refine the DST. We will aim to refine some content of the DST between iterations.

Acceptability questionnaire

Towards the end of this process (before or during the last iteration of the DST), we will recruit patients with TAD (n=5-10) and first- and second-degree relatives (n=15) to ask for feedback on the DST using an acceptability questionnaire.

There will be both electronic and paper-based options for the questionnaire.

Patients with TAD will be identified by healthcare professionals when they are attending an outpatient appointment. Staff will briefly outline the study and give the patient a Participant Information Flyer. If the patient is interested in taking part in the questionnaire, the healthcare professionals will give the patient a study information pack with a summary PIS, a full PIS, a reply slip and pre-paid envelope. If they are interested in taking part, they will complete the reply slip with their name and contact details and confirm they consent to a research study member contacting them. The researcher will contact them to ask whether they want to complete the questionnaire on paper or electronically. The researcher will then send a copy of the DST, a consent form and the questionnaire via post or email (depending on their preference). If the participant wants to complete the questionnaire electronically, they will be provided with a link and informed consent will be collected as part of the electronic questionnaire. Or participants may wish to have a researcher administer the questionnaire. In this case we will do this over the telephone.

First- and second-degree relatives will be identified by clinical staff if they are attending with a patient with TAD, or through the researcher asking participants with TAD that are taking part, whether they have any relatives that may wish to take part. The patient will then be given a study information pack, containing a summary PIS, a full PIS, a reply slip and pre-paid envelope, to pass on to their relative. If they are interested in taking part, they will complete the reply slip with their name and contact details and confirm they consent to a research study member contacting them. The process documented above will then be followed.

First- and second-degree relatives of deceased patients with TAD will be approached by the lead of the Aortic Dissection support group who will present information about the study to members. Those members who might be interested in completing the questionnaire will be given a study information pack with a summary PIS, a full PIS, a reply slip and pre-paid envelope. If they are interested in taking part, they will complete the reply slip with their name and contact details and confirm they consent to a research study member contacting them. The process documented above will then be followed.

Healthcare professionals

Healthcare professionals will be recruited purposively by clinical discipline from two hospitals. We will conduct interviews (face to face, online or by phone) with healthcare professionals (Aortic Specialist Nurses, Inherited Cardiac Conditions Specialist Nurses or other Clinical Staff involved in shared decision making) [N = 8 -10] to review DST content, the Implementation Toolkit, and discuss training required to support the delivery of the DST.

7.3.2 Consent

All potential participants will be assumed to have capacity unless otherwise indicated at the time of interactions.

All potential participants will have given consent to be contacted for research purposes.

Consent processes are described in section 7.3.1.

Written or electronic (acceptability questionnaire only) informed consent will be obtained prior to the participant undergoing any activities that are specifically for the purposes of the study. All potential participants will have the opportunity to ask questions and have time to read through study information.

8. QUALITY ASSURANCE PROCEDURES

The study will be conducted in accordance with the current approved protocol, GCP, the principles of the Declaration of Helsinki, relevant regulations and SOPs.

8.1 Monitoring, audit and inspection

The University of Leicester as Sponsor operates a risk-based monitoring programme which this study will be subject to.

9. PROTOCOL COMPLIANCE

9.1 Protocol Deviations

A study related deviation is a departure from the ethically approved study protocol or other study document or process (e.g. consent process or administration of study intervention) or from Good Clinical

Practice (GCP) or any applicable regulatory requirements. Planned deviations or waivers are not allowed however it is acknowledged that accidental protocol deviations may occur. Any deviations from the protocol will be documented in a protocol deviation form and filed in the Trial Master File/Investigator Site File as applicable.

If a protocol deviation occurs, then the CI (or delegate) will document this in accordance with the University's SOPs Identifying and Reporting Deviations and Serious Breaches of GCP and/or the Protocol.

Deviations from the protocol which are found to frequently recur will be explored and where necessary an amendment to the protocol will be made.

9.2 Serious breach

A "serious breach" is a breach of the protocol or of the conditions or principles of GCP which is likely to affect to a significant degree –

(a) the safety or physical or mental integrity of the trial subjects; or
(b) the scientific value of the research

In the event that a serious breach is suspected the Sponsor will be contacted within one working day. In collaboration with the CI, the serious breach will be reviewed by the Sponsor and, if appropriate, the Sponsor will report it to the approving REC committee and the relevant NHS host organisation within seven calendar days.

10. ETHICAL AND REGULATORY CONSIDERATIONS

10.1 Assessment and management of risk

We will be approaching and interviewing patients with TAD and first- and second-degree relatives about a serious health condition. We anticipate that some participants may be anxious. The qualitative researcher has conducted qualitative interviews with patients with a range of health conditions and is experienced with dealing with this situation sensitively. There is also a Distress Protocol (Appendix 13.2) which covers what to do if a participant feels anxious or distressed during the interview. The Distress Protocol documents that an interview may be stopped (temporarily or permanently), and participants may be directed to speak to their GP or specialist nurse at their TAD clinic. Due to the nature of the questions that we will be asking, it is unlikely that safeguarding issues will arise. However, if they do, we will let the participant know we have a duty of care to report their situation to their clinical care team. In the unlikely scenario that a participant discloses suicidal thoughts, we will contact the site PI and ask them to notify the person's GP. In an immediately life-threatening situation, we would call the police to request a welfare check. We will also include in the PIS that we may suggest participants contact their GP or clinical team, if we feel they need extra support.

The research team comprises of researchers and patients and relatives from the ADA-UK&I charity group as well as their support group for relatives of a deceased patient with TAD. We will be able to signpost participants to these groups where they can access information and support.

10.2 Research Ethics Committee (REC) and other Regulatory review & reports

Once the initial Sponsor review process is complete, a reference number has been allocated, and all requested documentation has been received and checked, authortisation from the University of Leicester's Researcher Governance Office will be issued to book further regulatory review of the proposed research. The NHS Research Ethics Committee (REC) and Health Research Authority (HRA) will then review the proposal. Agreement in principle is subject to the research receiving all relevant regulatory permissions. Submission for regulatory approvals will occur via the Integrated Research Application System (IRAS). The CI will ensure that all regulatory approvals, confirmation of capacity and capability from NHS sites and sponsor green light are in place before participants are approached.

For any required amendment to the study, amendments will be submitted to the Sponsor in the first instance for review and approval to submit the amendment for external regulatory approval. Amendments must be implemented in line with Sponsor Standard Operating Procedures.

The Research Governance Office's Standard Operating Procedures will be followed for the duration of the study.

The CI will notify the REC when the study has ended by completing the end of study notification form and will submit a final report of the results within one year after notifying the REC.

A study master file will be maintained for the duration of the study and will be stored for a minimum of 6 years after the study has ended. The only time this could be exceeded, is if samples are being retained beyond the scope of the original study i.e. there is consent for future research. In this circumstance ICFs would have to be retained for as long as the samples are in existence, as we have a legal requirement to provide the samples were obtained with consent.

10.2.1 Regulatory Review & Compliance

Before any site can enrol patients into the study, the CI, PI or designee will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance.

For any amendment to the study the Sponsor, or their representative in agreement with the Sponsor, will submit information to the appropriate body in order for them to issue approval for the amendment. The CI or designee will work with sites (Research and Development ((R&D)) departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their continued support for the study.

10.3 Peer review

The study has been externally peer reviewed as part of the NIHR funding application process.

10.4 Patient and Public and Engagement Involvement

Design of the study and acceptability of research

This research is the result of a 5-year partnership between TAD survivors, relatives, and researchers. The co-lead of the NIHR Programme is a TAD survivor and member of the ADA-UK&I charity research team. The charity initiated the NIHR DECIDE-TAD research programme after a prioritisation exercise identified cascade screening as an unmet need and a top research priority for patients with NS-TAD and their relatives.

Management of the research

The PMG includes five aortic dissection survivors or relatives. The PMG meets at least monthly to discuss specific work packages within the programme.

We have produced the patient facing documents with members of the ADA-UK&I charity. We will also work closely with them to recruit relatives of deceased patients. We will discuss findings from iterations of data collection to refine the DST before the next iteration and consider changes to the topic guide before the next iteration.

Analysis of results:
The analysis of findings from each iteration of data collection will feed into the final results, and will have PPIE collaboration and agreement.

Dissemination of findings
This part of the NIHR programme may identify learning about cascade screening as well as the DST. We will work with members of the ADA-UK&I charity to consider who might benefit from the findings and develop a dissemination strategy.

10.5 Data protection and patient confidentiality

All investigators and study site staff will comply with the requirements of the Data Protection Act 2018 and General Data Protection Regulation (and other applicable regulations) with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

The University of Sheffield is the data custodian and data is collected only for research purposes. Data will be stored on the University of Sheffield secure server (The University of Sheffield is conducting the interviews, administering the questionnaires and collecting the data). Only named researchers from the DECIDE-TAD team will have access to the drive (along with some IT administration staff for IT security and audit purposes only).

Participants will be allocated a unique ID number. This will be used for naming transcripts of interviews. Participants will be asked to not identify themselves during the interview, but any identifiers will be removed when the interview is transcribed. The audio recordings will be deleted following transcription. Any quotes shared from interviews will not contain any identifiers.

Names and addresses will be stored in a password-protected, limited access folder on the University of Sheffield x-drive or in a locked filing cabinet in a secure location at the University of Sheffield accessible only by the research team. Names and addresses will only be stored until the participant has taken part in the interview and their interview has been transcribed. The file will then be permanently deleted, and no names or addresses will be retained.

If participant's have consented to receive a summary of the findings, their names and contact details will be retained until the information has been sent out and will then be deleted.

Data transfer will be conducted within Caldicott and University Information Governance guidelines. Data will be stored for 6 years.

10.6 Indemnity

Sponsorship and insurance for study design and management will be provided by the University

of Leicester.

If a participant is harmed due to negligence and/or the conduct of the study, this will be covered by the local NHS Trust(s) indemnity arrangements for all participants in clinical studies. If a study participant wishes to make a complaint about any aspects of the way they have been treated or approached during the research project, the standard National Health Service complaint system will be available to them. Details of this are made available to participants in the PIS.

10.7 Contractual arrangements

Contracts will be in place with a third party transcription service.

10.8 Access to the final study dataset

Some members of the Research Team involved in reviewing analysis will have access to anonymised datasets.

We will share anonymised data from the questionnaire. Qualitative data will not be shared. Anonymised data sets from the questionnaire will be stored on ORDA, the University of Sheffield research archive, for a period of 6 years. Other researchers can request access to the data set for future ethically approved research. Any requests would be rigorously evaluated, and REC approvals and data sharing agreements would be required. This is included in the Informed Consent Form.

11. DISSEMINIATION POLICY

11.1 Dissemination policy

For this part of the NIHR programme (Work Package 1.4), the lay summary of results will include a summary of the changes we made to the DST based on participants' feedback, where the participant has provided explicit consent for this in the ICF.

11.2 Authorship eligibility guidelines and any intended use of professional writers

All of the research team will be authors on the final synopsis report published by NIHR. If there is a publication from this part of the NIHR Programme, we will adhere to the NIHR Programme publishing policy for authorship.

All publications will adhere to the NIHR requirements for open access.

12. END OF STUDY ARRANGEMENTS

The end of the study will be classed as when all planned data collection activities (interviews and questionnaire) have been completed. We anticipate this to be 31/08/2026.

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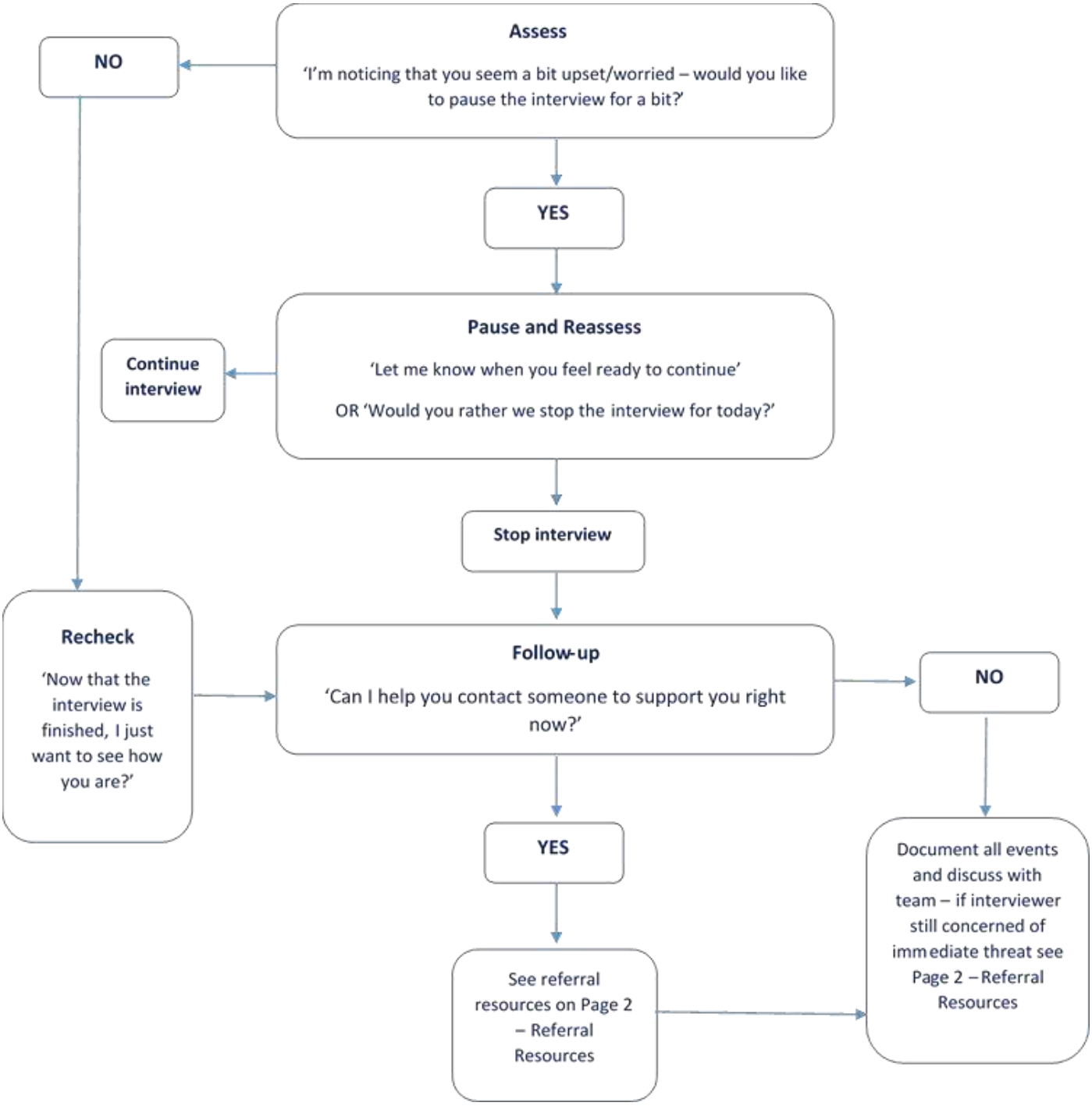
14. APPENDICIES

14.1 Appendix 1– Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
N/A – Initial Application	1.1	30-07-2025	Jane Hughes	Minor amendments to text following initial REC/HRA&HRCW review: - Section 10.5 Data protection and confidentiality – additional detail relating to steps taken to ensure confidentiality of participants. - Section 12 End of Study Arrangements – addition of section.
SA01	2.0	25-09-2024	Jane Hughes	Minor amendments to text to reflect the addition of Participant Identification Centres for the study and the introduction of a screening log.
NSA05	2.1	12-12-2025	Jane Hughes	Extension to the end date of the study.
SA02	3.0	16-01-2026	Jane Hughes	Introduction of a summary PIS.
NSA06	3.1	11-02-2026	Jane Hughes	Extension to the end date of the study. Addition of ISRCTN Number.

14.2 Appendix 2– Distress Protocol

The protocol for managing signs of distress during interviews for DECIDE-TAD WP1.4



Referral Resources

Clinical Care Team:

- Have you considered contacting someone from your care team, do you have a specialist nurse that you see – there might be a number on the appointment letters?
- I can help you find the number if you would like? (Have relevant numbers/names on hand).
- Would you like me to contact them for you? I would not tell them what we have been discussing unless you are happy for me to do so.

Non-DECIDE-TAD specific:

- Have you thought about contacting your GP for some help with any worries that you might be having? Would you like some help to contact them?
- If you want to talk to someone about anything that might be worrying you without going to your GP the NHS have a talking therapies service that you can self-refer to. Would you like any help to find out how to contact them? – (google talking therapies contact for the area they are in).
- Also - Samaritans phone number – call 116 123 or text SHOUT to 85258
- The British Heart Foundation has information and support about Thoracic aortic aneurysms – www.bhf.org.uk. The charity also has a Genetic Information Service with a helpline – 0800 802 1234.

If Interviewer is still concerned:

1) If you are NOT concerned about an immediate risk of harm then you can contact the police on 101, explain the situation, and ask them to conduct a 'safe and well check' – they can pass this on to another force if it is not within their area.

2) If you ARE concerned about an immediate risk of harm then contact the police on 999 and tell them that you are concerned about **a risk to life** – they can pass this on to another force if it is not within their area.

ALWAYS –

- Document everything that you can remember - what they said and how you responded including dates, times and locations.
- Inform someone else in the team and discuss what has happened.