Testing the feasibility of a **CO**ro**N**ary a**N**gioplasty d**EC**ision **T**ool **(CONNECT)**

STUDY PROTOCOL

A cluster randomised controlled feasibility study of CONNECT: a patient decision aid designed to improve the quality of shared decision-making for planned coronary angioplasty.

RESEARCH REFERENCE NUMBERS

IRAS Number:	319363
SPONSORS Number:	TBC
FUNDERS Number:	NIHR 204012

PROTOCOL VERSION 0.4 6-10-2023

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 requirements (UK Policy Framework for Health and Social Care Research, the Data Protection Act 2018 and the Principles of Good Clinical Practice (GCP) as set out in the UK Statutory Instrument (2004/1031) and subsequent amendments thereof.

By signing the IRAS form for this study, The Open University agrees to act as a sponsor of this study confirm their approval of this protocol. 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 feasibility study will be made 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.

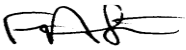
1.For and on behalf of the Study Sponsors:

1.1Signature: ..... Date:..../...../.....

Name: Professor Kevin Shakesheff,

Position: Pro-Vice-Chancellor, Research & Innovation, The Open University (Kevin.Shakeheff@open.ac.uk).

2.Chief Investigator

Signature: 

Name: Professor Felicity Astin

Position: Professor of Nursing, The Open University, (Felicity.Astin@open.ac.uk). Date:..19/12/22

3. **Co-Lead**

Signature:  Date:19/12/22

Name: Dr Emma Harris

Position: Research Fellow The Open University,

(Emma.Harris@open.ac.uk).

3. **Statistician**

Signature  Date:19/12/22

Name: Dr Rebecca Simpson

Position: Lecturer in Medical Statistics, University of Sheffield, (R.Simpson@sheffield.ac.uk)

TABLE of CONTENTS

SIGNATURE PAGE	2
KEY STUDY CONTACTS	4
SPONSORSHIP AND FUNDING	6
PROTOCOL CONTRIBUTORS	7
STUDT SUMMARY	8
STUDY SCHEMA	9
BACKGROUND, RATIONALE AND THEORETICAL FRAMEWORK	10
AIMS/OBJECTIVES	12
STUDY DESIGN AND SETTING	12
PATIENT AND PUBLIC INVOLVEMENT	14
ELIGIBILITY	16
CONSENT PROCESS	17
RECRUITMENT, SCREENING AND RANDOMISATION	19
STUDY INTERVENTION AND USUAL CARE	21
OUTCOME MEASURES AND STUDY PROCEDURES	22
ADVERSE EVENT REPORTING	28
DATA HANDLING AND RECORD KEEPING	29
QUALITY CONTROL AND QUALITY ASSURANCE	31
STATISTICAL METHODS AND DATA ANALYSIS	31
STUDY ORGANISATION	32
ETHICAL AND REGULATORY CONSIDERATIONS	34
DISSEMINATION POLICY	36
REFERENCES	37
APPENDICES	40

KEY STUDY CONTACTS

Chief Investigator	Dr Felicity Astin Professor of Nursing The Open University School of Health, Well-Being, and Social Care Horlock Building, Walton Hall, Milton Keynes, MK7 6AA Visiting Professor of Nursing Calderdale and Huddersfield NHS Foundation Trust Research and Development Huddersfield Royal Infirmary, Acre Street, Lindley, Huddersfield HD3 3EA E: Felicity.Astin@open.ac.uk T: 07850684065
Co-Lead	Dr Emma Harris Research Fellow Applied Health Research The Open University School of Health, Well-Being, and Social Care Horlock Building, Walton Hall, Milton Keynes, MK7 6AA Emma.Harris@open.ac.uk
Sponsors	1. The Open University Professor Kevin Shakesheff (Pro Vice Chancellor Research & Innovation), E. Kevin.Shakesheff@open.ac.uk.
Funder(s)	National Institute for Health and Care Research Grange House 15 Church Street Twickenham TW1 3NL T: 020 8843 8000 E: ccf@nihr.ac.uk
Key Protocol Contributors	Professor Felicity Astin (contact details above) Dr Emma Harris (contact details above) Dr Rebecca Simpson Lecturer in Medical Statistics Design, Trials, and Statistics, ScHARR University of Sheffield Regent Court 30 Regent Street Sheffield S1 4DA T: +44 (0) 114 222 4390 E: r.simpson@sheffield.ac.uk

	Dr Dwayne Conway Consultant Interventional Cardiologist Sheffield Teaching Hospitals NHS Foundation Trust Chesterman Wing Northern General Hospital Herries Road Sheffield S5 7AU E: dwayne.conway@nhs.net Dr Jeremy Butts Consultant Interventional Cardiologist Calderdale Royal Hospital Salterhebble Halifax HX3 0PW E: Jeremy.Butts@cht.nhs.uk Mr Mark Lewis Patient Representative E: markandsandie@hotmail.com Dr Kristian Hudson Implementation Specialist Improvement Academy Bradford Institute for Health Research Temple Bank House Duckworth Lane Bradford BD9 6RJ E: Kristian.Hudson@yhia.nhs.uk

FUNDING AND SUPPORT IN KIND

FUNDER	FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN
National Institute for Health and Care Research (NIHR) Funding scheme: Research for Patient Benefit (RfPB)	Financial; investigator led grant.
This project is funded by the NIHR RfPB Programme. The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.	(Funding was awarded to Calderdale and Huddersfield NHS Foundation Trust (CHFT) with Chief Investigator and Co-Lead (Open University), and the research team (Sheffield NHS Trust, the University of Sheffield & The Improvement Academy) following a competitive process and three rounds of independent peer review. The sponsor is the Open University.

ROLE OF STUDY SPONSOR AND FUNDER

The sponsors are responsible for satisfying itself that the research protocol, research team and the research environment have passed appropriate scientific quality. This includes satisfying itself that the study has ethical approval before it begins, that arrangements are kept in place for good practice in conducting the study, and for monitoring and reporting, including prompt reporting of suspected unexpected serious adverse events or reactions and ensuring arrangements are in place for insurance and indemnity to meet the potential legal liability of the sponsor for harm arising from the research. Decisions relating to research and dissemination of findings will be made by the Chief Investigator, research team in conjunction with associated steering/advisory groups. The sponsors will be updated about progress and outputs prior to publication.

PROTOCOL CONTRIBUTORS

The research team have all contributed and approved the research protocol. The draft protocol was prepared by Professor Felicity Astin (Applied Health Researcher and Registered Nurse), Dr Emma Harris (Applied Health Researcher) and Dr Rebecca Simpson (Lecturer in Medical Statistics). The co-investigators reviewed the study protocol (Dr Dwayne Conway (Consultant Cardiologist), Dr Jeremy Butts (Consultant Cardiologist), Mr Mark Lewis (Patient Representative), Mr Chris Essen (PPI Lead) and Dr Kristian Hudson (Implementation Scientist). The protocol has also been reviewed by NIHR Senior Investigators Professor Stephen J Walters (Professor of Medical Statistics and Clinical Trials), Professor Steven Julious (Professor of Medical Statistics), Tracy Wood (Research and Development Lead) and Lesley Thomis (Interim Research Manager) Calderdale and Huddersfield NHS Foundation Trust).

KEY WORDS:

Angina

Coronary angioplasty,

Coronary angiogram

Patient decision aid

Shared decision-making,

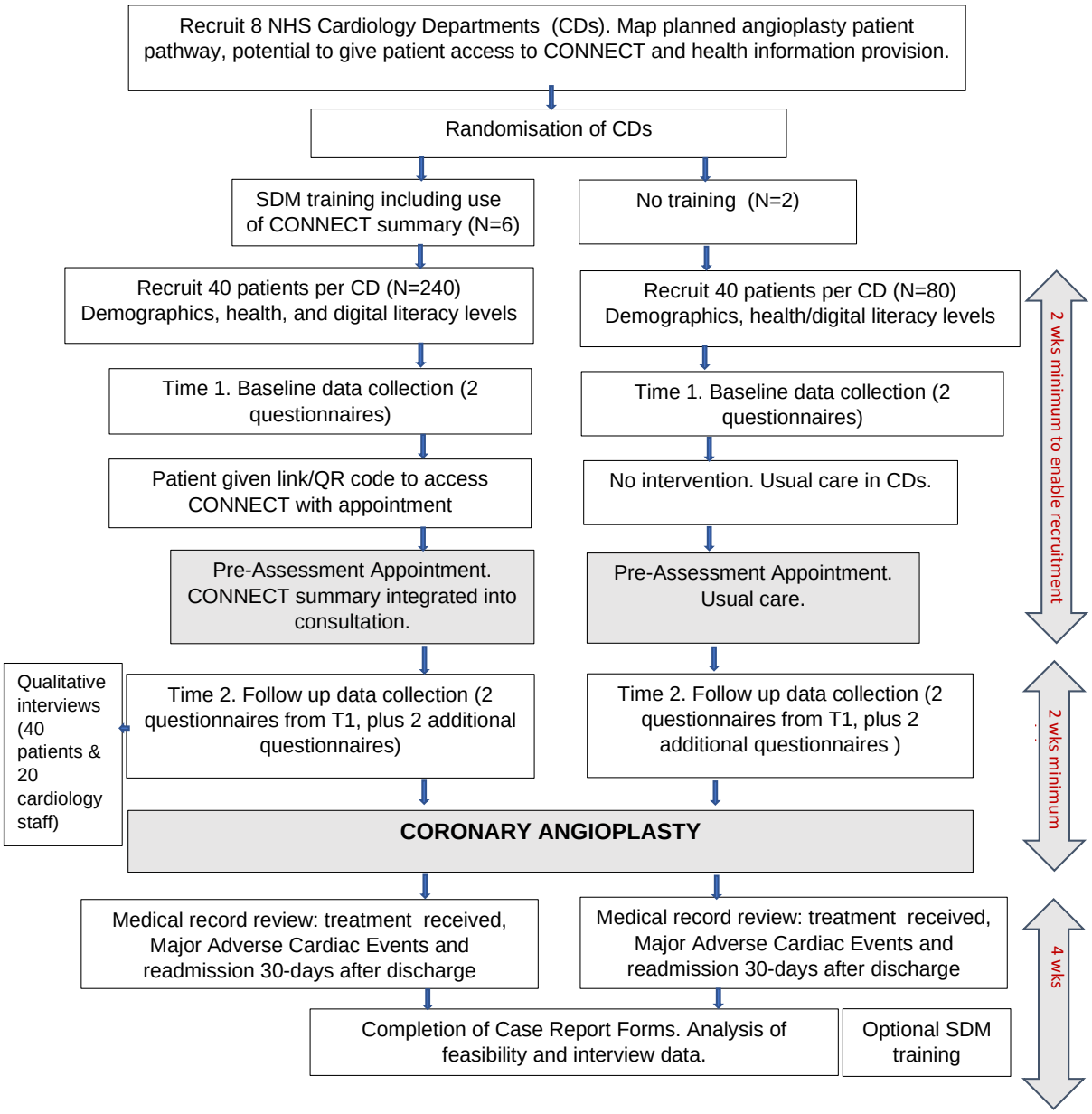
Feasibility,

STUDY SUMMARY

Study Title	Cluster randomised controlled feasibility study of CONNECT: a patient decision aid designed to improve the quality of shared decision-making for planned coronary angioplasty.
Internal ref. no. (or short title)	Testing the feasibility of using a digital decision aid.
Study Design and Setting	This is a cluster randomised controlled feasibility study with a nested qualitative study. Eight clusters (NHS Cardiology Departments delivering planned coronary angiogram/angioplasty in England) will be recruited and randomised to the control or intervention arm at a 1:3 allocation ratio. Six will implement a digital Patient Decision Aid 'CONNECT' and two will continue with usual care only.
Participants	Patients, 18 years or older, with stable angina scheduled for planned coronary angioplasty treatment. This also includes diagnostic coronary angiography with the potential to proceed immediately to treatment with coronary angioplasty ("angio query proceed") and NHS staff providing their care.
Sample Size	Feasibility study: 40 patient participants from each cardiology department (N=320 patients from 8 sites). Nested qualitative study: a sub-sample of up to 40 patient participants, and 20 NHS staff, recruited across Cardiology Departments allocated to the intervention arm.
Intervention	CONNECT is a digital Patient Decision Aid designed to provide decision support (see appendix 1).
Control	Usual care
Objectives	Feasibility outcomes
1. Determine the feasibility of recruitment and retention. 2. Evaluate willingness to be randomised. 3. Determine diversity and inclusivity of sample. 4. Explore the characteristics and appropriateness of questionnaires as outcome measures for a cluster randomised controlled trial (c-RCT). 5. Estimate the Intra-cluster Correlation Coefficient and sample size calculation for a c-RCT. 6. Explore the practical implementation of CONNECT 7. Evaluate the acceptability of CONNECT and study procedures.	• Cardiology department recruitment rate. • Patient participant recruitment and retention rate. • Characteristics of participating cardiology departments and patient demographics. • Number of non-English speaking patient participants requiring interpreter support. • Number of patient participants without digital access. • Item response rate and percentage of completed patient questionnaire data sets. • Descriptive (Intra-cluster correlation, effect size and sample size calculation) and inferential statistical analysis (Compare questionnaire scores pre and post CONNECT intervention). • CONNECT usage: website metrics (no of visits), % of patient participants who access, and use, in consultations. • A detailed narrative account of patient participants and NHS staff views regarding: 1) the acceptability and practicality of CONNECT and 2) the acceptability of study procedures.

STUDY SCHEMA

Figure 1. Flow chart for multi-centre, unblinded, two group, prospective, cluster randomised, controlled feasibility study of COroNary aNgioplasty dECision Tool (CONNECT)



1. BACKGROUND AND RATIONALE

1.1 Background

1.1.1 Coronary heart disease and angina

Coronary heart disease is caused by a build-up of fatty 'plaques' in the coronary arteries that supply the heart muscle. Coronary heart disease remains a leading cause of death and disability globally with 9.7 million deaths in 2019 alone[1]. Angina is the name given to symptoms of chest discomfort, or pain, caused by coronary heart disease. Angina can be debilitating because it has a negative impact upon mental health, physical functioning, and health-related quality of life[2].

1.1.2 Angina treatment

The first-line treatment for angina is medication. If medications are not effective, an adjunct invasive procedure may be indicated. Firstly, the coronary arteries need to be 'seen' to establish the presence of any narrowings. This can be done with a diagnostic coronary angiogram or Computed Tomography imaging. Depending on the diagnostic findings, planned coronary angioplasty and stenting may be indicated to 'physically' widen narrowed coronary arteries. This may follow immediately after diagnostic angiogram, or separately at a later consultation.

1.1.3 Deciding to have treatment

Deciding whether to continue with medications alone, or to progress to more invasive treatment with coronary angioplasty is not always straightforward. This is because randomized controlled trials have shown that medicines and planned coronary angioplasty confer similar health benefits, although coronary angioplasty is marginally better for the long-term relief of angina[3-4]. So, patients with minimal, or no angina symptoms, are unlikely to benefit from elective coronary angioplasty compared to medications alone[5]. Despite the trial evidence, planned coronary angioplasty procedures are sometimes performed unnecessarily which exposes patients to potential harms[6,7]. Whilst death, stroke and heart attack are unlikely complications of planned coronary angioplasty, the risk is greater in older people who live with multiple comorbidities.

1.1.4 Promoting shared decision-making and patient involvement

When evidence supports several treatments options, the 'best' decision reflects the doctor's evidence-based recommendations combined with the patient's values and preferences[8]. However, eliciting patients' values and preferences within a short consultation requires considerable skill and time. Research shows that patients with stable angina are not always very involved in the shared decision-making process, and frequently misunderstand the risks and benefits of coronary angioplasty, mistakenly seeing it as a 'fix' [9,10]. In summary, patients considering planned coronary angioplasty have unmet decision-support needs, and attendant cardiology teams need support to strengthen shared decision-making in the patient pathway[11].

1.1.5 The potential of patient decision aids

Shared decision-making is a collaborative process, in which patients and healthcare professionals work together, to help the patient make treatment decisions that are right for them[12]. Facilitating shared decision-making within the time constraints that NHS teams face is a challenge. Using a Patient Decision Aid may provide a potential solution.

1.2 STUDY RATIONALE

1.2.1 How can patient decision aids benefit patients and health services?

Patient Decision Aids (PtDAs) are evidence-based interventions known to be effective in improving the quality of shared decision-making[13]. PtDAs are more than educational tools; they help patients clarify their own health values and treatment preferences and facilitate participation in the decision-making process. Evidence shows that PtDAs also increase patients' knowledge levels about treatments and support more accurate perceptions of associated benefits and risks[13].

1.2.2 National Institute for Health and Care Excellence recommendations

In 2021, the National Institute for Health and Care Excellence (NICE) published evidence-based guidelines recommending the use of PtDAs[12]. However, despite the benefits of PtDAs and recommendations in clinical guidelines, they are not routinely used in clinical practice.

1.2.3 Choice of intervention

For UK patients suffering from stable angina and considering planned coronary angioplasty, there is no high-quality, up to date, PtDAs available. To address this gap, we co-created a digital PtDA called CONNECT (COroNary aNgioplasty dECision Tool) and conducted preliminary pilot work with stakeholders in non-NHS settings[14]. We plan to conduct a future large-scale evaluation of CONNECT.

1.2.4 Is a future large-scale evaluation of CONNECT feasible?

First, we need to conduct some groundwork to address uncertainties about our future large-scale evaluation to test the effectiveness of CONNECT in the planned coronary angioplasty patient pathway.

1.2.5 What we will learn from this feasibility study

Findings from this study will provide us with the necessary data to establish whether a future large-scale evaluation of CONNECT is feasible. In addition, patients who receive CONNECT as part of this study may benefit from a higher quality shared decision-making process. Learning about the barriers and enablers of implementing a PtDA in Cardiology Departments may be transferable to other elective invasive procedures.

1.3 THEORETICAL FRAMEWORKS

1.3.1 Patient Decision Aids

A PtDA, such as CONNECT, is classified as a complex intervention. It has several interacting components and is dependent upon the context in which it is delivered, as well as the behaviours of those giving or receiving it[15]. The Medical Research Council framework identifies four recommended developmental stages for a complex intervention: 1. 'intervention development', 2. 'feasibility', 3. 'evaluation' and 4. 'implementation'[15]. We have completed stage 1[14].

1.3.2 Feasibility

The proposed study will build upon this work and focus upon stage 2. 'feasibility'. In this way we will address uncertainties about how the intervention (CONNECT) will work in NHS settings and assess predefined progression criteria to the proposed definitive evaluation study[15]. The proposed feasibility study is not powered to test the primary outcome of the future large-scale evaluation but is designed to 'prepare the ground' for a future cluster randomised controlled trial (c-RCT) as per NIHR guidance on feasibility studies (nihr.ac.uk).

1.3.3 Underpinning theory

The development of CONNECT and the design of the proposed evaluation (e.g., choice of anticipated primary outcomes) was informed by the Ottawa Decision Support Framework, which is underpinned by multiple theories on decision analysis/making, social support and self-efficacy[16].

2. AIMS AND OBJECTIVES

This is a cluster randomised controlled feasibility study (c-RCT) with a nested qualitative study.

2.1 Aims

The overarching aim of this study is to determine whether it is feasible to conduct a future c-RCT to test the effectiveness of CONNECT for improving shared decision-making for patients with stable angina.

The quantitative and qualitative data collected will enable us to assess 1) the feasibility of delivering CONNECT in the planned coronary angioplasty patient pathway; 2) explore the acceptability of CONNECT to patients and cardiology teams; and 3) assess the feasibility and acceptability of trial procedures.

2.2 Objectives

1. Determine the feasibility of recruitment and retention.
2. Evaluate willingness to be randomised.
3. Determine diversity and inclusivity of sample.
4. Explore the characteristics and appropriateness of questionnaires as outcome measures for c-RCT.
5. Estimate the Intra-cluster Correlation Coefficient and sample size calculation for a c-RCT.
6. Explore the practical implementation of CONNECT
7. Evaluate the acceptability of CONNECT and study procedures.

3. STUDY DESIGN AND SETTING

3.1 Study design

This is a cluster randomised controlled feasibility study with a nested qualitative study. Figure 1. shows the flow chart for this multi-centre, unblinded, two group, prospective, cluster randomised, controlled feasibility study. Our statistician advised that a minimum of eight clusters in total is needed to best estimate the Intra-cluster Correlation Coefficient (ICC)[17]. We aim to recruit eight clusters (NHS Cardiology Departments delivering care for patients scheduled to have planned coronary angiogram query proceed or planned coronary angioplasty in England) which will be

randomised to the control or intervention arm at a 1:3 allocation ratio. Six clusters will implement a digital Patient Decision Aid 'CONNECT' and two will be usual care.

3.2 Rationale for study design

C-RCTs are study groups, or clusters of individuals, rather than the individuals themselves[18]. The rationale for this choice was to reduce potential contamination identified by clinical colleagues; a scenario that occurs when aspects of an intervention, such as CONNECT, are adopted by patients not randomised to receive it[19]. Clusters also avoid the challenge of trying to conceal allocation to the intervention (CONNECT), versus usual care, from both the health professional teams and participating patients' perspectives. Training half the sites (in the full trial) also limits the training burden on the study team. All staff at the intervention sites can receive the training as a group, which could lead to the staff using CONNECT more efficiently and effectively.

3.3 Stop/Go criteria for progression to future c-RCT

To progress to a full-scale c-RCT, we will need to demonstrate that it is feasible and acceptable to implement CONNECT in the planned coronary angioplasty patient pathway. We will also need to determine the acceptability of study procedures. Progression criteria will guide decisions about advancement to a future large-scale trial. Feasibility data may also inform the study design of other trials that test PtDAs. Table 1 below shows the preliminary Stop/Go criteria that will be developed by the Study Advisory Group and determine progression to the development of an application for a future c-RCT.

Table 1. Stop/go criteria

STOP/GO Criteria	Green-Go	Amber-Change	Red-Stop	Proposed action if Amber targets are attained
Cluster recruitment targets: Number of Cardiac Departments recruited in the first 4 months of the study	8	6-7	≤5	Review reasons for non-participation on EoI document and consider alternative strategies.
Patient recruitment targets: Average number of patients recruited per month, per cluster	4+	3	1-2 (<50% target)	Review recruitment processes and reasons for non-consent. Consider alternative strategies.
Adherence targets: % of the patient sample who access CONNECT before pre-assessment clinic	75%+	66%-75%	<66%	Review qualitative data for reasons for non-adherence. Consider strategies to improve CONNECT engagement.
Retention targets: % of the patient sample who complete the study.	80%+	60%-80%	<60%	Review attrition reasons and identify strategies to prevent before full c-RCT.
Willingness to be randomised: Number of Cardiac Departments (n=98) who are willing to be randomised (anticipated cluster number for full trial: 24 - 42)	33+	24 - 33	<24	Review reasons for non-participation on EoI document and consider alternative strategies and/or trial designs, such as delayed-intervention trial.

Anticipated Primary Outcome acceptability: % patient sample completion of Decisional Conflict Scale questionnaire.	80%+	60%-80%	<60%	Review the outcome measures with PPI group and revise ahead of c-RCT.
Patient and Cardiology Health Professional acceptability of CONNECT and study procedures.	-	-	-	Review qualitative data on patient and cardiology health professional acceptability of CONNECT.
Adverse events*: Number of adverse events at one-month follow-up after the pre-assessment clinic.	0	0	1+	All adverse events will be reviewed by the local PI. Treatment may continue without the use of CONNECT.

*****Potential adverse events linked to using a patient decision aid (CONNECT). EoI: Expression of Interest

3.4 Outline of future large-scale c-RCT

The anticipated outcomes of the future full-scale c-RCT are:

3.4.1 Anticipated Primary outcome:

Decisional Conflict measured from the Decisional Conflict Scale total score.

3.4.2 Anticipated Secondary outcomes:

Knowledge of coronary angioplasty, concordance of patient preferences with delivered treatment, usefulness of CONNECT in preparing participants for decision-making, and perceived level of involvement in care, measured using self-report questionnaires.

3.5 Feasibility study sample and setting

We aim to recruit up to eight Cardiology Departments in England within NHS hospitals that offer planned coronary angioplasty or coronary angio query proceed, to adults with suspected, or diagnosed, chronic coronary artery disease.

3.6 Identification of participants

Adults scheduled for planned angiography query proceed, or planned coronary angioplasty, in elective settings will be identified via booking systems/waiting lists, outpatient clinics and chest pain clinics. A local Principal Investigator (PI) (Cardiologist, Specialist Nurse, or Allied Health Professional) from the direct care team, at each participating NHS Trust, will identify eligible patients and seek permission to share contact details with a Clinical Research Nurse. Local PIs will receive support from the local Research and Development Department and Clinical Research Team.

3.7 Patient & Public Involvement

We have worked with 121 expert patients and 65 health professionals, over a 2-year period, to understand their priorities and help us to co-create CONNECT to meet their needs. An expert patient/co-applicant and an experienced PPI lead will coordinate involvement throughout our study.

Study design: We will recruit a member of the public to be a member of the Advisory Group, which will meet four times throughout the study. An important part of the study design is the development of progression criteria to a full randomised trial. The PPI Advisory Group member will participate in these discussions in the first Advisory Group meeting.

We will convene a PPI Group, which will consist of a PPI lead, lay member co-applicant, and the Steering Group and Advisory Group lay members. The PPI lead and lay member co-applicant have contributed to the study design by providing feedback on the bespoke coronary angioplasty knowledge questionnaire and the interview topic guides. They have also provided feedback on the study protocol, lay summary and study participant documents (e.g., study invitation letter, participant information sheet, consent form, PtDA instructions).

The Steering Group and Advisory Group PPI representatives will attend their respective Group meetings and will be encouraged to actively participate. We will ask the PPI Group to write the lay summary of the study progress reports.

The PPI representatives will contribute to discussions about the study results and the future trial protocol in the relevant meetings. We will seek their advice on the best ways to disseminate the results to patients and the public. They will also have an opportunity to write the PPI section on the final study report and in the publication using the GRIPP2 checklist.

3.8 Assessment of Risk

In assessing the potential risk to participants, the Chief Investigator discussed any potential risks to patient and health professional participants with two consultant cardiologists. Their view was that using CONNECT, which is not classified as a medical device, would not constitute any major risk, and that any risk would be no greater than the risk of standard medical care. In addition, a Cochrane Review reported that PtDAs improved patient knowledge levels about their treatment options and reduced their personal uncertainty about feeling uninformed and unsure about their personal values[13]. Moreover, there were no apparent adverse events on patient health outcomes including increased anxiety, or decreased satisfaction, associated with the use of PtDAs; these findings support our risk assessment[13]. In some cases, the use of PtDAs reduced the uptake of discretionary surgery[12]. As there is evidence that planned coronary angioplasty is sometimes used inappropriately[6-7], the use of a PtDA may reduce this practice if it is evident. The findings regarding the impact of using a PtDA on consultation duration have shown mixed results; six studies reported no difference in consultation duration, one reported a reduction and two an increase (median 2.55 minutes longer). CONNECT was tested in non-clinical settings with people who had received coronary angioplasty treatment as part of the development process[14]. No adverse outcomes were noted, and user feedback was generally positive[14].

There are no anticipated additional COVID-19 risks from participation in the proposed feasibility study for patient participants. The additional patient interactions within this feasibility study are:

1. Cardiology Department randomisation to intervention or control arm
2. Introduction to the study and agreement to share personal contact details if interested in participating
3. Discussion about the Patient Information Sheet (PIS), consent to participate and completion of Brief Health Literacy Screening Tool and E health literacy scale.
4. Completion of T1/baseline questionnaires (Angioplasty Knowledge questionnaire, Decisional Conflict)
5. Access and use of PtDA ‘CONNECT’, unless allocated to control arm
6. Discussion of PtDA ‘CONNECT’ summary as part of usual care pre-assessment consultation, unless allocated to control arm

7. Completion of T2 questionnaires (Angioplasty Knowledge questionnaire, Decisional Conflict, Preparation for Decision-Making Scale, Perceived Involvement in Care Scale)
8. Discussion about the interview study and PIS, consent to participate and participation in a remote interview (a subsample of 40 patient participants from intervention arm only).

It is likely that most interactions will be done remotely either by telephone or through video. Health professional interviews (n=20) will be conducted via video or telephone.

Where possible the interactions will be integrated within the existing patient pathways, consultations, and contacts. Cardiology Departments will receive study specific training. The intervention arm will receive training about the study procedures, the use of CONNECT, and principles of shared decision-making. The principles of Good Clinical Practice (GCP) in research will also be reviewed. The control arm will receive training about the study procedures and GCP principles, with the option to complete training on shared decision-making upon study completion.

4. ELIGIBILITY

Cardiology Centres (clusters) will be recruited, and patient participants recruited from within each cluster to the main feasibility study and nested qualitative study. NHS staff will also be recruited from the clusters to participate in the nested qualitative study.

4.1. Cardiology Centre and local Principal Investigator eligibility

Any NHS centre in England providing care for patients treated with planned coronary angiography query proceed, or coronary angioplasty, will be eligible to participate. The inclusion criteria for Cardiology Departments are:

- NHS Trust is in England
- Pre-assessment clinics embedded in the patient pathway.
- Has the capacity to recruit 40 patient participants within 12-months.
- Willing to be randomised to the intervention, or control arm, and adhere to arm allocation.
- Cardiology teams are willing to participate in a 2-3-hour training session about the intervention CONNECT.

Local PIs at each participating Cardiology Department will oversee the recruitment of patient participants. They will ensure that participants' eligibility criteria are confirmed by themselves, or an appropriately delegated member of the team, such as a Clinical Research Nurse. The local PI will ensure that they, or a delegate, has accessed the medical records of a potential patient participant to confirm and document their eligibility. A Clinical Research Nurse, or delegate, (as per the Standard Operating Procedures of the participating Research and Development Department) will seek informed consent.

4.2 Patient Participants (Feasibility Study)

Patient participants scheduled for planned coronary angiography query proceed, or coronary angioplasty, will be eligible to participate. Eligible patient participants will be:

- Adult patients (≥ 18 years) presenting with stable angina.
- Suspected or diagnosed chronic coronary artery disease.
- On the waiting list for planned coronary angioplasty or planned angiography query proceed to coronary angioplasty ("angio query proceed"). See Figure 1 for more detail.
- Capacity to give informed consent.

Patient participants who are clinically unstable, scheduled for urgent or emergency coronary angioplasty, or lack capacity to give informed consent at the time of recruitment will be excluded.

4.3 Patient Participants (Nested Qualitative Study)

From the 240 patient participants recruited to the intervention arm of the main feasibility study, we will recruit a sub-sample of up to 40 patient participants (6-7 from each Cardiology Centre). Eligible patients will be those who are participating in the feasibility study and have not withdrawn from the study.

4.4 Cardiology Department Staff (Nested Qualitative Study)

Eligible NHS staff participants will be:

- Working, or have worked, in the cardiology department delivering care for people scheduled for coronary angioplasty or “angio query proceed”.
  and/or
- Have had direct involvement in the delivery of CONNECT and/or the feasibility study procedures.

4.5 Co-enrolment

Patient participants who have been recruited into other interventional studies that do not involve an educational intervention, or significantly alter the amount of health professional contact, or involve the administration of self-report questionnaires, are permitted to be included in this feasibility study. Sites should contact the Chief Investigator to discuss details prior to co-enrolment.

5. CONSENT PROCESS

5.1 Patient participants

The local PI at each participating Cardiology Department, (or a trained delegate e.g., specialist nurse or clinical research nurse), will be responsible for obtaining oral informed consent from each patient participant. For consent to be valid it must be voluntary, informed, specific, current, and given by a person with capacity at the time.

Eligible patients will be identified and first approached by the local PI, or delegate, and provided with introductory information about the study. This person will be a member of the patient’s care team. Interested patients will then be asked for their permission to share their personal details (hospital number, address, telephone, email) with the clinical research team. If they agree they will be sent a study pack (Invitation letter, patient information sheet, oral informed consent form and baseline questionnaires) by post or email. Potential patient participants will then be telephoned 3-5 days later to discuss the study, during which time oral informed consent will be sought from willing participants. Eligible participants will be asked if they have had sufficient time to read and consider the information in the patient information sheet (PIS) and given an opportunity to ask questions. During the oral consent process, the participant will be able to refer to a blank copy of the oral informed consent form (sent in the study pack) to support their understanding. The person seeking informed consent will explain to the patient participant:

- That consent is sought for regulatory authorities, members of the research team and or representatives of the sponsor to have direct access to participant’s medical records.
- That consent is sought to take part in a feasibility study of a PtDA and a nested qualitative interview study for those in the intervention arm

- That the feasibility study will evaluate whether a future trial of a PtDA 'CONNECT' is possible and whether it will work in the NHS and be acceptable to patients and health professionals
- That the PtDA 'CONNECT' will be allocated at random to Cardiology Departments so not all participants will get to use it.
- What the study procedures will involve for the participant.
- That participation is voluntary, and they may withdraw from the study at any time, and that their decision will not influence their treatment and care.
- The anticipated benefits and risks of taking part in the study.
- The requirement to feedback to the local PI should any instances of poor clinical practice or safeguarding issues become apparent.
- Those participants taking part in the feasibility study, or qualitative interview study (intervention arm only), will be entered into a prize draw or receive a voucher, respectively.

The consent form for the intervention arm will have two sections. The first addresses participation in the main feasibility study, and the second addresses participation in the qualitative study, which takes place some months later. Informed consent for both elements will be sought simultaneously, and ongoing willingness rechecked ahead of the qualitative interviews. Since the qualitative study is only for participants in the intervention arm, the consent form for the control arm will only have one section that addresses participation in the main feasibility study. If the patient participant wishes to proceed, the researcher will sign the oral consent form on their behalf. The patient participant will be asked if they would like to receive a copy of the signed document.

The oral informed consent process will take place ahead of any study procedures and conducted as per an agreed Standard Operating Procedure. Details of the informed consent process (Date and summary of discussion and consent process followed) will be recorded in the patient medical record and CONNECT Study Log (Patients Identification Log, Patients Screening Log, Patients Participant Enrolment and Withdrawal Log). Participants will have the right to withdraw from the study at any time.

The local PI, or delegate, will liaise with their Research and Development department to ensure that the completed informed consent form is archived in the local site file and is available to the Chief Investigator for review if required. To reduce administration burden for GPs we have adopted a pragmatic approach and have chosen not to inform them about patients in their care participating in the study. This is because participation in the study is not anticipated to influence the patient health condition and the current workload for GPs in primary care settings is significant.

5.2 Health professional/NHS staff participants

During site set up and training, Cardiology Department staff in the intervention arm will be informed that they will have the opportunity to participate in a qualitative interview once all recruited patient participants at their site have completed their pre-assessment consultation. The local PI, or delegate, will identify NHS staff involved in the patient pathway for planned "angio query proceed", coronary angioplasty, and/or the delivery of CONNECT study procedures at their site. All eligible participants will be emailed a study pack (invitation letter, PIS and oral informed consent form) and invited to email, or telephone, the Research Fellow leading the qualitative study if interested in participating. The Research Fellow will contact interested individuals and ensure that they have had sufficient time to read the PIS, ask questions and deliberate with others. The Research Fellow will explain to the NHS staff participant:

- That consent is sought to take part in a nested qualitative interview study

- The requirement to feedback to the local PI of any instances of poor clinical practice, or safeguarding issues, should they become apparent.
- What the study procedures will involve for the participant.
- The anticipated benefits and risks of taking part in the study.
- That participation is voluntary and that they may withdraw from the study at any time.
- Those participants taking part in the qualitative interview study will not be reimbursed for any expenses.

If the NHS staff participant wishes to proceed, the Research Fellow will sign the oral consent form on their behalf and asked if they would like to receive a copy of the signed document. Participants will have the right to withdraw from the study at any time.

The oral informed consent process will take place ahead of any study procedures and conducted as per an agreed Standard Operating Procedure. Details of the informed consent process (Date and summary of discussion and consent process followed) will be recorded in an NHS Staff Participant Log by the Research Fellow and archived as per the Open University data management plan.

6.0 Recruitment, Screening and Randomisation

6.1 Recruitment and screening

Recruitment will take place at three levels: 1) Cardiology Departments/Clusters in England. Then within Cardiology Departments/Clusters 2) patient and 3) health professional/NHS staff participants will be recruited.

6.1.1 Cardiology Departments/Clusters

Recruitment of Cardiology Departments/Clusters will be done through the dissemination of an Expressions of Interest (EoI) document by the National Institute of Health Research Yorkshire and Humber Clinical Research Network to all NHS Trusts in England that provide cardiology services. Informal meetings will be scheduled to discuss site suitability against eligibility criteria. Signing of an agreement will constitute consent to participate. The list of participating Cardiology Departments will be available on the trial registration site.

6.1.2 Patient Participants (Feasibility Study)

Potentially eligible patient participants who are scheduled for planned “angio query proceed” or coronary angioplasty will be screened and approached by a local PI, or a delegated person. We have adopted a flexible approach to recruiting patient participants as the patient pathway for planned angio/coronary angioplasty varies across NHS Trusts in England and is subject to change at short notice as measures are introduced to reduce waiting lists. We envisage that patient participants will be identified by a member of the direct care team within three settings:

1. **Planned catheter laboratory waiting lists - by a catheter laboratory scheduler, specialist nurse, cardiologist trainee or consultant.**

The local PI, or delegate, will identify eligible patients from the waiting list and contact them by telephone. The study will be briefly introduced, identified as optional and not related to their treatment. Interested participants will be asked to give their permission to share their personal details (name, patient hospital number, contact number, home address or email) with a member of the Clinical Research Team. Participants must have a minimum of a 2-week lead in time before their pre-assessment consultation (See Figure 1). This should be feasible because average

waiting times for elective cardiology procedures in England are between 13 and 20 weeks and are predicted to increase[23].

2. **Cardiology outpatient clinics at the point of referral for planned coronary angioplasty or "angio query proceed" – by a specialist nurse or cardiologist trainee or consultant.**

Patients are typically referred for planned coronary angioplasty, or "angio query proceed" by their cardiologist at an outpatient consultation, (Face-to-face, telephone or video consultation). The local PI, or delegate, will screen and approach eligible patients during this clinic and the same recruitment process described for waiting list participants will be adopted.

3. **Chest pain clinics at the point of referral for planned coronary angioplasty or "angio query proceed" – by a specialist nurse or cardiologist trainee or consultant**

Patients are typically referred for planned coronary angioplasty, or "angio query proceed" by their cardiologist or specialist nurse at chest pain clinics (Face-to-face, telephone or video consultation). The local PI, or delegate, will screen and approach eligible patients during this clinic and the same recruitment process described for waiting list participants adopted.

We will liaise with cardiology teams at site set-up to establish which approaches are both feasible and preferred. For all three recruitment pathways a member of the direct care team will screen and approach eligible patient participants, document in the medical record and complete the Patient Identification Log. For potential participants who speak languages other than English, an interpreter would normally be booked as part of standard practice. This would be recorded on the Patient Identification Log. If a patient does not want to be contacted, no further communication will be made regarding the study

The contact details of patient participants who are potentially interested in participating in the research will be shared with a member of the Clinical Research Team who will immediately post/email the Study Pack (Invitation Letter, Patient Participant Information Sheet, Patient Consent Form, Baseline questionnaires). For interested participants who speak a language other than English, study documents will be provided in the patient's first language and the research nurse will arrange an interpreter to be present during the telephone call. If a patient participant does not answer the phone or respond to emails, two further attempts at contact over a one-week period will be made. If no response, there will be no further contact about the study

6.1.3. Patient participants (Nested qualitive study)

A sub-sample of up to 40 patient participants (6-7 from the 6 clusters in the intervention arm) will be purposively sampled. The participants will have consented to be contacted by the Research Fellow during enrolment for the main study. The qualitative interview will be conducted within 1-2 weeks following the participant's pre-assessment consultation. The local PI, or delegate, will inform the Research Fellow when participants have attended their usual-care pre-assessment clinic consultation. The Research Fellow will telephone the participant within 1 week of the consultation to ascertain their willingness to continue participating in the study. For participants who wish to continue, a date for the qualitative interview (telephone or video) will be arranged. Verbal informed consent will be reconfirmed by the Research Fellow before the start of the interview and audio recorded.

6.1.4 Cardiology team participants (Nested qualitive study)

During site set up and training, Cardiology Department staff in the intervention arm will be informed that they will have the opportunity to participate in a qualitative interview once all recruited patient participants at their site have completed their pre-assessment consultation. The

local PI, or delegate, will identify NHS staff involved in the patient pathway for planned “angio query proceed”, coronary angioplasty, and/or the delivery of CONNECT study procedures at their site. All eligible participants will be emailed a study pack (invitation letter, PIS and oral informed consent form) and invited to email, or telephone, the Research Fellow leading the qualitative study if interested in participating. Informed consent will be obtained by the Research Fellow. See section 5.2 for a description of the oral informed consent process.

6.2. Randomisation

The eight Cardiology Departments are the units of analysis and will be randomised using stratified block randomisation with an allocation ratio of 3:1 to the intervention group and block size of four. Cardiology Departments will be stratified as appropriate, by factors such as the presence, or absence, of on-site surgical provision.

Details of the Cardiology Departments in England that have expressed an interest in participating in the study through the submission of an Expression of Interest document will be recorded. A separate linkage file will be developed by the Chief Investigator or delegate (Co-Lead, Research Fellow) in which each Cardiology Departments will be anonymised through the allocation of a unique identifier. In this way the identity of participating Cardiology Departments will be blinded to the study statistician, who will generate the allocation sequence (computer generated random numbers) and implement it.

The allocation ratio was chosen to maximise the number of clusters in the intervention arm to test the feasibility, practicality, and acceptability of the intervention. A control arm was included to evaluate the feasibility and acceptability of trial procedures such as the willingness of Cardiac Departments to be randomised. This study is not a ‘mini-version’ of the future c-RCT designed to test the effectiveness of the intervention.

6.3 Blinding

Participating Cardiology Departments will be randomised to the intervention or control group after they have agreed to participate. The statistician conducting the randomisation will be blinded to the identity of the Cardiology sites. A cluster design was chosen for this feasibility study to minimise the contamination that could result from allocating patient participants to either an intervention or control within a cardiology department. It would not be possible to blind participants to their allocation to the intervention or control.

7. STUDY INTERVENTION AND USUAL CARE

7.1 Usual care and site requirements

Before opening the study, all Cardiology Departments will receive study-specific training on the logistical and operational aspects of the study. As part of this process, we will map the patient pathway to understand the number and duration of patient contacts. Cardiology Departments randomised to the control arm will not receive training about CONNECT or shared decision-making and will deliver standard care. However, for equity, we will offer Cardiology Departments in the control arm the option of completing training on shared decision-making at the end of the study if desired. Information about treatment options will be provided to patients in the control arm during the referral consultation and at the pre-assessment consultation as usual (See Figure 1). Participants in the intervention and control arms will complete identical questionnaires. To understand how usual care compares with the intervention and potential sources of contamination, we will ask Cardiology Department to provide us with copies of any written or

digital material provided to patient participants regarding their treatment (coronary “angio query proceed” and planned coronary angioplasty). We will also include a question on the Angioplasty Knowledge Questionnaire about the format and content of any health information they received before their treatment, as part of usual care.

7.2 PtDA CONNECT

CONNECT (COroNary aNgioplasty dECision Tool) is a digital Patient Decision Aid hosted on a university website. Like other PtDAs, CONNECT is an intervention designed to encourage patient involvement in health-related decision-making. CONNECT is not a medical device. It is an educational tool, that goes beyond simply providing information. It uses multimedia (images, diagrams, animations, audio) to inform patients about their treatment choices and the associated risks and benefits of each. Through interactive activities (i.e., questions about angina symptoms, what matters to them and their preferred treatment choice) CONNECT enables users to clarify and communicate their personal values in relation to each treatment option. CONNECT generates a personalised summary derived from self-report questionnaires that can be saved as a PDF file. The summary identifies self-reported angina symptom burden and the impact on daily life, personal values, treatment preferences, worries, concerns, and unanswered questions. This personalised summary can inform patient consultations and potentially act as a ‘primer’ for health professionals, alerting them to specific areas that the patient may wish to discuss. See appendix 1. for a detailed description of CONNECT using the template for intervention description and replication (TIDieR) checklist[20]. CONNECT is accessible at the following link https://uoh-connect.staging.ginger-root.co.uk/

Patient participants at the Cardiology Departments in the intervention arm will receive information about how to access CONNECT either as part of usual care correspondence from the hospital confirming their pre-assessment consultation and/or procedure date. The information about CONNECT and the weblink or QR code will be delivered on a paper or digital letter, email, or text message, depending on the usual approach adopted by the Cardiology Department. Or, if this approach does not align with the patient pathway of care, then a Clinical research nurse will send CONNECT access instructions 1-2 weeks after consent.

Participants will be invited to use CONNECT and save their personal summary before attending their usual-care pre-assessment clinic consultation. To standardise the delivery of CONNECT across Cardiology Departments, we will create training materials that will be delivered during site set up.

7.3 Compliance with Intervention

In this feasibility study, adherence to CONNECT will be conceptualised as the percentage of patient participants who report being able to successfully access CONNECT. In addition, we will ask the patient participant and pre-assessment nurse if the CONNECT summary was taken to the pre-assessment consultation.

7.4 Use of CONNECT after study completion

We will make CONNECT available to those sites who wish to continue to use it providing it remains available on the website.

8. OUTCOME MEASURES AND STUDY PROCEDURES

8.1 Feasibility and nested qualitative study outcomes

Table 2. shows an overview of the outcomes for the proposed feasibility study and nested qualitative study.

Table 2: Overview of feasibility study uncertainties and outcomes

Uncertainty	Outcomes
Feasibility of cluster recruitment and their willingness to participate	• Number of Cardiology Departments approached, the number of responses to the 'Expression of Interest', and the number willing to participate. • Recruitment rate (Number of Cardiology Centres recruited in 4 months).
Feasibility of patient participant recruitment and retention	• Number of eligible patient participants, approached, consented, and recruited. • Recruitment rate (Number of patients recruited per month, per site). • Retention rate, defined as the proportion completing the anticipated primary outcome questionnaires (Decisional Conflict Scale questionnaire at T2). • Attrition (loss of participants who were assigned to intervention or control). • Rates of MACE and hospital readmission within 30-days of discharge.
Diversity and inclusivity of sample	• Characteristics of Cardiology Departments: geographical location, Index of Multiple Deprivation (IMD), size of cardiology workforce, presence or absence of on-site surgical cover, annual volume of planned angio/coronary angioplasty procedures. • Patient participant demographics: age, gender, ethnicity, level of social support, health and E-literacy, cardiac diagnosis, co-morbidities. • Number of non-English speaking participants requiring interpreter services (verbal and/or translation of documents). • Number of participants without access to digital technology (including smartphones, tablets, laptops, and the internet).
Characteristics and appropriateness of questionnaires as outcome measures in the future c-RCT	• Response rate (Number of participants who completed and returned the questionnaires divided by number of participants in the sample). • Item response rate (Number of valid responses divided by total number of responses requested).
Intra-cluster Correlation Coefficient (ICC) and sample size calculation for full scale c-RCT	• Estimate of the ICC of the Decisional Conflict Scale at T2 using a marginal or random effects model. • The full c-RCT sample size will be calculated based on estimates of the effect size (alongside previous research), the standard deviation and the ICC from the anticipated primary outcome analysis.

Uncertainty	Outcomes
Practicality of implementing CONNECT in NHS settings	CONNECT implementation: • Number of participants who access CONNECT. • Percentage of pre-assessment clinic visits in which the CONNECT • summary was used during the consultation. • Qualitative analysis of training session minutes and interview transcripts to summarise: • Potential variations in usual-care patient pathway for planned coronary angioplasty. • Practicalities of providing a digital PtDA in the NHS. • Barriers and enablers to integrating the CONNECT summary.
Reasons for non-consent to study participation	Qualitative analysis to summarise: • Reasons for Cardiology Departments nonparticipation. • Reasons for patient nonparticipation.
Acceptability of CONNECT and study procedures	Qualitative analysis of interviews to explore: • Self-reported adherence to CONNECT and how it was used by patients at home and during the pre-assessment clinic. • Barriers and enablers to recruitment and using CONNECT at home and during pre-assessment clinic. • Understanding, appropriateness, and potential burden of questionnaire completion.

8.2 DATA COLLECTION

Feasibility data will include logged numeric and narrative data, data from self-administered questionnaires and in-depth interviews. Table 2 provides a detailed overview of data (see pages 22-24). Table 3. shows an overview of enrolment, interventions and assessments for site set-up and the study period.

Table 3. Study Activities		**Study Period**						
	Site set-up	Recruitment		Data collection				Follow-up
Approximate Timepoints**	- 3 mths	- 1-2 wks	0	+1-2 wks	+1 mths	+ 2 mths	+ 2.5 mths	+ 1-6 mths
Cluster Expression of Interest	X							
Cluster set-up and training	X							
Patient identification		X						
Patient 'Study Packs' sent to patient participants.		X						
Member of Clinical Research Team approaches patient			X					
Informed consent			X					
Enrolment: Patient demographics, medical history and health and digital literacy levels			X					

Baseline questionnaires (T1)				X				
CONNECT link given at time of receiving pre-assessment consultation date letter					X			
Usual care pre-assessment clinic						X		
Post pre-assessment clinic questionnaires (T2)						X		
Interview							X	
Medical record review								X

**Times will vary across Cardiology Departments due to variations in the patient pathway and waiting times for planned coronary angioplasty procedure.

8.2.1 Patient identification

During patient identification a member of the direct care team (local PI, or delegate), will identify eligible patients, approach them giving introductory information about the study, and seek permission to access their medical records and share personal details (name, hospital number, address and telephone number) with Clinical Research Nurse, or delegate. The local PI, or delegate, will complete the Patient Identification Log, which will determine the following outcomes:

- Number of eligible patients.
- Number of patients approached by the local PI or delegate.
- Number of patients who were unable, or declined, to be contacted.
- Number of patients who agreed to be contacted by the research nurse.
- Number of non-English-speaking participants requiring interpreter services

8.2.2 Patient recruitment and enrolment

A Clinical Research Nurse, or delegate, will liaise with the local PI, or delegate, and send study information pack to interested patients. The Clinical Research Nurse, or delegate, will then telephone eligible patients 3-5 days later. Completion of the Screening Log and the Enrolment and Withdrawal Log will determine the following outcomes:

- Number of patients approached by the Clinical Research Nurse.
- Number of patients who were unable to be contacted.
- Number of patients who declined participation, with reasons, where given.
- Number of participants without digital access (internet or device).

Following informed consent and enrolment into the study, the research nurse will administer the 3-item BRIEF Health Literacy Screening Tool[21] and the 8-item eHEALS: eHealth Literacy Scale[22] to participants during the telephone call and record responses in the electronic questionnaire document and enter the data into the site's Case Report Form. The Clinical Research Nurse, or delegate, will also remind participants to complete and return the baseline (T1) questionnaires, which will have already been sent to participants with the study information pack. They will also document the outcomes below in a Case Report Form:

- Patient participant demographics such as but not limited to age, gender, ethnicity, level of social support (live alone), employment.
- Relevant medical history; cardiac diagnosis, co-morbidities.

8.2.3 Baseline

Participants will have received the baseline (T1) questionnaires in the study information pack. This will include instructions to complete them within 7 days of consenting to participate and return in the stamped-addressed envelope or via e-mail to the Research Fellow. The baseline (T1) questionnaires are the 10-item Decisional Conflict Scale[23] and the bespoke coronary angioplasty knowledge questionnaire. The Research Fellow will collate returned questionnaires to determine the following outcomes:

- Number of returned self-report questionnaires at baseline (T1).
- Item response rate (Number of valid responses on each questionnaire divided by total number of responses requested).
- Number of patients who had complete data for each questionnaire at baseline.

Participant answers and questionnaire scores will be input into a CRF by the Research Fellow.

8.2.4 Pre-assessment clinic

Participants at all eight clusters will attend their usual-care pre-assessment clinic consultation with a cardiac nurse specialist which may be in-person or conducted remotely (telephone or online video call). Patient participants in the intervention arm will have received a 'communication' from the hospital confirming their pre-assessment consultation date. This may be a paper or digital letter, email, or text. Instructions on how to access CONNECT, via a web link, or QR code, will be included in the 'communication' and tailored to match the style of the Cardiology Department approach. Participants will be invited to use CONNECT and save their personal summary before attending their usual-care pre-assessment clinic consultation.

Those in the intervention group will be asked if they were able to access CONNECT and the personal summary. If available, the personal summary will be referred to during the consultation. Approaches to integrating the CONNECT summary into consultation will be discussed during the study set up training sessions. If the patient participant fails to attend the clinic consultation, their consultation will be rearranged as per usual care. Immediately following each consultation with a participant, the cardiac nurse specialist will complete the Pre-Assessment Log for collection of the following outcomes:

- Number of missed pre-assessment clinic consultations.
- Number of participants who used the CONNECT summary during the consultation
- Duration of pre-assessment clinic consultation

8.2.5 Post pre-assessment clinic (T2) questionnaires

The Clinical Research Nurse, or delegate, will liaise with the pre-assessment lead nurse weekly to update them about which patient participants had consented to study participation and attended the pre-assessment consultation. Participants at all eight clusters who attended the pre-assessment consultation will be sent four T2/Follow-up questionnaires: the Decisional Conflict Scale[23], the Coronary Angioplasty Knowledge questionnaires sent at T1/Baseline and the 10-item Preparation for Decision-Making Scale[24] and 13-item Perceived Involvement in Care Scale[25]. The latter two questionnaires are validated tools designed to evaluate the quality of the decision-making process[26]. Two extra questions will be included at the end of the Angioplasty Knowledge questionnaire to evaluate what health information patients accessed ahead of planned coronary angioplasty and their satisfaction with discussions about treatment options. In the intervention arm, two extra questions will ask whether participants were able to access CONNECT and take the personal summary to the pre-assessment appointment. Participants will be instructed to complete and return them to the Research Fellow within 7 days of receipt using the stamped-addressed envelope.

The Research Fellow will collate returned questionnaires to determine the following outcomes:

- Number of returned self-report questionnaires at post-pre-assessment.
- Number of patients who had complete data for each questionnaire at post-pre-assessment.
- Item response rate (Number of valid responses divided by total number of responses requested).
- Retention: defined as the proportion of participants completing the anticipated primary outcome questionnaires (i.e., completing the Decisional Conflict Scale questionnaire at T2/after pre-assessment).
- CONNECT adherence: The percentage of patient participants in the intervention arm who report being able to successfully access CONNECT and take the personal summary to the pre-assessment consultation

Participant answers and questionnaire scores will be input into a CRF by the Research Fellow.

8.2.6 Nested qualitative interviews (Patients and Health Professionals)

Individual semi-structured interviews will be conducted remotely (telephone or video Teams call) with patient and health professionals/NHS staff participants. Patient participant interviews will be conducted within 1-2 weeks of their pre-assessment clinic consultation. Cardiology/research team participant interviews will be conducted once the last patient participant has attended their pre-assessment consultation. Participants' experiences of using CONNECT, including any barriers and enablers, and their views on the study procedures will be explored using topic guides (see appendix 3). These data will address uncertainties concerning the acceptability of CONNECT and study procedures. Interview data will be audio recorded and fully transcribed using Otter Business Transcription services. We will also collect demographics from health professionals/NHS staff participants (e.g., age, gender, job role).

8.2.7 Medical record review

At the end of the study the clinical research nurse will review participants' medical records to extract and document their actual treatment/procedure received (i.e., medicines only, or coronary angiogram only, coronary angioplasty, or other (e.g. no intervention)) and medical record review for all-cause mortality, Major Adverse Cardiovascular Events (MACE), defined as acute myocardial infarction, death due to a cardiac or unknown cause, emergency revascularization, ventricular arrhythmia, or cardiogenic shock) and rates of hospital readmission, 30-days after hospital discharge.

i. Patient Questionnaires

Table 4 below shows the timepoints for the administration of measures.

Measures	**Enrolment**	**Baseline (T1)**	**Post Pre-Assessment (T2)**
Brief Health Literacy Screening Tool (Chew et al 2004)[21]	X		
eHealth Literacy Scale (Norman & Skinner 2006)[22]	X		
Decisional Conflict Scale (O'Connor, A. 2010)[23]		X	X

Coronary Angioplasty Knowledge questionnaire. (Researcher Team generated)		X	X
Preparation for Decision-Making Scale (Bennett et al. 2010)[24]			X
Perceived Involvement in Care Scale (Lerman et al. 1990)[25]			X

Enrolment: After informed consent for study participation.
Baseline: Before using CONNECT at least 1 week before Pre-Assessment Clinic.
Post Pre-Assessment Clinic: After pre-assessment, but before coronary angio/angioplasty procedure.

The Brief Health Literacy Screening Tool is a 3-item measure designed to evaluate functional health literacy with responses recorded on a 5-point Likert scale[21]. The tool takes approximately one minute to complete, can be administered orally, performs well compared to other longer standard measures, and has been shown to have adequate validity and reliability when administered by nurses in clinic settings[27].

The eHealth Literacy Scale is an 8-item measure designed to evaluate peoples' knowledge, comfort, and perceived skills at accessing and using health related electronic health information with responses recorded on a 5-point Likert scale[22]. It is the most frequently used measure to evaluate e-literacy, has acceptable psychometric properties, but has a relatively narrow scope having been designed before the era of social media[28]. Regardless, other comparable measures have 18-items, or more, making them impractical for use in NHS settings.

The Decisional Conflict Scale evaluates; 1) uncertainty in making a treatment choice/decision, 2) modifiable factors that potentially contribute to uncertainty, such as self-reported level of understanding about treatment risks and benefits, clarity about personal values and perceived level of social support and 3) perceptions about ability to make a treatment-related decision[23]. To reduce patient burden and support inclusivity for people with different levels of health literacy we have selected the 10-item Decisional Conflict Scale; this version has been validated in populations with lower literacy levels and is shorter than the 16-item version[23]. The primary outcome measure in the future large-scale evaluation will be the difference in Decisional Conflict Scale scores between the intervention and control arms. The outcome measure will be deemed as acceptable to patient participants (Green/Go criterion) if 80% of patient participants fully complete this 10-item measure, with 60% completion deemed as acceptable for the Amber/Change criterion.

To evaluate patient participants' knowledge about coronary angioplasty, an 8-item researcher generated Angioplasty Knowledge questionnaire was developed. The measure was informed by items developed in other similar studies[9, 29-34].

The Preparation for Decision-Making Scale[24] (10-item version) is a tool designed to evaluate a person's perception of the value of a decision support intervention, such as CONNECT, in helping them to prepare for consultations with health professionals which involve shared decision making about a treatment option. The scale has been reported to have acceptable levels of validity and reliability.

The Perceived Involvement in Care Scale (13-items) is a validated tool that measures three concepts using dichotomous (Yes/No) responses: 1) perceived clinician facilitation of patient involvement (subscale F), 2) perceived level of information exchange between patient and health professional (subscale I) and 3) perceived level of the patient participation in health-related decision-making (subscale DM)[25].

8.2.8 Change of Status/Withdrawal

As a study progresses there may be a change in participants preferred level of participation. A participant may decide that they no longer wish to contribute with the study and cease involvement in any ongoing data collection. Participants may also be withdrawn from the study by the research or clinical care team due to clinical deterioration (e.g., hospitalisation). In these scenarios, data that has already been collected before change of status/withdrawal will be analysed unless participants specifically ask for it to be deleted. Any change of status/withdrawal will be recorded (date of withdrawal, reason and type of withdrawal) in the site Case Report Form and the Chief Investigator informed. As this is a feasibility study, participants who have a change of status/or are withdrawn will not be replaced.

9. ADVERSE EVENT REPORTING

The UK Policy Framework for Health and Social Care Research,[35] states that research teams must '*ensure participants' safety and well-being in relation to their participation in the research (e.g., by asking questions about the patient's experience with the research intervention) and reporting adverse events where expected or required'*.pg 17

A Cochrane review of 105 studies evaluating the effects of PtDAs on outcomes for patients facing health treatment or screening decisions reported no adverse effects on anxiety levels, general and condition specific health outcomes and satisfaction. No other adverse events were reported[13].

It will be the responsibility of the local PI to report any adverse events and escalate to the Chief Investigator as required. The occurrence of an adverse event caused by being in the intervention or control seems very unlikely. We looked at other similar studies and consulted with cardiology consultants.

We will record MACE, (acute myocardial infarction, death due to a cardiac or unknown cause, emergency revascularization, ventricular arrhythmia, or cardiogenic shock) that participants may suffer as a complication of treatment with "angio query proceed" or planned coronary angioplasty and hospital readmission within 30 days of treatment.

10.DATA HANDLING AND RECORD KEEPING

10.1 Source Data

The local PI working with the Research and Development department at each participating site will be responsible for managing the data outlined below:

- Patient medical records (demographic, medical history, actual procedure/ treatment received, MACE or hospital readmission within 30-days of discharge).
- Brief Health Literacy and E-Literacy questionnaires
- Study logs: Patient identification Log, Screening Log, Enrolment/Withdrawal Log, and Pre-Assessment Log,
- Case Report Forms (demographic data not routinely recorded in medical records will be collected verbally from participants and entered directly onto the form)

The research team and their line manager, at the Open University will be responsible for managing the data outlined below.

- Patient participant questionnaires (Decisional Conflict Scale, Coronary Angioplasty Knowledge questionnaires, the 10-item Preparation for Decision-Making Scale and the 13-item Perceived Involvement in Care Scale.
- Interview audio files including verbal consent
- Interview transcripts

10.2 Case Report Form completion

Case Report Forms (CRFs), self-report questionnaires, and study logs will be the primary data collection instruments and treated as source data. Data entry into the CRF will be conducted by the study delivery team at site. (This excludes data entry from the T1 and T2 participant questionnaires, which will be entered by the Academic Research Team).

As part of the study set up, guidance on the completion of the study logs and the CRF will be provided. This will include information about which forms to complete when, data format, how to enter corrections, what to do if there is missing, incomplete or unknown data or if a subject withdraws from the study. Each enrolled participant will be allocated a unique study ID to protect their anonymity. Linkage logs will be password protected and stored at each participating NHS Trust.

Data entered into CRF's should be consistent with any source documents or the discrepancies should be explained. If information is not known, this must be clearly indicated on the digital CRF. Digital CRF's will be password protected and emailed to the Chief Investigator/Research Team monthly to review for completeness, missing and ambiguous data. Meetings will be convened, as required, to resolve any data queries. In all cases, it remains the responsibility of the local PI (or delegate) at each participating site to ensure that the CRF has been completed correctly and that the data are accurate. PIs (or delegates) will be required to sign off on all patients. CRF formatting may be amended, and the versions updated as appropriate, throughout the duration of the study. Whilst this may not constitute a protocol amendment, new versions of the CRFs must be implemented by participating sites immediately on receipt. The electronic password protected CRFs will be held on a Share Point/Teams site at the Open University.

10.3 Data Management and Security

The Open University has policies in place designed to protect the security, accuracy, integrity, and confidentiality of personal data. The study will be registered with the Data Protection Officer.

The data collected in this study falls into overlapping groups:

1. Data Logs: (see page 25-26) feasibility data will be collected at each participating NHS site by 1) the local PI, or delegate, 2) a clinical research nurse, or delegate and 3) pre-assessment nurse, or delegate. Collectively the NHS team will be responsible for the management and completion of Data Logs (Source data) with oversight from the Research and Development department and the research team. At study set up an instruction manual will be provided to participating NHS staff providing details about the Patient identification, Screening, Enrolment, Withdrawal and Pre-Assessment Logs. The local PI, or delegate, will extract data from the medical records regarding MACE or readmission within 30-days of discharge home. The documents will be stored and managed by the participating NHS Trust. Data will not be routinely accessed by staff outside the NHS organisation, but in the event of an audit the data would need to be made available to the Chief Investigator or personnel conducting the audit.

2. Self-report questionnaire data (Patient Reported Outcome Measures PROMS): patient participants will complete a total of eight questionnaires during the study (See Table 4. Page 27). The clinical research nurse will administer 1) The Brief Health Literacy and 2) eLiteracy questionnaires verbally following informed consent. Scores will be entered onto the Case Report Form by the Clinical Research Nurse, or delegate. The other paper-based questionnaires/PROMS will be sent by post/email, at two time points, and once completed, returned to the Research and Development department at Calderdale and Huddersfield NHS Foundation Trust (The contracting organisation). The envelopes will be securely stored in a locked file within a locked office. The Academic Research team will access the questionnaires on site and enter the questionnaire/PROMS data into a CRF, using an NHS computer. Once data entry is completed the Statistician will be sent the password protected CRF containing the pseudo anonymised questionnaire/PROMS data for analysis.

3. Qualitative Interview Study: the clinical research nurse from each participating NHS Trust will liaise with the Research Fellow to indicate which patient participants have expressed an interest in taking part in the qualitive interview study and agreed to share their contact details. Health Professionals will be contacted by their local PI, or Research and Development Department, and emailed the study pack and contact details of the Research fellow. Consenting patient and Health Professional participants will be interviewed and a digital recording stored on a secure server at The Open University and fully transcribed.

10.4 Patient Decision Aid ‘CONNECT’

The PtDA CONNECT will be hosted by an IT company called ‘Ginger Root’. Patient participants will access CONNECT via a link, which enables users to create and save their own personalised summary as a PDF stored only on their personal device. The summary would not contain identifiable (name, DOB etc.) and clinical data, other than their own self-report of angina symptoms. The research team at the Open University will be responsible for the secure storage of qualitative interview data (audio recordings and anonymised transcripts and minutes) on the University’s secure network drive.

11. QUALITY CONTROL AND QUALITY ASSURANCE

The research team will deliver training on CONNECT (to intervention arm only) and the study processes (protocol procedures, data collection, record keeping and importance of protocol compliance) as part of the site set up. The local PI, and team, at each site will be required to complete GCP training.

The research team will monitor the CRFs to evaluate the quality of the data and follow-up with sites if required.

The Chief Investigator and local PIs will comply with any required audits, ethical reviews, and regulatory inspections. The sponsors will be notified of any serious breach of the study protocol or GCP principles in the unlikely event that they should occur to enable them to notify the Research Ethics Committee.

The end of the study will be 6 months after the last data capture to allow for completion of data input and analysis. The funder and ethics committee will be sent a final report.

12. STATISTICAL METHODS AND DATA ANALYSIS

12.1 Sample size

12.1.1 Feasibility study

A formal power calculation is not required for a feasibility study as testing intervention effectiveness is not the aim. However, the sample size should be sufficient to estimate the uncertain critical parameters: Standard Deviation (SD) of the primary outcome, recruitment/consent rates, ICC and the average cluster size needed to inform the design of the main RCT with sufficient precision. Our statistician advised that a minimum of eight clusters in total is needed to best estimate the ICC[17]. Using Swiger's formula for the variance of the ICC[36], the precision gain of the ICC estimate diminishes after 30-50 patients per cluster. As more clusters with fewer patients is preferred, we will, therefore, aim to recruit an average of 40 patients from each Cardiac Department, leading to a total sample of 320 patients. Allowing for a median consent rate of 70%[37], a total of 457 patients will be approached to participate, approximately 57-58 per cluster. This sample size will be efficient to estimate the feasibility outcomes.

12.1.2 Nested qualitative study

Qualitative research does not require a power calculation. Rather, the aim is to maintain some flexibility and continue with data collection until no new theoretical insights are evident in participants' accounts; a sample of 20-30 is typically sufficient to reach data adequacy[38]. Accordingly, a sub-sample of patient participants (n=40) from the main feasibility study, will be purposively sampled from Cardiology Departments in the intervention arm. We will aim to maximise variation by gender, health literacy and E-literacy level scores (Scores in upper and lower quartiles). A purposive sample of 20 health professionals/NHS staff (including cardiologists, specialist nurses and clinical research nurses) from all clusters (2-3 per cluster) will participate in in-depth face-to-face interviews.

12.2 Quantitative data analysis

As this is a feasibility study the main analysis will be predominantly descriptive and focus on confidence interval estimations rather than formal hypothesis testing. The baseline demographics and clinical characteristics of the patients will be reported overall and by randomised group. For the continuous variables (e.g., age) either mean and SD will be presented or median and inter quartile range (IQR) depending on the distribution of the data. The number of observations used in each calculation will be presented alongside the summaries. We will look at differences between groups for the anticipated primary outcome (Decisional Conflict Scale) using analysis methods appropriate to the design of the study. Analysis will be described in detail in the Statistical Analysis Plan. This difference and its associated confidence interval will be used to check that the likely effect is within a clinically relevant range (as confirmation that it is worth progressing with the full trial) and to inform the sample size calculation for the definitive study as outlined previously. The mean/median anticipated secondary outcomes (Coronary Angioplasty Knowledge questionnaire) at baseline and post-pre-assessment (along with its variability) will be reported for all participants. For the anticipated primary outcome (Decisional Conflict Scale) at follow up, the ICC for patients treated with the same site will be estimated using a marginal or random effects model. Details of the 'Stop'/'Change'/'Go' criteria derived from data collected in this feasibility study will determine progression to a future large-scale evaluation (c-RCT).

12.3 Qualitative data analysis

The training session minutes, and interview transcripts will be analysed using framework analysis[39]. This analytical process progresses from familiarization; identifying a thematic framework; indexing; charting; mapping to interpretation[39]. NVivo software will support the management and retrieval of the data. Emerging themes from the training session minutes will be compared to the constructs described in the Consolidated Framework for Implementation Research (CFIR)[40]. To support the trustworthiness of the study, a clear audit trail of the study procedures will be recorded, 3-4 researchers will be involved in the data analysis and coding

process, including an implementation scientist. A series of meetings will be convened to discuss and support reflexivity.

13. STUDY ORGANISATION

13.1. ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Figure 2. provides an overview of the roles and responsibilities which will reflect the UK policy framework on health-social-care-research. A co-sponsorship agreement details the specific responsibilities of the co-sponsors across the study. Professor Astin will be responsible for the overall conduct of the research with the wider research team. Local PIs at each participating site will be responsible for the conduct of the research, and control of data, in their NHS Trust working with their Research and Development Department.

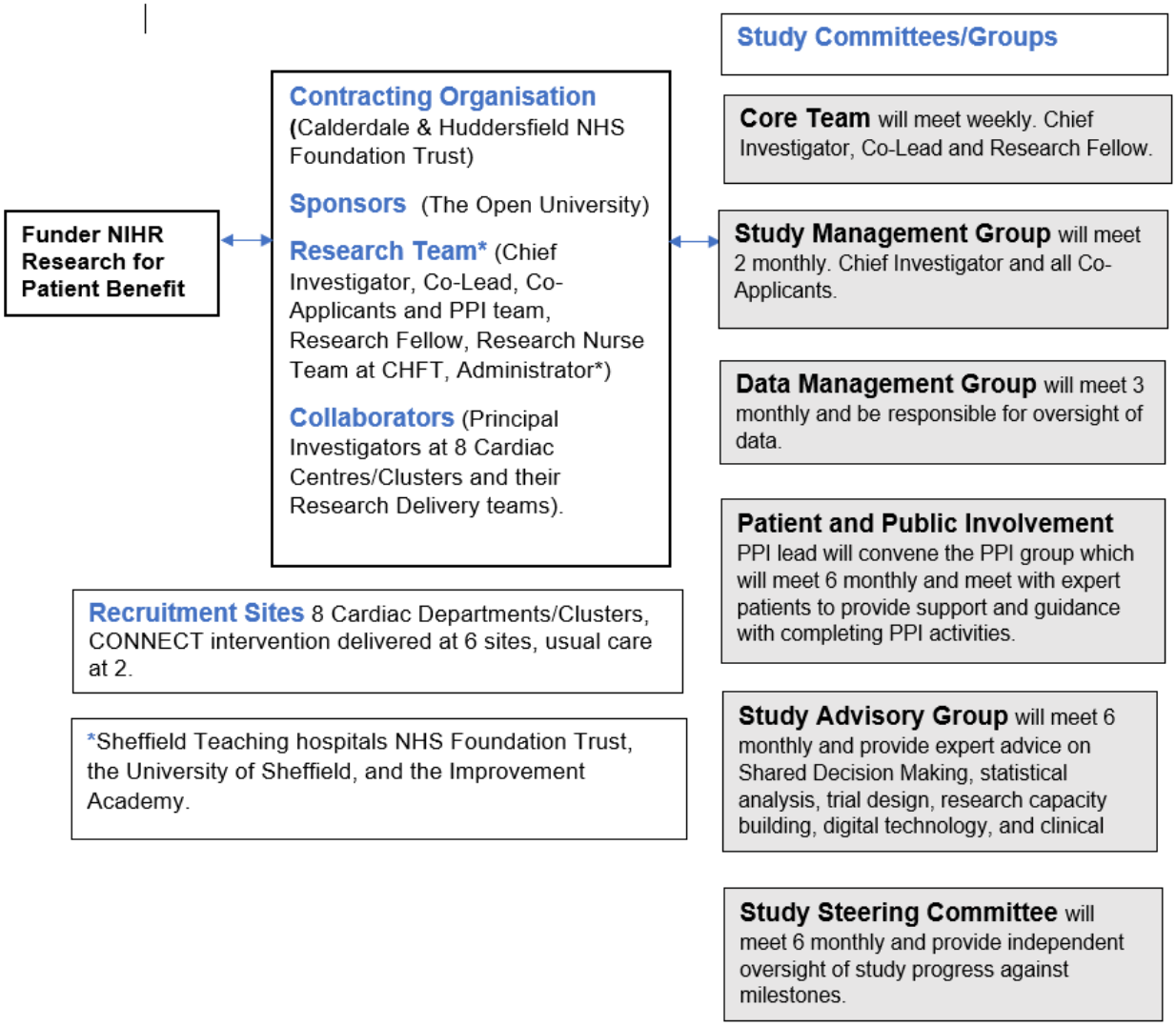


Figure 2. Project Management Schema

The core team at The Open University (Chief Investigator Professor Felicity Astin, Co-Lead Dr Emma Harris, and Research Fellow (To be appointed) will meet weekly to progress study milestones against specified timeline. The Research and Development (R&D) Teams responsible for recruitment at each of the participating NHS cardiology departments will update the core team on progress with participant recruitment. The core team will report to 1) the Study Management Group (all Co-applicants and patient representatives) bi-monthly to update them on progress, and 2) 6-monthly to the Study Steering Committee, comprising an independent Chair, Calderdale & Huddersfield NHS Foundation Trust (CHFT) Director, Finance Director/Research Manager (CHFT and the Open University) and Associate Dean for Research (Open University). A data-management sub-group will include the statistician co-applicant and CHFT R&D manager. The Study Advisory Group will include representatives with expertise relevant to the study (Shared decision-making, digital interventions, and clinical cardiology). The Study Management Group, host Trust, participating Trusts and sponsors will be responsible for ensuring that the feasibility study complies with Good Clinical Practice guidance and all regulatory requirements, including adverse event reporting. There will be patient representative members on the Study Management Group, Study Advisory Group and Study Steering Committee. The Patient and Public Involvement (PPI) group will be Chaired by an experienced PPI coordinator.

This feasibility study is not supported by a Clinical Trials Unit. The Study Management Group, chaired by the Academic Research team, will work with the Data Protection Officer at The Open University and participating NHS sites to oversee data management, monitoring and analysis. This will support the quality of data, analysis plan and safe storage to aligns with the Health Research Authority approved study protocol and in accordance with the Data Protection Act 1998.

14. ETHICAL AND REGULATORY CONSIDERATIONS

The study will be conducted in accordance with the UK Policy Framework for Health and Social Care Research. We will seek ethical approval to conduct the study from the NHS Research Ethics Committee and Health Research Authority. Below is a summary of the main ethical issues that the study might face:

14.1 Recruitment:

It is important that patients do not feel coerced to participate in the study. The research nurses recruiting participants are trained in assessing capacity. All eligible participants will be offered the opportunity to participate in the proposed research. Study documentation will be written in 'plain' English using images to increase accessibility to underserved populations often excluded from clinical research. All participant information will be reviewed by our PPI Group and feedback incorporated. To avoid the exclusion of non-English speaking patients, we have included costs for interpreter time and translation of participant information documents.

14.2 Participant consent:

It is important that patients are fully informed about the study before agreeing to participate. The participant information sheet provided to potential participants will contain written information about the study rationale, purpose, aims of the study and what the participant would be required to do as a part of the study. The information document and consent form will make it clear that taking part in the research is optional and participants can withdraw at any time. Before any protocol-required procedures are performed, the participant must provide informed consent. If the individual agrees to take part in the study, informed consent will be sought by the Research Nurse at participating sites. The research nurses will have completed Good Clinical Practice training and will follow their local informed consent Standard Operating Procedures.

14.3 Balancing the benefits and harms of the study

The intervention: Patient decision aid (PtDA)

There are no obvious harms from using a PtDA. A Cochrane systematic review and meta-analysis evaluating 50 different PtDAs from 105 studies, provides evidence that PtDAs are more likely to benefit patients, compared to usual care[13]. Patients receiving a PtDA are more likely to have accurate risk perception and select a treatment that is more congruent with their values and preferences. The review found no negative effect on health outcomes between the PtDA and usual care groups, indeed, some studies found a reduction in symptoms of anxiety.

In non-emergency situations, it is an ethical and legal requirement that patients provide informed consent before medical treatment. Patients must therefore be fully informed about their options. The PtDA provides comprehensive information about their treatment options (coronary angioplasty or medical therapy) including the potential risks, benefits, and side-effects. It is possible that patients may change their mind about having elective coronary angioplasty after receiving the PtDA. However, this is no different to usual care; patients in the control group who receive usual care (i.e., patient information leaflet) are also free to change their mind about having the procedure. We will record the number of patients in both groups who choose to receive medical therapy only, following referral for elective angioplasty. Receiving the PtDA will not replace consultations with the cardiologist or cardiac specialist nurse.

Participating in the interview

In the unlikely event that a participant becomes distressed during the research interview, the interview will be stopped. The participant will be given the option to terminate the interview or reconvene when they feel ready. The British Heart Foundation has a free patient line, which provides support and counselling. Details of this resource will be made available to participants and included in the participant information sheet. Participants will be able to stop the interview or withdraw from the study at any time without giving a reason. The Research Fellow will be conducting interviews alone remotely via telephone or Microsoft Teams. They can choose to end the interview if the participant displays inappropriate behaviour or makes inappropriate and personal remarks. Regular debriefs between Research Fellow and supervisory team will be scheduled.

Data protection and patient confidentiality

Participants will be reassured that confidentiality will be maintained unless information is disclosed during the interview, which raises concerns about their safety or poor clinical practice. Information about confidentiality and data storage will be included in the participant information sheet and consent form.

Data will be stored in accordance with the General Data Protection Regulation (GDPR) 2018 and the Data Protection Act 2018. Following informed consent, participants will be assigned a unique study identification number. To support anonymity, study documents relating to each participant will contain only the participant ID number and no personal data (i.e. name, address, DOB). However medical and demographic data will be included. A password protected linkage log (recording hospital number and unique participant study number), stored by each participating NHS Trust as per their data protection policy, will allow re-identification of patient participant data if required). The interview transcripts will be anonymised by removing all identifies (e.g., names, locations). All participants involved in the research will be anonymised in any publications or reports. Once participation is completed, all personal data that has been retained to communicate with the participant will be kept for one year in case further correspondence is required. Anonymised research data generated from the study will be retained and stored in the study Sponsor's Storage server for up to 10 years in line with the University Data Protection Policy and the Medical Research Council (2017) Retention Framework for Research Data and Records. Henceforth, the study co-Sponsor (Open University) will be responsible for data security.

Financial and other competing interests for the chief investigator, PIs at each site and committee members for the overall study management

The Chief Investigator, co-lead, and several co-investigators were involved in the development of CONNECT. Having conducted a market analysis it was concluded that CONNECT would be unlikely to have any commercial value but may be of interest to industry partners who may want to take over the ownership and embed CONNECT as part of their offer to their customer base. CHFT will own the foreground IP. So, there are potential ownership interests to disclose that could be potentially affected by the study results. We will/ convene a steering group with representation to discuss plans regarding the use of CONNECT after study completion. At the time of writing the protocol not all sites/personnel may have been identified. When this is the case then the protocol should state that this information will be collected and where it will be documented.

14.4 Adverse Events

We discussed the possibility of adverse events with consultant cardiologists and their expert opinion was that there were no obvious adverse events associated with using CONNECT which is an educational resource with built in interactive learning aimed to encourage patient involvement in the shared decision-making process. A Cochrane review on PtDA reported no adverse events because of using PtDAs[13]. However, we will record MACE, defined as acute myocardial infarction, death due to a cardiac or unknown cause, emergency revascularization, ventricular arrhythmia, or cardiogenic shock) and rates of hospital readmission 30-days after hospital discharge.

14.5 Participant Incentives

Patient participants completing the main feasibility study will be entered into a prize draw for a gift voucher in acknowledgement of their time (one prize draw per site). Patient participants taking part in the interview will also receive a gift voucher.

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

Before the start of the study, a favourable opinion will be sought from the UK NHS Research Ethics Committee (REC) and Health Research Authority (HRA). Amendments to the protocol or associated documents (i.e., consent form, participant information documents) will firstly be sent to the study sponsor for approval prior to submission to the NHS REC and HRA for approval. The participating sites' R&D department and local PI will also be notified to any pending amendment. All approved study documents will have a version number and date. Current versions of study documents and amendments will be tracked in a log which will be updated by a member of the study management group. The research plan has been independently reviewed by external expert reviewers, not directly involved in the study, as part of the National Institute for Health research review process. The Investigator should not deviate from the protocol. Any deviations from the protocol will be documented in a protocol deviation form and reported to the Chief Investigator and Sponsor immediately.

15. DISSEMINATION POLICY

We will disseminate the study's findings to patients and the public via a national one-day dissemination event/conference 'Using Patient Decision Aids to Support Shared Decision Making in Cardiology'. The event will be advertised to patients and members of the public through established networks such as the Cardiovascular Care Partnership, Heartbeat: The Brighouse Heart Support Group, and CREW Heart Support Group. We will share study findings with Heart Research UK, the British Heart Foundation, and their patient British Heart Foundation support

groups. Study participants will also be invited to the event. We will also write a 'Plain English' report of the study findings with input from the PPI Group. The report will be disseminated to the networks mentioned above, including the European Society of Cardiology and British Cardiac Society, which both have patient advocacy groups.

The Chief Investigator will draft the final report and associated outputs with input from all members of the research team. All research team members will be authors providing their contribution aligns with guidance on defined authorship criteria ethical publication Committee on Publication Ethics. There will be no professional writers used.

16. REFERENCES

1. Roth GA, Mensah GA, Johnson CO, Addolorato G, Ammirati E, Baddour LM, et al. Global Burden of Cardiovascular Diseases and Risk Factors, 1990-2019: Update from the GBD 2019 Study. J Am Coll Cardiol. 2020;76(25):2982-3021.

2. Schopfer DW, Beatty AL, Meyer CS, Whooley MA. Longitudinal Association Between Angina Pectoris and Quality of Life. The American Journal of Cardiology. 2022;164:1- 6.

3. Bangalore S, Maron DJ, Stone GW, Hochman JS. Routine Revascularization Versus Initial Medical Therapy for Stable Ischemic Heart Disease: A Systematic Review and Meta-Analysis of Randomized Trials. Circulation. 2020;142(9):841-57.

4. Maron DJ, Hochman JS, Reynolds HR, Bangalore S, O'Brien SM, Boden WE, et al. Initial Invasive or Conservative Strategy for Stable Coronary Disease. The New England journal of medicine. 2020; 382(15):1395-407.

5. Spertus JA, Jones PG, Maron DJ, O'Brien SM, Reynolds HR, Rosenberg Y, et al. Health-Status Outcomes with Invasive or Conservative Care in Coronary Disease. New England Journal of Medicine. 2020; 382(15):1408-19.

6. Desai NR, Bradley SM, Parzynski CS, Nallamothu BK, Chan PS, Spertus JA, et al. Appropriate Use Criteria for Coronary Revascularization and Trends in Utilization, Patient Selection, and Appropriateness of Percutaneous Coronary Intervention. JAMA. 2015; 314(19):2045-53.

7. Malik AO, Spertus JA, Patel MR, Dehmer GJ, Kennedy K, Chan PS. Potential Association of the ISCHEMIA Trial with the Appropriate Use Criteria Ratings for Percutaneous Coronary Intervention in Stable Ischemic Heart Disease. JAMA internal medicine. 2020;180(11):1540-2.

8. Elwyn G, Durand MA, Song J, Aarts J, Barr PJ, Berger Z, et al. A three-talk model for shared decision making: multistage consultation process. BMJ (Clinical research ed). 2017; 359:j4891.

9. Astin F, Stephenson J, Probyn J, Holt J, Marshall K, Conway D. Cardiologists' and patients' views about the informed consent process and their understanding of the anticipated treatment benefits of coronary angioplasty: a survey study. European Journal of Cardiovascular Nursing. 2020;19(3):260-8.

10. Probyn JG, J. Holt, J. Conway, D. Astin, F. Percutaneous coronary intervention patients' and cardiologists' experiences of the informed consent process in Northern England: a qualitative study. BMJ open 2017;7:e015127.

11. Coylewright M, O'Neill E, Sherman A, Gerling M, Adam K, Xu K, et al. The Learning Curve for Shared Decision-making in Symptomatic Aortic Stenosis. JAMA Cardiology. 2020; 5(4):442-8.4. 5.

12. National Institute for Health and Care Excellence (NICE). Shared decision making: NICE Guideline. UK: NICE; 2021 17/06/2021.

13. Stacey D, Legare F, Lewis K, Barry MJ, Bennett CL, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev. 2017;4(4):Cd001431.

14. Harris E, Conway D, Jimenez-Aranda A, Butts J, Hedley-Takhar P, Thomson R, et al. Development and user-testing of a digital patient decision aid to facilitate shared decision-making for people with stable angina. BMC medical informatics and decision making. 2022; 22(1):143.

15. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. BMJ (Clinical research ed). 2021; 374:n2061.

16. Stacey D, Légaré F, Boland L, Lewis KB, Loiselle M-C, Hoefel L, et al. 20th Anniversary Ottawa Decision Support Framework: Part 3 Overview of Systematic Reviews and Updated Framework. Medical Decision Making. 2020;40(3):379-98.

17. Eldridge S, and Kerry SM. A practical guide to cluster randomised trials in health services research. 2012, Chichester, West Sussex: John Wiley & Sons.

18. Chondros, P, Ukoumunne, OC, Gunn, JM, Carlin, JB. When should matching be used in the design of cluster randomized trials? Statistics in Medicine. 2021; 40(26: 5765– 5778. https://doi.org/10.1002/sim.9152.

19. Dron L, Taljaard M, Cheung YB, Grais R, Ford N, Thorlund K, Jehan F, Nakimuli-Mpungu E, Xavier D, Bhutta ZA, Park JJH, Mills EJ. The role and challenges of cluster randomised trials for global health. The Lancet Global Health. 2021, Vol 9 (5); e701-e710.

20. Hoffmann T, Glasziou P, Boutron I, Milne R, Perera R, Moher D, Altman D, Barbour V, Macdonal H, Johnston M, Lamb S, Dixon-Woods M, McCulloch P, Wyatt J, Chan A, Michie S. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ. 2014;348:1687.

21. Chew LD, Bradley KA, Boyko EJ. Brief questions to identify patients with inadequate health literacy. Fam Med. 2004;36:588–594.

22. Norman CD, Skinner HA. eHEALS: The eHealth Literacy Scale. Journal of Medical Internet Research. 2006;8(4):e27.

23. O'Connor, A. (2010) User Manual-Decisional Conflict Scale (10 Item Statement format) Ottawa Hospital Research Institute, Ottawa https://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_decisional_conflict.pdf

24. Bennett C, Graham ID, Kristjansson E, Kearing SA, Clay KF, O'Connor AM. Validation of a preparation for decision making scale. Patient Education and Counseling. 2010;78(1):130-3.

25. Lerman CE, Brody DS, Caputo GC, Smith DG, Lazaro CG, Wolfson HG. Patients' Perceived Involvement in Care Scale: relationship to attitudes about illness and medical care. Journal of General Internal Medicine. 1990;5(1):29-33.

26. Sepucha KR, Borkhoff CM, Lally J, Levin CA, Matlock DD, Ng CJ, et al. Establishing the effectiveness of patient decision aids: key constructs and measurement instruments. BMC Medical Informatics and Decision Making. 2013;13(2):S12.

27. Wallston KA, Cawthon C, McNaughton CD, Rothman RL, Osborn CY, Kripalani S. Psychometric properties of the brief health literacy screen in clinical practice. J Gen Intern Med. 2014 Jan;29(1):119-26. doi: 10.1007/s11606-013-2568-0. Epub 2013 Aug 6. PMID: 23918160; PMCID: PMC3889960.

28. Lee J, Lee E, Chae D eHealth Literacy Instruments: Systematic Review of Measurement Properties J Med Internet Res 2021;23(11):e30644. doi: 10.2196/30644PMID: 34779781PMCID: 8663713.

29. Case BC, Qamer SZ, Gates EM, Srichai MB. Shared Decision Making in Cardiovascular Disease in the Outpatient Setting. JACC Case Rep. 2019 Aug 21;1(2):261-270. doi: 10.1016/j.jaccas.2019.06.005. PMID: 34316804; PMCID: PMC8301252.

30. Doll, J. A., Jones, W. S., Lokhnygina, Y., Culpepper, S., Parks, R. L., Calhoun, C., Au, D. H., & Patel, M. R. (2019). PREPARED Study: A Study of Shared Decision-Making for Coronary Artery Disease. Circ Cardiovasc Qual Outcomes, 12(2), e005244. https://doi.org/https://doi.org/10.1161/circoutcomes.118.005244

31. Hinsberg, L., Marques, F., Leavitt, L., Skubisz, C., Sepucha, K., & Wasfy, J. H. (2018). Comparing the effectiveness of two different decision aids for stable chest discomfort. Coron Artery Dis, 29(3), 230-236. https://doi.org/10.1097/mca.0000000000000581

32. Morgan, M. W., Deber, R. B., Llewellyn-Thomas, H. A., Gladstone, P., Cusimano, R. J., O'Rourke, K., Tomlinson, G., & Detsky, A. S. (2000). Randomized, controlled trial of an interactive videodisc decision aid for patients with ischemic heart disease. J Gen Intern Med, 15(10), 685-693. https://doi.org/10.1046/j.1525-1497.2000.91139.x

33. Rothberg, M. B., Scherer, L., Kashef, M. A., Coylewright, M., Ting, H. H., Hu, B., & Zikmund-Fisher, B. J. (2014). The effect of information presentation on beliefs about the benefits of elective percutaneous coronary intervention. JAMA Intern Med, 174(10), 1623-1629. https://doi.org/https://dx.doi.org/10.1001/jamainternmed.2014.3331 (Comment in: Ned Tijdschr Geneeskd. 2015;159:A8488; PMID: 25563787 [https://www.ncbi.nlm.nih.gov/pubmed/25563787])

34. Sepucha, K. (2010). Decision Quality Worksheet: Treatments for Coronary Artery Disease. v.1.0. In: Massachusetts General Hospital.

35. UK Policy Framework for Health and Social Care Research (2017) accessed December 2022.

36. Swiger LA, Harvey WR, Everson DO, Gregory KE. The Variance of Intraclass Correlation Involving Groups with One Observation. Biometrics. 1964;20(4):818-826.

37. Walters SJ, Bonacho dos Anjos Henriques-Cadby I, Bortolami O, Flight L, Hind D, Jacques RM, et al. Recruitment and retention of participants in randomised controlled trials: a review of trials funded and published by the United Kingdom Health Technology Assessment Programme. BMJ Open. 2017; 7(3):e015276.

38. Vasileiou K, Barnett J, Thorpe S, Young T. Characterising and justifying sample size sufficiency in interview-based studies: systematic analysis of qualitative health research over a 15-year period. BMC Medical Research Methodology. 2018;18(1):148.

39. Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In: Bryman A, Burgess RG, editors. Analysing Qualitative Data. London, UK: Routledge; 1994. p. 173 – 94.

40. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implementation Science. 2009;4(1):50.

17. APPENDICES

Appendix 1: Description of CONNECT

CONNECT is described below using the Template for Intervention Description and Replication (TIDieR) checklist, which aims to improve the completeness of reporting of interventions.

NAME: CONNECT is a Patient Decision Aid (PtDA), which is a complex intervention (It is not a medical device). CONNECT is accessible at the following link https://uoh-connect.staging.ginger-root.co.uk/. Preliminary testing with 63 patients/health professionals indicates that CONNECT shows promise, but it has not yet been tested in NHS settings. Preliminary acceptability findings were presented at the Health Services Research UK 2020 annual conference. The presentation can be viewed at the following link: https://www.youtube.com/watch?v=9pvWG0-EF2U .

WHY: Research shows that patients diagnosed with stable angina, who are making decisions about an invasive procedure (coronary angioplasty) have unmet decision support needs. CONNECT was developed in response to this unmet need, using International Patients Decision Making Standards, which are underpinned by decision theory. PtDAs are effective tools to improve the quality of shared decision making (SDM).

WHAT: Like other PtDAs, CONNECT is a 'tool' designed to help people to take part in decision-making about treatment options. It uses multimedia (images, diagrams, animations, audio) to make patients aware of their treatment choices, associated risks and benefits and includes interactive activities (i.e., questions about angina symptoms, what matters to them and treatment choice) to clarify and communicate patients' personal values that are associated with different aspects of each treatment option. CONNECT provides a personalised summary (see section 2 for example), which can be saved as a PDF file and gives details of patients' angina symptoms, the impact of these on daily life, personal values, treatment preferences, worries, concerns, and any unanswered questions. This personalised summary can inform patient consultations and potentially act as a 'primer' for health professionals, alerting them to specific areas that the patient may wish to discuss.

HOW: CONNECT is a web based PtDA that supports individual self-directed learning at a pace set by the user. It was co-created with patients and health professionals and can be used on multiple devices (computer, iPad, tablet, or mobile phone).

WHO: Health Professionals (Cardiologists and Specialist Cardiac Nurses) implementing CONNECT will receive training on SDM and using CONNECT.

WHEN/WHERE/HOW MUCH: Patients on the waiting list for planned coronary angioplasty will receive a link to CONNECT along with instructions, which they can use at home ahead of a (usual care) pre-assessment consultation (30-45 minutes) with a specialist cardiac nurse. Following discussions, we know that there are variations in how NHS Trusts contact patients (paper letter, text message, QR code, patient portals) to communicate upcoming consultations and share

patient information. Therefore, the link to the CONNECT website will be delivered flexibly according to the Trust's preferences. The instructions for accessing and using CONNECT will include frequently asked questions, which will be informed from our preliminary acceptability findings. The time taken to use CONNECT varies according to the user. Estimates from our study in non-clinical settings showed that patients took up to an hour to work through the content and appreciated being able to revisit CONNECT multiple times if needed.