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Testing the feasibility of using a digital patient decision aid

Submission date 14/07/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 25/09/2023	**Overall study status** Completed	
Last Edited 17/09/2024	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Questionnaires sent to over 70,000 NHS patients in 2020 show that people often do not feel involved in making decisions about their own healthcare. Something we want to change. Patient decision aids (PtDAs) are 'tools' that are proven to improve the 'quality' of: 1) The decisions made, and 2) The decision-making process. However, they are not often used in NHS practice.
We co-created a digital PtDA, with service users, called CONNECT, for people with coronary heart disease who are considering treatment with planned coronary angioplasty. Earlier research we completed suggested that almost half of patients receiving this treatment are not fully involved in decision-making, do not understand the information they are given, and misunderstand the benefits and risks of their treatment.
We want to test CONNECT, in a larger study (trial), to see if it improves the quality of shared decision-making. But trials are expensive, so we need to do some groundwork first to understand what works best. In this preliminary fact-finding study, run over 24 months, we will ask 8 NHS Cardiac Centres, and 320 of their angina patients, about the best way to run a future trial. Six centres will use CONNECT and two will not.

Who can participate?
People aged 18 years and over with angina (chest pain/discomfort) are invited to take part. We're particularly interested in those considering planned coronary angioplasty treatment.

What does the study involve?
We want to improve how patients and doctors make decisions about treatments. In this study, we'll ask 320 patients from 8 NHS Cardiac Centres to try out a web-based tool called 'CONNECT'. This tool helps patients understand their options for treatment. Participants will complete forms, questionnaires, and interviews to help us learn what works best.

What are the possible benefits and risks of participating?
By participating, you can help improve the way decisions are made about treatments. There are no physical risks, but you might find some questions thought-provoking. Your insights will guide future research and could lead to better healthcare for others.

Where is the study run from?
The Open University (UK)

When is the study starting and how long is it expected to run for?
April 2023 to April 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
319363

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 55375, NIHR204012, IRAS 319363

Study information

Scientific Title
Cluster randomized controlled feasibility study of CONNECT: a patient decision aid designed to improve the quality of shared decision-making for planned coronary angioplasty.

Study objectives
Given that the research is designed as a feasibility study, the primary focus of the analysis will be on descriptive assessments and confidence interval estimations, rather than formal hypothesis testing. As such, the researchers do not have a traditional hypothesis to test for statistical significance. Instead, the study aims to explore and gather valuable information to guide the planning and execution of a future large-scale evaluation (c-RCT).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/04/2023, Health Research Authority, London - Brighton & Sussex Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0) 207104 8202; brightonandsussex.rec@hra.nhs.uk), ref: 23/PR/0129

Study design
Interventional cluster randomized feasibility study

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Cardiovascular Disease

Interventions
CONNECT is a Patient Decision Aid (PtDA), which is a complex intervention (It is not a medical device). 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). 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.

Following completion of two baseline questionnaires, participants on the waiting list for planned coronary angiogram/planned coronary angiogram±stenting will be invited to access a digital link to CONNECT along with instructions (sent via letter/email/mobile phone), which they can use at home ahead of a (usual care) pre-assessment consultation (30-45 minutes) with a specialist cardiac nurse. Metrics on participant engagement with CONNECT/website will be recorded.

CONNECT produces a personalised summary and the researchers will record the number of summaries brought to pre-assessment consultations. After pre-assessment consultations, but before their planned angiogram/angio±stenting participants will complete four follow-up questionnaires.

The researchers will use a 1:3 allocation ratio for the eight clusters (two control, six intervention). They have chosen this 1:3 allocation ratio as it maximises the number of clusters in the intervention arm so they can test the feasibility, practicality, safety and acceptability of the intervention, alongside having some clusters assigned to the control arm. The researchers will use stratified block randomisation with block size four and aim to stratify clusters by low (<400) and high (>400) volume centres. As the intervention 'CONNECT' is a website, there will be no blinding. (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 large-scale trial designed to test the effectiveness of the intervention).

Intervention Type
Behavioural

Primary outcome measure
1. Number of cardiology departments contacted: count of departments approached, responses to 'expression of interest,' and willing participants, measured using expressions of interest sent by email
2. Recruitment rate of cardiology centres: number of cardiology centres recruited within a 4-month period, measured using the number of expression of interests completed by cardiac centres sent by email
3. Patient recruitment: count of eligible patient participants approached, consented, and recruited by clinical research nurse over 12 months
4. Patient recruitment rate per site: number of patients recruited per month, per site, recruited by clinical research nurse over 12 months
5. Retention rate: proportion completing Decisional Conflict Scale questionnaire (T2) over 16-month period
6. Attrition rate: loss of participants assigned to intervention or control, measured at study completion

Secondary outcome measures
1. Rates of major adverse cardiac events (MACE) and hospital readmission: rates within 30 days of discharge, measured using medical records at study completion
2. Cardiology department characteristics: geographical location, index of multiple deprivation (IMD), cardiology workforce size, presence/absence of on-site surgical cover, annual procedure volume, measured using expressions of interest at study completion
3. Patient demographics: age, gender, ethnicity, social support level, health and e-literacy, cardiac diagnosis, co-morbidities, measured using medical records and questionnaires at baseline
4. Non-English speaking participants: count of participants requiring interpreter services, measured using case report forms at the end of the study
5. Participants without digital technology access: count of participants lacking access to digital devices and the internet, measured using case report forms at the end of the study
6. Response rate: participants completing and returning questionnaires divided by sample size, measured at the end of the study
7. Item response rate: number of valid responses divided by total responses requested, measured at the end of the study

8. Intraclass correlation coefficient estimation for decisional conflict scale: estimation using marginal or random effects model at T2
9. Full c-RCT sample size calculation: based on effect size estimates, standard deviation, and intraclass correlation coefficient from primary outcome analysis
10. CONNECT usage: number of participants accessing CONNECT, measured using case report forms at the end of the study
11. Usage of CONNECT during pre-assessment clinic visits: percentage of visits where the CONNECT summary was utilized, measured using case report forms at the end of the study
12. Qualitative analysis of training and interviews: summarizing variations, practicalities, barriers, and enablers, from month 6 until the end of the study (month 21)
13. Reasons for cardiology department nonparticipation, measured using expressions of interest at the end of the study
14. Reasons for patient nonparticipation, measured using expressions of interest at 12 months
15. Self-reported adherence to CONNECT: how CONNECT was used by patients at home and during pre-assessment, measured using qualitative interviews from month 6 until the end of the study (month 21)
16. Barriers and enablers to recruitment and CONNECT usage: during home and pre-assessment clinic stages, measured using qualitative interviews from month 6 until the end of the study (month 21)
17. Understanding and appropriateness of questionnaire completion, measured using qualitative interviews from month 6 until the end of the study (month 21)

Overall study start date
23/04/2023

Completion date
30/04/2025

Eligibility

Key inclusion criteria
1. CLUSTERS/CARDIOLOGY DEPARTMENTS
Any NHS centre in England providing care for patients treated with planned (i.e. non-urgent) coronary angiogram query proceed, or coronary angioplasty, will be eligible to participate. The inclusion criteria for Cardiology Departments are:
1.1. NHS Trust is in England
1.2. Pre-assessment clinics embedded in the patient pathway.
1.3. Has the capacity to recruit 40 patient participants within 12 months.
1.4. Willing to be randomised to the intervention or control arm and adhere to arm allocation.
1.5. Cardiology teams are willing to participate in a 2-3-hour training session about the intervention CONNECT.

2. PATIENT PARTICIPANTS
Patient participants scheduled for planned coronary angiogram query proceed, or coronary angioplasty will be eligible to participate. Eligible patient participants will be:
2.1. Adult patients (>=18 years) presenting with stable angina.
2.2. Suspected or diagnosed chronic coronary artery disease.
2.3. On the waiting list for planned coronary angioplasty or angiogram ± coronary angioplasty.
2.4. Capacity to give informed consent.

3. HEALTH PROFESSIONAL PARTICIPANTS
Eligible NHS staff participants will be:
3.1. Working, or have worked, in the cardiology department delivering care for people scheduled for coronary angioplasty or coronary angiogram ± coronary angioplasty.
3.2. Have had direct involvement in the delivery of CONNECT and/or the feasibility study procedures.

Participant type(s)
Patient, Health professional

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 340; UK Sample Size: 340

Key exclusion criteria
1. Clusters/Cardiology Departments who do not fulfil the inclusion criteria will be excluded.
2. 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.
3. Health professionals not involved in the CONNECT study or 'angioplasty' patient care will be excluded.

Date of first enrolment
25/09/2023

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northern General Hospital
Herries Road

Sheffield
United Kingdom
S5 7AU

Study participating centre
Calderdale Royal Hospital
Godfrey Road
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https://ror.org/05mzfcs16

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Publication and dissemination plan
The researchers 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. The researchers 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. The researchers 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 the 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.

Intention to publish date
30/04/2026

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study will be stored in a publicly available repository: ORDO (Open Research Data Online), https://ordo.open.ac.uk/, which is the Open University's research data repository. Data sharing will be postponed for 12 months after the end of the study to allow time for publication of the study findings. The data will be anonymous and available on ORDO for 10 years. Participants will have provided written informed consent for their anonymous data to be uploaded to a public repository.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3	06/03/2023	22/09/2023	No	Yes
Protocol file	version 0.4		23/10/2023	No	No
Statistical Analysis Plan	version 1	21/02/2024	23/04/2024	No	No