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

PARTICIPANT INFORMATION SHEET

FUNDED BY
NIHR | National Institute for Health and Care Research

You are invited to take part in a research study…

Before you decide whether to take part, it is important to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

PART 1 tells you about the purpose of this study and what will happen if you take part.

PART 2 gives you more detailed information about the conduct of the study and what happens to your information.

If you are unsure of anything, feel free to ask questions. Our contact details are provided on page 4.

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PART 1: ABOUT THE STUDY

1. WHAT IS THE STUDY ABOUT?

Patient Decision Aids (PtDAs) are evidence-based interventions known to be effective in improving the quality of shared decision-making. For UK patients suffering from stable angina and considering planned coronary angioplasty, there is no high-quality, up to date, PtDA available. To address this gap, we co-created a digital PtDA called CONNECT (COroNary aNgioplasty dECision Tool). In the future, we want to run a large research study to find out if CONNECT improves shared decision-making. In the future study, some people will be given CONNECT and other people will not. To do this, we need to compare patients' experiences of decision-making between those who receive CONNECT and those who receive usual care. In the future study, one group of patients will have access to CONNECT, and the other group will not have access and will receive usual care.

But first, we need to find out what approaches will work best to run a future study and how people feel about taking part. We also want to find out if it's possible for patients and health professionals to use CONNECT in the NHS. So, in this feasibility study we will ask 6 hospitals to test CONNECT with 240 people with stable angina. We will also ask 80 people from 2 other hospitals to be part of the study, but they won't be given CONNECT. After the study has ended, we want to talk to the cardiology and research teams involved in running the study to find out what worked well and what didn't.

2. WHY HAVE I BEEN INVITED?

We are inviting 3-4 cardiology team members/ Research and Development Department staff from each hospital who used CONNECT,

to talk to a member of the research team about their experience of running the study. You are being invited to take part because you are part of the team running the CONNECT feasibility study at your hospital.

3. WHAT WILL I NEED TO DO?

Interview: We would like you to take part in an interview with a member of the research team. The interview will take place by online video call, or over the telephone on a day and time of your choice, and will last for about 1 hour. The researcher will ask about your experience of being involved in running the study, and barriers and facilitators to implementing CONNECT. We will record the interview using an audio recorder. Only the research team will have access to this recording. We will also record your age, gender, and job role.

4. DO I HAVE TO TAKE PART?

No, taking part is completely up to you. You are free to leave the study at any time, without giving a reason.

5. WHAT ARE THE BENEFITS OF TAKING PART?

By taking part in the study you will be helping to increase knowledge about how patient decision aids can be used in the NHS. The study may help to improve patient communication in the future for people who have stable angina that are considering their treatment options.

If you would like a summary of the study findings, please contact [INSERT MEMBER OF RESEARCH TEAM DETAILS].

6. WHAT IS THE POSSIBLE DISADVANTAGE OR RISK OF TAKING PART?

You may feel that the interview is time-consuming. The interview will be as brief as possible, lasting for about 1 hour. You will be free to stop at any time and disclose information at your discretion.

7. WHAT HAPPENS NEXT?

If you are interested in taking part in the research interview, please contact **[insert name of research fellow].** A suitable date/time for the interview will be arranged. Before any information is collected, you will be asked to provide consent. The researcher will talk through the consent form with you. If you don't want to take part, you will not be contacted again about the interview study.

8. WHO IS CONDUCTING THE RESEARCH?

Chief Investigator: Professor Felicity Astin

Professor of Nursing

The Open University. Email: felicity.astin@open.ac.uk

Co-Lead: Dr Emma Harris

Research Fellow

The Open University. Email: emma.harris@open.ac.uk

[INSERT RESEARCH FELLOW DETAILS]

[INSERT NAME, ROLE AND CONTACT DETAILS OF LOCAL PI]

Co-Investigators

- **Dr Rebecca Simpson,** Lecturer in Medical Statistics, University of Sheffield
- **Dr Dwayne Conway,** Consultant Interventional Cardiologist, Sheffield Teaching Hospitals NHS Foundation Trust

- **Dr Jeremy Butts,** Consultant Interventional Cardiologist, Calderdale and Huddersfield NHS Foundation Trust
- **Mr Mark Lewis,** Patient Representative
- **Dr Kristian Hudson,** Implementation Specialist, Improvement Academy, Bradford Institute for Health Research

PART 2: DATA AND STUDY CONDUCT

9. WHAT DATA WILL YOU COLLECT FROM ME?

If you take part in the study, we will collect the following information:

- Personal data and contact details: name, e-mail address, telephone number (where applicable), age, gender, and job role
- The audio recording of the research interview

10. HOW WILL WE USE INFORMATION ABOUT YOU?

The Open University, based in the UK, is the sponsor of this study and will act as the Data Controller. This means that we are responsible for looking after your information and using it properly. You can find out more about how we use your information at:

- www.hra.nhs.uk/information-about-patients
- [INSERT OPEN UNI DATA PROTECTION WEBSITE]

We will need to use information from you and from your medical records for this research project. We (the Sponsor of this study) will collect information described above. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and

secure. The only reason we would break confidentiality and share any information is if we felt that you or someone else was at risk of harm.

The audio recording of the interview will be transcribed into a written document by the researcher who conducts the interview. Direct quotes from your interview may be used for workshops, presentations, reports, publications, and education resources, bu

t will be fully anonymised. Your name, contact details, and the audio recording of the interview will be held securely by the Open University for one year after the research study has ended. It will then be safely destroyed.

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have, unless you tell us to destroy it.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

11. WHO IS ORGANISING AND FUNDING THE STUDY?

The study is funded by the National Institute for Health and Care Research and is sponsored by the Open University. Calderdale and Huddersfield NHS Foundation Trust is hosting the study.

12. WHO HAS REVIEWED THIS STUDY?

This study has been reviewed and given favourable opinion by Brighton and Sussex RESEARCH ETHICS COMMITTEE, the UK Health Research Authority and the Open University.

13. WHAT IF THERE IS A PROBLEM?

If you have a concern about any aspect of this study, you should contact Professor Felicity Astin (Chief Investigator) by e-mail (felicity.astin@open.ac.uk) or telephone [telephone number].

Email: [INSERT SITE EMAIL]

Tel: [INSERT SITE NUMBER].

Thank you for taking the time to read this information sheet.