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Shared decision-making in the emergency department using T-MACS Choice for patients experiencing chest pain

Submission date	**Recruitment status**	[X] Prospectively registered
22/09/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/10/2021	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/10/2021	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Every day approximately 1.4 million patients with chest pain attend emergency departments (EDs) in the UK. Emergency doctors then need to decide who requires hospital admission and who is safe to be discharged home. While the clinical assessment is important it is often not enough to reliably predict if a patient is likely to have a heart-related event. Therefore, clinicians have come to increasingly rely on risk prediction models. However, the personal risk and options available are not universally shared with patients leading to a situation where doctors alone decide what is best.

In this study, funded by the Royal College of Emergency Medicine, we want to understand if testing the implementation of shared decision-making as a new communication strategy for adult patients with chest pain in the ED can practically be done. This is important so we know what needs improving before proceeding to a larger scale study to definitively proof benefits of shared decision-making.

Who can participate?

Adult patients with chest pain attending the ED.

What does the study involve?

We will survey patients (1 survey following the clinical encounter and 1 survey at 30 days on patient permission) and clinicians (1 survey about training and 1 survey following seeing a patient with chest pain) about their experience without affecting clinical care. With the patient's permission we will follow them up at 30 days by contacting their general practitioner and checking their medical records to see if they had any heart-related events.

What are the possible benefits and risks of participating?

There will be no direct benefits to you by taking part. However, you might appreciate the chance of providing your opinion on how we provide you with information about your chest pain and the options available. Also, you might enjoy having a greater involvement in decisions about your care. Regardless you may benefit from the findings of this study if you have attended the ED with the same problem in the future. As this study does not involve any changes to your clinical

care there are no particular risks to you. Filling in the short survey(s) might take a few minutes of your time and could feel like an inconvenience. Some patients might find a greater level of involvement in decisions about their care challenging.

Where is the study run from?
University of Manchester (UK)

When is the study starting and how long is it expected to run for?
December 2019 to December 2022

Who is funding the study?
Royal College of Emergency Medicine (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
271018

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 50175, Grant Codes: G/2019/3, IRAS 271018

Study information

Scientific Title
The Troponin-only Manchester Acute Coronary Syndromes (T-MACS) Choice feasibility study

Acronym
T-MACS CFS

Study objectives
The study aims to assess the feasibility of a full scale stepped wedge cluster randomised controlled trial evaluating the impact of using Shared Decision Making aided by the decision aid T-MACS Choice for patients presenting to the ED with suspected cardiac chest pain in a multifaceted way.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/08/2021, Wales REC 7 (Public Health Wales Meeting Room, Building 1, St. David's Park, Carmarthen, SA31 3HB, UK; +44 (0)2920 230457; Wales.REC7@wales.nhs.uk), ref: 21/WA /0255

Study design
Interventional non randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Acute coronary syndromes

Interventions
We will use a cluster stepped-wedge randomised controlled trial design to investigate the impact of shared decision-making in the envisaged full scale study. In this feasibility study we will run a much smaller version of the intended larger study to test if the design. The two emergency departments will each represent a cluster. Both emergency departments use the T-MACS risk prediction model as part of their routine care in a dedicated pathway already.

Once the study has obtained the necessary approval, we will use a concealed envelop to decide which of the two emergency department will be the first study site to open. This is creating what is called the stepped wedge approach were different study sites start recruiting in a randomly allocated sequence. This will help us control for potential changes or differences in patients over time. In our study there will be a 1-month difference in start date between the two emergency departments.

Each emergency department will start to recruit participants in the so called control period meaning that they continue to use the T-MACS risk prediction model as part of routine care.

After recruiting for 2 months the emergency department enters a transition period. In this period no participants will be recruited. This time will be used to ensure that the T-MACS software is supporting the shared decision-making element as well as providing all physicians in the department with a dedicated training session on shared decision-making. This session on the theory of shared decision making and simulation will last between 30-45 min and will be provided by a member of the research team. Where possible this teaching session will be provided face to face. However considering constraints of the COVID-19 pandemic alternatively the teaching session will be provided live online as well as be available on-demand as a recording for members of staff who start working in the department with no timely live session available.

After this 1 month long transition period the emergency department enters the 2 months shared decision-making period and will again recruit participants. Shared decision making with the decision aid T-MACS Choice will replace the previous routine care pathways for all patients presenting with chest pain that warrants investigating for a heart-related cause and therefore will be used for all patients regardless of their participation in the study. The T-MACS Choice decision aid will support the clinician to discuss the three options available to the patient: 1) going home without any regular follow-up; 2) going home and returning later for a second blood test; 3) being admitted to hospital for a second blood test.

Patients attending the emergency department will be informed about the study taking place by posters or their physician providing them with ample opportunity to opt-out from participation if they wish to. The clinical care (history, ECG, blood tests and whatever else is clinically indicated) of participants will not be affected or delayed in any way as this is the priority in an emergency setting.

A patient is an eligible participant when their physician decides to complete the T-MACS risk prediction model as the inclusion criteria of this study match the criteria for using T-MACS. At the end of the clinical encounter every eligible patient will be asked to complete a short post-encounter survey about decisional conflict and their control preference, unless the patient have or want to opt-out. As part of this survey we will ask participants if they are happy for us to inform their GP about them participating in the study and if we can contact their GP and consult their medical record once at 30 days to follow up about heart-related outcomes.
Those outcomes will be capture in a dedicated GP case report form that gets returned by the GP practice including information on GP contacts regarding heart conditions and mortality status. A second case report form will be completed by a research nurse after review of the medical record, GP CRF and study pack including the surveys as applicable summarising clinical mortality status, clinical relevant outcomes, discharge disposition, shared decision-making decisions and heart-related events.
Participants that have been recruited in the shared decision-making period of the study will also be asked if they are happy to be contacted once at 30 days either by telephone or via email for a 5 question survey to ask for decision regret.

Emergency physicians that provide care to patients with chest pain will be asked to complete a survey at the end of the shared decision-making training they receive and will also complete a brief survey at the end of the clinical encounter while also given the opportunity to opt-out from completing the survey.

Intervention Type
Other

Primary outcome measure
Measured at the end of the study (feasibility outcomes):
1. Number of eligible participants per months recruitment period measured as natural frequency in the eligibility log (T-MACS database)
2. Recruitment rate measured as percentage of eligible patients that did not opt-out by referencing the opt-out log against the eligibility log
3. Retention measured as percentage of those eligible who complete follow up and potential subsequent questionnaires without opt-out at a later stage (referencing opt-out log)
4. Percentage of missing data in secondary outcomes measured recorded in questionnaires and 30 days follow up case report forms data entered onto REDCap database
5. Ability to deliver physician training in shared decision making measured with qualitative notes from trainers to record potential problems of delivering physician training sessions as well as free text feedback on the session from physician training questionnaire
6. Ability to transition between control and intervention in transition time of 1 month measured with qualitative notes recording any problems in the process causing potential transition delays

Secondary outcome measures
1. Decisional conflict measured with the low literacy decisional conflict scale questionnaire as part of the patient post-encounter questionnaire on initial ED attendance
2. Control Preferences Scale instrument completed as part of the patient post-encounter questionnaire on initial ED attendance
3. Patient disposition recorded at 30 days follow up from medical records review distinguishing four categories (discharge home from ED without serial troponin sampling, discharge home from ED with patient returning a later time for serial troponin sampling, admission under ED for serial troponin sampling, admission under medical team for serial troponin sampling). Choice rates will be recorded in the shared decision making group will be extracted from decision aid copies on the medical record at 30 days follow up
4. Cardiac events at 30 days follow up including index visit AMI as well as a composite of MACE consisting of incident AMI, cardiac death and urgent coronary revascularisation including percutaneous coronary intervention and coronary artery bypass graft will be measured by review of the participants medical record. Cardiac outcomes will be adjudicated by two independent investigators with access to relevant clinical information but blinded for research results.
5. Patient decision regret measured by validated 5-item decision regret scale questionnaire in participants in the shared decision making intervention group at 30 days following their initial ED attendance
6. Physician experience with
6.1. Delivering SDM intervention by a physician post encounter questionnaire that is completed after the initial patient encounter in the ED
6.2. Training received on SDM measured by a clinician training questionnaire provided to them at the end of the training session physicians receive in the transition period between and control and intervention period

Overall study start date
31/12/2019

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Adult patients aged 18 years or above
2. Presenting to the ED with:
2.1. Pain, discomfort, or pressure in the chest, epigastrium, neck, jaw, or upper limbs
2.2. No obvious non-cardiac source
2.3. Symptoms the treating emergency physicians feel warrant investigation for suspected ACS

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 800; UK Sample Size: 200

Key exclusion criteria
1. Patients with peak symptoms >12 hours before presenting to the ED
2. Patients requiring referral for immediate primary percutaneous coronary intervention due to unequivocal evidence of ST elevation myocardial infarction
3. Patients requiring hospital admissions for another medical condition
4. Patients that lack mental capacity to provide written informed consent
5. Patients whose level of English does not allow them to participate in the SDM conversation in a meaningful way.

Date of first enrolment
03/01/2022

Date of final enrolment
31/07/2022

Locations

Countries of recruitment
United Kingdom

Study participating centre
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Albert Edward Infirmary
Wigan Lane
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United Kingdom
WN1 2NN

Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Research organisation

Funder Name
Royal College of Emergency Medicine

Alternative Name(s)
RCEM

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Findings will be disseminated multiple ways to maximise impact and accessibility to a wide audience including: (a) publication in peer reviewed academic journals, (b) presentation at national and international scientific conferences; (c) publication on the trial and research group websites; (d) dissemination via press releases and (e) to promote public engagement, social media and blog posts. Participants that have indicated an interest in being kept informed will be updated when results become available.

Intention to publish date
01/06/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as data sharing has not been agreed with the funder. The patient related data collected is regarded sensitive in nature prohibiting sharing.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	12/07/2021	23/09/2021	No	No
HRA research summary			28/06/2023	No	No