RESEARCH PROTOCOL

The Troponin-only Manchester Acute Coronary Syndromes (T-MACS) Choice Feasibility Study

Stepped wedge cluster randomised controlled feasibility trial

Contents

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2) SUMMARY

Background

A recent shift in how we deliver patient-centred care has brought shared decision making (SDM) to new attention. However, relatively little is known about how to apply SDM in the emergency department (ED). A US study has demonstrated that SDM can be successfully used in ED chest pain patients but used a now outdated algorithm to inform the SDM. The T-MACS Choice decision aid uses a contemporary algorithm, was co-designed with patients and now requires evaluation in clinical practice.

Objectives

Our primary objective is to establish if conducting a full-scale stepped wedge cluster randomised controlled trial evaluating the impact of SDM aided by the decision aid T-MACS Choice is feasible based on a composite of feasibility outcomes including eligible patient per time period of recruitment, recruitment rate, compliance with intervention and retention. Furthermore, we will collect data on the envisaged primary and secondary outcomes of the full-scale trial to evaluate if collecting the data is feasible by measuring missing data and providing some proof of concept. Those outcomes include decisional conflict, control preference, cardiac events, decision regret and physician satisfaction with the SDM training and delivering the intervention.

Plan of investigation

We will conduct a feasibility stepped wedged cluster randomised controlled trial using opt-out consent in adult patients presenting to the ED with suspected cardiac chest pain. The two ED's, representing the two clusters, will begin recruitment as 'controls' using standard care protocols based on T-MACS for 2 months. After a 1-month training period, the sites will then implement the SDM intervention using T-MACS Choice calculating the probability of a major adverse cardiac event and share that with patients through SDM. Feasibility data will be recorded throughout the study through different measures including the T-MACS database and a dedicated opt-out log. Clinical and study outcome data will be collected during the initial ED visit through a post-encounter patient survey measuring control preference and decisional conflict. Participants will be followed up at 30 days, considering their permission, for relevant secondary outcomes. Physician experience will be evaluated in a clinician post encounter survey and a survey following the SDM teaching session in the transition stage. A trial steering committee will decide on feasibility informed by pre-determined criteria. If shown to be feasible, we will proceed to apply for funding for a larger, definitive stepped wedge RCT.

3) BACKGROUND

The concept of SDM goes back to 1972, before a landmark paper identified the four key components still found in modern definitions: (a) involvement of at least two parties, usually physician and patient, (b) sharing of information, (c) physician and patient both taking steps to participate in the decision making, and (d) agreement on the decision.(1) The shift in how we deliver patient centred care and the ethical imperative underpinning SDM is clearly reflected in the 2012 Health and Social Care Act and the "Liberating the NHS: 'No decision about me without me" guidance.(2) While the mandate for SDM is clear, there is still a notable evidence gap with no research addressing the impact of implementing SDM in UK emergency medicine (EM).

A priority setting partnership (PSP) between the Royal College of Emergency Medicine (RCEM) and the James Lind Alliance ranked the question on chest pain investigation strategies alongside SDM sixth, highlighting the SDM component as the main priority for future research.(3)

Through the Greater Manchester T-MACS initiative, T-MACS has become one of the country's leading algorithms for patients presenting to the ED with suspected cardiac chest pain. T-MACS was derived by our group using a logistic regression model that provides the treating physician with a probability of their patient having ACS. This patient specific probability incorporating details the patient's symptoms, electrocardiographic (ECG) findings and a single cardiac troponin concentration measured on arrival in the ED can be used to inform clinical decision making.(4) However, even with modern prediction models like T-MACS and advances in cardiac troponins, the large numbers of patients presenting to the ED with chest pain remain a challenge, partially explained by physicians being fairly risk averse. Research into what is considered acceptable risk demonstrated that only 4 out of 10 ED physicians would accept a 1% risk of a major adverse cardiac event (MACE) at 30 days when taking the sole responsibility in making decisions.(5)

With SDM presenting a possible solution it has mainly been the last decade that has brought more evidence for the concept in emergency medicine. A narrative systematic review published in 2012 including 3 cross-sectional studies and 2 randomised controlled trials (RCT) on SDM supported by decision aids in the ED found no evidence to suggest that SDM could not be used in the ED with all 5 included studies reporting positive findings from implementing SDM supported by decision aids.(6)

To date three randomised controlled trials have looked at SDM with patients with suspected cardiac chest pain in the ED. The earliest RCT by Kline et al provided physicians and low risk chest pain patients a printout of a quantitative pre-test probability of acute coronary syndromes (ACS). No difference in missed or delayed diagnosis of ACS between groups was found while also showing a trend towards increased patients satisfaction with physician explanation, decrease in admission rate as well as significantly reduction in radiation exposure of the chest.(7)

Among other findings, the two most significant randomised controlled trials to date by Hess et al. showed increased patient knowledge and decreased decisional conflict when using SDM with the decision aid Chest Pain Choice in ED chest pain patients when deciding on whether the patient wants to undergo stress testing or follow up with a physician within 72 hours.(8,9) In secondary analyses they further showed that the benefits of SDM were similar across socioeconomic groups, a high desire to participate in SDM across all demographic groups and decreased diagnostic testing without worsening outcomes at 45 days in the SDM arm.(10–12)

In a co-design process involving patients, emergency physicians and other stakeholders we developed the T-MACS Choice decision aid in accordance with the International Patient Decision Aid Standards instrument

criteria.(13,14) T-MACS Choice is combining the strength of the T-MACS risk prediction model with a communication support tool that will allow for clinical implementation in the UK ED setting to generate the first evidence of the impact SDM could have for ED patients with chest pain in the UK.

4) STUDY OBJECTIVES

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

4.1 Primary Question/Objective:

The primary objective of this feasibility trial is to assess if delivering a full scale stepped wedge cluster randomised controlled trial investigating the impact of SDM aided by the T-MACS Choice decision aid in patients with suspected cardiac chest pain in the ED is feasible. Therefore, we will conduct a pilot of the envisaged full scale trial to asses for eligible participants, recruitment, retention and missing data.

4.2 Secondary Question/Objective:

As part of the feasibility trial we will further asses the feasibility of collecting the envisage primary and secondary outcome measures. Furthermore, we will gather feedback from the physicians regarding the training they receive about delivering SDM with T-MACS Choice. The envisaged outcome measures we will collect data on are:

1) Decisional conflict
2) Control Preferences Scale
3) Patient disposition and choice rates
4) Cardiac events
5) Patient decision regret at 30 days
6) Physician experience with
    a. delivering SDM intervention
    b. training received on SDM

5) STUDY DESIGN & PROTOCOL

5.1 Participants

We will recruit adult participants presenting with suspected cardiac chest pain to the ED as further specified in the in- and exclusion criteria under 6.1 and 6.2. Recruitment will happen during two 2 months blocks as specified below under 5.2.

5.2 Study Intervention and/or Procedures

We will undertake a stepped wedged cluster randomised controlled feasibility trial at two emergency departments (representing individual clusters): Manchester Royal Infirmary and the Royal Albert Edward Infirmary Wigan. With no site initially exposed to the shared decision making intervention, they will subsequently cross over after 2 months to intervention with a 1-month transition period for training purpose. The start date for each site will be randomly assigned.

Months	1	2	3	4	5	6	7	8
Trial set up								
Recruitment 1st centre								
Recruitment 2nd centre								
Data entry &verification								

Control group: Patients presenting with suspected cardiac chest pain receive diagnostic and treatment interventions according to local emergency department protocols based on T-MACS that have been verified for compliance with national or international guidance and are already in use at both hospitals as part of routine clinical care.

Transition stage: On completion of the recruitment time in the control arm the cluster will enter a designated 1-month transition stage. The purpose of this stage is twofold:
1) to allow installation of an update T-MACS Calculator with integrated SDM feature allowing to print off of the bespoke T-MACS Choice decision aid; and
2) physicians to undergo a designated training session on SDM including theory of the three talk communication model and demonstration of a shared decision making conversation using T-MACS Choice. This teaching session will be delivered as a face to face teaching session lasting 30-45 min by a member of the research team where possible. However, considering ongoing constraints on face-to-face teaching in light of the COVID-19 pandemic the teaching session where necessary will be provided as a live or on-demand online session allowing it to be readily accessible.

Intervention**:** We will examine the use of SDM with the previously designed decision aid T-MACS Choice. The treating emergency physician will routinely evaluate the patient as well as review blood tests including an initial troponin result before entering relevant information into the T-MACS calculator. The calculator will generate a personalised decision aid incorporating the calculated probability that the patient has a MACE within 30 days. This will then be used in the SDM conversation following the three-talk model.(15) Patient disposition including serial troponin testing will be decided on in the SDM conversation.

6) STUDY PARTICIPANTS

6.1 Inclusion Criteria:

- Adult patients ≥18 years of age presenting to the ED with:
    - Pain, discomfort or pressure in the chest, epigastrium, neck, jaw or upper limbs
    - No obvious non-cardiac source
    - Symptoms the treating emergency physicians feels warrant investigation for suspected ACS

6.2 Exclusion Criteria:

- Patients with peak symptoms >12 hours before presenting to the ED
- Patients requiring referral for immediate primary percutaneous coronary intervention due to unequivocal evidence of ST elevation myocardial infarction
- Patients requiring hospital admissions for another medical condition
- Patients that lack mental capacity to provide written informed consent

- Patients whose level of English does not allow them to participate in the SDM conversation in a meaningful way.

6.3 Recruitment:

Recruiting to research in an emergency setting is always challenging due to combination of factors including a high clinical work load, a proportion of eligible patients presenting out of hours with research teams often not being able to support recruitment and not least patients experiencing this as a stressful high-stake situation. Experience with the targeted patient population presenting with suspected cardiac chest pain captured in a qualitative interview study as part of the original MACS pilot RCT showed that patients often struggle with the concept of formal written informed consent in a situation they perceive as high stakes and they when they are in discomfort.(16)

However, recruiting a consecutive sample of patients allowing all patients with suspected cardiac chest pain to participate is vital to minimise recruitment bias and make findings generalisable. In this study we therefore plan to recruit 24 hours a day, 7 days per week at both clusters to evaluate our ability to deliver training to physicians in shared decision making and ultimately their ability to deliver the concept using the T-MACS Choice decision aid in clinical care. To achieve this, we will adopt a proportionate opt-out consent process as the risk of harm to patients is negligible. This allows trained clinicians to recruit patients as part of providing routine care with support of the research team in the daytime during weekdays.

This process has specifically been designed to ensure that patients are sufficiently informed and provided with dedicated opportunities to ask questions and engage with the study at their preference and indicate their desire to opt out from all or parts of the research. This study does not change the clinical treatments patients receive. It rather implements communication training to facilitate SDM with the decision aid T-MACS Choice allowing clinicians to communicate available options in a different way. With the strong ethical imperative underpinning SDM (17,18) and the extensive evidence for T-MACS as reliable prediction model, SDM and the decision aid T-MACS Choice will be implemented for all patients with suspected cardiac chest pain at cluster level (in both ED's) regardless of patients participation in the study. Notably, SDM does involve a consensual interaction between physician and patient as one of the core principles. A patient not engaging with the process of SDM is therefore opting out by non-participation.

To inform patients about the study we will display relevant information in the appropriate areas of the participating ED's describing the study and assuring patients that their clinical care will not be affected in any way regardless of their decision to participate. Patients that have a T-MACS score calculated are considered to meet eligibility criteria of this study as the in- and exclusion criteria are identical with those clinicians use when considering if applying T-MACS is indicated. The individual patient will be offered a patient information sheet (PIS) including a description of the study and a point of contact. PIS documents will be numbered with individual study ID-numbers that will be linked to the T-MACS database that is routinely created on entering the participants clinical data into the T-MACS calculator. The existing T-MACS database will therefore serve as a list of eligible participants while also ensuring that every eligible participant has received a PIS. At the end of each week the T-MACS database will be cross-checked against the patient post-encounter surveys to check for any patients that have opted out and to highlight their opt-out status on potential follow up on a dedicated opt-out log.

The additional interventions that deviate from normal practice patients will undergo, unless they opt-out, is a short post-encounter survey about their experience of the clinical encounter during their initial visit to the ED. Those participants in the SDM group that opt-in for follow up will complete a second survey at 30 days

remotely via telephone or via email linking them to a survey within the Research Electronic Data Capture (REDCap) database. All participants that opt-in for follow up on their clinical outcomes at 30 days will have their GP contacted and their medical records checked by the research team to verify any cardiac events. Participants are free to opt-out or opt-in from all or some of the follow up components as they wish to.

As part of the monitoring process the opt-out log will be cross-referenced with the REDCap database at the end of each month in the recruitment period and upon finishing data collection.

Clinician training on SDM will be mandatory for all clinicians providing care in the respective ED's once T-MACS Choice is implemented to provide safe and effective clinical care and should be viewed as mandatory induction. Physicians who wish not to complete the clinician survey at the end of the training can opt out from participation on that survey. Nevertheless, once the training is completed, they are still able to recruit participants to the study. Similar to patients, clinicians during the recruitment period wishing not to participate in the research can opt-out from completing the clinician post encounter survey.

6.4 Randomisation:

The order in which the two clusters in this study will commence recruiting patients will be decided randomly. For that purpose, we will be using a computer-generated random number list.

6.5 Participants who withdraw consent [or lose capacity to consent]:

Participants can opt out and withdraw consent at any time without giving any reason, as participation in the research is voluntary, without their care or legal rights being affected.

If a participant decides to opt-out during the study we will use the data they have provide up to that point unless they indicate they wish for their collected data to be removed. From the point of opt-out we will collect no further data on that participant.

7) OUTCOME MEASURES

Primary outcome

The primary outcome is a composite of feasibility outcomes:

- Number of eligible participants per months recruitment period
- Recruitment rate
- Retention
- Percentage of missing data in secondary outcomes
- Ability to deliver physician training in shared decision making
- Ability to transition between control and intervention in transition time

Secondary outcomes

To determine if SDM is a successful intervention requires a multi-faceted approach. Therefore, as part of this feasibility study we will be collecting data on the envisaged outcome measures of the full scale stepped wedge trial to show feasibility of collecting these measures.

The envisaged primary outcome of the full-scale trial is a patient-related outcome of **decisional conflict**. This will be measured by the validated low literacy decisional conflict scale (LL-DCS) at the end of the ED

consultation as part of a post-encounter survey. The LL-DCS consists of a questionnaire with 10 questions and 3 response categories as well as an option preference. The overall LL-DCS score is regarded as a measure of the patients personal perception of 1) uncertainty in choosing options; 2) modifiable factors contributing to uncertainty such as feeling uninformed, unclear about personal values and unsupported in the decision making; and 3) effective decision making such as feeling the choice is informed, value-based, likely to be implemented and expressing satisfaction with the choice.(19,20)

The other envisaged secondary outcomes of the full-scale trial we are planning to collect data are:

- **Patient disposition and choice rates** will be recorded in the control and intervention group distinguishing four categories: 1) discharge home from the ED without serial troponin sampling; 2) discharge home from the ED and patient returning for serial troponin sampling at later time point; 3) admission under ED care for serial troponin sampling; and 4) admission under the medical team for serial troponin sampling. Choices in the intervention group will be recorded on the decision aid and will also be monitored for adherence in those deciding to be discharged home without and with follow up.
- **Control preferences scale (CPS)** will be recoded as part of the pre-encounter survey to establish the degree of control a participant prefers when it comes to making a decision about their care.(21)
- We will also establish specific **cardiac events** 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 at 30 days.
  Cardiac outcomes will be adjudicated by two independent investigators provided with access to relevant clinical information but blinded to research investigation results. A third independent investigator will be consulted to resolve discrepancies. AMI will be defined according to the Fourth Universal Definition of AMI. All patients meeting inclusion criteria can be regarded as having symptoms and signs consistent with myocardial ischaemia. Therefore, patients will be deemed to have met the outcome of AMI if they develop a rise and/or fall above the 99th percentile upper reference limit. Contrary to current guidance some patients may opt upon SDM to not undergo serial troponin testing. Establishing a formal diagnosis of index visit AMI will not be possible in this group of patients.
- **Decision regret** will be evaluated using the validated 5-item decision regret scale in patients that have received the intervention.(22) This is based on the assumption that with the current standard of care the proportion of patients actively participating in any disposition decision is insignificant. The control group will therefore be regarded as having no decision regret. A high level of decision regret in the intervention group would be considered a negative outcome on one of the essential domains of shared decision making.
- To establish **physician experience**, we will ask physicians to complete two questionnaires. The first one is a bespoke clinician training survey about the training session on SDM they receive in the transition period. The second bespoke survey is the clinician post-encounter survey they will complete at the end of a clinical encounter.

8) DATA COLLECTION, SOURCE DATA AND CONFIDENTIALITY

All outcome measures will be recorded on a dedicated REDCap database. REDCap is fully compliant with GCP, 21 CFR Part 11, GDPR, ISO 27001 and ISO 9001. The database will be password protected and only accessible to certain members of the study team. Patient identifiable data will be pseudo anonymised using individual study ID numbers. Those will be assigned on creation of a T-MACS record by conversion of the time stamp using random conversion factor. The pseudo anonymised data will be held on either the REDCap database or

as a paper case report form (CRF) Patient identifiable data will never be downloaded or transferred along with research data. Access to patient identifiable data will be restricted to the Chief Investigator and people who audit the data collection process in a password protected key document. Research data will only be downloaded for the purpose of statistical analysis onto a secure, fire-wall and password protected University computer system. The researcher conducting the analysis will have no access to patient identifiable information. Patient identifiable from this study will be stored for 5 years after the study has finished in order to comply with regulations.

With the participants permission, we will inform their GP about their involvement in the study to a) contact the GP for follow up information and b) allow the GP to voice any potential concerns about participation of a participant in the study.

Clinical blood samples will be taken and processed according to standard care procedures as is the standard of care for patients presenting with chest pain to an emergency department. All patients undergoing serial troponin testing as part of routine care will receive testing in accordance with national and international guidance involving measuring high sensitivity troponin concentrations on arrival and either 3 hours after arrival or 12 hours after the onset of peak symptoms. A high sensitivity troponin assay is defined as an assay that can detect troponin concentrations in at least 50% of apparently healthy individuals with a co-efficient of variation of <10% at the 99th percentile cut-off.

As part of this study one (two in some participant) patient directed survey will be administered:

- Post-encounter survey:
    - LL-DCS
    - Highest educational level
    - Opt-in for 30-day follow up (SDM group)
    - Opt-in for follow up via GP contact and medical record review (both groups)
- 30-day follow up:
    - decision regret scale (if participant in SDM group opted in)

Any provided contact details and contact preferences will only be used to contact participants about the research study, to make sure that relevant study information is recorded about their care and to oversee the quality of the study.

Furthermore at 30-day follow up clinical outcomes will be recorded from the participants medical record and/or from a dedicated GP case report form if the participant gave permission for their GP to be contacted.

Equally two physician direct surveys will be administered during this study:

- Clinician SDM training survey
- Clinician post-encounter survey.

9) STATISTICAL CONSIDERATIONS

9.1 Statistical Analysis

The primary analysis will focus on the feasibility outcomes. A mean or proportion of the feasibility measures will be calculated per cluster.

The same approach will be taken for the secondary outcomes with a per cluster analysis. We will calculate the mean difference between intervention and control groups by cluster with 95% confidence intervals in decisional conflict as our envisaged primary outcome as evidence towards proof of concept. Patient disposition and choice rates overall and stratified for the 4 distinct T-MACS risk categories (very low, low, moderate and high risk), choice adherence, adverse cardiac events and decision regret in the intervention group as well as physician satisfaction will be summarised using descriptive statistics in a cluster similar to the feasibility outcomes. The statistical analysis will be completed using SPSS version 23.

9.2 Sample Size:

No formal sample size calculation was conducted as part of this feasibility trial. Instead each cluster will have a dedicated 2-month recruitment period in each the control and intervention arm within the remit of our funding and available time line. We are estimating that each cluster should have about 200-300 eligible patients present to the department every month.

10) DATA MONITORING AND QUALITY ASSURANCE

To ensure collection of good quality data in accordance with Good Clinical Practice, remote monitoring visits will be undertaken monthly by the study co-ordinator. A separate monitoring plan will be provided to each site with specific instructions. Data monitoring will be done using the REDCap database that will be used throughout the study for data storage.

11) SAFETY CONSIDERATIONS AND ADVERSE EVENTS

An Adverse Event is any untoward medical occurrence, unintended disease or injury or any untoward clinical signs (including laboratory finings) in a study participant, which may or may not be related to the study intervention. This includes events related to the procedures involved in the study.

A Serious Adverse Event is an occurrence that has led to the death of a participant or serious deterioration in the participants' health.

Due to the nature of the study involving ED patients with suspected cardiac chest pain, it is to be expected that a proportion of the enrolled patients will have abnormal ECGs and/or abnormal (i.e. elevated) cardiac troponin levels as part of their routine care. Those will therefore not be recorded as an AE. Equally, we will not record acute myocardial infarction or revascularisation as a SAE in those who have opted to have serial troponin testing as these outcomes are to be expected in a proportion of the target population. However, those events will be recorded as SAE in participants who have opted to not pursue serial troponin testing and will be reviewed by an independent panel at the end of the study. Running the panel with preliminary results during the short 2-month period of the intervention arm will not be feasible.

SDM involves presenting patients with the possibility of "doing nothing" which in our study would equate to going home without serial troponin testing. While this intuitively sounds risky and potentially hazardous when thinking of patients identified having a moderate or high risk for ACS, mentioning the option is merely representative of real-life choice options. Offering choice should not be confused with actively advocating for a particular option. During development of the decision aid with patient groups, it was clear that they felt SDM should be offered to all patients, regardless of risk group. With ethical implications in mind, the intervention and training have been carefully designed to ensure that high-risk patients do not perceive that doctors are potentially allowing them to go home; rather, that they are being kept fully informed of their

clinical status and the recommended treatment. Ultimately, the choice, as long as it represents an informed decision, does lie with the patient respecting their autonomy.

12) PEER REVIEW

This study has undergone peer review as part of the RCEM research grant application process and was deemed of sufficient academic quality to be awarded funding. Furthermore, the grant application had undergone peer-review prior to submission for the grant application. Since funding was awarded there has been further input from the NIHR Research Design Service improving in shaping this feasibility trial so it can provide the best possible information for a full-scale trial.

13) ETHICAL and REGULATORY CONSIDERATIONS

13.1 Approvals

NHS Research Ethics Committee and Health Research Authority (HRA) approval will be obtained before commencing this research study.
The study will be conducted in full conformance with all relevant legal requirements and the principles of the Declaration of Helsinki, Good Clinical Practice (GCP) and the UK Policy Framework for Health and Social Care Research 2017.

13.2 Risks

SDM involves presenting patients with the possibility of "doing nothing" which in our study would equate to going home without serial troponin testing. While this intuitively sounds risky and potentially hazardous when thinking of patients identified as having a moderate or high risk of ACS, mentioning the option is merely represents real life options. Offering choice should not be confused with actively advocating for a particular option. Ultimately the choice does and should lie with the patient, as long as it represents an informed decision as this is respecting their autonomy.

14) STATEMENT OF INDEMNITY

The University has insurance available in respect of research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The University also has insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University.

15) FUNDING and RESOURCES

Funding for this study was obtained from the Royal College of Emergency Medicine - RCEM Grant Number: G/2019/3.

16) PUBLICATION POLICY

This study will provide hardly needed evidence on the impact of SDM in UK emergency medicine and more specifically its role in the diagnostic process of patients presenting with suspected cardiac chest pain to the ED.

We will disseminate our findings in a multiple ways to maximise impact and accessibility to a wide audience including: (a) publication in peer reviewed academic journals, aiming for journals with high impact and a relevant target audience; (b) presentation at national and international scientific conferences; (c) publication on the trial and research group websites; (d) dissemination via press releases (including by Central Manchester University Hospitals NHS Foundation Trust; The University of Manchester; the NIHR

Clinical Research Network); and (e) to promote public engagement, social media and blog posts. Participants that have indicated an interest in being kept informed will be updated as and when results will become available.

17) PROCEED CRITERIA

Depending on the outcome of the feasibility study the following proceed criteria have been agreed by the Trial Steering Committee:

Green	Yellow	Red
>50% of eligible patients complete post-encounter survey	<25% under target recruitment rate	>50% under target recruitment rate
<20% of patient opt-out from 30 day follow up in intervention arm	<25% of patient opt-out from 30 day follow up in intervention arm	>30% of patient opt-out from 30 day follow up in intervention arm
<5% opt-out to follow up on medical record/GP record review at 30 days	>5% opt-out to follow up on medical record/GP record review at 30 days	>15% opt-out to follow up on medical record/GP record review at 30 days
<10% missing data on LL-DCS	<20% missing data on LL-DCS	>20% missing data on LL-DCS
<20% missing data on other secondary outcomes	<30% missing data on other secondary outcomes	>30% missing data on other secondary outcomes

In case all feasibility outcomes are regarded 'green' we will proceed to a full scall trial with the currently envisaged protocol. In case of 'green' and 'yellow' outcomes adjustments will have to be made to the protocol based on the where the problem lies. A single 'red' criterion might be rectifiable with adjustments. However, in case of mainly 'red' criteria with no clear vision on how this could be rectified we will not proceed to a full-scale trial.

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