Imperial College London

Research Governance and Integrity Team

Imperial College Healthcare NHS Trust

Template Protocol for non-CTIMPs

TELE-ACS

Remote Acute Assessment of Patients with High Cardiovascular Risk Post-Acute Coronary Syndrome

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Name & Role	Date	Signature

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Funder

King Khalid University

The Saudi Arabian Cultural Bureau in the UK will serve to act as a liaison between King Khalid University and Imperial College London relates to scholarship matters.

This protocol describes the TELE-ACS study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the UK Policy Frame Work for Health and Social Care Research. It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

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GLOSSARY OF ABBREVIATIONS

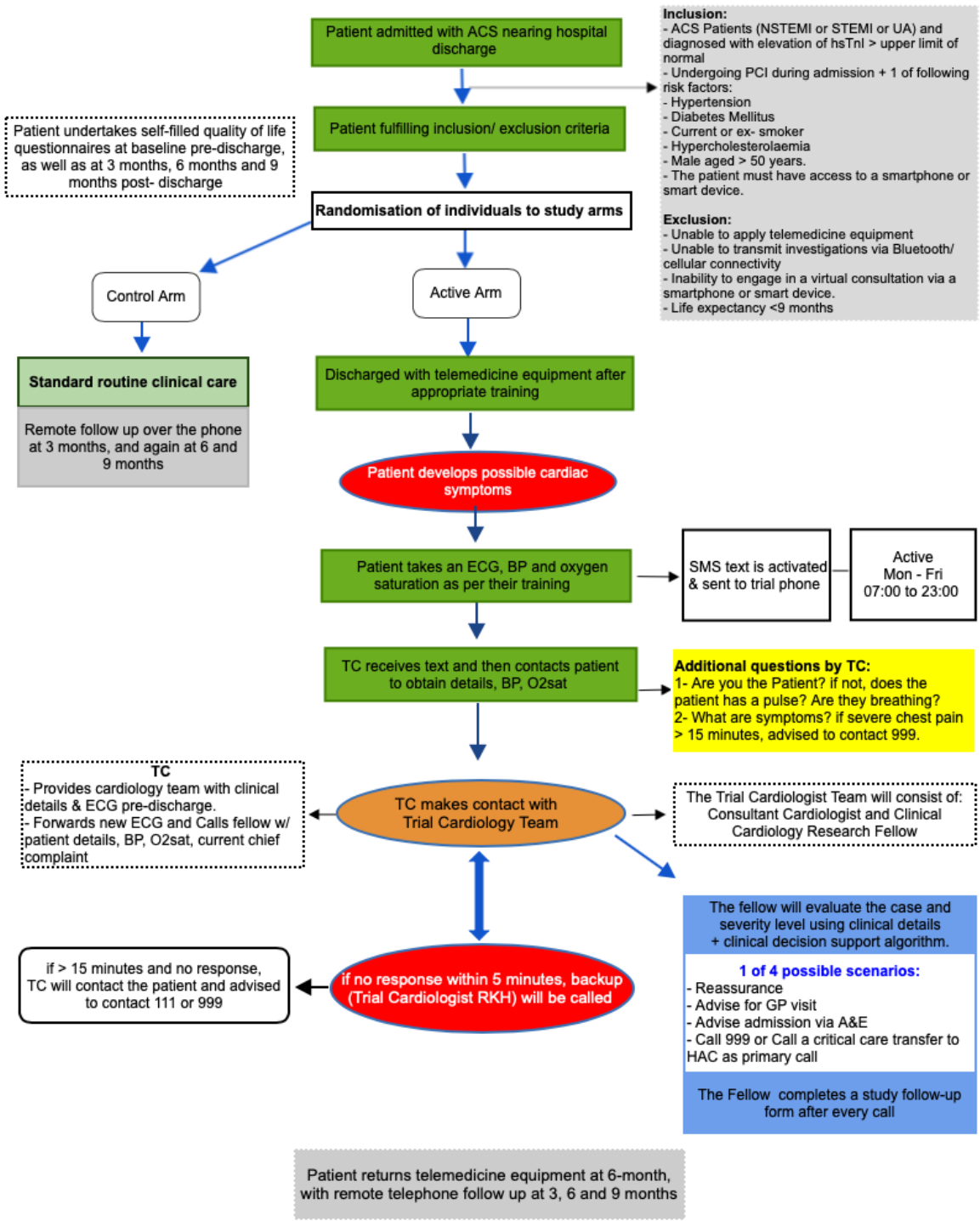
ACS	*Acute coronary syndrome*
A&E	*Accident and emergency*
BP	*Blood pressure*
ECG	*Electrocardiogram*
HAC	*Heart assessment centre*
HF	*Heart failure*
hsTnI	*High sensitivity troponin I*
MI	*Myocardial infarction*
NSTEMI	*Non-ST-segment elevation myocardial infarction*
PCI	*Percutaneous coronary intervention*
STEMI	*ST-segment elevation myocardial infarction.*
TELE	Telemedicine
TC	*Trial Coordinator*

KEYWORDS
Myocardial infarction, Acute coronary syndrome, Telemedicine

STUDY SUMMARY

TITLE	Remote Acute Assessment of Patients with High Cardiovascular Risk Post-Acute Coronary Syndrome
DESIGN	Randomised Controlled Trial
AIMS	1- Ensuring that patients present appropriately even though there is an inherent risk to attend post-myocardial infarction. 2- To prevent unnecessary presentations, as assessed by well-validated technologies coupled with an urgent remote consultation with a specialist.
OUTCOME MEASURES	**Primary:** All hospital readmission rates (formal admissions and not emergency room visits) at 6 months of follow up in intervention vs control groups. **Secondary:** Total length of stay, All-cause mortality, morbidity, and MACE, Medical intervention for acute coronary syndromes or heart failure, Emergency Room visits not requiring admission or further intervention, 9 months readmission rates, and Patient-reported quality of life outcome measures
POPULATION	The patient population will comprise the most vulnerable patients to further myocardial infarction
ELIGIBILITY	ACS Patients diagnosed with elevated high-sensitivity troponin I who have undergone coronary intervention for non-ST-segment acute coronary syndrome (NSTE-ACS) or ST-segment elevation myocardial infarction (STEMI) or unstable angina (UA). The patients must have at least one additional cardiovascular risk factors.
DURATION	9 Months

REFERENCE DIAGRAM



Abbreviations: *ACS, acute coronary syndrome; A&E, accident and emergency; BP, blood pressure; ECG; electrocardiogram; HAC, heart assessment centre; hsTnI, high sensitivity troponin I; NSTEMI, non-ST-segment elevation myocardial infarction; PCI, percutaneous*

coronary intervention; STEMI, ST-segment elevation myocardial infarction; TC, Trial Coordinator.

1. INTRODUCTION

1.1. BACKGROUND

Myocardial infarction remains one of the leading causes of mortality in the UK, despite cutting edge medical and interventional therapy. As length of stay in hospital for myocardial infarction decreases in line with global trends, UK unplanned re-admission rates remain high at about 10% at 30-days (1). This is representative of global data, with a recent meta-analysis reporting 30-day readmission rates of between 11-14%, and are even higher in the USA (2). Table 1 shows several studies have previously analysed the readmissions rates for patients with Acute Coronary Syndrome (ACS) within 30-day, 3-month and 1-year. The readmission rate of 61.7% reported in the study by Southern et al., who evaluated the rate of readmissions in 3,411 patients within 1-year after first admission for ACS in Canada, even though 34.1% readmitted within 30-day as inpatient and 27.6% emergency department only (3). A study conducted in the USA reported women of all ages have a higher risk of readmission compared with men at 1-year after AMI and the readmission rate was 24.5% (Figure 1) (4). These readmissions are for both cardiovascular causes (such as further myocardial infarction, anginal chest pain or heart failure) as well as non-cardiovascular causes, most prominently non-cardiac chest pain, in up to 50% (1). Regardless, the mortality in patients 30-days post-discharge for acute myocardial infarction is 7.3% with little change over time (5). Indeed the most current UK data of 30-day mortality in those undergoing coronary intervention for acute coronary syndromes varies between 1.6-43.1%, depending on the presence of ST-segment elevation and shock at presentation (6).

1.2. RATIONALE FOR CURRENT STUDY

The utilisation of telemedicine devices has the potential to provide remote, clinically necessary, diagnostic information, without the need for hospital attendance. One such device is the smartheart™ (SHL Telemedicine), which is a CE/ FDA-approved personal mobile 12-lead ECG device, that produces and transmits hospital-grade electrocardiograms (ECGs) within 30 seconds, via Bluetooth and cellular communication. Indeed, use of SHL Telemedicine devices along with their bespoke call centre and mobile intensive care unit has previously been demonstrated to reduce post-acute myocardial infarction readmission rates to 5.3% in a retrospective study (7).

Emergency presentation with acute coronary syndromes has significantly reduced during the COVID-19 pandemic globally, and specifically in the UK (8, 9). There are multiple explanations for this, including perceived increased health risks of hospital attendance, as well as a reluctance to seek medical attention in order to limit the burden on the healthcare system. This is likely to have significant short-term and long-term health sequalae. Out-of-hospital cardiac arrests have transiently doubled in frequency over the course of the lockdown, in line with reduced survival (10, 11). This is likely attributable to the effects of the virus itself, as well as reluctance to seek medical attention and adjustment of healthcare services. Expected long-term consequences of reduced emergency department attendance for acute coronary

syndromes will include an increase in ischaemic cardiomyopathy, heart failure and mortality. Similar patterns of acute cardiac care service usage were expected if a second surge of COVID-19 were to occur. Thus, there is a clear mandate to reduce unnecessary hospital readmissions, increase and encourage appropriate emergency attendance and reduce mortality rates in patients following acute myocardial infarction.

2. STUDY OBJECTIVES

The study objective is to determine the effect of utilising telemedicine devices to provide remote, clinically necessary, diagnostic information, without the need for hospital attendance. The aim of this project is to equip and empower patients known to be at high risk of acute coronary syndromes to seek urgent medical help without going to the hospital, if they experience symptoms, and to make a decision to present to the emergency services whenever necessary. This serves two aims: 1) ensuring that patients present appropriately to the emergency services if needed, and 2) to prevent unnecessary presentations, as assessed by well-validated technologies coupled with an urgent remote consultation with a specialist.

3. STUDY DESIGN

The study will be conducted at the Hammersmith Hospital. Patients will be recruited from the cardiology clinical areas of Hammersmith Hospital (i.e. the Heart Assessment Centre, Cardiac Day Ward or A7 Ward). We propose to utilise a bespoke hybrid remote telemonitoring system to assess patients who are discharged from hospital following an acute myocardial infarction and the format of a randomised controlled trial will be used to achieve the aims of this project.

The participants will choose between these two telemedicine packages, desponds on patient preference and devices availability:

The 1st telemedicine package will consist of the following equipment:

- SHL smartheart (SHL Telemedicine, Tel Aviv, Israel), FDA-approved and CE-marked
- Omron Basic M2 blood pressure monitor (Omron Corporation, Kyoto, Japan), CE-marked and validated by the British & Irish Hypertension Society
- Kinetik Wellbeing Finger Pulse Oximeter (Kinetik Wellbeing, Surrey, UK), CE-marked

The 2nd telemedicine package will consist of the following equipment:

- SHL smartheart (SHL Telemedicine, Tel Aviv, Israel), FDA-approved and CE-marked.
- Current Health (Respiration rate, Oxygen saturation, Pulse rate, Body temperature and Mobility & step count), FDA-approved and CE-marked.
- iHealth Feel Wireless Blood Pressure Monitor, FDA-approved and CE-marked.

- ◊ **SHL smartheart + BP/Sats:** Patient develops possible cardiac symptoms, takes an ECG, BP and oxygen saturation as per their training. Activated text which goes to trial phone (Active: Mon – Fri between 07:00 to 23:00). Trial Coordinator (TC) receives text and then contacts patient to obtain details, BP, O2sat and views uploaded ECG. TC provides the trial cardiologist with patient past medical history from trial documentation, forwards ECG, calls the trial cardiologist with patient details, BP, O2sat, and current chief complaint. Patient will receive a phone call by the trial cardiologist who will have access to a high-quality ECG trace, as well as blood pressure and oxygen saturations, and coupled with the clinical history, can decide on the most appropriate course of further management.
- ◊ **SHL Smartheart + Current Health:** Patient develops possible cardiac symptoms, takes an ECG, BP and oxygen saturation as per their training. Activated text which goes to trial phone (Active: Mon – Fri between 07:00 to 23:00). TC receives text and then contacts patient to obtain details, BP, O2sat and views uploaded ECG. TC provides the trial cardiologist with patient past medical history from trial documentation, forwards ECG, calls the trial cardiologist with patient details, BP, O2sat, and current chief complaint. Patient will receive a phone call by the cardiologist who will conduct an emergency video consultation using Current Health platform, an approved web-based platform. The trial cardiologist will have access to a high-quality ECG trace, as well as blood pressure, respiration rate, oxygen saturation, pulse rate, body temperature, and coupled with the clinical history, can decide on the most appropriate course of further management.

The disadvantages of taking part include needing to train to use the equipment, which is usually straight forward. There is a very small risk that an incorrect decision is made by the research team, the participant is not treated when he/she could have been. However, this is a very small risk, as the research team are experienced, and the clinical decision support algorithm has been designed to be safe.

The participant will have adequate training prior to discharge for these two telemedicine packages by the local research fellow and cardiac research nurse, covering how and when to perform the home monitoring and how to contact the clinical trial team. There will be follow up training calls to perform a remote ECG, within 2 weeks; 4 weeks and 8 weeks from discharge.

The patient will be informed that monitoring is available Monday - Friday between 07:00 and 23:00. If the patient develops chest pain wakening from sleep or other significant cardiovascular symptoms during the night, the patient will be advised to contact 111 or 999. If a participant does not hear from the trial cardiology team within 15 minutes of trigging an ECG, participant should do what he/she normally would do by contacting 111 or 999.

A total of 338 patients will be randomised 1:1 using computer randomisation software to the 2 trial arms over 9 months. Patients in the intervention group will be discharged from hospital with the telemedicine package as outlined above. In the *active* arm when patients seek medical attention by performing an ECG, the data provided by the telemedicine package will be acted upon, as appropriate, by the trial team. Conversely, in the *control* arm, standard routine clinical care will be carried out, with remote follow up over the phone at 3, 6 and 9 months.

In the *active* arm, the patient's smartphone will be paired with the SHL 'Smartheart' and they should perform an ECG with the 'Smartheart' before discharge. Depending on which telemedicine package the participant chooses; they will receive a phone call or one of the trial cardiologists will conduct an emergency video consultation using the Current Health platform. When the patient experiences chest discomfort, acute breathlessness, sustained palpitations or other cardiovascular symptoms and requires attention, they will take an ECG, BP and oxygen saturation as per their training. A text SMS message is activated which goes to the trial phone (Active: Mon – Fri between 07:00 to 23:00). The TC receives the SMS text and then contacts the patient to obtain details. The cardiologist will have access to a high-quality ECG trace, as well as blood pressure, pulse rate and oxygen saturations (if using the SmartHeart + BP/Sats), as well as respiratory rate and body temperature reading (if using the SmartHeart + Current Health package). This clinical information, coupled with the history from the patient and guided by the clinical decision support algorithm (Appendix 3), will inform the trial cardiology team on the most appropriate course of further management (1 of 4 possible scenarios, as outlined in the flow diagram above). On each occasion that the telemedicine package is used, the outcomes will be documented by the trial cardiologist on the electronic record system and detailed on a study record form, with appropriate follow up arranged for that specific event.

Patients will retain the telemonitoring package for the first 6 months following discharge, with remote follow up over the phone at 3 months, and again at 6 months and 9 months. The telephone review will assess any admissions/ presentations to emergency services and the use of the telemedicine package. Patients will undertake a self-filled quality of life questionnaires [The Short Form (36) Health Survey and The Seattle Angina Questionnaire-7 (SAQ-7)] at baseline pre-discharge, as well as at 3, 6 and 9 months post-discharge.

A total of 338 patients will be randomised 1:1 to the two management arms over 9 months.

3.1. STUDY OUTCOME MEASURES

The primary outcome is:

- All hospital readmission rates (formal admissions and not emergency room visits) at 6 months of follow up in intervention vs control groups.

The secondary outcomes are:

1) Total length of stay (LOS) at 3, 6, and 9 months.
2) Myocardial infarction, stroke and all-cause mortality at 9-months. We will also report data on heart failure and cardiovascular mortality and morbidity.
3) Medical intervention for acute coronary syndromes or heart failure, including coronary angiography/ angioplasty, injectable therapy or oxygen therapy.
4) Emergency Room visits not requiring admission or further intervention.
5) 9 months readmission rates (with 3 months without intervention) to investigate learning effect of intervention.
6) Patient-reported quality of life outcome measures (weighted to treatment satisfaction domains).

4. PARTICIPANT ENTRY

4.1. PRE-REGISTRATION EVALUATIONS

No specific pre-registration evaluations are required. All study assessments are made post-randomization. The study will be conducted at the Hammersmith Hospital. Patients will be recruited from the cardiology clinical areas of Hammersmith Hospital (i.e. the Heart Assessment Centre, Cardiac Day Ward or A7 Ward). We will recruit patients who are discharged from hospital following an acute myocardial infarction.

4.2. INCLUSION CRITERIA

1. ACS Patients diagnosed with elevated high-sensitivity troponin I who have undergone coronary intervention for non-ST-segment acute coronary syndrome (NSTE-ACS) or ST-segment elevation myocardial infarction (STEMI) or unstable angina (UA).
2. In addition, the patients must have at least one additional cardiovascular risk factors:
    - Current or ex-smoker
    - Diagnosed with hypertension
    - Diabetes mellitus
    - Hypercholesterolaemia.
    - Male aged > 50 years.
3. The patient must have access to a smartphone or smart device.

4.3. EXCLUSION CRITERIA

1- The inability to apply the telemedicine equipment/ transmit the ECG via Bluetooth or cellular connectivity/ engage in a virtual consultation.
2- Life expectancy of 9 months or less.

4.4. WITHDRAWAL CRITERIA

The participant would need to be fully aware, in order to participate further in the trial, so If a participant loses capacity to consent during the study, they will be withdrawn.

5. ADVERSE EVENTS

5.1. DEFINITIONS

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward and unexpected medical occurrence or effect that:

- **Results in death**

- **Is life-threatening** – *refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe*

- **Requires hospitalisation, or prolongation of existing inpatients' hospitalisation**
- **Results in persistent or significant disability or incapacity**
- **Is a congenital anomaly or birth defect**

Medical judgement should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

5.2. REPORTING PROCEDURES

All adverse events should be reported. Depending on the nature of the event the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

5.3.1 Non serious AEs

All such events, whether expected or not, should be recorded- it should be specified if only some non-serious AEs will be recorded, any reporting should be consistent with the purpose of the trial end points.

5.3.2 Serious AEs

An SAE form should be completed and emailed to the Chief Investigator within 24 hours. However, relapse and death due to myocardial infarction, and hospitalisations for elective treatment of a pre-existing condition do not need reporting as SAEs.

All SAEs should be reported to the London - Fulham Research Ethics Committee where in the opinion of the Chief Investigator, the event was:

- 'related', ie resulted from the administration of any of the research procedures; and
- 'unexpected', ie an event that is not listed in the protocol as an expected occurrence

Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the NRES SAE form for non-IMP studies. The Chief Investigator must also notify the Sponsor of all related and unexpected SAEs.

Local investigators should report any SAEs as required by their Local Research Ethics Committee, Sponsor and/or Research & Development Office.

Contact details for reporting SAEs
RGIT@imperial.ac.uk
CI email (and contact details below)
Fax: +44(0)2076811775, attention
Please send SAE forms to: r.khamis@imperial.ac.uk
Tel: +44(0)2075946842 (Mon to Fri 09.00 – 17.00)

6. ASSESSMENT AND FOLLOW-UP

A total of 338 patients will be randomised 1:1 to the two management arms over 9 months. Patients will be randomised in a 1:1 fashion using computer randomisation software to the 2 trial arms. Patients in the intervention group will be discharged from hospital with the telemedicine package as outlined above. However, in the *active* arm when patients seek medical attention, the data provided by the telemedicine package will be acted upon, as appropriate, by the trial cardiologist. Conversely, in the *control* arm, stranded routine clinical care carried out, with remote follow up over the phone at 3 months, and again at 6 and 9 months.

The research team and the direct care team will review all the results/findings including the incidental findings and these findings will be documented. Additionally, these findings will be reported to the chief investigator of this study, the participant's GP, clinical care team.

To measure our primary and secondary outcomes, we will use the informatics infrastructure at Imperial College Healthcare NHS Foundation Trust to extract follow-up data on hospital readmissions from primary and secondary care electronic health care records at the defined time periods of 6 and 9 months, as per protocol.

In particular, for those admitted to Imperial College Healthcare NHS Trust, we will use the NIHR Health Informatics Collaborative to extract data on patient demographics, hospital admission details including length of stay and discharge diagnosis, blood test results, imaging, and procedure requests (and results, where available). For those admitted to a different hospital within North West London, we will be using the Whole System Integrated Care (WSIC) dataset. Whilst the WSIC dataset does not hold granular procedural or blood test data, patient demographic and hospital admission data will be accessible for extraction

We plan to run this pilot study for 22-month, from December 2021 to September 2023, recruiting 338 patients and following them each up for 9 months. The intervention will be stopped at 6 months but both groups will be followed up until 9 months. We intend to be able to analyse the full results at 22-month from first recruitment, after follow-up has completed and initial data analysis taken place.

The end of study happens by the end of recruiting 338 patients and following them each up for 9 months.

7. STATISTICS AND DATA ANALYSIS

We estimated that the baseline event rate for readmission in the standard therapy arm would be 30% readmission at 6 months, with a relative hazard of 0.5 for the telemedicine arm. Assuming a high censoring rate of 15% in each arm due to competing risks and withdrawal of consent due to difficulty with the telemedicine protocol, we calculated a total of 338 patients with a 1:1 randomisation ratio would provide 80% power at a two tailed alpha of 0.05.

8. REGULATORY ISSUES

8.1. ETHICS APPROVAL

The Study Coordination Centre has obtained approval from the London - Fulham Research Ethics Committee (REC) and Health Research Authority (HRA). The study must also receive confirmation of capacity and capability from each participating NHS Trust before accepting participants into the study or any research activity is carried out. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

8.2. CONSENT

Informed consent will be sought after discussion between the recruitment team and patient. Patient information sheets will be freely available. To be randomised and proceed into the study patients will have to provide written consent and the trial consent form. All participants are free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment.

8.3. CONFIDENTIALITY

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act.

8.4. INDEMNITY

Imperial College London holds negligent harm and non-negligent harm insurance policies which apply to this study.

8.5. SPONSOR

Imperial College London will act as the main Sponsor for this study. Delegated responsibilities will be assigned to the NHS trusts taking part in this study.

8.6. FUNDING

King Khalid University (KKU) is funding this study. KKU funds the consumables for this project.

8.7. AUDITS

The study may be subject to audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Frame Work for Health and Social Care Research.

9. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through the trial team. There will be Steering, Safety and Endpoint committees appointed to oversee the study. Furthermore, a data monitoring committee will adjudicate the trial safety on a weekly basis.

10. PUBLICATION POLICY

Trial results will be released in several manuscripts providing outcomes of the trial as a whole. All publications and presentations relating to the trial will be authorised by the Trial Steering Committee. Named authors will include the Investigators from all participating investigational centres. We will aim to publish our findings and use this study to decide on a large multicentre randomised controlled trial.

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12. EXAMPLES APPENDICES

Appendix 1. Summary of investigations, treatment and assessments

Exam		Week of Treatment							
	Patient admitted with ACS nearing hospital discharge	1	2	3	4	8	12	24	36
Informed consent	X								
PIS provided to patient	X								
Patient recruited	X								
Confirmation that ACS Patients diagnosed with elevated high-sensitivity troponin I who have undergone coronary intervention for non-ST-segment acute coronary syndrome (NSTE-ACS) or ST-segment elevation myocardial infarction (STEMI) or unstable angina (UA).	X								
Confirmation that the patient would have adequate training prior to discharge for these two telemedicine packages by the local research fellow and cardiac research nurse, covering how and when to perform the home monitoring and contact the on-call cardiology team.	X								
Follow up training calls with these patients, to perform a remote ECG, within a few weeks from discharge.			X		X	X			
Self-filled quality of life questionnaire	X						X	X	X
3 months follow up (over the phone)							X		
6 months follow up (over the phone)								X	
9 months follow up (over the phone)									X

Appendix 2 – TELE-ACS trial workflow

Workflow	Person responsible	Comments
The electronic healthcare records will be automatically screened to identify cases that satisfy the following 'structured' data: Inclusion criteria: • ACS Patients (NSTEMI or STEMI or UA) and diagnosed with Elevation of hsTnI > upper limit of normal • Undergoing PCI during admission • 1 of following risk factors: • Hypertension • Diabetes Mellitus • Current or ex- smoker • Hypercholesterolaemia • Male aged > 50 years. • The patient must have access to smartphone Exclusion criteria: • The inability to apply the telemedicine equipment/ transmit the ECG via Bluetooth or cellular connectivity/ engage in a virtual consultation. • Life expectancy of 9 months or less.	HIC Team*	The HIC team will generate an eligibility criteria dataset based on screening the 'structured' data components of all inclusion criteria and specific exclusion criteria. Comorbidity data will be extracted using ICD-10 and SNOMED codes from historical patient encounters. A HIC patient list will be generated following this automated screen. A new patient list will be provided to the research team on a daily basis.
The research fellow/nurse will review the HIC patient list against all exclusion criteria.	Research Nurse	
Eligibility verified by Doctor	Research Fellow	
Consent form given to patient	Research fellow /Nurse	
PIS given to patient	Ward/ Research Team	
Eligible patients randomised	Research Fellow/Nurse	Electronic randomisation with age and sex matching
ACTIVE arm - Call ward team to determine if consent signed, not given or more information requested.	Research Fellow/ Nurse	Research Nurse will: • provide & discuss additional information • Collect consent forms • Ensure patients have adequate training prior to discharge for the telemedicine packages
CONTROL Arm - Call ward team to determine if consent signed, not given or more information requested	Research Fellow/Nurse will provide & discuss	Research Fellow/Nurse will: • Provide & discuss additional information • Collect consent forms • inform ward team that no other intervention is required
Daily review of results	Research Fellow	Database will automatically alert for any safety issues that we specify e.g. Dangerous ECG rhythms.

		Research Team will: • review the data and any alerts • check clinical team are aware for review any potential risk to participants.
Safety monitoring	Research fellow	The chief investigator and the research team will review any adverse events in case study need to be stopped early.
When patient discharged, there will be a follow up training calls with these patients, to perform a remote ECG, within a few weeks from discharge	Research Fellow	Ensure patient discharged will have a follow up training calls with these patients, to perform a remote ECG, within 2 weeks; 4 weeks and 8 weeks from discharge
Self-filled quality of life questionnaire	Research Fellow	Patients will undertake a self-filled quality of life questionnaire at baseline pre-discharge, as well as at 3, 6 and 9 months post-discharge.
3-month follow-up	Research Fellow	Patient will receive remote follow up over the phone by the Research Fellow at 3 months
6-month follow-up	Research Fellow	Patient will receive remote follow up over the phone by the Research Fellow at 6 months
9-month follow-up	Research Fellow	Patient will receive remote follow up over the phone by the Research Fellow at 9 months

***HIC Team:**
The NIHR Health Informatics Collaborative (HIC) was initially made up of five BRCs and their respective NHS Trusts and university partners – Oxford University Hospitals NHS Foundation Trust, Imperial College Healthcare NHS Trust, Guy's and St Thomas' NHS Foundation Trust/Kings College Hospital NHS Foundation Trust, Cambridge University Hospitals NHS Foundation Trust and University College London Hospitals NHS Foundation Trust. Since then the collaborative has expanded to include 23 NHS Trusts from across England.

The aim of the HIC is to improve the availability and quality of routinely captured hospital data and to make it available for multi-site translational research. The collaborative then uses this data in an anonymised form to answer pressing clinical and research questions, helping us understand the complex care delivered in the NHS and how care can be improved to provide the best services to patients.
Collecting data directly from electronic patient record systems drastically reduces the time and cost for data collection for research and allows for the creation of much larger datasets compared to traditional research projects, which rely on recruiting patients individually.

The use of routinely captured data does however also bring its own challenges. The fact that each participating NHS site has its own electronic patient record system means that data are captured differently at each trust; this can make the process of compiling all sites' data into one dataset challenging. Additionally, not all data are collected electronically at each site, and large amounts of crucial electronic data are often recorded in free text rather than in a structured format.

The HIC overcomes these issues by creating data warehouses at each site that read in and transform data to standardised structures and formats, validating and cataloguing data so that it is clear what the data was captured for and how it should be used. The collaborative also has projects running that aim to extract structured data from free text and share methods and codes across the NHS to reduce duplication of methods.

Appendix 3. Clinical decision support algorithm

Assessment Categories	Scoring Criteria	
Symptoms	Palpitations	Absent
		Present
	Chest Pain	No Symptoms
		New or worsening chest Pain
	Shortness of breath (SOB)	Absent
		New or worsening SOB
	Dizziness	Absent
		Presyncope
		Syncope
Heart Rate	Heart rate 50 to 110 bpm	
	Heart rate 110 -150 bpm	
	Heart rate 35 -50 bpm	
	Heart rate ≥150 bpm	
	Heart rate <35 bpm	
Blood Pressure	SBP 90 – 170 mmHg	
	SBP ≥170 mmHg	
	SBP <90 mmHg	
Saturation (SpO2)	100% - 94%	
	93% - 90%	
	< 89%	
ECG	Normal sinus rhythm (HR: 50 - 100 bpm)	
	New Sinus tachycardia (HR ~120 bpm)	
	New Sinus bradycardia (HR <50 bpm)	
	New Atrial arrhythmia: Atrial flutter & Atrial fibrillation	
	New horizontal or downsloping ST-depression ≥ 0.5 mm in two contiguous leads and/or T inversion > 1 mm in two contiguous leads with prominent R wave or R/S ratio > 1	
	Severe bradycardia (HR <35 bpm) or complete heart block	
	New Left bundle branch block (LBBB)	
	Ventricular tachycardia	
	New ST-elevation at the J-point in two contiguous leads with the cut-point: ≥ 1 mm in all leads other than leads V2–V3 where the following cut-points apply: ≥ 2mm in men ≥ 40 years; ≥ 2.5 mm in men < 40 years, or ≥ 1.5 mm in women regardless of age	

The action taken post assessment- Intervention:

1. All green - Reassure and routine follow up with cardiology or GP as previously planned
2. One amber - GP visit
3. Two ambers or more- A and E or if not possible 999.
4. One red – 999