1. PROTOCOL SYNOPSIS

**Study title**
TeleClinical Care Cardiac - Efficacy and safety of adjunctive virtual models of care in the secondary prevention of cardiovascular events

**Short title**
TCC-Cardiac

**Protocol version**
Version 5.0

**Study Objective**
The overall objective of the TCC Cardiac study is to examine the comparative efficacy of the TCC-Cardiac smartphone app-centric model of care and its patient messaging component as standalone (TCC-Text), as an adjunct to usual care in patients who are being discharged home following an acute cardiac event.

**Study Design**
Prospective, multicentre pragmatic trial. Patients admitted with myocardial infarction (MI) or decompensated heart failure (HF) being discharged home will be allocated to 1 of 3 cohorts, using predefined criteria according to their access to technology in a pragmatic design, including 1) TCC-Cardiac randomisation, 2) TCC-text randomisation, or 3) usual care registry. Cohort 1: patients will be randomised at point of hospital discharge in a 1:1 ratio to the TCC-Cardiac program in addition to usual care, or to usual care alone. Cohort 2: patients will be randomised 1:1 to receive supportive text messages (TCC-Text) in addition to usual care, or to usual care alone. Cohort 3 is a registry of patients discharged home per usual care.

Randomisations will be stratified by primary diagnosis (HF vs MI) and enrolling site. Total enrolment in each cohort will be capped by the primary diagnosis to aim for approximately 50% HF and 50% MI in the study population.

**Primary end point**
Unplanned hospital readmission at 6 months.

**Secondary end points**
Composite of death, myocardial infarction, stroke, unplanned coronary revascularisation and unplanned hospital readmission at 30 days, 6- and 12-months

Individual components of composite secondary end point at 30 day, 6- and 12-months

Unplanned cardiac hospital readmissions at 30 days, 6- and 12-months

Cost effectiveness at 6 and 12 months

Cardiac rehabilitation completion rates

Guideline recommended medications and doses at 6 and 12 months (HFrEF patients)

Medication compliance
Additional end points at baseline and 6 months (Cohort 1 only):

- Quality of life
- Fasting LDL and HDL
- BP
- Waist and hip circumference, BMI
- Exercise capacity (6-minute walk test)
- Mental wellbeing

**Planned sample size**

2500 patients comprising 1000 patients in the main randomisation (Cohort 1), 1000 patients randomised in cohort 2 and 500 patients in the cohort 3 registry.

**Study criteria**

**Inclusion criteria**

- Age ≥ 18 years
- Being discharged home following admission for acute Cardiac event (MI) or decompensated Heart Failure (HF)
- Provides written informed consent

**Exclusion criteria**

- Cognitive Impairment
- Limited English prohibiting adequate operation of the app, comprehension of messages, and/or communication with remote monitors
- Terminal illness
- Patients who plan to travel overseas within the first 30 days of joining the study
- Enrolled in another active study
- High chance in the opinion of the investigator that the potential participant will not or cannot adhere to study requirements

**Cohort eligibility and assignment**

- Patients who have a compatible smartphone and the capacity to use the TCC-Cardiac app will be assigned to cohort 1 and randomised to TCC Cardiac solution vs usual care alone.
- Patients who do not meet the above criteria but have a mobile phone and capacity to receive and understand text messages, will be assigned to cohort 2 and randomised to TCC-Text vs. usual care.
- Consecutive patients who do not meet the above criteria for cohorts 1 or 2 will be assigned to cohort 3, the usual care registry.

**Study procedure**

Potential participants will be screened in-hospital and approached prior to discharge. Eligible patients who provide informed consent will be enrolled and allocated to one of the 3 study cohorts. Baseline characteristics will be collected, and patients in Cohorts 1 and 2 will be randomised in a 1:1 ratio into either the control arm or the intervention arm using a randomisation schedule created by
an independent statistician. The schedule will be kept secure in the web-based application REDCap.

Cohort 1. Participants randomised to intervention will receive access and support to use the TCC app, as well as wireless devices for measuring blood pressure, pulse rate and weight. HF patients will also receive a device for measuring oxygen saturation. Data from the app is transferred to a web-based online portal (KIOLA) which will be monitored by a central research team on weekdays during business hours. If patient parameters meet predetermined criteria (e.g., >2 kg weight gain over 2 days), an alert will be triggered for review by the central research team. Upon review, the patient and/or the medical team may be contacted if appropriate. This will be supplementary to, and work in concert with, the usual cardiovascular care available at each site. Patients in the control group will receive usual care alone.

Cohort 2. Participants randomised to intervention will receive text messages on their mobile phone in addition to usual care.

All patients will have final follow-up at 12 months.

**Sample size calculation**

Pilot randomised data demonstrated a 34% reduction in the rate of 6-month readmissions in an analogous population associated with enrolment in the TCC solution. Using marginally more conservative assumptions in the power calculations, 1000 patients in Cohort 1 provides 90% power to detect a 30% reduction in events from 35%, with a two-sided alpha of 0.05 and allowing for an additional 10% for loss to follow-up and study withdrawal.

**Duration of the study**

The total duration of the study is 2 years. Each patient will be followed for 12 months post-study enrolment.
2. STUDY FLOW CHART

[Flow chart diagram]

Eligible Patients: Patients for discharge home following hospital admission with MI or decompensated HF

Patient screening including Access to technology

Compatible Smart Phone
Cohort 1

Non-compatible Mobile Phone
Cohort 2

No Mobile Phone
Cohort 3

Randomisation 1:1

TCC-Cardiac and usual care N=500
Usual care alone N=500

TCC-Text and usual care N=500
Usual care alone N=500

Usual care registry N=500