A risk-guided disease management and tele-rehabilitation program to reduce re-admissions in coronary artery disease (Risk-Guided CAD)

PROTOCOL

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- **i.** Heart Foundation Vanguard Grant (APP ID: 104773)
- **ii.** HCF Research Foundation
- **iii.** Baker Department of Cardio-metabolic Health
- **iv.** Perpetual IMPACT funding (IPAP 2020/0606)

CLINICAL TRIAL REGISTRATION

The Risk-Guided CAD study is registered with the Australian New Zealand Clinical Trials Registry (ANZCTR No. TBA).

ETHICS

Ethics approval was obtained from the Alfred Hospital Ethics Committee (Project number 266/21).

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Table 1: Study outline

			Follow-up		
	Screen	**Baseline visit**	**30 days**	**90 days**	**12 month visit**
Eligibility (inclusion/exclusion)	**X**				
Informed consent	**X**				
PEGASUS-TIMI 54[1] risk evaluation	**X**				
Medical background	**X**	**X**			
Randomisation		**X**			
Questionnaires		**X**			**X**
Clinic assessment		**X**			**X**
Venous blood sample		**X**			**X**
Exercise capacity		**X**			**X**
Physiology/cardiac function (echocardiography)		**X**			**X**
Quality of care assessment				**X**	
Outcome data			**X** (medical record review)	**X** (medical record review)	**X**

1. SUMMARY

Coronary artery disease (CAD) is a major cause of ill health in Australia and is an expensive disease group to treat owing to costly hospital readmissions. Many of these readmissions can be prevented with improved management following a diagnosis of CAD. The need to achieve effective secondary prevention is likely to remain as great or increase as a consequence of the COVID-19 pandemic. Therefore, predicting higher risk patients with the greatest likelihood of recurrent ischaemic events permits targeting of chronic disease management programs to reduce hospital readmissions.

Disease Management Programs (DMP) and cardiac rehabilitation programs are known to improve long-term cardiovascular outcomes and quality of life. However current approaches to traditional models have tended to be insufficient and during COVID-19, the practice of social isolation has disrupted the typical delivery and access to routine health care. e-Health and medical-related apps offer a valuable addition for patient care and for enhancing health service delivery. Integrating digital solutions with nurse management will maintain access to secondary prevention, whilst minimising COVID-19 exposure and providing benefit to those living in areas where residents have greater risk factor burden and socioeconomic disadvantage.

2. BACKGROUND

2.1 CAD is the greatest cause of morbidity and mortality in Australia

CAD remains the number one killer of Australians[2], is among the most expensive disease groups to treat[3] and continues to be a disease burden[4]. CAD accounts for almost half of all cardiovascular disease (CVD) deaths and nearly one third of CVD-related hospitalisations[5]. Readmissions to hospital for CAD patients are among the highest of any disease; our CIs showed, using contemporary data from a Queensland state-wide linkage study of ≈140,000 CVD patients, that 37% of CAD patients were readmitted within 90 days post discharge (Table 1). This rate was greatest for younger patients of working age (i.e. <65 years). CAD results in the biggest productivity losses due to death and absenteeism compared to other types of CVD.

Table 1. 90-day readmission rates for major types of CVD in Queensland (2010)

Condition type	90 day readmission (all)	90 day readmission (aged <65 years)
Coronary artery disease	37% (n=7,396)	42% (n=8,439)
Heart Failure	49% (n=1,889)	13% (n=511)
Stroke	33% (n=559)	38% (n=636)

2.2 Health disparities are greatest among low socioeconomic populations

CVD affects people from lower socioeconomic groups more than people from higher socioeconomic groups. In general, population data show that individuals from the lowest socioeconomic groups (i.e. greatest disadvantage) have higher rates of chronic conditions, a shorter life expectancy, more health risk factors and a greater burden of disease than people in the highest groups (of least disadvantage)[6].

The local government area of Wyndham (south-west of Melbourne) [7], whereby the Baker has established a clinical trials research facility, has a moderate level of relative socio-economic disadvantage. Compared to Greater Melbourne in 2016, fewer people in Wyndham had a Bachelor or Higher degree qualification (24.4% vs. 27.5%), had completed year 12 (or equivalent) schooling (58.2% vs. 59.4%), owned their own home (19.2% vs. 29.0%) and more people were unemployed (8.2% vs. 6.8%) and had a mortgage (46.3% vs. 34.3%). Wyndham is identified as a heart attack hot spot, in part due to[8]:

- Being overweight and obese - 83% compared to Victorian average 51% [32% higher]
- Being insufficiently physical active - 56% compared to Victorian average 44% [12% higher]
- Smoking - 21% compared to Victorian average 17% [4% higher].

2.3 Secondary prevention models of care

Nurses can play a key role in providing case management in secondary prevention, with potential cost-savings via reduced and fewer days of hospitalisation. In heart failure, implementation of DMPs when transitioning from hospital to home can have clinical benefit through reduced hospital readmissions and mortality and improved standards and knowledge of health. These findings emphasise that nurse-led case management could be an effective strategy for managing patients.

Cardiac rehabilitation (CR) programs have demonstrated significant evidence of benefit on mortality, re-hospitalisation, psychological wellbeing, quality of life and CVD risk factors. However, traditional models for delivery of secondary prevention and CR programs are increasingly problematic, especially following the advent of COVID-19, and do not suit younger, busy, remote and/or socially isolated individuals. . To improve the current poor participation rates, different strategies for delivering CR programs using e-Health have emerged. In a systematic review, it was concluded that there was no need to rely on traditional hospital-based CR alone to deliver effective CR and community-based programs could be just as effective[9]. The COVID-19 pandemic has also disrupted traditional face-to-face program delivery. COVID-19 has affected patients' visits to health care professionals, clinical testing (e.g. imaging), pathology and attendance for CR. However, patients with CAD must still continue to receive management and support. Novel modalities of providing secondary prevention and CR can be enabled by e-Health and telehealth strategies thereby overcoming some of the barriers to the traditional delivery of health care delivery.

2.4 Using digital technology to strengthen DMPs

E-Health and medical-related apps offer a valuable adjunct for patient care and for enhancing health service delivery which is convenient, low cost and has broad population reach. Smartphones and digital devices are entrenched in everyday life. A report by Deloitte found a majority of middle-aged Australians use smartphones or tablets (75% of those aged 50-64 years)[10] and many users have downloaded and used a medical-related app[11]. In advanced chronic kidney disease, a smartphone-based self-management system was feasible and clinically useful[12] and in our own work using an avatar heart failure digital coach, patients had better knowledge, self-care and health related quality of life (*unpublished data*). These data give some assurance that integrating e-Health solutions with nurse management will improve patients' access to secondary prevention programs. E-health and telehealth strategies could help overcome some of the barriers to routine health care by improving accessibility and uptake. The potential for this multi-component innovative model of care in clinical practice will be tested using the SmartCR app by *Cardihab*.

2.5 Risk guidance of secondary prevention

In secondary prevention, the conventional risk assessment of a recurrent event/ rehospitalisation is that *all* patients are *equally* at high risk and should be treated *similarly*. However, risks are not distributed equally and may vary over time. Risk scores, such as the PEGASUS-TIMI 54 criteria[1] to select higher risk patients with the greatest likelihood of recurrent ischaemic events, permits targeting of DMPs to reduce hospital readmissions. CIs Huynh and Marwick have shown greater reductions via intensified nurse intervention in heart failure readmissions or death in patients with the highest risk of short-term (30-day) readmission[13] (Figure 1). More recently, these CIs have found from the Queensland state-wide linkage study that CAD patients at higher predicted risk stand to gain more from up-titration of cardio-protective therapies to target levels. Targeting DMPs to those most likely to benefit,

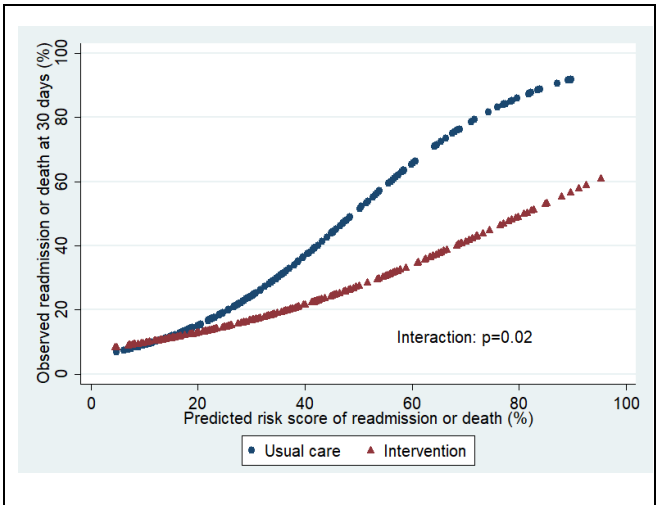

Figure 1. Relationship between predicted and observed 30-day events[13]

whilst still providing care to lower acuity risk patients, facilitates the allocation of available resources to manage those at higher risk compared to expending resources on patients less likely to be readmitted.

3. AIMS

We aim to test a nurse-led, technology-enabled model of health care delivery, called Risk-Guided CAD, to reduce readmissions following CAD, thereby enhancing recovery and survivorship. The objectives are to assess:

a. feasibility and acceptability of Risk-Guided CAD;
b. effectiveness of Risk-Guided CAD in reducing readmissions or death after CAD

4. HYPOTHESIS

We envisage that a novel risk-guided DMP will be favourable to patients and associated with high-level participation. We hypothesise that high-risk patients randomised to Risk-Guided CAD will have reduced hospital readmissions or death compared with those randomized to usual care.

5. STUDY DESIGN

Risk-Guided CAD is an effectiveness and feasibility trial of a technology-enabled DMP to reduce hospital readmissions in CAD patients with greater socioeconomic disadvantage.

Patients with CAD will be eligible to undergo risk-evaluation by the recruitment nurse, using a previously developed and validated risk score (PEGASUS-TIMI 54)[1]. Those classified as low-risk [score <6] will receive usual care (control group) consisting of the uniform application of a standard management plan. High-risk patients [score ≥6] according to PEGASUS-TIMI 54 criteria will be randomised to either usual care or a remote DMP (intervention group, our Risk-Guided CAD), (Figure 2). All participants will be assessed at baseline and 90 days (primary endpoint), with short-term and long-term follow-up at 30 days and 12 months, respectively (secondary endpoints).

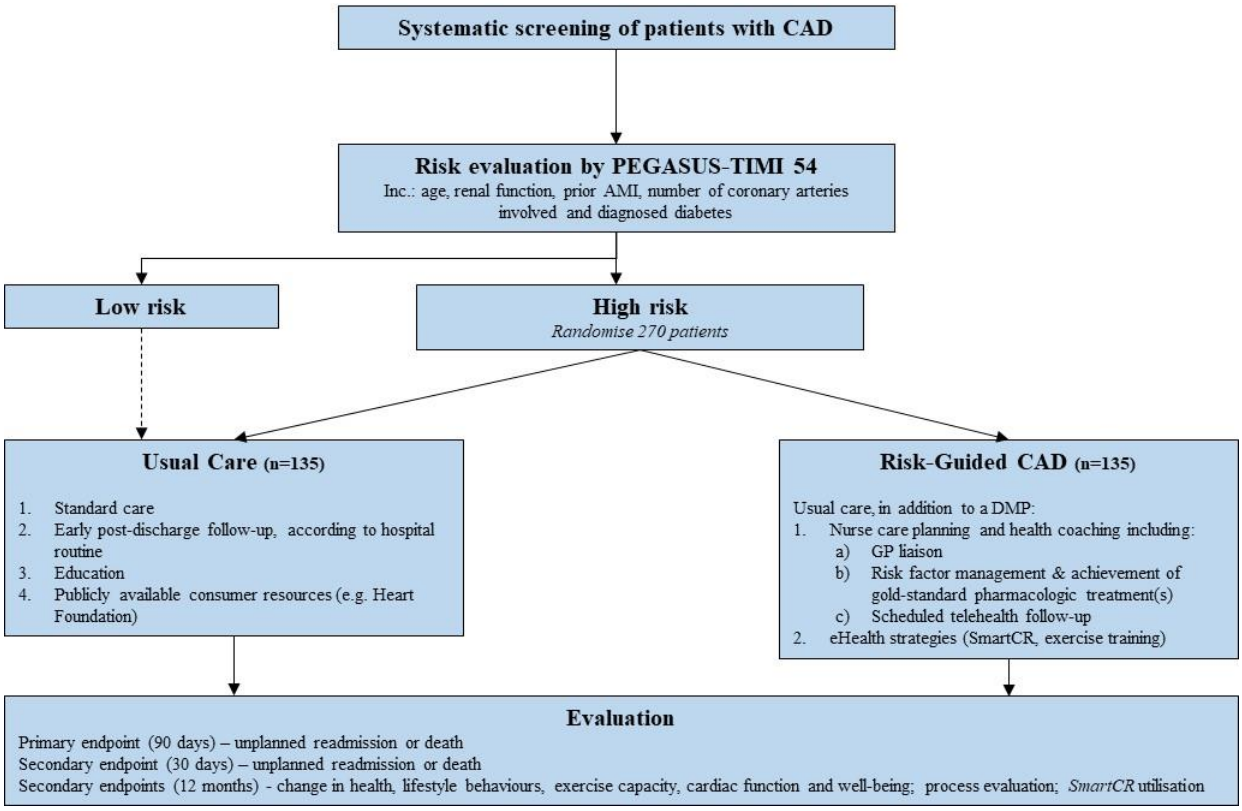

Figure 2. Risk-Guided CAD study schema.

6. END POINTS

6.1 Primary end-point

The primary endpoint is unplanned all-cause readmission or death at 90 days post-discharge.

6.2 Secondary end-points

A secondary endpoint will measure short-term unplanned all-cause readmission or death at 30 days post-discharge.

Other secondary outcome measures will include changes in quality of life, exercise capacity and cardiac function at 12 months. Process evaluation (including uptake, adherence and completion rates) of our Risk-Guided CAD program will also be undertaken. *SmartCR* will be evaluated by measures of app engagement by quantifying data entry events and other indicators of program participation.

7. RECRUITMENT

Recruitment will occur via HeartWest cardiology clinics at the Baker Clinical Trials Research Centre in Wyndham. This facility provides health services for a geographic area where residents generally have greater CVD burden and socioeconomic disadvantage, and are the primary target population for this proposed research. HeartWest personnel (or authorised study personnel granted access) will routinely screen (2-3 times weekly) appointment bookings and discharge summaries to identify potentially eligible patients from the HeartWest database. This list will be provided to the study co-ordinator and eligible patients will be contacted by a Baker study team member via telephone to introduce and explain the study. For interested individuals, a letter of invitation and Participant Information and Consent Form (PICF) will be posted and these patients will be given 3-5 days to review and consider participation. A Baker study team member will make a telephone follow-up call to seek their interest to make an appointment to undergo a baseline visit, hopefully within 2 weeks post-discharge. At this visit, informed written consent will be obtained by the cardiac nurse.

8. ELIGIBILITY

Eligible patients are identified and selected according to the following criteria:

Inclusion criteria:

a. Aged between 30 to 74 years; AND
b. Hospitalised (must be within 14 days post discharge) with CAD or other eligible cardiac procedure or condition including AMI (STEMI or NSTEMI), unstable angina, coronary artery bypass grafting or percutaneous coronary intervention; AND
c. Defined as higher risk (score ≥ 6) by PEGASUS-TIMI 54[1] criteria
d. Eligible for Medicare.

Exclusion criteria:

a. Inability to provide written informed consent; OR
b. Non-English speaking; OR
c. Inability to attend clinic visits; OR
d. Inability to engage with an app due to low technical literacy or lacking access to a smartphone or wi-fi; OR
e. Hospitalised with a primary diagnosis of heart failure; OR
f. Requiring palliative care; OR
g. Concomitant terminal non-cardiac illnesses that could influence 12-month prognosis (e.g. advanced malignancy); OR
h. Participating in another study with a potential but unknown effect on outcome.

9. RANDOMISATION

Using a pre-determined computer generated sequentially numbered randomisation schedule, eligible participants will be allocated in block sizes of 20 into one of two trial arms according to a 1:1 ratio. REDCap will be used to obtain the next random allocation to eliminate selection bias by concealing it from nurses. Due to the nature of the intervention, blinding participants and nurses will not be possible.

10. PROCEDURES

Risk-Guided CAD is an effectiveness and feasibility trial of a DMP to reduce hospital readmissions in CAD patients with greater socioeconomic disadvantage. We seek to do this by adopting innovative approaches to:

a. a community-based secondary prevention DMP;
b. supported by a novel e-Health app (*SmartCR* developed by CardiHab) to address components of a CR program; and
c. selection of higher risk patients for appropriate management by validated (PEGASUS-TIMI 54) criteria[1].

10.1 Risk evaluation

Patients will be stratified based on their level of predicted risk. PEGASUS-TIMI 54 criteria[1] outlined in Table 2 will be used for selection of high risk patients with a score ≥6 (who have ~3-4 times higher risk of a secondary event than the remainder).

Table 2. PEGASUS-TIMI 54 criterion and weighted scores

	Weighted score
Age > 65 years	2
eGFR <60 ml/min/1.73m^2	2
Prior AMI	4
Multi-vessel CAD	3
Diabetes mellitus	2
Maximum score	**13**

10.2 Baseline measures

Eligible individuals will be invited to attend the Baker clinic at Wyndham to undergo a baseline assessment. Data will be collected by electronic questionnaire using REDCap and sent automatically to participants at specific time points, with assistance from a cardiac nurse, if required. Clinical assessments will be conducted by registered study nurses and specialist personnel:

a. Medical background details will be abstracted from clinical records including –
    i. In-hospital details and assessment of clinical features (including severity and number of affected vessels);
    ii. Pathology (full blood count, renal function, liver function, troponin, lipid profile, HbA_{1C}, B-type natriuretic protein and hs-C-reactive protein);
    iii. Co-morbidities and CVD risk factors
    iv. Medications.

b. Questionnaires - to determine:

i. Socio-demographic indicators: age, sex, marital status, living alone, language background, ethnicity, income and education.

ii. Lifestyle factors: smoking, diet and alcohol.

iii. Mental health: to assess depression via the Patient Health Questionnaire (PHQ-9) [14] and anxiety via the Generalised Anxiety Disorder Assessment (GAD-7) [15]

iv. Quality of life: via the Assessment of Quality of Life (AQoL-8D) [16] questionnaire.

v. Questions about patient satisfaction and acceptability of the intervention *(intervention participants only)* will occur at 90 days post baseline.

c. Health assessments -

i. *Clinical assessment*: BP, heart rate, anthropometry (height, weight, BMI), abdominal and hip circumference and electrocardiogram (ECG), if not performed in hospital.

ii. *Pathology (intervention group only):* any outstanding tests listed in 10.2.a.ii that were not collected as part of the index hospitalization (estimated 15-45 ml). At 4-6 weeks post-hospitalisation, a lipid profile will be requested.

iii. *Mild cognitive impairment*: assessed via the Montreal Cognitive Assessment [17].

iv. *Exercise capacity:* via cardiopulmonary exercise testing and quantified as VO_2 peak. Additional important prognostic markers will also be assessed including ventilatory efficiency (VE/VCO_2 slope), heart rate reserve and recovery.

v. *Physiology/cardiac function (if not done in-hospital)*: via two-dimensional echocardiography (including left ventricular ejection fraction, left ventricular volume index, left atrial volume index, right atrial pressure, pulmonary arterial systolic pressure and estimated LV filling pressure (E/e'), using standard techniques and procedures[18]

d. Process evaluation - will be conducted to assess contextual factors that may influence study outcomes, as well as intervention fidelity, maintenance and reach, consistent with Medical Research Council guidance[19].

i. *Program fidelity*: The cardiac nurse will record details of program delivery for each intervention patient; details of program use will also be available via the *SmartCR* app and from patients when they undergo their assessments. The number and proportion of patients engaging with the online CardiHab platform compared to personalised exercise program sessions will be determined. Attendance and topics addressed at telehealth appointments will be recorded.

ii. *Qualitative interviews*: will be undertaken with 20 consumers, 5 GPs and cardiologists and 2 cardiac telehealth nurses. Interviews will explore barriers and facilitators to delivery of the intervention. Interviews will be recorded either via Zoom or a digital audio recorder and later deleted following transcription by an external service within 10-15 days. Information gathered will be securely stored in a password protected folder on the Baker Heart and Diabetes network, with access restricted only to authorised study personnel.

11. FOLLOW-UP PROCEDURES

Patients will be followed up for a total of 12 months, with clinic reviews at 12 months. Clinic reviews in Melbourne will occur at the Baker Clinical Trials Research Centre in Wyndham.

At 30 and 90 days follow-up, data on readmissions will be collected from medical records and at 90 days, patients will complete a questionnaire to assess the quality of CAD-specific care received via the Patient Assessment of Chronic Illness Care (PACIC) [20].

At 12 months follow-up, a brief clinical assessment, including pathology blood tests noted in 10.2.a.ii (estimated 15-45 ml) and some questionnaires (10.2.b) will be repeated. Repeated echocardiogram and exercise capacity will also be performed by personnel blinded to the patient's treatment group.

12. INTERVENTION GROUP – DISEASE MANAGEMENT PROGRAM

Intervention patients will receive the Risk-Guided CAD program after hospital discharge in addition to standard care. Risk-Guided CAD will follow the evidence-based direction and guidance on Phase 2 CR program content, as recently outlined by the Heart Foundation[21]. Risk-Guided CAD will be led by a nurse care co-ordinator who will oversee delivery of a multi-component intervention and remain responsible for assessing participant progress. Key features include the following.

12.1 Nurse care planning and health coaching

Nurses will be appropriately trained to deliver a patient-centred program and to facilitate transition of care from hospital to home via:

a. *GP/Specialist liaison* - enabled via case conferences (by Zoom video-conference, phone or email) to review patient care plans and provide education opportunities to facilitate optimisation of therapy. Nurses will escalate any identified risks/gaps in service delivery and contribute to development of the care plan incorporating medication up-titration (completion of MBS Item 721 and 723 will facilitate referrals to other allied health providers or pharmacists as appropriate).

b. *Risk factor management* and *provision of gold standard pharmacologic treatments* in order to achieve ideal goal levels and ensure application of pharmacologic therapy[22] that is advocated to achieve maximal cardiac protection. Standard medical therapy will be administered to all patients, at the clinician's discretion[22]. Default medications for all patients are aspirin (or dual antiplatelet therapy if indicated), statin, β blocker and angiotensin converter enzyme inhibitor[22]. There will be no attempt to influence the selection of medications. However, the default position, arranged as part of transition care for intervention patients particularly those with LVEF <40%, will be a planned up-titration with consideration to other prescribed medications and any advice from the GP or cardiologist to the contrary (refer Table 3). Such advice might be provoked by side-effects such as hypotension (i.e. systolic BP <100mmHg) or bradycardia (i.e. heart rate <50/min), with these criteria pre-specified in a GP letter. Drug intolerance (e.g. to statin) will be addressed by a pre-specified drug substitution, preceded by statin withdrawal if necessary for symptoms. The GP will be notified in advance and GP appointments (fortnightly) will be made accordingly during the up-titration phase.

Table 3. An example of a planned up-titration of cardio-protective therapies in LVEF <40%

	Weeks since starting therapy								
	0	2	4	6	8	10	12	14	16
ACE-inhibitor: Ramipril (mg/day)	1.25	2.5	2.5	2.5	2.5	2.5	2.5	5	10
β blocker: Carvedilol (mg/day)	0	0	6.25	12.5	25	37.5	50	50	50
Statin: Atorvastatin (mg/day)	80	80	80	80	80	80	80	80	80

c. *Scheduled telehealth follow-up* (fortnightly x2, 4 weekly x2, 6 weekly x6) provided by the cardiac nurse via Zoom video-conferencing. The objective is to provide health education, guidance on lifestyle changes, ensure adequate medication supply and discuss any clinical signs and symptoms. GP and other medical appointments will also be reviewed. Behavioural counselling will help reinforce self-care and management plans.

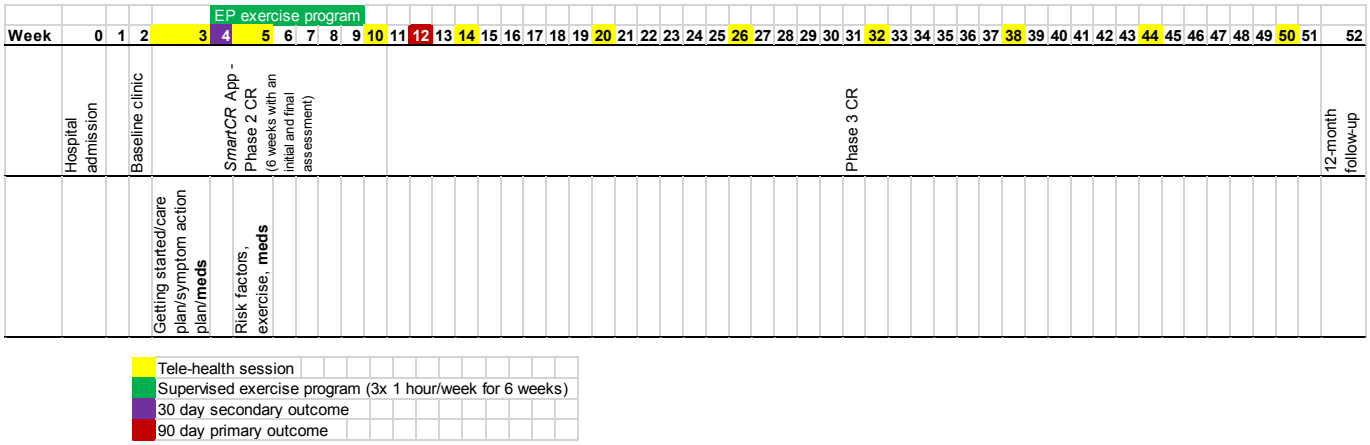

Figure 3. Schedule of tele-health sessions.

12.2 eHealth strategies

eHealth strategies will offer greater flexibility whilst enabling continued access to routine health care and services. Risk-Guided CAD will integrate healthcare practices into nurse care co-ordination that will be supported by the following electronic processes:

a. *SmartCR* is a smartphone/tablet compatible app developed by Cardihab which follows Australian guidelines to address all components of a Phase 2 CR program[23]. As shown in Figure 4, this health platform monitors health and exercise and delivers motivational and educational materials to patients via prompted tasks and links to audio, written articles and video files (including education on symptoms and disease management). Physical activity monitoring will be collected through self-report and the in-built pedometer. The whole program will be delivered over six weeks, according to weekly themes and elements. CR nurses will provide scheduled telehealth consultations of ~15 to 30 minutes each (as per Figure 3). The first two weeks after discharge will be dedicated to transition of care, medication reconciliation and up-titration, development of the care plan and GP communication. The *SmartCR* program will therefore start in study week 3 and be completed by week 10. Before commencing the program, all intervention patients will receive detailed program information and training on technology use. Technical support will be provided by a member of the study team or if necessary, Cardihab. Nurses will access *SmartCR* data and use this to guide behaviour change during telehealth follow-up.

b. ***SmartCR app data use and storage-***

Personal information and data collected in the Cardihab application will be securely stored on a cloud based server in Australia. This information will only be accessible to permitted individuals in the research team or clinicians given access by the research team via a clinical portal. Data stored on the app will remain for as long as the patient has the app on their phone. Data is synced to Cardihab's cloud storage and will be retained as per Australian Privacy Act Cth(1988) and Health Records Act. However, Cardihab has chosen to archive and store indefinitely on behalf of the owner Baker Heart and Diabetes Institute.

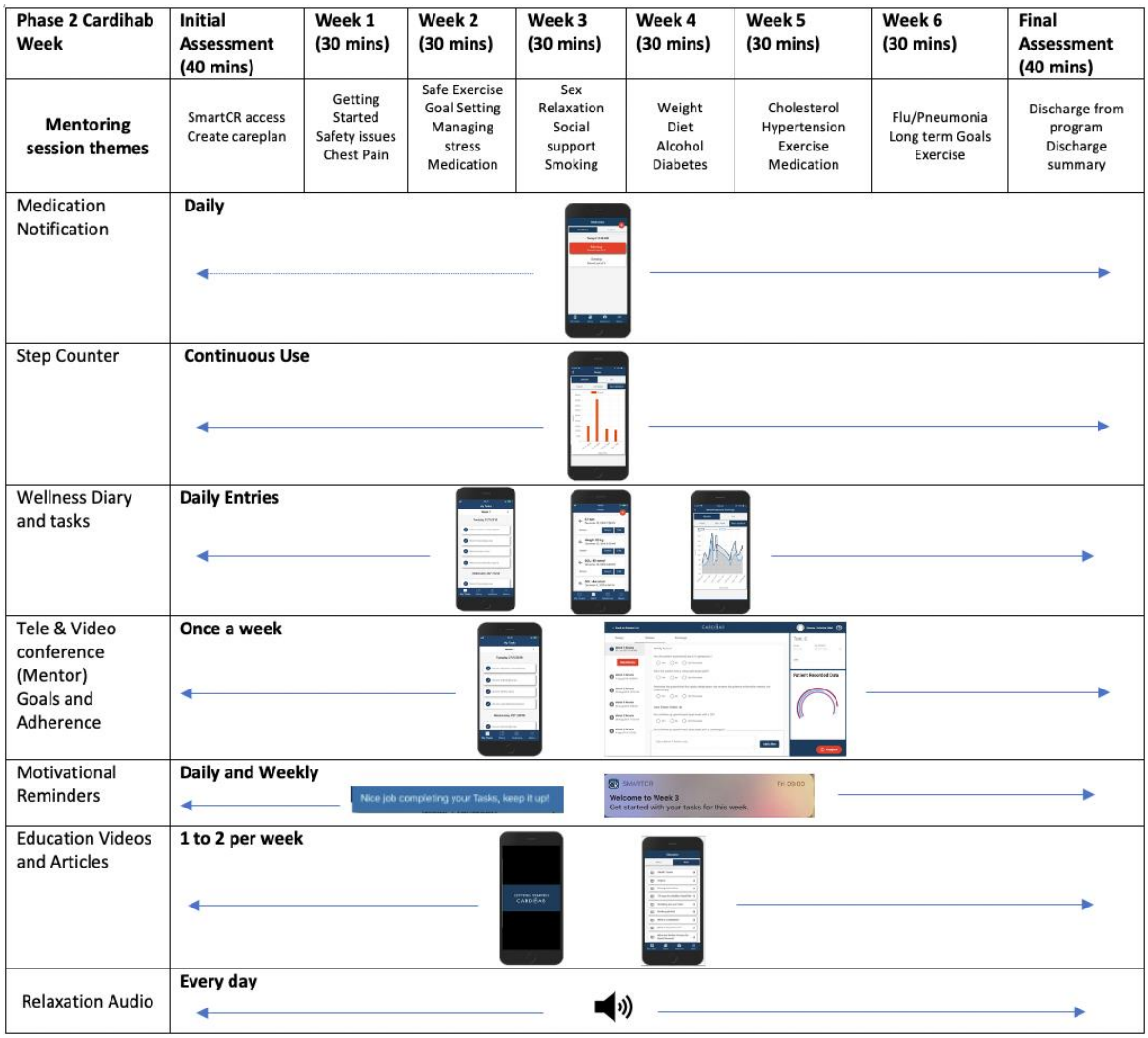

Figure 4. Cardihab Phase 2 CR program.

c. *Exercise* programs will be individually tailored from the baseline fitness assessment for patients on an opt-in basis. The supervised program, matched to a 6-week duration, is planned to be delivered from ~Week 4 via a combination of in-person visits progressing to unsupervised home activity[24]. The exercise prescription will include 3 x 60 minute sessions per week, including a combination of moderate intensity and high-intensity interval exercise training. Whole-body resistance circuit training will also be performed in the supervised setting, including 6-8 movements. After completion of the 6-week supervised phase, participants will be provided with a home-based program involving 3 exercise sessions per week for the remaining ~42 weeks. Participants will be supervised by an Accredited Exercise Physiologist and sessions will be conducted in groups of up to 6. During supervised sessions, rating of perceived exertion, heart rate and workload will be documented for all participants to monitor adherence to the exercise protocol.

The initial exercise session will include education and familiarisation with the exercise program. Specifically the participants will be educated on monitoring and adjusting exercise intensity to achieve the desired exercise stimulus. Through educating participants and encouraging a patient centred approach to exercise, we aim to promote self-efficacy to encourage exercise continuation in the non-supervised phase. Participants will receive continued support from the Exercise Physiologist through the supervised phase and via the study nurse following completion of the supervised program.

13. CONTROL GROUP

Usual care patients will receive standard cardiology care as scheduled that includes adherence to guideline-based care (medications and physical activity), education (self-care), a treatment plan to manage co-morbidities, early post-discharge follow-up/support and routine preventative care.

14. STUDY TIMELINE

Study recruitment will occur for 9-12 months (≈5-7 patients/week) which is feasible from referrals to eight HeartWest cardiologists. The intervention and follow-up visits will be completed by the end of 2022 for study evaluation.

15. STUDY POWER

As derived from our contemporary Australian data, assuming a readmission rate at 90 days in patients aged <65 years of 42% and 40% reduction in risk with a DMP intervention, we require 117 patients per group. Allowing for attrition of 15%, 135 per group will be required to be randomised.

16. STATISTICAL ANALYSES

All analyses will be performed on an intention-to-treat basis. The primary endpoint (all-cause readmission or death at 90 days) will be analysed using a log-binomial regression. Secondary endpoints will be assessed by modelling of change in outcome variables (eg. in QoL, exercise capacity and cardiac function) adjusted for baseline values. Multiple logistic regression will determine independent correlates of readmission. Cox proportional hazards regression will be used to analyse repeated readmissions during the follow-up period.

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