STUDY PROTOCOL

Improving physical and psychological outcomes of cardiac patients using the Naluri app: A study protocol for a randomized controlled trial [version 1; peer review: awaiting peer review]

Darlina H. Fadil Azim1-3, Azmee Mohd Ghazi2,4, Siew Hoon Ong2,4, Hariyati S. Abdul Majid2, Karen Morgan1,3, Anne Hickey1

1Department of Psychology and Behavioural Science, Perdana University, Royal College of Surgeons (PURCSI), Kuala Lumpur, 50490, Malaysia
2Naluri Hidup Sdn Bhd, Kuala Lumpur, 50490, Malaysia
3Department of Health Psychology, Royal College of Surgeons in Ireland, Ireland, D02 YN77, Ireland
4Cardiology Department, National Heart Institute Malaysia, Kuala Lumpur, 50400, Malaysia

Abstract

Background: Coronary artery disease (CAD) continues to be a significant burden to public health. Poor treatment and management can lead to more severe cardiac events that could result in death or disability. Early interventions like cardiac rehabilitation programs can provide patients the required knowledge, skills and support to recover from and prevent more cardiac events. Electronic health (eHealth) interventions have potential to complement hospital-based rehabilitation programs. This study aims to investigate the effectiveness of the Naluri app in improving health behaviours, clinical and psychological outcomes in a sample of cardiac patients in Malaysia.

Methods: This study is a two-arm, parallel, superiority randomized control trial to be conducted at the Malaysian National Heart Institute. A total of 200 patients will be randomly assigned to either a 16-week theory-based Naluri app in addition to usual care (treatment) or to usual care only (control). Outcomes will be measured at baseline and at 16 weeks. Health behaviour outcomes include physical activity and diet. Clinical outcomes include BMI, hemoglobin A1c (HbA1c), and lipid levels. Psychological outcomes include anxiety, depression, and health related quality of life (HRQOL). The Naluri app theoretical framework is based on the Health Action Process Approach (HAPA) theory. Risk perception, self-efficacy, planning, intentions, outcome expectancies, illness perceptions and psychological outcomes will be measured using self-reported measures.
**Discussion**: This trial will determine the effectiveness of the Naluri app intervention in improving various outcomes of cardiac patients after four months. It will provide data on the applicability of the HAPA theory in Mobile health (mHealth) intervention and the acceptance and efficacy of mHealth as a cardiac rehabilitation program for patients in Malaysia. The results may inform the potential implementation of the app for use with patients with other chronic illnesses like diabetes, stroke, and depression.

**Registration**: Australia New Zealand Clinical Trials Registry (14/01/2019, ACTRN12619000104156).

**Keywords**
eHealth, health behaviours, mental health, coronary artery disease, cardiac rehabilitation

---

**Corresponding author**: Darlina H. Fadil Azim (darlina.fadilazim@perdanauniversity.edu.my)

**Author roles**: Fadil Azim DH: Conceptualization, Methodology, Writing – Original Draft Preparation; Mohd Ghazi A: Conceptualization, Methodology, Writing – Review & Editing; Ong SH: Conceptualization, Methodology, Writing – Review & Editing; Abdul Majid HS: Conceptualization, Methodology, Supervision; Morgan K: Conceptualization, Methodology, Supervision, Writing – Review & Editing; Hickey A: Conceptualization, Methodology, Supervision

**Competing interests**: The authors declare the following financial interests that may be considered as potential competing interests: DH Fadil Azim and SH Ong are part time coaches on the Naluri app and are reimbursed on the time spent coaching on the app. A Mohd Ghazi and HS Abdul Majid are advisors for Naluri Life Sdn Bhd. All other authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

**Grant information**: Financial support for this trial is being provided by PlaTCOM Ventures Sdn Bhd to Mr Azran Osman-Rani from Naluri Hidup Sdn Bhd. In-kind support is being provided by the Malaysian National Heart Institute. Funders will have no involvement in the study design, data collection, management, analysis and interpretation; report writing; or decision to submit reports for publication. Naluri Hidup Sdn Bhd will only be involved in the back-end data collection and management of the patients using the Naluri app. *The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.*

**Copyright**: © 2022 Fadil Azim DH et al. This is an open access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

**How to cite this article**: Fadil Azim DH, Mohd Ghazi A, Ong SH et al. Improving physical and psychological outcomes of cardiac patients using the Naluri app: A study protocol for a randomized controlled trial [version 1; peer review: awaiting peer review]

HRB Open Research 2022, 5:75 [https://doi.org/10.12688/hrbopenres.13629.1](https://doi.org/10.12688/hrbopenres.13629.1)

**First published**: 17 Nov 2022, 5:75 [https://doi.org/10.12688/hrbopenres.13629.1](https://doi.org/10.12688/hrbopenres.13629.1)
Introduction

Background

Coronary artery disease (CAD) is a cardiovascular disease (CVD) that is also often referred to as coronary heart disease (CHD) or ischemic heart disease (IHD). CAD is often caused by atherosclerosis, which is the narrowing or blockage of the coronary arteries (Lusis, 2000). This blockage reduces the blood flow to the heart and can cause one of the most common symptoms of CAD, which is angina, or chest pain and discomfort. However, many may not experience any symptoms. Over time, CAD can cause heart failure, myocardial infarction (MI) or heart attack and even cardiac death.

The risk factors for CAD include genetics, the environment or the interaction of both. Risk factors can be categorized into two groups – those that cannot be controlled or modified and those that can (Hajar, 2017). Risk factors that cannot be controlled include age, sex, race and strong family history of heart disease. Controllable risk factors are those that can be modified via lifestyle factors such as hypertension, high blood cholesterol, overweight or obesity, lack of physical activity, unhealthy diet and stress.

Treatment of CAD depends on the severity of the disease. Treatment options include healthy lifestyle changes, therapeutic drugs and medical procedures such as percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG). Lifestyle changes are aimed at reducing controllable risk factors and include recommending patients have healthy and balanced meals, exercise regularly, maintain a healthy weight, reduce or quit smoking and manage stress (Malakar et al., 2019).

In Malaysia, heart disease continues to be the leading cause of morbidity and mortality for more than a decade (Department of Statistics Malaysia, 2018). More than 30,000 Malaysians died from CHD in 2017, which is 22.13% of total deaths. The age-adjusted death rate is 137.02 per 100,000 population. This is an increase from the 98.9 deaths per 100,000 population in Malaysia in 2012, or 29,400 deaths (20.1% of all deaths) (World Health Organization, 2021). The average age of Malaysians getting heart disease is 58 years old, which is also lower than other countries in the region, such as Thailand (63.5 years old) and Singapore (median: 68.3 – 69.2 years old) (Ministry of Health Malaysia, 2017). Malaysia also has higher death rates due to CHD compared to developed countries such as the UK and Australia. In the UK, there are around 64,000 deaths each year due to CHD with age-adjusted death rate of 107 per 100,000 population (British Heart Foundation, 2019a). While in Australia, the age-adjusted death rate caused by CHD has been on a downward trend from 297 per 100,000 population in 1980 to 66 in 2015 (AIHW, 2017).

Mental health

An important aspect of cardiac health is mental health and psychological well-being. Studies of cardiac patients have shown a significant relationship between anxiety, depression, and health related quality of life (HRQOL) and cardiac morbidity, mortality, adherence to treatments, revascularisation rates and adverse cardiac events (Azmi et al., 2015; Celano et al., 2015; Gan et al., 2014; Gu et al., 2016).

Illness perceptions also have a significant impact on health outcomes and health behaviours and can also be influenced by many factors. Identifying patients’ illness perceptions and providing the necessary information and support to improve those perceptions can go a long way in improving their QOL, psychological well-being and functioning. The illness perceptions of CAD patients have been found to be associated with psychological outcomes (Bagherian Sararoudi et al., 2016; Foxwell et al., 2013), clinical outcomes (Sawyer et al., 2019), return to work (Kabe et al., 2018; Wearden, 2009) attendance at cardiac rehabilitation programs (French et al., 2006) and medication adherence (Kucukarslan, 2012).

Cardiac rehabilitation

Even though there is an increasing trend in the prevalence of heart disease, patients with CHD are able to reduce the severity of the symptoms by making some lifestyle changes such as improving their diet and increasing their daily physical activities (Mertens et al., 2018; Summer et al., 2017). Many hospitals now offer both inpatient and outpatient cardiac rehabilitation programs that involves a variety of therapies, including risk factor education, exercise and physiotherapy, diet consultation and drug therapy. These programs are offered to individuals after cardiac events to aid recovery and prevent further cardiac illness (Sadeghi et al., 2015).

In Malaysian hospitals, cardiac rehabilitation programs (CRP) are offered to ensure that patients, upon discharge from the hospital, take control of their health by taking the prescribed medications and making the necessary lifestyle changes. This is to assist the patients to recover from any cardiac events and to prevent the recurrence of further cardiac events. CRP may include interventions that focus on food intake, activities of daily living (ADL), stress management, adherence to medication, physiotherapy care and smoking cessation (Yew & Leong, 2016). The Clinical Practice Guidelines (CPG) issued by the Malaysian Ministry of Health lists four phases of the CRP. Phase 1 is inpatient CRP where the focus is on patient education and is provided prior to discharge from hospital. Phase 2 focuses on outpatient CRP whereby patients attend CRP on appointment basis. Phase 3 is extended CRP meant for patients who require an extended course of rehabilitation before returning to usual functioning and Phase 4 is lifetime CRP (Ministry of Health Malaysia, 2017). Components of the CRP include smoking cessation, dietary intervention, regular exercise, control of hypertension and good glycaemic control. The uptake of outpatient CRP in Malaysia has been low with an enrolment rate of only 27.3% and program completion of only 15.3%. Some reasons given were travel constraints and not willing to attend the CRP (Chai et al., 2019). This lower uptake rate
is similar to Australia, which has a 30% uptake rate (Astley et al., 2020), but lower than the UK that has an uptake rate of 50% (British Heart Foundation, 2019b).

Reviews of the literature shows that the effectiveness of centre or hospital-based CRP in yielding desired clinical health outcomes has been mixed (Dibao-Dina et al., 2018; Sumner et al., 2017; Yamamoto et al., 2018). Systematic reviews and meta-analyses have shown that, although effective in producing desirable cardiac outcomes, CRP are almost always underutilized as highlighted by low referral rates and even lower completion rates (Giuliano et al., 2017). Patients attendance or engagement with CRP can be influenced by their perceptions regarding the services offered by these programs, patient’s identity such as age and sex; suitability and scheduling of the programs, their perception on the severity of their heart disease, and financial or occupational constraints (Clark et al., 2013). Social influences like health care provider recommendation, input from family and peers as well as psychological distress plays a role on whether patients participate in these CR programs (Rouleau et al., 2018).

Electronic health (eHealth) based cardiac rehabilitation Recognizing that support given through centre or hospital-based consultations may no longer be as effective in encouraging patients to make lifestyle changes, there is now an increased interest in the role that complementary and adjunct services play in explaining the above gap. A growing body of research has begun looking into innovative delivery models for cardiac programs, offering similar health services provided by centre-based programs, but at a lower cost. eHealth and Mobile health (mHealth) are examples of such innovation.

Electronic health or better known as eHealth can be broadly referred to as the utilization of technologies in healthcare (Oh et al., 2005). A conceptual model of eHealth consists of three domains, which are the use of digital technologies to monitor, track and inform; for communications between health practitioners and to improve health care and services. The optimum point is when all of these three domains overlap with each other to empower patients to be active in their own healthcare (Shaw et al., 2017).

Mobile health or mHealth is a subset of eHealth and uses mobile devices such as mobile phones, patient monitoring devices, personal digital assistants and other wireless devices to deliver health services to patient (World Health Organization, 2011). Another definition of mHealth is the personalized and interactive service with the aim of providing universal access to medical information to customers via any mobile device (Akter et al., 2010).

A systematic review by Park and colleagues (Park, 2016) of studies that investigated the use of mobile technologies to change behaviours as part of disease management shows that in general, text messaging, mobile applications, and tele-monitoring via mobile phones are effective in improving cardiovascular outcomes. However, mobile applications are not sufficient in improving outcomes when used alone, but when combined with text or chat messaging, yield more significant changes. CRP, through the use of smart mobile phone and offered as a home-care based program, show better physical and psychological health outcomes post-MI, compared to centre-based cardiac rehabilitation programs (Varnfield et al., 2014).

The findings suggest that positive changes in health behaviours are more likely to happen, and in many instances, sustained, when the interventions are more persons centred, more accessible to patients, more engaging, constant and consistent interaction with healthcare providers, educational contents are more personalised for patients and the interaction are based on principles of behavioural activation and modifications.

Health Action Process Approach (HAPA) Theory

The HAPA (Schwarzer et al., 2011) has been used to design intervention programs for improving health behaviours such as physical activity (Antypas & Wangberg, 2014; Knoll et al., 2018), dietary behaviours (Renner et al., 2008) and medication adherence (Presseau et al., 2017). Several of these interventions were also web-based or eHealth interventions (Antypas & Wangberg, 2014; Blondon et al., 2017). This theory has also been applied in various populations of patients with chronic diseases such as coronary disease patients (Platter et al., 2016), type 2 diabetes (MacPhail et al., 2014), schizophrenia (Arbour-Nicitopoulos et al., 2017) and knee osteoarthritis (Knoll et al., 2018).

The HAPA theory has two parts, which includes the motivational phase and volitional phase. The initial motivation phase is where the intention to act is formed. This intention may be influenced by task self-efficacy, outcome expectancies and risk perceptions. Once intention is formed, it will need to be translated into action through action planning and coping planning. And once action has started, it will then need to be maintained. All these different phases can also be affected by self-efficacy, and also barriers and resources like social support and psychological factors (Schwarzer et al., 2011).

In this study, an app called Naluri will be offered to patients as a CR program. As per the HAPA model, the Naluri app guides and coaches the patients from the initial motivation phase of health behaviour change all the way until the maintenance stage and also to help with any psychological challenges and barriers patients may face. The Naluri app is an integrated and personalized mobile app that educates, tracks, logs, and forms actionable tasks for patients aiming to improve their current state of health through a mobile, online and smartphone-based platform. The Naluri app provides confidential, user-friendly and interactive access to a multidisciplinary team of health coaches (psychologists, dieticians, medical advisors, fitness instructors and executive life coaches) to guide, facilitate and mentor patients to adopt and sustain the recommended modifications in their health-related lifestyles, for improved wellness.
One of the reasons cited for the failure of many patients to make the necessary lifestyle changes following discharge from the hospital is lack of access to centre-based structured CRP (Pedersen et al., 2018; van Gaans & Tonkin, 2017). The Naluri application can act as a platform that complements the services provided by hospitals. It provides a holistic CR service that patients can access remotely and consistently upon discharge from the hospital.

The current research, hence, aims to address these gaps. It will assess whether the Naluri app, that features access to two-way communication between health coaches, and patients, provided remotely, consistently, constantly, backed by evidence-based modules and tasks, when used as an adjunct to an existing hospital-based cardiac rehabilitation program, would yield better clinical health outcomes, compared to standard care for patients post hospitalization.

The study protocol follows the Standard Protocol Items: Recommendations for International Spirit (SPIRIT) 2013 Statement (Chan et al., 2015) (Fafid Azim, 2022) and was prospectively registered in the Australia New Zealand Clinical Trials Registry (ANZCTR) on 14 January 2019 with the registration number ACTRN1261900104156. The intervention is as per the Consolidated Standards of Reporting Trials (CONSORT)-eHealth Checklist (Eysenbach, 2011).

Research objectives
The primary objectives of this study are to compare the changes in physical activity, diet, clinical and psychological outcomes among cardiac patients who use the Naluri app compared with standard care at four months. The study will also assess patient’s engagement with and acceptance of the Naluri app.

The secondary objectives are to identify the main factors that influence the participants’ intention to change their health behaviours and to identify the relationships between intention, planning and action for improving their health behaviours.

Methods
This study is a two-arm, parallel group randomized controlled trial conducted at the Malaysian Heart Institute (NHI) in Kuala Lumpur, Malaysia. Data will be obtained from the patients at two time points: baseline (T1) and follow-up (T2) at approximately four months later (+/- 4 weeks). Ethical approval was received from IJN Research Ethics Committee (IJREC/243/2018) on 10 January 2019 and internal approval from Perdana University Institutional Review Board (PUIRBHR0260) on 26 June 2020. All participants will provide written informed consent to participate.

Study participants and recruitment
The inclusion criteria are patients who are admitted to the NHI for an angiogram procedure and have a diagnosis of CAD, are smartphone users, literate in Malay or English, are willing to use the Naluri application, have follow-up appointments in NHI and are discharged from the hospital in less than four weeks. Patients who will be excluded from the study are those who are pregnant, those with end stage chronic liver and kidney disease, history of cancer undergoing active treatment, patients with life-threatening co-morbidities such as cancer, HIV or on palliative care, patients with limited ability to communicate with the researchers, those who are on weight loss medications, on active psychotropic medications, patients who are already using similar health intervention applications, and patients who are physically immobile or bedridden.

Patients will be approached at the ward and invited to participate in the study. The objective, nature of the study and compensation for completing the study will be explained before obtaining consent from the patients. Recruitment will continue until 200 patients have been enrolled in the trial. Patients will be assessed at two time points. The baseline assessment will be carried out before the patients are discharged from the hospital (T1). All patients will take a blood test and be given the questionnaires to complete in the ward. Patients in the treatment group will download the Naluri app in their smartphones and will be given the Naluri Bluetooth weighing scale.

The second assessment (T2) is four months (+/-4 weeks) later. These patients will be met at the follow-up clinic and will be requested to take a blood test and complete the questionnaires again. Patients who are not able to come to the clinic at T2 will be given the option of completing the questionnaires online. Patients in the control group will be offered the Naluri application. All patients who complete the study will be paid a compensation fee of RM 100 (USD 23).

Researchers will be trained on how to approach the patients to complete the questionnaires, download the Naluri app and answer any queries from the patients. Blood tests will be conducted by the hospital and relevant results will be obtained from the hospital medical records database. To improve adherence to the use of the Naluri app, patients who are not engaging with the app will be contacted to gauge any difficulties that they may be facing with the app. Patients may withdraw due to health complications such as reinfarction, diagnosed with a new serious illness or disability, or if patient is no longer interested to participate in the study. Data from patients who withdraw will still be used for the study, which will be included in the consent form signed before data collection.

Sample size
To obtain an 80% power to detect 30% improvement in physical activity and diet (McDevitt-Petrovic et al., 2017; Pfaeffli Dale et al., 2015) and assuming a 44% dropout rate (Simblett et al., 2018), sample size is set to 100 participants per group.

Randomization, allocation concealment, and blinding
Patients who consent to join the study will be randomly allocated to either the standard cardiac care only (control) or the standard cardiac care with the Naluri application (treatment) using simple random allocation. A colleague who
is not involved in this study will use a computerized-sequence number generation to assign 100 control and 100 treatment labels into 200 sealed envelopes. Both patients and researchers will be blinded prior to the treatment allocation. After allocation, the treating doctors and healthcare professionals in the hospital will be blinded to the allocation of patients. The schedule of enrolment, interventions, and assessments are illustrated in Table 1.

Data management
Patient identity will remain anonymous with each only identifiable by a code designed for this study. Personal health data and scores on all measures will be kept confidential. These data will only be accessible by the research team. All hard copies of the data will be kept in a secured cabinet in the Clinical Research Department of the hospital. Range checks will be conducted for data values and 10% of data will be checked against source data for consistency.

There is no Data Monitoring Committee (DMC) for this trial as it is a short trial with minimal risks. Any interim analyses will be conducted by the researcher and reviewed by the research team.

Harms
A potential risk is technology stress, for patients who are new to digital health applications. The study may also result in study fatigue for patients using the application for the whole duration of the study.

Study outcomes
The study measures will be translated to Malay using the back translation method (Brislin et al., 1973) except for the International Physical Activity Questionnaire - Short Form (IPAQ-SF), Brief Illness Perception Questionnaire (BIPQ) and the Hospital Anxiety and Depression Scale (HADS) that already have validated Malay versions.

Physical activity: The 7-items International Physical Activity Questionnaire – Short Form (IPAQ-SF) (IPAQ Group, 2011) will be used to measure physical activity. This tool has good reliability (Spearman \( p > 0.65 \)) and validity among 18–65 year olds (Craig et al., 2003). The Malay version that will be used in this study also has good reliability (intra class coefficient, ICC = 0.54-0.92, \( p < 0.001 \)) and validity (\( p < 0.001 \)) (Chu & Moy, 2015).

Diet and HAPA variables: The Risk Appraisal and Consequences Korea (RACK) (Renner et al., 2008; Schwarzer et al., 2011) questionnaire will be used to measure diet, risk perception of illness and self-efficacy, planning, intentions and outcome expectancies of improving diet and physical activity. A study on the health behaviours of 580 adults found good reliability for risk perception (Cronbach’s \( \alpha = .78 \)), self-efficacy (Cronbach’s \( \alpha = .85 \)), intention (Cronbach’s \( \alpha = .91 \)) and outcome expectancies (Cronbach’s \( \alpha = .81 \)) (Schwarzer & Renner, 2000).

Illness perceptions: Each of the 9-item Brief Illness Perception Questionnaire (BIPQ) (Broadbent et al., 2006) will be used to measure one dimension of illness perceptions — consequences, timeline, personal control, treatment control, identity, illness concern, coherence, cause and emotional representations of the illness. The BIPQ has concurrent validity and good test-retest reliability ranging from 0.42 to 0.73. The Malay version also has good cross-cultural validity and moderate construct validity. The test-retest reliability was also moderate from 0.58 to 0.78 (Chew et al., 2017).

Table 1. Schedule of enrolment, interventions, and assessments (SPIRIT).

<table>
<thead>
<tr>
<th>Months</th>
<th>Enrolment</th>
<th>Baseline</th>
<th>Post-allocation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENROLMENT:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eligibility screen</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Informed consent</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Allocation</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>INTERVENTIONS:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Usual care (N=100)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Naluri App (N=100)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASSESSMENTS:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sociodemographic</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Clinical outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>HbA1c</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Lipid profile</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Blood pressure</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Psychological outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Anxiety</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Health-related QoL</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Health behaviours</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food intake</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Physical activity</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>HAPA Theory</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk perception</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Planning</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Intentions</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Outcome expectations</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Illness perceptions</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

To assess patient’s engagement with and acceptance of the Naluri app, an adapted version of the Systems Usability Scale (SUS) (Brooke, 1996) will be used. The word “systems” will be replaced with “app” in this 10-item questionnaire. It measures the ease of use, integration, need for support, training and the complexity of the app. The total score will provide a global view of subjective assessments of the usability of the app. This scale has good validity and test-retest reliability ranging from 0.70 to 0.95 (Lewis, 2018).

To investigate the facilitators and barriers to adhering to health behaviours, qualitative data will be collected through interviews with patients who completed the study.

Clinical and psychological outcomes
The clinical outcomes such as blood sugar level, lipid levels and BMI will be obtained from the hospital medical records database. The psychological outcomes like HRQOL, depression and anxiety symptoms will be measured using the Heart Quality of Life (HeartQOL) (Oldridge et al., 2014) and Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983).

Health related quality of life: The 14-item Heart Quality of Life (HeartQOL) will be used to assess HRQOL, which has two subscales — physical and emotional, and an overall global score. This scale has good validity and test-retest reliability of more than 0.8 (Oldridge et al., 2014).

Anxiety and depression symptoms: The 14-item Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983) will be used to assess anxiety and depression symptoms, which has two subscales for each psychological outcome. This scale has good internal consistency with Cronbach alpha of 0.8 and 0.76 for anxiety and depression subscales, respectively (Mykletun et al., 2001). The Malay version that will be used in this study also has good internal consistency, 0.88 for anxiety and 0.79 for depression subscales (Yusoff et al., 2011).

Intervention and control
All patients will receive standard cardiac care, which includes a health talk by a dietician prior to discharge from hospital. Those in the treatment group will receive the Naluri app, which allows them to have unlimited access to a multidisciplinary team of health coaches and healthcare professionals via chat, they can track their food intake, emotional status and health goals via the app features like the food journal, thought journal and weight logs, and they will also have access to more than 70 modules that provide information on diet, exercise, motivation, self-care, chronic conditions and even on managing finances. The overall goals of intervention are to help patients to improve their health behaviours, identify and acknowledge their current health status, to encourage them to improve their health conditions and ultimately to develop and sustain new health habits and lifestyle.

The main coaches will first assess the patient’s current perception and evaluation of their health conditions. Based on that, the main coach will strategize and guide the patient on setting suitable and actionable goals to improve their health conditions over a period of 16 weeks. Patients are encouraged to complete one module per day, take pictures of their daily food intake using the app, and weigh themselves once a week if it is aligned with their health goals. Details of the Naluri app features are as follows.

Naluri app content
Chat feature. The chat feature allows patients to have unlimited access to various coaches such as psychologists, pharmacists, medical advisors, dieticians, fitness trainers, executive coach, financial planners and holistic health coach who are available to respond to the patients 24 hours a day. The psychologist acts as the main coach and guides the patient through this 16 weeks program.

Food journal. There is no need for calorie counting or lengthy descriptions of meals, using the food journal feature, which allows patients to upload pictures of their meals, dieticians will give a rating of ‘poor’, ‘moderate’ and ‘good’ and provide feedback on how to further improve their food intake. There are daily notifications to remind patients to upload food pictures in the food journal.

Thought journal. The thought journal allows patients to easily log their thought patterns and behaviours, which help both the coaches and patients to better understand the patients and help come up with strategies to prevent negative recurrences.

Daily interacting modules. These modules provide information and feedback on topics like diet, nutrition, exercise, self-care, maintaining success and chronic conditions. Each module takes about 5-10 minutes to complete.

Planner feature. Patients can use the planner feature to set their own challenges and reminders and then keep track of their progress.

Bluetooth connected weighing scale. Patients can instantly sync their weight reading from the Bluetooth weighing scale to the app for immediate tracking of progress.

Statistical analysis
The primary analysis will be unadjusted, following an intention-to-treat principle, in which the participants will be analysed in the group that they were randomized to. If there are clear differences in baseline characteristics between groups, then sensitivity analyses with additional adjustments for baseline characteristics will be performed. Missing value analysis will be performed for patients with missing data for primary outcomes at T2, for example patients who withdrew or were lost at follow-up, will be considered non-adherent (non-responder imputation). Data imputation will be used to compensate for the missing data.
Prespecified subgroup analyses will be performed for age, sex, level of education, household income, clinical and psychological outcomes at baseline, and Naluri app/usual care. Statistical analysis will be performed using IBM SPSS Statistics (RRID:SCR_016479) Version 24 (IBM, 2016). The criterion for statistical significance will be set at p < 0.05.

A series of two-way mixed model analyses of variance (ANOVA) will be carried out to analyse the intervention effects. The intervention condition of treatment vs. control groups will be set as the between-participant effect, while time (pre vs. post intervention) will be set as the within-participant effect. The effect of the intervention on physical activity, diet, clinical and psychological outcomes will be analysed. Paired samples t-test will be conducted to explore any significant interaction effects.

To examine the secondary research objectives, multiple linear regressions will be conducted to identify the main factors that influence intention to change health behaviours and also to investigate the relationship between intention, planning and action for improving physical activities and diet.

To assess patient’s engagement with and acceptance of the Naluri app, data collected from the SUS as well as from the Naluri database will be summarised as frequency and percentage. Naluri database will provide data on how active the patients are on the various features of the app. Qualitative data via interview with patients from both groups who have completed the study will be conducted to determine the facilitators and barriers to adhering to health behaviour changes. Interviews will be conducted until data saturation is reached.

Dissemination policy
It has been agreed that names and order of authors will be discussed for each publication. Dissemination will include peer-reviewed publications, conference presentations and funder’s marketing purposes.

Study status
Data collection for this study was completed in February 2021. Data analysis was completed in July 2022.

Discussion
This study will determine the effectiveness of the Naluri app in addition to usual care in improving the clinical and psychological outcomes of cardiac patients after four months of being on the app. The use of mHealth in CRP is very new in Malaysia. Most of the studies conducted were not focused on behaviour change but were more on the use of mHealth in providing health information, monitoring health status or studies on telemedicine (Abu Seman & Ramayah, 2017; Kc et al., 2021). The low uptake of CRP (Chai et al., 2019) and also the increasing rates of heart disease in Malaysia could make mHealth generally, and the Naluri app specifically, a suitable alternative option for cardiac patients’ rehabilitation. These clinical and psychological outcomes are also applicable for other chronic illnesses such as diabetes, stroke, chronic lung disease and also mental illnesses like depression and anxiety, hence this study will provide useful data for future studies that may look into the use of mHealth for other chronic illnesses.

The application of HAPA in the Naluri app will contribute to the body of knowledge of the use of HAPA in mHealth design as well as for the changes in health behaviours of cardiac patients. This study will also determine the acceptance of and the usability of a new digital health app among cardiac patients in Malaysia. It can also provide valuable information on how to further improve the Naluri app in order to have a greater impact in improving patients’ health behaviours.

Ethics approval and consent to participate
Ethical approval was received from IJN Research Ethics Committee (IJNREC/243/2018) and internal approval from Perdana University Institutional Review Board (PUIRBHR0260). Any changes to the protocol will need to be approved by IJNREC and PUIRB. All participants will provide written informed consent to participate that will be obtained from the research team.

Data availability
Underlying data
No data are associated with this article.

Reporting guidelines

Data are available under the terms of the Creative Commons Zero “No rights reserved” data waiver (CC0 1.0 Public domain dedication).

Author contributions
DH Fadil Azim: Conceptualization, Methodology, Writing – Original Draft. HS Abdul Majid: Conceptualization, Methodology, Supervision. A Mohd Ghazi: Conceptualization, Methodology, Writing – Review & Editing. SH Ong: Conceptualization, Methodology, Writing – Review & Editing. K Morgan: Conceptualization, Methodology, Writing – Review & Editing, Supervision. A Hickey: Conceptualization, Methodology, Supervision.
References

Publisher Full Text

Reference Source

Akerl S, D’Ambra J, Ray P: User perceived service quality of m-Health services in developing countries. 2010. 
Reference Source

PubMed Abstract | Publisher Full Text | Free Full Text

PubMed Abstract | Publisher Full Text | Free Full Text

PubMed Abstract | Publisher Full Text | Free Full Text

PubMed Abstract | Publisher Full Text | Free Full Text

PubMed Abstract | Publisher Full Text | Free Full Text

Reference Source

Reference Source

Reference Source

PubMed Abstract | Publisher Full Text

Publisher Full Text

PubMed Abstract | Publisher Full Text | Free Full Text

Reference Source

PubMed Abstract | Free Full Text

PubMed Abstract | Publisher Full Text | Free Full Text

Chu AHY, Loy FM: Reliability and validity of the Malay International Physical Activity Questionnaire (IPAQ-M) among a Malay population in Malaysia. 2015; 27(2): NP2329. 
PubMed Abstract | Publisher Full Text | Free Full Text

PubMed Abstract | Publisher Full Text

PubMed Abstract | Publisher Full Text

Reference Source

PubMed Abstract | Publisher Full Text | Free Full Text

PubMed Abstract | Publisher Full Text | Free Full Text


PubMed Abstract | Publisher Full Text

PubMed Abstract | Publisher Full Text

PubMed Abstract | Publisher Full Text | Free Full Text

PubMed Abstract | Publisher Full Text | Free Full Text

PubMed Abstract | Publisher Full Text | Free Full Text

PubMed Abstract | Publisher Full Text | Free Full Text

PubMed Abstract | Publisher Full Text | Free Full Text

PubMed Abstract | Publisher Full Text | Free Full Text

PubMed Abstract | Publisher Full Text | Free Full Text

PubMed Abstract | Publisher Full Text | Free Full Text

PubMed Abstract | Publisher Full Text | Free Full Text

Publisher Full Text

PubMed Abstract | Publisher Full Text | Free Full Text

PubMed Abstract | Publisher Full Text | Free Full Text

PubMed Abstract | Publisher Full Text | Free Full Text

PubMed Abstract | Publisher Full Text | Free Full Text

PubMed Abstract | Publisher Full Text | Free Full Text

Reference Source