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## Protocol paper

# A protocol for the Heart Matters stepped wedge cluster randomised trial: The effectiveness of heart attack education in regions at highest-risk



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## Abstract

**Aim:** To describe the Heart Matters (HM) trial which aims to evaluate the effectiveness of a community heart attack education intervention in high-risk areas in Victoria, Australia. These local government areas (LGAs) have high rates of acute coronary syndrome (ACS), out-of-hospital cardiac arrest (OHCA), cardiovascular risk factors, and low rates of emergency medical service (EMS) use for ACS.

**Methods:** The trial follows a stepped-wedge cluster randomised design, with eight clusters (high-risk LGAs) randomly assigned to transition from control to intervention every four months. Two pairs of LGAs will transition simultaneously due to their proximity. The intervention consists of a heart attack education program delivered by trained HM Coordinators, with additional support from opportunistic media and a geo-targeted social media campaign. The primary outcome measure is the proportion of residents from the eight LGAs who present to emergency departments by EMS during an ACS event. Secondary outcomes include prehospital delay time, rates of OHCA and heart attack awareness. The primary and secondary outcomes will be analysed at the patient/participant level using mixed-effects logistic regression models. A detailed program evaluation is also being conducted. The trial was registered on August 9, 2021 (NCT04995900).

**Results:** The intervention was implemented between February 2022 and March 2023, and outcome data will be collected from administrative databases, registries, and surveys. Primary trial data is expected to be locked for analysis by October 31st 2023, with a follow-up planned until March 31st 2024.

**Conclusion:** The results from this trial will provide high-level evidence the effectiveness of a community education intervention targeting regions at highest-risk of ACS and low EMS use.

**Keywords:** Myocardial infarction, Acute coronary syndrome, Cardiovascular disease, Community education, Emergency medical services, Health promotion, Step-wedged design

Reperfusion therapies in acute coronary syndrome (ACS) improve survival,<sup>1</sup> especially when administered early. Every 30-minute delay to reperfusion increases the risk of 1-year mortality<sup>2</sup> A significant barrier to achieving optimal outcomes is the patient's delay in recognising ACS symptoms and seeking appropriate and timely medical attention.<sup>3</sup> Public education is recommended internationally to enhance ACS awareness and prompt individuals promptly contact emergency medical services (EMS) for early treatment.<sup>4-6</sup>

Mass media campaigns addressing psychological barriers and providing actional plans have shown positive results in increasing knowledge and treatment-seeking behaviours in ACS.<sup>7,8</sup> Although emerging evidence suggest sustained exposure to these campaigns is necessary for long-term effectiveness. The National Heart Foundation of Australia (NHFA) conducted a 4-year campaign targeting middle-aged adults, which achieved high reach<sup>9</sup> and led to improved symptom knowledge in the general public,<sup>10</sup> appropriate treatment seeking behaviours<sup>9,11,12</sup> and reduced rates of out-of-hospital

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cardiac arrest (OHCA).<sup>13</sup> However, the campaign's effects on symptom knowledge were short-lived<sup>10</sup>, and its high cost (\$16 million) was not sustainable. Targeting regions with high ACS rates and poor symptom knowledge and treatment-seeking behaviours is suggested as a more effective approach.<sup>8,14</sup>

The NHFA's Australian Heart Maps provide interactive dashboards accessible to the public, with heart health statistics which can identify areas with high rates of ACS.<sup>15</sup> A comprehensive analysis of Victorian regions (local government areas, LGAs) with high and low rates of acute myocardial infarction (AMI) revealed distinct characteristics in high-rate regions, including lower education levels, socio-economic disadvantage, higher cardiovascular risk factors, elevated prevalence of other cardiovascular conditions, lower cardiovascular knowledge, and lower likelihood of using EMS during ACS.<sup>16</sup>

To address these disparities, the Heart Matters trial was established. The trial aims to investigate the impact of community-level education, providing information on ACS risk factors and symptoms, while addressing the known barriers to calling EMS (Fig. 1). This trial builds upon previous community-based trials, such as the REACT study,<sup>14</sup> by specifically focusing on regions at highest AMI risk and evaluating the long-term effects of the intervention.<sup>7</sup> The hypothesis is that the Heart Matters education program will improve ACS knowledge within these communities, leading to an increased awareness of personal risk and prompt and appropriate treatment-seeking behaviours when experiencing ACS.

## Methods

### Trial design

The Heart Matters study is a community-based, pragmatic, cluster-randomised trial. It employs a stepped-wedge design, with eight clusters (high-risk LGAs in Victoria) transitioning from control to intervention sequentially every four months, along with a two-month transition phase (Fig. 2). Two pairs of closely located LGAs cross over together to prevent contamination. Cluster randomisation was necessary as the intervention is implemented at the regional level. The stepped-wedge design was chosen due to cost and resource limitations, as well as the need for equity across all LGAs.

Delays occurred due to the COVID-19 pandemic and associated lockdown measures. Data collection began on December 1st, 2021, and the intervention phase was conducted from February 1st, 2022, to March 31st, 2023. Primary trial data is expected to be received by

September-October 2023, with a longer-term follow-up planned until March 31st, 2024. The study is registered on [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04995900) (NCT04995900) and received ethics approval from the Monash University Human Ethics Committee (2020-26296-52553) on January 7th, 2021.

### Partnership approach

Heart Matters is funded by a National Health and Medical Research Council Partnership Grant (GTN 1180282). This scheme requires funding and in-kind contributions from partner organisations. For this study, these organisations include the NHFA, the Victorian Department of Health and Ambulance Victoria. Investigators from these partner organisations were involved in the development of the study protocol and delivery of the intervention.

### Study setting and site selection

The intervention was implemented in eight LGAs located in Victoria (Australia), representing approximately 28% ( $n = 1.8$  million) of the state's population. Four LGAs are located in metropolitan Melbourne, including one in the inner city and three on the outskirts. The remaining four LGAs are in rural locations.

These eight LGAs were selected based on data analysis from the Victorian Heart Maps, which identified the 16 LGAs with the highest ACS admissions. Using estimates from a previous study,<sup>11</sup> the final LGA selection considered sample size requirements and geographical distance to prevent contamination between intervention and control areas.

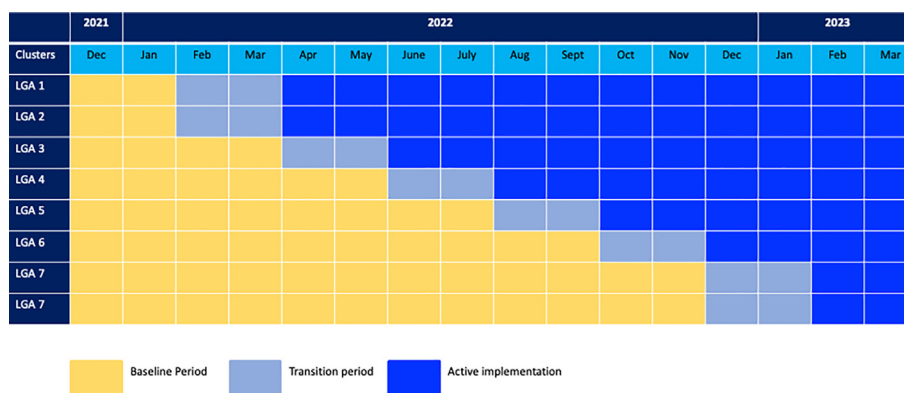
### Eligibility criteria and engagement strategies

The educational intervention was available to all adult community members in the selected LGAs. To enhance engagement and delivery, Heart Matters Coordinators were provided with specific subgroups and postcodes within each LGA that had the lowest symptom knowledge<sup>10</sup> or low EMS use for ACS.<sup>11</sup>

Community engagement strategies were implemented under the guidance of an experienced project manager (JW). Approaches that had proven successful in engaging with local communities previously were used.<sup>17</sup> Existing relationships within the communities were leveraged, and collaboration with local government, community leaders, and health service providers facilitated the identification of community groups, local events, and promotional opportunities. Local advertising channels, including newspapers, pharmacies, general practices, and a dedicated website, were utilised to ensure widespread awareness of Heart Matters activities.



**Fig. 1 – The Heart Matters intervention.**



**Fig. 2 – Stepped wedge cluster randomised trial design including baseline, transition, and active implementation periods.**

### Consumer and Public Co-Design and feasibility

Before implementing the intervention, an online survey<sup>10</sup> involving 560 adult residents from the eight LGAs was conducted to ascertain their interest in such an intervention, particularly considering the challenges posed by the COVID-19 pandemic. The survey results indicated that approximately 50% of respondents were very likely or somewhat likely to attend face-to-face educational sessions on heart health in community groups. Additionally, around 60% expressed a strong likelihood or some likelihood of watching a video on heart health via social media platforms.

To ensure a consumer-centred approach, a community representative sits on the Heart Matters Steering Committee. Workshops were also conducted involving experts and community groups to gather insights on effectively reaching culturally and linguistically diverse populations. These workshops aimed to obtain input on designing inclusive and accessible educational materials and resources, including translation services.

### Heart Matters intervention

The intervention involved delivering the Heart Matters education program to the communities in each LGA (Fig. 1). Dedicated HM Coordinators, qualified in relevant fields and familiar with the LGAs, were appointed and received comprehensive training. They were supported by a Project Manager. Once all LGAs transitioned to the intervention phase, a geotargeted social media campaign (e.g. brief videos on Facebook) was launched.

The educational materials used included Partner resources, such as the NHFA's Heart Attack Action Plan (available in multiple languages), and program-specific materials such as lived-experience videos and presentation slides. These materials were based on the Common-Sense Model of Self-Regulation<sup>18</sup> and addressed barriers to EMS use and patient delay in ACS.<sup>3,9,11,19</sup> Materials were developed and pre-tested with Partners, collaborators, and consumers. They were delivered through various modes (in person or digital, formal or informal). A detailed description of the intervention, adhering to the TIDieR checklist<sup>20</sup> and guide, will be reported with the main results.

### Randomisation

Randomization in the study occurs when clusters transition from the control period to the intervention period. The randomization process involved assigning LGAs to the specific sequences as illustrated in

Fig. 2, with 2 pairs of LGAs in close geographical proximity treated as “super-clusters” and randomised to the same sequence to lower the risk of contamination. Throughout the 16-month study duration, the LGAs transition into the intervention phase at two-month intervals.

To aid planning, the sequence generation was performed prior to the commencement of the study. The randomization process was conducted in a blinded manner by the Principal Investigator (JB), the study statistician (JeK), and overseen by an independent investigator.

Initially, each LGA was allocated a study number ranging from 1 to 8 by the Principal Investigator, which was then communicated to the independent investigator. Subsequently, the study statistician generated the randomisation sequence in Stata using the numbers 1 to 8, and this information was then linked back to the LGA allocation numbers.

### Sample size

The stepped wedge design in the schematic (a six-sequence stepped wedge design, with an implementation period and two clusters assigned to the first and last sequences) will give 80% power to detect a change in the proportion of ACS patients in the eight LGAs arriving via EMS of 11%,<sup>11,12</sup> from a baseline of 61%<sup>11</sup> to 72%, with a two-sided significance level of 5%. This detectable difference depends on an average of 40 ACS patients admitted per LGA in each two-month period (i.e., a total of 2240 ACS patients) and on the intra-cluster correlation, estimated to be 0.09 using data from the Victorian Emergency Minimum Dataset (VEMD) (2011–2015). This data indicated that more complex correlation structures, with decaying correlations over time, were unnecessary. The Stepped Wedge Stata Program was used for the sample size calculation.<sup>21</sup> No adjustment was made for LGA or participant attrition, as health services routinely collect the outcomes.

A sample size calculation was also conducted for two online surveys to determine a change in the level of knowledge of ACS symptoms. An online survey in 2020,<sup>10</sup> showed 25% of adults in the intervention LGAs (20% state-wide) could not name any heart attack symptoms. To detect a change from 25% to 10%, with 80% power and 2-sided significance level, requires a survey of 72 adults in each LGA in months 1–2 and again in months 9–10, assuming an intraclass correlation of 0.1, and a cluster autocorrelation of 0.9.

### Data collection

Most outcome data in this trial is collected prospectively in existing administrative datasets and registries. After quality checks, de-identified data for the 16-month study period and data at 12 months post-completion will be provided to the study statistician. The only trial-specific outcome data will be collected through three online surveys conducted among residents from the eight LGAs. The surveys will be conducted before the study, midway through the intervention phase, and after the study's completion, using an established survey and conducted by an independent research company. Further details on the survey methods can be found elsewhere.<sup>10</sup>

### Study outcomes

Outcomes will be examined for adult (aged 18 years or older) residents of the eight LGAs (except as noted in Table 1). The primary outcome is the proportion of ACS patients presenting to an emergency department by EMS. This outcome is routinely collected by the Victorian Department of Health for all patients presenting to public hospitals in Victoria and has been externally validated in ACS presentations.<sup>22</sup> Secondary outcomes are detailed in Table 1. We had originally planned to interview ACS patients from the LGAs for additional data on reach and effectiveness,<sup>9</sup> but this was not possible due to the restrictions on hospital research in the COVID pandemic.

### Statistical methods

Results from the trial will be reported according to the CONSORT extension for stepped wedge cluster randomised designs. LGA and patient demographics will be described by LGA and period. The primary analysis will include data from all eligible patients in the VEMD, where the intervention condition will be assumed to have been implemented as according to the trial schematic. All available binary primary and secondary outcomes will be analysed at the patient level using mixed-effects regression models with a binomial distribution and an identity link function, and a random intercept for cluster and fixed effects for each period and for the intervention. Results will be presented as risk differences and 95% confidence intervals; in the case of non-convergence, the log or logit link function will be applied, with risk or odds ratios reported. Continuous outcomes will be analysed similarly using linear mixed models. The Kenward-Roger correction will be applied to adjust for the small number of LGAs.<sup>23</sup> Since there may be imbalance between the LGAs with respect to various baseline characteristics, in a secondary analysis we will adjust for potential confounders known to influence EMS use that are available in the VEMD (e.g. age, sex, Australian born). Estimated effects will be expressed as odds ratios and as risk differences, with 95% confidence intervals. A secondary analysis will include an interaction between time and treatment to investigate a cumulative effect of the intervention over time. It has been shown that misspecification of the within-cluster correlation structure can lead to confidence intervals of incorrect widths,<sup>24</sup> so sensitivity analyses allowing for more complex within-cluster correlation structures<sup>25</sup> will be considered. Given that data are collected via the VEMD, we expect rates of data missingness to be low, thus complete-case analyses are planned. Subgroups analyses (e.g., age, sex, country of birth, ACS subtype) will be performed for the primary and some secondary outcomes. Analyses will be conducted in R (v 4.2.1 or later) and/or Stata (v17 or later) as appropriate.

We also plan to examine whether the effect of the Heart Matters intervention on the primary outcome was impacted by other factors

which limit the movement of the community and EMS access (e.g., COVID-19 restrictions and natural disasters). Heart Matters coordinators have been instructed to collect this information and dates. A model for the primary outcome will be fit as specified above, with the addition of a term for "under restrictions" and an interaction between this term and the intervention term. Estimates and 95% confidence intervals for the intervention effects for the settings of "under restrictions" and "not under restrictions", together with the p-value of the interaction term, will be reported.

### Program evaluation

We will also conduct a detailed program evaluation to examine implementation and inform the potential replication and scale-up. This evaluation is based on the RE-AIM Framework<sup>26</sup> and will include:

1. Participation rates in education: HM Coordinators completed a report for every session, recording number of participants, duration of the event, mode of delivery, location, resources used, and content. The NHFA will collect website hits and use of online resources (e.g. Heart Age Calculator).
2. Lessons learnt: through qualitative interviews with HM Coordinators.
3. Reach: the proportion of residents exposed to the HM intervention and social media reach.
4. Acceptability to individuals: evaluation surveys by participants who attended sessions and social media data (e.g. duration of video watching).

This data will be descriptively summarised and triangulated, as relevant, to provide information necessary for interpreting the study results.

### Economic evaluation

The potential cost-effectiveness of the intervention will be assessed using an economic simulation model based on a broad healthcare sector perspective. Costs will be expressed in 2022 Australian dollars. The costs of providing the program (HM Coordinators, education packages and other elements of the intervention) will be accounted for, as well as changes in health services utilisation. Potential cost offsets and changes in health outcomes will be estimated for the intervention and control groups. Data for the economic evaluation will be drawn from the study cohorts and other sources including information from the published literature, program operational data and change in activity (behaviour) data. The primary outcome for the economic evaluation will be the incremental cost per disability-adjusted life year avoided with intervention compared to usual care.

One-way sensitivity analyses will be conducted whereby model inputs are varied, such as the number of additional patients provided thrombolysis and the estimated disability-adjusted life years avoided from the earlier provision of thrombolysis or other acute treatments.

### Ethics and governance

Any modifications to the protocol were approved by the Monash University Human Ethics Committee, reported in the clinical trial register and will be included in any publications. All data will be provided to the investigators in a de-identified format under a waiver of consent. This is a low-risk study, and there are no perceived risks to participants. Therefore, no interim data analysis was necessary, and a data safety committee was not required.

**Table 1 – The Heart Matters Trial primary and secondary outcomes to be collected in adult residents of the eight Local Government Areas (time frames include main trial and long-term follow-up).**

Outcome (definition)	Data Sources/Agency Time frame for data collection
<b>Primary outcome</b>	
Emergency Medical Service (EMS) use for acute coronary syndrome (ACS) (proportion of ACS patients that present to the emergency department [ED] by EMS)	Victorian Emergency Minimum Dataset (VEMD)/ Department of Health December 2021–March 2024
<b>Secondary outcomes</b>	
The median ACS (STEMI) patient delay time (median time from symptom onset to decision to seek medical attention)	The Victorian Ambulance STEMI Quality Initiative (VASQI)/Ambulance Victoria The Victorian Cardiac Outcomes Registry (VCOR)/Monash University December 2021–March 2024
ACS (STEMI) patient delay time <60 minutes (the proportion of ACS [STEMI] patients with patient delay time <60 minutes)	The Victorian Ambulance STEMI Quality Initiative (VASQI)/Ambulance Victoria The Victorian Cardiac Outcomes Registry (VCOR)/Monash University December 2021–March 2024
The median ACS/STEMI patient prehospital delay time (median time from symptom onset to arrival at hospital)	VASQI/Ambulance Victoria VCOR/Monash University December 2021–March 2024
ACS/STEMI patient prehospital delay time <120 minutes (the proportion of ACS/STEMI patients with prehospital delay time <120 minutes)	VASQI/Ambulance Victoria (VCOR)/Monash University December 2021–March 2024
Awareness of own risk of heart attack (the proportion of adult members of the community who are aware of their own risk of heart attack)	Heart Watch Survey/Heart Foundation December 2021–January 2022 August 2021–September 2021 April–May 2023
Awareness of heart attack/heart disease as the leading cause of death (the proportion of members of the community who identify heart attack/disease as a leading cause of death)	Heart Watch Survey/Heart Foundation August 2021–September 2021 August 2022 April–May 2023
Awareness of heart disease (cardiovascular) risk factors (the proportion of adult members of the community who identify cardiovascular risk factors)	Heart Watch Survey/Heart Foundation August 2021–September 2021 August 2022 April–May 2023
The number of correctly named heart disease (cardiovascular) risk factors (the number of correctly named risk factors by adult members of the community)	Heart Watch Survey/Heart Foundation August 2021–September 2021 August 2022 April–May 2023
Awareness of heart attack signs and symptoms (the proportion of adult members of the community aware of any heart attack symptoms)	Heart Watch Survey/Heart Foundation August 2021–September 2021 August 2022 April–May 2023
The number of correctly named heart attack signs and symptoms (the number of correctly named ACS symptoms by adult members of the community)	Heart Watch Survey/Heart Foundation August 2021–September 2021 August 2022 April–May 2023
Confidence in knowing how to act (the proportion of adult members of the community who are confident about what they would do if experiencing a heart attack)	Heart Watch Survey/Heart Foundation August 2021–September 2021 August 2022 April–May 2023
EMS use in scenarios (the proportion adults who correctly state they would call an EMS for two heart attack scenarios)	Heart Watch Survey/Heart Foundation August 2021–September 2021 August 2022 April–May 2023
Heart Health Checks (rates of Medicare claims for Heart Health Checks)	Medicare data/Medicare December 2021–March 2024
Rates of ACS ED presentations (the rates of ED presentations that are ACS)	VEMD/Department of Health December 2021–March 2024
Rates of unspecified chest pain ED presentations (the rates of ED presentations that are unspecified chest pain)	VEMD/Department of Health December 2021–March 2024

(continued on next page)

**Table 1 (continued)**

Outcome (definition)	Data Sources/Agency Time frame for data collection
ACS ED presentations via General Practitioners (the proportion of ACS ED presentations referred by GPs)	VEMD/Department of Health December 2021–March 2024
Rates of ACS survival (the proportion of ACS patients surviving to hospital discharge)	Victorian Admitted Episodes Dataset (VAED)/ Department of Health December 2021–March 2024
Rates and incidence of out-of-hospital cardiac arrest (rates and incidence rates of out-of-hospital cardiac arrest)	Victorian Ambulance Cardiac Arrest Registry (VACAR)/Ambulance Victoria December 2021–March 2024
Out-of-hospital cardiac arrest survival (rates out-of-hospital cardiac arrest survival to hospital discharge)	VACAR/Ambulance Victoria December 2021–March 2024
Calls to EMS for chest pain (the proportion of chest pain [event type 10] calls to EMS)	Electronic computer-aided dispatch (CAD) records/Ambulance Victoria December 2021–March 2024
Calls to EMS for non-chest pain (the proportion of non-chest pain [non-event type 10] calls to EMS)	CAD records/Ambulance Victoria December 2021–March 2024

A Steering Committee, chaired by the Principal Investigator (JB), has met bimonthly during the intervention and includes all investigators, relevant partner organisation staff, study staff and a consumer representative. A smaller Management Committee has met fortnightly and oversees the daily management.

## Discussion

This study aims to assess the impact of community education on ACS recognition and response, and ultimately improve outcomes in communities at high risk of AMI, characterized by lower EMS use and ACS knowledge. The findings from this study will provide valuable evidence for policymakers and practitioners both in Australia and internationally.

The primary outcome will be obtained from an administrative dataset and is not subject to response rate or missing data.<sup>11,22</sup> The investigators have extensive experience working with all the outcomes and data sources involved in this study. Furthermore, the sample size has been carefully determined based on the current rates of ACS in the eight LGAs, ensuring feasibility and meaningful results.

The Partner organisations involved in this study have a proven track record of successfully engaging with and conducting community education initiatives. Additionally, strong relationships were established with major health services in each LGA, including investigators and local EMS branches.

### Limitations

A major limitation of the study is the potential for contamination, as people from other study LGAs may attend HM sessions in LGAs where the intervention has started. We will assess this issue by including participants' region of residence in the evaluation survey, as well as monitoring for other cardiovascular health promotion campaigns in the regions. Sensitivity analyses will account for other factors such as lockdown and natural disasters. The public survey is subject to typical limitations of survey design, including responder bias.

Results will be published in peer-reviewed journals, presented at conferences, and shared with Partner organizations. Main study

and long-term follow-up results will be published separately. Key findings will be disseminated through local media, social media, and the study website. Checklist tools (e.g. TIDiER<sup>20</sup> and CONSORT<sup>27</sup>) will be used to provide a comprehensive description of the intervention and results for future replication and understanding.

## Declaration of Competing Interest

The 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.

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## Author contributions

JB conceived the initial study design and drafted the protocol submitted to the National Health and Medical Research Council with contributions from all investigators (nine chief investigators and ten associate investigators) and three partner investigators listed in the grant application. JeK conducted the sample size calculation and drafted the statistical plan. DC and JoK drafted the economic evaluation plan. JW designed the community engagement and is managing the project. JB drafted the manuscript, and all other authors contributed to the revisions and approved the final version.

## Access to data

Data access is restricted to the Principal Investigator, the economic analysts, and the study statisticians. Contractual agreements for data provision do not allow for the sharing of data.

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