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Protocol paper

A study protocol for a cluster-randomised controlled trial of smartphone-activated first responders with ultraportable defibrillators in out-of-hospital cardiac arrest: The First Responder Shock Trial (FIRST)

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Abstract

Objective: To describe the First Responder Shock Trial (FIRST), which aims to determine whether equipping frequently responding, smartphone-activated (GoodSAM) first responders with an ultraportable AED can increase 30-day survival rates in OHCA.

Methods: The FIRST trial is an investigator-initiated, bi-national (Victoria, Australia and New Zealand), registry-nested cluster-randomised controlled trial where the unit of randomisation is the smartphone-activated (GoodSAM) first responder. High-frequency GoodSAM responders are randomised 1:1 to receive an ultraportable, single-use AED or standard alert procedures using the GoodSAM app.

The primary outcome is survival to 30 days. The secondary outcome measures (shockable rhythm, return of spontaneous circulation, event survival, and time to first shock delivery) are routinely collected by OHCA registries in both regions. The trial was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) (Registration: ACTRN12622000448741) on 22 March 2022.

Results: The trial started in November 2022 and the last patient is expected to be enrolled in November 2024. We aim to detect a 7% increase in the proportion of 30-day survivors, from 9% in patients attended by control responders to 16% in patients attended by responders randomised to the ultraportable AED intervention arm. With 80% power, an alpha of 0.05, a cluster size of 1.5 and a coefficient of variation for cluster sizes of 1, the sample size required to detect this difference is 714 (357 per arm).

Conclusion: The FIRST study will increase our understanding of the potential role of portable AED use by smartphone-activated community responders and their impact on survival outcomes.

Keywords: Resuscitation, Community response, Community responder, AED, Public access defibrillation, Out-of-hospital cardiac arrest

Introduction

Out-of-hospital cardiac arrest (OHCA) is a time-critical prehospital emergency and a leading cause of mortality and morbidity globally. In Australia and New Zealand, the rate of OHCA is one of the highest in the world, with over 30,000 OHCAs every year.[1] Less than one in ten patients survive to hospital discharge.[2] However, when CPR and defibrillation are provided quickly, alongside an emergency medical response, the chance of survival can improve three-fold.[3–6]

The sequential actions required for successful resuscitation are highlighted by the OHCA 'chain of survival'.[7] Actions in the chain

Abbreviations: EMS, emergency medical services, AED, automatic external defibrillator, GoodSAM, Good Smartphone Activated Medic, ROSC, return of spontaneous circulation, OHCA, out-of-hospital cardiac arrest, VACAR, Victorian Ambulance Cardiac Arrest Registry, CPR, cardiopulmonary resuscitation, PAD, public access defibrillator, FIRST, First Responder Shock Trial.

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of survival include community response (identification of cardiac arrest, calling Emergency Medical Services (EMS) for help, starting CPR, early defibrillation), EMS interventions (both basic and advanced), and in-hospital care. The activation of community responders bridges the gap between the EMS call and EMS arrival by providing early CPR and defibrillation. Whilst bystander CPR rates in Australia and New Zealand are relatively high (>70% in OHCA cases where EMS attempt resuscitation), community defibrillation rates remain low (16% and 5%, respectively).[8,9] A contributing factor to the poor community defibrillation rate may be the limited availability and accessibility of automated external defibrillators (AEDs) to members of the public.[10,11]

The **F**irst **R**esponder **S**hock **T**rial (FIRST) aims to determine whether equipping frequently responding smartphone-activated (GoodSAM) first responders with an ultraportable AED can increase 30-day survival rates in OHCA compared with the current strategy of retrieving the closest available community AED. The FIRST trial is a registry-nested clinical trial using routinely collected data from the Victorian Ambulance Cardiac Arrest Registry (VACAR)[12] and Aotearoa New Zealand OHCA Registry (NZ OHCARegistry).[13]

Methods

Protocol

The FIRST trial is presented according to SPIRIT guidelines (Appendix 1).[13] Each locality has a specific protocol: Ambulance Victoria Clinical Trial Protocol Version 4.1 (10 October 2022) and Hato Hone St John Clinical Trial Protocol Version 9 (22 August 2022). Both protocols are available on the trial website: https://www.ambulance.vic.gov.au/first/. The New Zealand addendum outlines the opt-out process for patients enrolled in the trial who survive the OHCA event (Appendix 2).

The trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12622000448741). Core study information is presented in Appendix 3.

Study design

FIRST is an investigator-initiated, bi-national, registry-nested, cluster-randomised controlled trial where the unit of randomisation is the smartphone-activated (GoodSAM) first responder.

Study setting

This multicentre trial in Victoria, Australia and Aotearoa, New Zealand is co-led by Ambulance Victoria (Melbourne, Australia) and Hato Hone St John (Auckland, New Zealand). The trial commenced recruitment in September 2022.

Ambulance Victoria, the sole EMS provider in Victoria, services a population of 6.6 million people over 227,500 km^2. Ambulance Victoria treated 7,361 OHCA patients in 2021/22.[9] New Zealand's population is approximately 5.1 million people, encompassing an area of 268,000 km^2. Hato Hone St John is the largest EMS provider in New Zealand and services 90% of the country, or approximately 4.4 million people, with the remainder serviced by Wellington Free Ambulance. Collectively, the New Zealand services report on OHCA incidents using the Aotearoa New Zealand OHCA Registry (NZ OHCA Registry). In 2021/22, 2,348 OHCA patients were treated by Hato Hone St John and Wellington Free Ambulance.[8]

EMS in both countries are activated through the national emergency number where structured, electronic call-taking algorithms are in place to detect OHCA and prompt bystander CPR using the same commercial call-taking software: Medical Priority Dispatch System™ (ProQA version 13.3; The International Academies Of Emergency Dispatch®, Utah, US). Identifying a suspected cardiac arrest in the emergency call simultaneously dispatches advanced life support and intensive care paramedics. In addition, firefighters and community volunteers capable of basic life support and defibrillation using an AED are also dispatched.[14,15]

Smartphone-activated (GoodSAM) responders

The Good Smartphone Activated Medics (GoodSAM) app was developed to alert volunteers to cardiac arrests occurring near the responder.[16] To register with GoodSAM in Victoria and New Zealand, individuals must have knowledge of CPR and AED application.

Since 2018, Ambulance Victoria and the New Zealand EMS providers have integrated the alerting of GoodSAM volunteers into their emergency dispatch system according to a standardised matrix (Appendix 4). Activation of a GoodSAM responder is determined by the call categorisation allocated by the emergency call-taker. The categorisation of the call type helps to ensure that first responders are not dispatched in some instances, including trauma, hangings, or where hazards may be present at the scene.

Suspected OHCA calls generate a community-responder GoodSAM activation when at least one GoodSAM responder is within the alert radius. In Victoria, any local government area with a population >7,500 receives up to three GoodSAM activations within 500 metres of the scene location. Less populated areas have an activation radius of 5,000 metres. In New Zealand, up to 3 GoodSAM activations occur for responders within 1,000 metres of the scene location. GoodSAM responders can accept or reject an alert; if no response is received, the GoodSAM system automatically alerts another responder nearby if available.[16]

The GoodSAM initiative, including the registration, dispatch, and follow-up of responders, is managed independently by Ambulance Victoria and New Zealand EMS. In Victoria, GoodSAM responders who accept an alert are followed up by Ambulance Victoria via telephone and provided with welfare support services if required. In New Zealand, GoodSAM responders who accept an alert are routinely sent a follow-up email with details of support services available. In both regions, GoodSAM responders must be registered health professionals, emergency service providers (ambulance, police, fire, or rescue), non-emergency patient transport staff, or members of the community familiar with CPR and AED use. Approximately half of all registered GoodSAM responders are paramedics, while 40% are fire and emergency personnel, health professionals, or non-emergency ambulance patient transport staff.[17] Approximately 32,000 and 10,000 people are registered as GoodSAM responders in Victoria and New Zealand, respectively.

Locating a nearby AED

Locations of AEDs in Victoria are geocoded into the GoodSAM app. In New Zealand, the AED Locations registry (https://aedlocations.co.nz/) is maintained by Abletech (Wellington, New Zealand). Alongside the NZ AED Locations website, GoodSAM responders can also view nearby AEDs using the GoodSAM app.

Eligibility criteria

The trial utilises pragmatic eligibility criteria reflecting the real-world application of AEDs in the community. The inclusion criteria are all OHCA patients assessed by EMS and with the activation of an eligi-

ble GoodSAM first responder where the responder accepts the alert and arrives on the scene before EMS.

Exclusion criteria

Patients with a Do Not Resuscitate (DNR) order or Advanced Care Directive, cardiac arrests secondary to trauma or hanging, and locations or events where scene safety issues apply are excluded.

High-frequency GoodSAM responders

To maximise the utilisation of ultraportable AEDs in the FIRST trial, high-frequency GoodSAM responders were invited to participate. High-frequency responders are defined as GoodSAM responders with an annual alert acceptance ratio $\geq$0.5 (number of alerts received/total time since registration with GoodSAM) (minimum of 1 accepted alert every two years).

Randomisation

High-frequency GoodSAM responders (clusters) were randomised 1:1 to either the intervention or control arm using a computer-generated randomisation sequence. For NZ, clusters were stratified by the 2015 District Health Board region (Statistics NZ) of the participant's residence and the alert acceptance ratio. For Ambulance Victoria, clusters were stratified by Statistical Area Level 4 (Australian Bureau of Statistics) and the alert acceptance ratio. The treatment allocation will remain unchanged over the life of the trial.

Study interventions

High-frequency GoodSAM responders randomised to the control arm follow standard care protocols: GoodSAM responders who accept the alert are provided with the location of the patient and the nearest AED if available. The GoodSAM responder may then collect the AED (if available) and proceed to the patient to render assistance or proceed directly without an AED.

High-frequency GoodSAM responders randomised to the intervention arm received an ultraportable AED (CellAED®, Rapid Response Revival Research Limited).[19] Intervention arm responders received the ultraportable AED by post and were instructed to watch a short ($\sim$12 minute) instructional video. The accompanying instructional booklet contained information regarding the storage and carriage of the ultraportable AED.

Regular emails and push notifications are sent to intervention arm responders, with reminders about the optimal storage and carriage conditions. Intervention arm responders who accept an alert will be provided with the location of the patient and the nearest AED if available. Intervention arm responders are instructed to use the nearest AED available (either ultraportable AED or another AED). The ultraportable AED is replaced automatically close to its expiry date or after every use.

For alerts where two or more GoodSAM responders accept (regardless of the study arm), one of the responders will still be instructed to retrieve the next closest AED before arriving on the scene.

Trial coordinators or the GoodSAM management teams in each region will engage (via email or telephone) with GoodSAM responders who use the ultraportable AED. Once used, the device is retrieved for data extraction.

Blinding

FIRST is an open-label trial. Using a sham device in the control group is inappropriate as this will influence the collection of other nearby AEDs. Blinded allocation of randomisation was performed by a statistician and responsible investigator, whereby the responder details were replaced with a unique responder ID. The primary outcome assessment will be performed by independent OHCA registry staff blinded to treatment allocation. Hospital outcome data are collected by registry staff who are blinded to treatment allocation. The dispatch of GoodSAM responders depends on the closest available responder to the scene and there is no preferential dispatch of responders who are allocated an ultraportable AED.

Outcome measures

Fig. 1 shows the study flow diagram.

Primary outcome measure

The primary outcome of the trial is patient survival to 30 days.

Secondary outcome measures

The secondary outcomes include: Proportion of patients with return of spontaneous circulation (ROSC); Proportion of patients who survive the event; Proportion of patients with defibrillation pads applied; Proportion of patients receiving defibrillation before EMS arrival; Proportion of patients with initially shockable rhythms; Time from emergency call to first shock delivery. The 12-month functional recovery and quality-of-life outcomes (proportion with good functional recovery (Glasgow Outcome Scale Extended $\geq$7), median Euroqol 5D score and proportion returning to work (who worked prior to their arrest)) are collected by Victoria only.

Data collection methods

Data collected for the trial are outlined in Table 1. The Victorian Ambulance Cardiac Arrest Registry (VACAR) records details of all OHCA events where EMS are in attendance.[18] In-field treatment data is captured electronically using computer tablets operated by paramedics. In Victoria, adult patients discharged alive following OHCA are invited at 12 months post-arrest to undergo a structured telephone interview using validated quality-of-life survey tools.[19] The NZ OHCA Registry prospectively collects information on all OHCA cases attended by Hato Hone St John and Wellington Free Ambulance.[15] The VACAR and NZ OHCA Registry follow the Utstein guidelines for all data collection and definitions.[20] The electrocardiogram and event data are extracted from the ultraportable AED after deployment. VACAR and the NZ OHCA registry capture information on GoodSAM attendance using the GoodSAM app and prescribed survey questions (via a phone interview in Victoria or an online survey in NZ).

Qualitative survey data on ultraportable AED usability is obtained from an online survey. All GoodSAM responders randomised to the ultraportable AED arm are invited to participate in an online survey after accepting a GoodSAM alert. The survey aims to identify the acceptability, ease-of-use, perceived benefits, and perceived barriers of using the ultraportable AED.

The data variables harmonised for the study data are shown in Table 1.

Data management

Registry-based data is managed according to existing ethics approvals governing the VACAR and the NZ OHCA Registry. Ambulance Victoria is the coordinating centre for the trial. All patient data from the study is stored in a computer database maintaining confi-

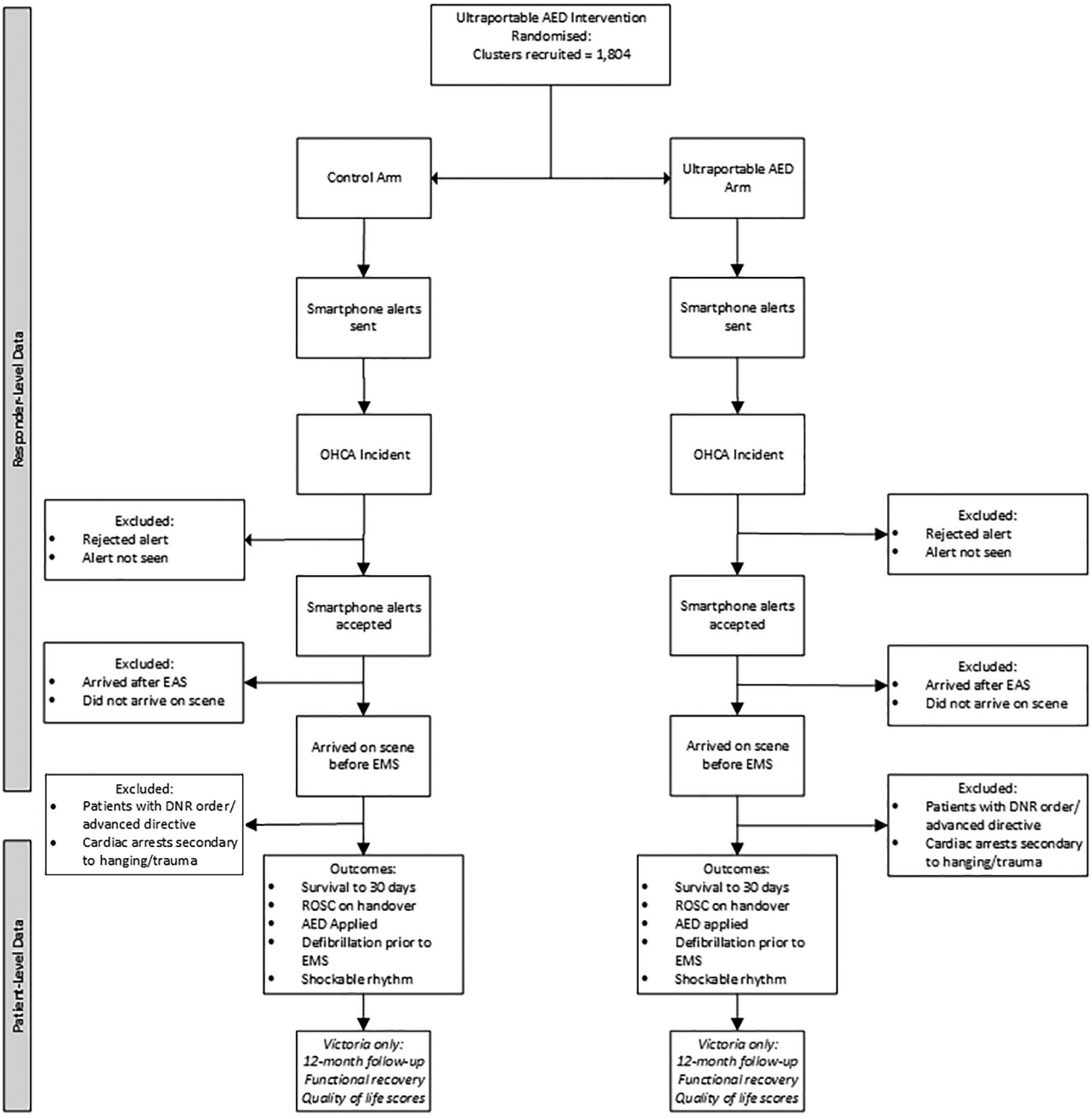

Fig. 1 – The study flow diagram for the FIRST trial at the Victorian and New Zealand localities.

dentiality in accordance with legislation on privacy and the use of health data.

Statistical methods

Sample size calculation

Based on historical data captured by the VACAR and the NZ OHCA Registry (2018–2022), there were 2,194 GoodSAM responders with an annual alert accept frequency $\geq$0.5. These responders arrived on scene to 1,047 OHCA patients, of which the rate of initially shockable rhythms was 22%, the bystander defibrillation rate was 13% (for initially shockable rhythms), and the 30-day survival rate was 9% for all EMS-attended OHCA. As most eligible responders will only attend one OHCA event during the study period, we assumed that the within-cluster variation (intraclass correlation coefficient) would be very low or negligible (ICC $\sim$ 0.01). We aim to detect a 7% increase in the proportion of 30-day survivors, from 9% in control responders to 16% in responders randomised to the ultraportable AED intervention arm. With 80% power, an alpha of 0.05, a cluster size of 1.5 and a coefficient of variation for cluster sizes of 1, the sample size required to detect this difference is 714 (357 per arm).

Data analysis

An independent biostatistician will perform data analyses for the primary and secondary outcomes. Variables that approximate a normal distribution will be summarised as mean ± standard deviation, and groups will be compared using t-tests. Non-normal variables will be

Table 1 – The data variables and sources included in the FIRST trial.

Data Variable	Definition	Source AV	Source HHStJ
30-Day Mortality	Death within 30 days of the event date	VACAR/BDM	Ministry of Health
Alert Status	Accepted/Rejected/Not seen	GoodSAM	GoodSAM
Is OHCA event	Confirmed as OHCA by EMS	VACAR	NZ OHCA Registry
GoodSAM on scene	Yes/No if GoodSAM responder arrived at the scene	GoodSAM responder survey	GoodSAM responder survey
GoodSAM on scene first	Yes/No if GoodSAM arrived on scene before EMS and/or Fire and Emergency personnel	GoodSAM responder survey	GoodSAM responder survey
AED on Scene	Yes/No of whether AED was present on scene before arrival of EMS or First Response Unit	GoodSAM responder survey	GoodSAM responder survey
AED on scene type	The type of AED used on scene: ultraportable, both, Other	GoodSAM responder survey	GoodSAM responder survey
Pads applied before EMS arrival	Yes/No for AED application to patient prior to EMS arrival	VACAR	GoodSAM responder survey
Defibrillation Prior to EMS Arrival	Yes/No of whether a shock was delivered prior to EMS or Fire and Emergency arrival	VACAR	GoodSAM responder survey CellAED event report NZ OHCA Registry
Number of shocks delivered	Count of shocks delivered prior to EMS or First Response Unit	VACAR	NZ OHCA Registry CellAED event report
Location	Location of the event: Private residence, public location, other	VACAR	NZ OHCA Registry
Initial rhythm	Presenting rhythm from the first AED or ECG	VACAR	CellAED event report NZ OHCA Registry
Attempted Resus	Whether resuscitation was attempted by EMS	VACAR	NZ OHCA Registry
Presumed cardiac	Yes/No from aetiology recorded by EMS	VACAR	NZ OHCA Registry
ROSC	Yes/No for return of spontaneous circulation (ROSC) on hospital handover	VACAR	NZ OHCA Registry
Quality of Life scores		VACAR	N/A

VACAR – Victorian Cardiac Arrest Registry.
BDM – Births Deaths and Marriages Victoria.
GoodSAM – Good smartphone-activated medic.
NZ OHCA Registry – Aotearoa New Zealand Out-of-Hospital Cardiac Arrest Registry.

summarised as median and first and third quartiles (Q1, Q3), and groups will be compared using Mann-Whitney rank sum tests with exact inference. Binomial variables will be expressed as proportions and 95% confidence intervals (exact binomial), and groups will be compared using the chi-squared test. The primary outcome will be examined using mixed-effects logistic regression analysis, controlling for clustering by responder. If the intraclass correlation coefficient is negligible (<0.01), simple logistic regression will be used instead. The primary analysis will consider all eligible OHCA patients where a participating GoodSAM responder arrived before EMS (per-protocol). In addition, we will also examine primary and secondary outcomes in all OHCA patients where a participating GoodSAM responder was alerted to the event, regardless of whether they accepted the alert, arrived on scene, or met eligibility criteria.

Pre-specified sub-groups

We will examine the effect of the intervention on the primary outcome across several subgroups, including age groups (<65/≥65 years), initial arrest rhythm (shockable vs. non-shockable), arrest location (public vs. private), EMS response time (<6/6–10/≥10 minutes), aetiology (presumed cardiac vs. other), and witness status (unwitnessed vs. bystander witnessed). We will also provide a descriptive analysis of characteristics and outcomes in OHCA patients who are treated by an intervention arm responder using an ultraportable AED, but who were not alerted to the event through the GoodSAM system.

Data monitoring

The data safety monitoring board (DSMB) will undertake an interim analysis after 150 patients have been enrolled in each treatment arm. The study will be stopped if there is a significant difference in the primary outcome measure between the two arms (p <.001) at the interim analysis based on the Peto approach.[21] During the interim analysis, the DSMB will also review cluster sizes and intra-class correlation and determine if changes to the sample size are required.

Adverse events

The application and use of AEDs by lay bystanders in Australia and New Zealand is recommended even if the bystander has no specific training. The trial will record details of all adverse events (AE), defined as any untoward medical occurrence in a clinical trial subject or participant. Untoward medical occurrences are inevitable as the population includes those affected by OHCA. Therefore, reporting AEs will be restricted to events that are considered related to the use of the ultraportable AED (possibly, probably, or definitely). A serious adverse event is defined as any adverse event that is life-

threatening, requires hospitalisation or prolongation of current hospitalisation or results in persistent or significant disability or incapacity.

Ethics

The study protocol has been approved by the Monash University Human Research Ethics Committee (MUHREC) (Project ID 31983) and the New Zealand Northern B Health and Disability Ethics Committee (reference 2022 FULL 12835). The study is conducted in accordance with the Declaration of Helsinki and Good Clinical Practice (GCP) guidelines.

Consent

In both localities, GoodSAM responders meeting the alert frequency criteria were invited to participate in an opt-in process. Responders can opt out of the trial at any stage. GoodSAM responders are predominantly registered health professionals[17] who have agreed to the GoodSAM privacy principles, codes of conduct, and operational requirements.[22]

Since the intervention of applying an ultraportable AED will have already occurred, consent from the patient is only sought for the use of event data and follow-up. The VACAR (Monash University Human Research Ethics Committee ID #24377) and the NZ OHCA Registry (Health and Disability Ethics Committee ID #19/NTB/187/AM01) have existing ethics approvals. The Victoria-based FIRST patients are covered under a waiver of consent.

The Hato Hone St John locality will mail patients presumed to be alive within four weeks of the post-cardiac arrest. Mortality data will be obtained from the Manatū Hauora Ministry of Health. All patients without a date of death will be sent information on the study and the opt-out process to remove patient data from the study. If a patient opts out, all data will be removed unless the analysis has been completed.

Protocol amendments

Protocol amendments will only occur after approval by both the Monash University Human Research Ethics and Health and Disability Ethics Committees and consultation with the DSMB. The FIRST Management Team will introduce protocol amendments at each locality.

Dissemination of findings

The findings from the FIRST trial will be shared with the emergency medical services involved in the trial. The publication of results from the FIRST trial will be targeted to high-impact journals. Findings will be presented following the CONSORT guidelines.[23]

Discussion

The First Responder Shock Trial (FIRST) is a world-first trial that aims to identify whether providing ultraportable AEDs to community responders improves survival from OHCA. The primary outcome of this trial is survival to 30 days. The secondary outcome measures (ROSC, event survival, AED applied, defibrillation before EMS arrival, shockable rhythm, time to first shock and 12-month functional recovery) utilise variables currently collected in the VACAR and the NZ OHCA Registry or within the GoodSAM responder app and post-event survey.

The FIRST trial evaluates the impact of increased availability and portability of AEDs on the delivery of community responder defibrillation. Timely response by bystanders remains a crucial factor driving favourable outcomes for patients with an initial shockable rhythm.[2,17] Defibrillation by bystanders using an AED can produce survival rates of over 50%.[5,6] Early defibrillation by bystanders is also associated with better short-term and long-term functional recovery outcomes.[4,24–28] Unfortunately, only one in ten OHCAs with an initial shockable rhythm receive defibrillation from bystanders.[6] Developing strategies to increase bystander defibrillation has been identified as a leading research priority.[29]

A critical international knowledge gap recognised by the International Liaison Committee on Resuscitation (ILCOR) is the use of digital media applications to enhance first responders' ability to deliver timely defibrillation, particularly in the home.[29] The most significant barrier to increasing the use of AEDs by bystanders is their location; although 75% of OHCA currently occur in the home, most AEDs are in high-density public locations.[5] Furthermore, there is inequity in AED placement: the most deprived communities (with the highest OHCA rates) have the lowest access to AEDs.[10]

Smartphone activation of first responders can help significantly improve rates of bystander CPR and defibrillation.[16,30–34] A large observational study from Denmark showed that when smartphone-activated responders arrived before EMS, the odds of providing bystander CPR increased by 76%, and the odds of bystander defibrillation increased more than three-fold.[30] Unfortunately, rates of AED use remain low among smartphone-activated first responders (<12%), and this reflects the socioeconomic and geographical inequities in the current placement of AEDs across communities.[10,11] However, novel defibrillation technologies – such as the CellAED® – are emerging that may significantly improve the cost-effectiveness and accessibility of AEDs. The CellAED® is a single-use, ultraportable (smartphone-sized) AED which is available at a low cost (AUD$359). Combining GoodSAM-activated first responders with an ultraportable AED solution has the potential to dramatically transform the early response to OHCA patients and reduce inequity. A simulated cost-effectiveness analysis will be conducted as a substudy of the FIRST trial. The economic evaluation will be based on the consolidated health economics reporting standards and recommendations for economic evaluations of randomised trials using a cluster design.[35,36]

Conclusion

There is unequivocal evidence that early defibrillation saves lives for patients suffering cardiac arrest. The FIRST trial is a pragmatic, cluster-randomised controlled study that aims to improve 30-day survival rates in OHCA by equipping frequently responding, smartphone-activated (GoodSAM) first responders with a single-use, low-cost, ultraportable AED.

CRediT authorship contribution statement

Verity Todd: Resources, Conceptualization, Data curation, Funding acquisition, Investigation, Methodology, Project administration. **Bridget Dicker:** Resources, Conceptualization, Data curation, Funding acquisition, Investigation, Methodology, Project administration. **Daniel Okyere:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration. **Karen Smith:** Conceptualization, Funding acquisition, Investi-

gation, Methodology. **Tony Smith:** Conceptualization, Investigation, Methodology. **Graham Howie:** Conceptualization, Funding acquisition, Investigation, Methodology. **Dion Stub:** Resources, Conceptualization, Investigation, Methodology. **Michael Ray:** Conceptualization, Investigation, Methodology. **Ralph Stewart:** Conceptualization, Investigation, Methodology. **Tony Scott:** Conceptualization, Investigation, Methodology. **Andy Swain:** Conceptualization, Investigation, Methodology. **Natalie Heriot:** Conceptualization, Data curation, Investigation, Methodology. **Aroha Brett:** Conceptualization, Investigation, Methodology. **Emily Mahony:** Conceptualization, Investigation, Methodology, Project administration. **Ziad Nehme:** Resources, Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: 'Rapid Response Revival Limited have provided 1000 CellAED® devices in-kind for use in the trial. Rapid Response Revival Limited has not and will not be involved in the design or conduct of the trial and will not be involved in any generation, interpretation, or publication of results. BD, VT, TS, AB are employees of Hato Hone St John. ZN, DS, MR, EM, DO and NH are employees of Ambulance Victoria. DS research is supported by NHF and NHMRC fellowships. ZN is supported by a NHF fellowship. Funding for the project is provided through National Heart Foundation Vanguard Grant (#106763), Australia, and the Auckland University of Technology's Faculty Research Development Fund.'.

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Appendix A. Supplementary material

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