





# BMJ Open Improving community-based first response to out of hospital cardiac arrest (FirstCPR): protocol for a cluster randomised controlled trial

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## ABSTRACT

**Introduction** Out-of-hospital cardiac arrest (OHCA) is associated with poor survival outcomes, but prompt bystander action can more than double survival rates. Being trained, confident and willing-to-perform cardiopulmonary resuscitation (CPR) are known predictors of bystander action. This study aims to assess the effectiveness of a community organisation targeted multicomponent education and training initiative on being willing to respond to OHCA. The study employs a novel approach to reaching community members via social and cultural groups, and the intervention aims to address commonly cited barriers to training including lack of availability, time and costs.

**Methods and analysis** FirstCPR is a cluster randomised trial that will be conducted across 200 community groups in urban and regional Australia. It will target community groups where CPR training is not usual. Community groups (clusters) will be stratified by region, size and organisation type, and then randomly assigned to either immediately receive the intervention programme, comprising digital and in-person education and training opportunities about CPR and OHCA over 12 months, or a delayed programme implementation. The primary outcome is self-reported 'training and willingness-to-perform CPR' at 12 months. It will be assessed through surveys of group members that consent in intervention versus control groups and administered prior to control groups receiving the intervention. The primary analysis will follow intention-to-treat principles, use log binomial regression accounting for baseline covariates and be conducted at the individual level, while accounting for clustering within communities. Focus groups and interviews will be conducted to examine barriers and enablers to implementation and costs will also be examined.

**Ethics and dissemination** Ethical approval was obtained from The University of Sydney. Findings from this study will be disseminated via presentations at scientific conferences, publications in peer-reviewed journals, scientific and lay reports.

**Trial registration number** ACTRN12621000367842.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study will evaluate a novel approach of targeting community organisations to increase the rates of participants willing and trained to respond in out-of-hospital cardiac arrest.
- ⇒ The evaluation will be in a large cluster randomised trial and involve a detailed process evaluation.
- ⇒ The intervention development uses strong codesign methods involving multiple stakeholders across diverse community groups, health professional groups, government and academics.
- ⇒ Outcomes will be measured through serial surveys of self-reported items on training and willingness-to-perform cardiopulmonary resuscitation.
- ⇒ Cluster allocation will not be blinded to participants or research staff, though researchers conducting analysis will be blinded to allocation status.

## INTRODUCTION AND BACKGROUND

Out-of-hospital cardiac arrest (OHCA) is a major public health issue, with current survival rates of about 1 in 10.<sup>1</sup> A range of patient, population and health system factors influence the chance of survival<sup>2</sup>; however, none are more significant than the response associated with the actions of bystanders.<sup>3</sup> Commencing bystander cardiopulmonary resuscitation (CPR) in OHCA doubles the chance of survival<sup>3,4</sup>; and the use of an automated external defibrillator (AED) to treat shockable rhythms increases survival by a further 50%–70%.<sup>5,6</sup> Yet in many jurisdictions, bystander CPR and AED usage rates are low, with only 30%–50% arrests receiving bystander CPR,<sup>1,7</sup> and 2%–15% using an AED.<sup>8</sup>

Many factors influence the provision of bystander CPR and AED use. These include

language barriers when communicating with emergency services as well as frailty, disability, location of arrest, CPR knowledge and training of the first responders.<sup>9–12</sup> Early analyses of the COVID-19 pandemic also suggest that bystanders are less willing-to-perform CPR in the event of an OHCA.<sup>13</sup> Having prior CPR training is strongly associated with being more likely to be willing-to-perform CPR.<sup>14</sup> This is consistent with observations that areas with low bystander CPR and OHCA survival rates have lower rates of CPR training.<sup>12 15 16</sup> CPR-trained survey respondents report higher levels of confidence to perform CPR and use of AEDs in the event of OHCA.<sup>17</sup>

In Australia, the surf life-saving culture has raised awareness of CPR.<sup>18</sup> An online survey of Australian adults found 90% had heard of CPR, but only 56% had CPR training and fewer had recent training (22% within the last year).<sup>17</sup> CPR-trained people were more likely to be born in Australia and have greater than 12 years of education. In the event of a cardiac arrest, about two-thirds said they would perform CPR, but only 3% said they would locate a defibrillator. Asked specifically if they would perform CPR on a stranger, 45% said they would not. Confidence to perform CPR was a barrier to bystander CPR, with only 28% reporting feeling confident in their ability to perform CPR. In an analysis of emergency calls for adults in regions of low bystander CPR in Victoria, three types of barriers were identified: procedural barriers (time lost due to language barriers and communication issues; telephone problems), CPR knowledge (skill deficits; perceived benefit) and personal factors (physical frailty or disability; patient position; emotional factors).<sup>9</sup>

In Australia, community-wide CPR training is not compulsory and is mandated only for certain professions.<sup>17</sup> There are some initiatives to encourage awareness and training in first aid and basic life support by New South Wales (NSW) government, NSW Ambulance as well as established community and charitable organisations.<sup>19–24</sup> However, these are not routinely adopted across communities nor mandated across schools. They often involve a cost and require grassroots efforts by community members and volunteers to fundraise for defibrillator grants and access awareness programmes from provider organisations.<sup>25–27</sup> Defibrillator grant programmes targeted at sports organisations were recently implemented in NSW; however, currently similar initiatives are not offered to other social groups or networks. There are no specific initiatives for people less likely to be trained or recently trained, for example, seniors' groups, migrant communities.<sup>17 24 28–32</sup> Public access to defibrillator programmes are likely to be more effective when training on CPR and use of defibrillators is also addressed.<sup>33</sup>

Several community intervention trials have examined ways to improve bystander CPR rates.<sup>34–41</sup> Some of these have focused on improving CPR training and others on the quality of CPR technique.<sup>34–36</sup> Other successful strategies to increase bystander CPR rates include dispatch of lay and/or professional voluntary responders by emergency services and use of apps to activate trained citizens

and off-duty paramedics and doctors.<sup>42–46</sup> In Australia, such initiatives are underway in some states but have not been adopted in NSW so far.<sup>47–50</sup>

A recent systematic review and meta-analysis of community interventions designed to increase bystander response to OHCA (with or without changes in health services in the area) identified 15 studies and reported associations with better survival rates and bystander CPR in the areas of intervention; however, limitations included heterogenous, and poorly described interventions.<sup>51</sup> Also, a recent scoping review identified 19 studies from the USA, Denmark, Republic of Korea and Japan and Singapore, and noted community interventions were mainly provision of instructor-led training and mass media or public campaigns.<sup>52</sup>

In Australia, exposure to messaging of the importance of CPR training due to the surf life-saving culture or international campaigns such as World Restart a Heart Day intended to motivate training uptake, have not had the desired impact of optimising training rates in the community.<sup>17</sup> None of the community-based initiatives identified to date have targeted community organisations, groups or clubs as a means of increasing training and willingness to respond to OHCA in the community, and this may be a way of improving the reach of public-orientated campaigns. As a result of literature review and multiple meetings with peak bodies and stakeholder groups (partnered in this project) including NSW Health, NSW Ambulance and other organisations with an interest in improving outcomes from OHCA, the FirstCPR concept arose.<sup>51 52</sup>

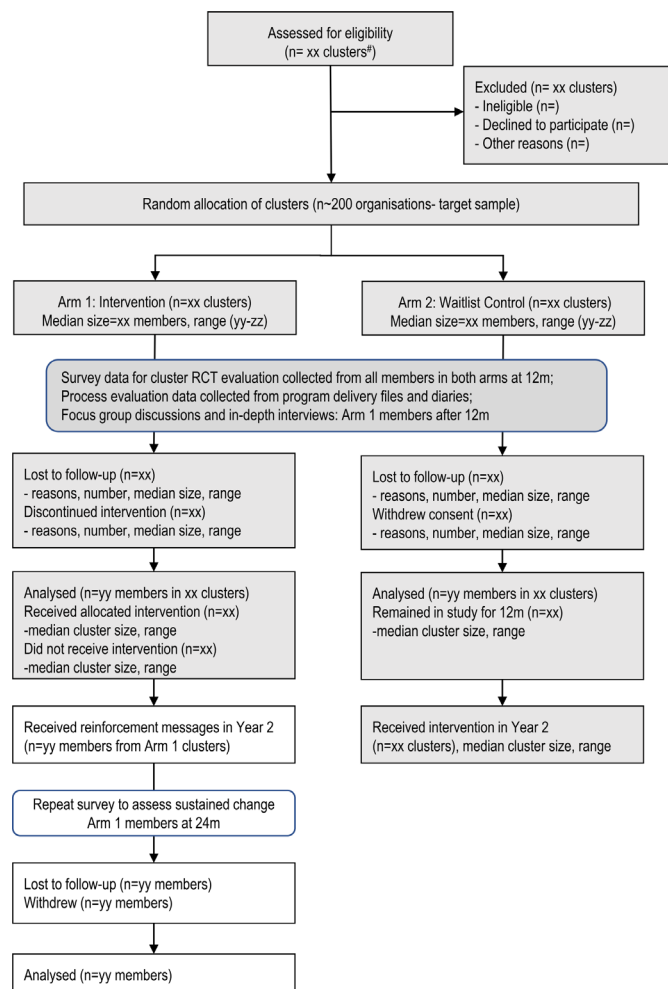
The primary objective of the FirstCPR trial is to determine whether a novel community group-targeted educational intervention in CPR and responding to OHCA can improve self-reported rates of CPR training, and willingness-to-perform CPR on a stranger. Secondary objectives are to evaluate the effects of such an intervention on knowledge and confidence to perform CPR and to use a defibrillator. In addition, we will examine the longer-term retention of knowledge, confidence and willingness among members of organisations that continue to receive reinforcement messages, and we will analyse rates of bystander CPR and survival in study areas. We also aim to evaluate the costs, reach and fidelity of the intervention along with barriers and enablers to implementation, especially among subgroups of interest such as elderly and minority populations.<sup>53</sup>

## METHODS AND ANALYSIS

Standard protocol items for reporting cluster randomised trials were followed using the Spirit reporting guidelines.<sup>54</sup>

### Trial registration

The study has been prospectively registered on the Australian New Zealand Clinical Trials Registry (ANZCTR). All items from the WHO Trial registration dataset can be found on the trial page on the ANZCTR registry online.



**Figure 1** FirstCPR Study flow chart. CPR, cardiopulmonary resuscitation; RCT, randomised controlled trial. #Community organisations with minimum of 50 registered members that can be contacted via digital means.

## Design

FirstCPR is a cluster randomised controlled trial (cRCT) involving 200 community groups across urban and regional NSW, Australia. The trial will involve random allocation of clusters (community groups) in a 1:1 ratio to intervention or control, with serial surveys across community groups to evaluate primary and secondary outcomes (figure 1).

The study will be complemented by a process and cost-effectiveness evaluation. In addition, we will conduct a quasi-experimental analysis to compare bystander CPR rates and OHCA survival rates before and after the study period in areas exposed to the cRCT compared with areas not exposed.

## Study setting

The study will recruit community groups and target regions of NSW as geographically defined by Local Health Districts (LHDs). NSW is the largest state in Australia with a residential population of 8 million. It is divided into 15 LHDs; 8 cover the Sydney metropolitan region and 7 cover rural and regional NSW. To select study LHDs, we

considered data from the Population Health Risks and Outcomes Registry (Data custodian: NSW Ministry of Health) on OHCA incidence and survival; community diversity measures (eg, socioeconomic index and population age) from the Australian Bureau of Statistics census data;<sup>55 56</sup> and the feasibility of conducting study procedures in the region through discussion with partners and stakeholders. We selected three LHDs with lower survival rates from OHCA and with substantial diversity in their population. This encompassed two metropolitan and one regional LHD.

Western Sydney LHD is in the metropolitan city of Sydney and covers an area of 780 km<sup>2</sup> with more than 120 suburbs. It has 1.3 million residents, 46.8% of residents were born overseas and 50.3% speak a language other than English at home.<sup>57</sup> South Western Sydney LHD covers an area of 6237 km<sup>2</sup> and is home to about 12% of the NSW population (n=966 450). It is a culturally diverse area with half the residents (n=51%) speaking a language other than English at home. Mid-North Coast LHD is located on the north coast of NSW and covers an area of 11 335 km<sup>2</sup>. It has an estimated population of 211 000 and 21% of residents are over the age of 65 years compared with 15% for NSW.<sup>56 57</sup> Organisations located in border suburbs of selected LHDs will be eligible for inclusion as members of these organisations often reside in or frequently visit the study area.

## Eligibility criteria for clusters and participants

### Clusters eligibility

Clusters are community groups, organisations or workplaces that operate for a specific purpose or to provide a specific service in a community for public benefit of the members of the community. Community groups will include sports and social clubs, faith-based and multicultural organisations. Workplaces, government workplaces and businesses (medium and large), will be considered if they have a community facing component to their business.

Inclusion criteria: (1) have at least 50 listed members (including employees); (2) have an ability to communicate regularly with their membership by electronic means (eg, email/text message/in-app communications/social media); (3) agree to supporting all steps of the implementation of the FirstCPR project; and (4) are located in areas selected for implementation of the study. We will minimise approaching community groups that are likely to have shared or overlapping memberships with other clubs, for example, those in close proximity either geographically or socially to each other. If groups have shared membership, they will be combined and treated as a single entity/cluster, or the second group excluded.

### Participant eligibility

Individual study participants will be adults (≥18 years) who are current members or committee members/employees of the randomised community groups.



## Recruitment of organisations

Potential community groups will be identified through collaboration with FirstCPR stakeholders, local council lists, internet searches and local knowledge. Sports organisations, social and faith-based groups and workplaces in our study areas will be approached. This will ensure a reasonably broad mix of people with diverse sociodemographic characteristics. We will target community groups that do not traditionally have CPR training, have an older average age of members and will specifically seek to enrich our sample to ensure a diverse cultural mix. Committee members and representatives at potentially eligible community groups and organisations will be approached via email and phone and invited to participate in the programme. Agreement to participate will be sought after explaining the purpose of the research, study design and what the FirstCPR campaign entails. We will seek the support of community stakeholders and organisation leaders to approach their members and facilitate member participation through provision of translated materials.

## Randomisation

The community organisation/group will be randomised in a 1:1 allocation ratio to intervention versus controls through a central computerised system. The allocation sequence will be generated by a computer using a code created by the study statistician, using randomised permuted blocks size 2 and 4. Stratification will be based on: geography (regional/metro); community group size; and community group type.<sup>58</sup> In order to reduce the predictability of random sequence, details of the code will be unavailable to those who enrol participants. Study research staff delegated to recruitment tasks will enrol organisations that are eligible, willing and able to participate, and enter their baseline information required for randomisation into the study database system. To minimise contamination, geographical distance will be maximised between community groups from control and intervention arms where possible and where cross membership with nearby organisations is deemed to be an issue. Study research staff will keep track of the geographical location of enrolled organisations by flagging them on a map and assess cross-membership with potential new eligible organisations prior to onboarding them. Study staff will further discuss the possibility of cross-membership with organisations in their screening questions. Allocation cannot be concealed from community organisations or research staff involved in implementation. Statisticians involved in analysis will be blinded to cluster allocation. On enrolment and randomisation, the intervention will be made available to the groups in the intervention arm in the first year, and the control groups in the second year. Researchers will forward the FirstCPR study link to the organisation liaison person to circulate to their members. The link will enable members to access the electronic Participant Information and Consent Sheet (PICF). Consenting members will be invited to complete

the baseline survey and opt to start receiving intervention messages and educational materials via email or text as per their preference. Where a need is indicated, researchers will visit organisations to meet with members and provide paper PICF and survey forms.

## Sample size

A sample of 200 community groups (100 per arm) will provide 80% power to detect an increase in the proportion that are 'trained and willing to do CPR by 10% (39%–49%)'. The estimate of 39% is from a survey of about 1000 community participants in Australia.<sup>17</sup> This assumes an intraclass coefficient (ICC) of 0.2, a cluster size of 30, and hence a total individual sample size of 6000 at a two-sided p value of 0.05. It also accounts for dropout of 15%. An ICC of 0.2 is used as a conservative estimate as ICC in other community groups have been reported to be 0.05–0.2.<sup>59–62</sup>

## Data collection

Table 1 outlines the proposed outline and schedule of enrolment, intervention and assessments. FirstCPR study started recruitment of organisations in April 2021 and intends to complete recruitment by the end of December 2021.

Baseline information on participating organisations such as organisation size, that is, number of members, type, geographical location will be collected at the time of screening and enrolment. In addition, information on organisations' ability to facilitate in-person training sessions, display of educational posters, and dissemination of educational information to members will be noted. Information on any AEDs installed at organisation including access hours for members and the public, existing policies for Basic Life Saving training and any recent or upcoming training organised for members and staff/employees at organisations will also be documented.

Surveys of community members will be conducted at baseline and at 12 months (assessment of primary outcome). The 12-month primary end-point evaluation timepoint was chosen as we thought that this would be give us sufficient time to implement the programme across the multiple organisations and for each organisation to be exposed to it for a sufficient time—that is, experience the combination of digital delivery of messages and video every 2–3 weeks as well as delivery of the in-person training session in their organisation. In addition, participants from the intervention arm will be invited to complete repeat surveys at 24 months for assessment of maintained benefits and enable evaluation of any individual determinants of change among participants in the intervention arm. Research Electronic Data Capture (RedCAP) will be used for capturing data and for completion of electronic surveys (see online supplemental appendix 1, Data management). Survey questionnaires will be sent via an electronic link to all on the enrolled organisations' membership lists. Paper surveys may be used to collect information from members at organisations where a

**Table 1** Schedule of enrolment, intervention and assessments

YEAR (Y)	Y1				Y2				Y3				Y4
QUARTER (Q)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
<b>Study approvals and registrations</b>													
Ethics and governance approval, trial registration	x												
<b>Screening and enrolment</b>													
Identify and assess eligibility of community organisations		x	x	x									
Enrol, organisation surveys, randomise to intervention or control		x	x	x									
Baseline surveys: intervention organisation members		x	x	x	x								
<b>Implementation</b>													
FirstCPR programme to intervention organisations		x	x	x	x	x	x	x	x				
FirstCPR programme to control organisations						x	x	x	x	x	x	x	x
FirstCPR reinforcement programme—intervention organisation members						x	x	x	x	x	x	x	x
<b>Evaluation</b>													
Evaluation surveys (intervention and control)						x	x	x	x	x	x	x	
Follow-up surveys—members participating in reinforcement programme											x	x	x
Focus groups, interviews: intervention organisation committee and members								x	x	x	x	x	x

Q1=January–February–March; Q2=April–May–June; Q3=July–August–September; Q4=October–November–December.

Table adapted from *BMJ* 2013;346:e7586.<sup>54</sup>

CPR, cardiopulmonary resuscitation.

need is indicated. At each timepoint, all members of the community groups will be invited to the survey. A 10% participation for each group (or n=30 for smaller groups) will be considered as a minimum acceptable rate, though we will aim for a higher response rate. Surveys will ask respondents on their knowledge and previous training of CPR, confidence and willingness-to-perform CPR and use an AED and will include basic demographic questions and an item on participant's general health condition. Most survey questions have been previously used and validated in Australia.<sup>10 17</sup> Current occupation or field of study item will collect information on those that belong to one of the professions or fields where CPR skills are expected or likely to be mandated, for example, medical/health, fitness instructors, aged care and childcare staff, law enforcement officers and firefighters, teachers, lifeguards among others. All survey items have been approved by the study team and piloted in a sample of 50 community members for face and content validity. Pilot survey respondents found the questionnaire clear, concise and easy to complete and no major amendments were necessary following the feedback and comments from participants. The study participant information sheet and survey questionnaires have been attached in the online supplemental appendices 2 and 3.

A subgroup of participants will also be invited to participate in focus groups and/or in-depth interviews with purposive sampling of a range of individuals to enable further understanding regarding determinants of change and understanding of barriers and enablers to CPR training and response to OHCA.<sup>63</sup> Most of the qualitative

data collection will occur among members that complete the surveys and received training or are administrative or coordinating staff at participating community organisations that support the implementation of the intervention.

#### Plan for participant (organisation) retention

Once organisations are enrolled, study staff will make every reasonable effort to follow and encourage organisations to remain in the study for the entire duration. Staff will strive to maintain and nurture the key relationships with contact/liaison persons in the enrolled organisations and highlight the benefits of participation to encourage them to stay in the study until all outcome data are collected. Regular communication with members, visits to organisation events, adopting flexibility in intervention implementation such as in-person visits to engage with organisation members, provision of incentives such as entry of completed surveys into a draw for grocery vouchers, free and discounted vouchers for members to access accredited CPR training courses, and a raffle at the end of the study to win an AED to be installed at the organisation venue are some of the strategies that will be employed to encourage retention. Organisations that decide to discontinue or are unable to implement some or all aspects of the study as per protocol will be invited to discuss over short phone interviews or via email the reasons for discontinuation and these will be documented in a deidentified format, and any data collected until the point of withdrawal will be evaluated and analysed.

### Additional data collection

Repeat surveys at 24 months after initiation will be sent to members of the intervention arm group at the end of the second year to examine maintained response. This will be sent after completion of the additional reinforcement messages. We will document the costs related to intervention implementation including training. We will also extract data from administrative datasets including CPR rates, OHCA survival, data related with treating OHCA patients in the NSW healthcare system with and without bystander intervention (extraction from NSW Ambulance, emergency department and admitted patient administrative data).

Focus groups with a subsample of participants from various community groups will be conducted to explore uptake, acceptability and engagement with the different intervention tiers. To obtain a broad range of views, we will use a maximum variation sampling method based on participant demographic characteristics and training component.<sup>63</sup> Sampling for focus groups will continue until thematic saturation is reached.

### FirstCPR intervention

The intervention comprises a targeted health promotion programme addressing training in CPR and response to OHCA. The primary intent of developing the intervention toolkit was to: (a) raise awareness, impart education and provide access to formal training in CPR and AED use for OHCA and (b) positively influence behavioural intention or 'willingness to act' (in the event of witnessing an OHCA emergency).

The intervention's design and development were informed by The Theory of Planned Behaviour, Theory of Reasoned Action, and mostly by the COM-B framework.<sup>64-66</sup> The COM-B framework describes key elements for behaviour change as capability (C), opportunity (O) and motivation (M) to perform a behaviour (B). Capability in this context can be seen as feeling psychologically and physically capable to perform CPR or use an AED, and motivation in this study is likely to be 'reflective' (defined in the COM-B framework as 'developing the intention to act'). The FirstCPR intervention toolkit's components are

designed to focus on developing the elements of 'capability' (psychological) and 'reflective motivation' needed when the 'opportunity' arises to perform CPR and when 'automatic motivation' (defined as the 'emotions and impulses from associative learning and innate disposition') will be called on for the behaviour/action of performing CPR.

Community groups allocated to the intervention group will receive the FirstCPR programme on commencement of the study and this will continue as part of a rolling campaign in the first year (figure 2: intervention components). The control arm will receive no intervention in year 1 and intervention in year 2. This means that there will be no study-initiated health promotion or educational initiatives offered at these sites in year 1. However, control sites may be incidentally exposed to health promotion related to CPR training through ongoing public health or non-governmental organisation initiatives outside of FirstCPR.

Re-enforcement messages will continue to be delivered to the intervention group organisations in the second year.

Committees that were convened to advise on intervention development, deliberate over study design and implementation plan are outlined in the online supplemental appendix 4, roles and responsibilities. The intervention was developed in an iterative process coordinated by an intervention development committee including representation by academics, clinicians, government and consumers. This included discussion of key messages to be conveyed, collation of existing materials used by peak organisations in resuscitation or cardiology in Australia, supplemented by searches to identify high-quality international material and material that can be used for culturally diverse populations. All intervention material and delivery formats were reviewed by an expert panel including health professionals and researchers to ensure the messaging was aligned with the key messages identified and prioritised by the intervention committee. The key messages focused on addressing the primary goals for FirstCPR—increasing training and increasing



**Figure 2** FirstCPR multicomponent intervention. CPR, cardiopulmonary resuscitation.



willingness-to-perform CPR. The delivery of the intervention considered the following parameters: low cost, ability to directly message participants, leveraging digital communication, incentivisation and was guided by behavioural change theories.<sup>65</sup>

The intervention will be delivered in the following components:

1. Digital delivery: materials in digital format will comprise of written, picture and video format and incorporate key messaging, education and information sent to members of participating organisations via text as per preference indicated by participants on a fortnightly basis over a period of 12 months. Following the launch of the digital intervention package, key training, awareness and motivation messages will be delivered less frequently (monthly) as reinforcement in the second year for intervention group members. These will aim to reinforce the key messages related with responding to an OHCA.
2. In-person information sessions: these will be provided by the study at locations selected by the community group and will be delivered in-person or online depending on COVID-19 restrictions. These will include a 30–45 min presentation of key points as well as a demonstration of how to perform CPR and use a defibrillator on a manikin, with the opportunity to ask questions at the end of the session.
3. Incentives to attend formal CPR training: by an accredited provider with the option of running the session at the group venue will be made available.
4. Attendees completing the requisite hands-on practice on a manikin will be eligible to obtain a nationally accredited training certificate. Display of educational materials at participating clubs and organisations: depending on feasibility at individual organisations, for example, videos, posters on notice boards and in foyer areas, social media posts, club apps or newsletter bytes.

### Intervention adherence

Strategies to encourage adherence to implementation and delivery of intervention components as per protocol will include regular training of study research staff and encouraging ongoing communication with organisation liaison people to ensure that the intervention material is delivered to members as intended. Educational messaging and material have been designed to be short, sharp and interesting to appeal to participants and encourage engagement. Delivery logs of all intervention components delivered are being maintained by study staff and will allow for evaluation of engagement and adherence to intervention delivery and uptake. RedCap has been designed to deliver and collect information that enables analysis of intervention uptake and viewing of educational material by study participants. Given commonly cited barriers of time constraints and lack of priority in attending traditional classroom-style training, we anticipate that not all organisation members will attend the educational or formal accredited sessions. In-person

session attendance numbers at each organisation will be noted and also asked in brief surveys at the end of the intervention period.

### Study outcomes

Primary and secondary outcomes will be assessed at the end of the first year. We will compare the intervention group to the control group, prior to the control group being offered the delayed programme. The primary outcome was selected as that reflecting the primary intent of the intervention. These outcomes will be assessed through surveys of members, who consent, from participating organisations.

1. Primary outcome: is a composite of self-reported affirmative responses to two items:
  - Received CPR training.
  - Willingness-to-perform CPR (on a stranger).
- a. Participants will be asked ‘have you received any training in CPR?’ and be given the options ‘yes’ and ‘no’. A ‘yes’ response will be counted towards the primary outcome. We are not specifying that this training is formal training or directly from the FirstCPR trainers for the primary outcome and will accept the response here as the perception of the participant that they have been trained.
- b. Participants will be asked to respond to the statement in relation to performing CPR on a stranger ‘I would be willing-to-perform CPR (either standard or hands-only) on a person collapsed and not breathing normally’. Response options are ‘definitely not’, ‘probably not’, ‘maybe’, ‘yes, probably’ and ‘yes definitely’. Participants that report ‘yes probably’ and ‘yes definitely’ will be counted to the primary outcome.
2. Secondary outcomes:
  - Components of the primary outcome described above.
  - Any CPR training in the last 12 months.
  - Accredited CPR training in the last 12 months.
  - Willingness-to-perform CPR for a family or friend.
  - Confidence in performing CPR (report ‘confident’ or ‘very confident’ response on a 5-point Likert scale).
  - Confidence in using an AED (report ‘confident’ or ‘very confident’ response on a 5-point Likert scale).
  - Willingness to use an AED (on a stranger).
  - Good knowledge of CPR (report ‘good’ or ‘excellent’ response on a 5-point Likert scale).
  - Good knowledge of AEDs (report ‘good’ or ‘excellent’ response on a 5-point Likert scale).

### Additional outcomes

1. Maintained response: we will report on whether willingness and confidence to do CPR is maintained at 24 months.
2. Analysis of administrative data: we will report on rates of bystander CPR and OHCA survival in the 2-year period before and after the intervention in areas where the FirstCPR study was implemented.

## Statistical methods

For the trial outcomes, analyses will be conducted by statisticians blinded to allocation status. Analyses will be conducted at the individual level accounting for clustering of participants within groups. Intention-to-treat principle will be followed with participants analysed according to their allocated group. The primary analysis at 1 year will use a log-binomial regression model or robust Poisson regression in case of convergence issues. The clustering will be accounted for in the model using a shared random effect for participants from the same cluster.<sup>67</sup> Relative risk and the associated 95% CI will be reported. Prespecified covariates, namely, age, gender, educational level, will be included in an adjusted analysis. The same models mentioned for the primary analysis will be used for the secondary objectives.

Subgroup analysis will be conducted to explore the interaction of the treatment effect by age groups, gender, socioeconomic status, cultural background, organisation type (social/sports/workplace), geography (metro/regional) and CPR training (prior/recent).

Qualitative analyses will be thematic, and coding will be carried out inductively based on emergent themes. NVivo V.9 will be used to assist with data analyses.

## PARTICIPANT AND PUBLIC INVOLVEMENT

Consumers were involved in the codesign of the intervention. This includes involvement in the steering committee, in discussion of component of intervention and in review and feedback cycles of intervention materials (n=62 respondents). These included in person and short consumer surveys. Consumers were also involved in piloting of survey questionnaire (n=50 respondents) and reviewing of intervention material. We also conducted group meetings with partner organisations and stakeholders at which we did not record the number of participants involved. Consumer profile included a range of members from work colleagues, representatives at partner organisations, to family members and friends of researchers.

## ETHICS AND DISSEMINATION

Ethics approval has been obtained from The University of Sydney Human Research and Ethics Committee Ref no: 2020/537 and the current ethics approved version of the Study Protocol is V.6, dated 07 October 2021. Request for approval to amendments to the protocol and study documents will be sought from the ethics committee, notified to the governance team and updated on the trial registry. The plan for audit and monitoring of the study is briefly described in the online supplemental appendix 5. Findings from this study will be disseminated via presentations at scientific conferences, publications in peer-reviewed journals, scientific and lay reports. Community organisation representatives and committee members will receive a summary report of the study findings in lay format. They will be encouraged to share the findings with their members

and their community via email and social media. Participants can also choose to have the report emailed to them by selecting this option at the time of consenting to participate.

## DISCUSSION

Survival following OHCA is maximised with rapid recognition of cardiac arrest, rapid response with CPR and defibrillation, and the rapid response of emergency services. Survival from OHCA and bystander responder rates vary by region. The focus of the FirstCPR study is to increase the proportion of members in the community that are willing and trained in doing CPR. There is some evidence that community-based interventions improve outcomes in OHCA through improved rates and quality of bystander CPR. However, there is minimal research on how to optimally implement interventions in the community that target diverse groups who may have less access to CPR training through work or school.

The study will use a cluster randomised trial design to allow for robust evaluation of outcomes, and a process evaluation to provide information on fidelity, adaptation and the potential for scaling up. The FirstCPR study will provide new knowledge on a scalable approach targeting community groups to improve the willingness and skills to respond in an OHCA, and specific information on implementation in social and culturally diverse communities.

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**Contributors** CC conceived the initial study design and drafted the first protocol submitted to the National Health and Medical Research Council with contributions from all investigators (nine chief investigators and ten associate investigators) and partners (four) listed in the grant application. SMunot is managing the project, did the first draft of the current manuscript summarising key elements of the original protocol and aligned this with the ethics application. SMunot, JEB, JR and CC have contributed to the development of the intervention, implementation plan and study processes described in the protocol. All other authors (BA, AB, AC, ARD, CF, GJ, PK, SK, KL, SK, SMarschner, PMM, MN, IO, CS, LT, MV and SW) have reviewed and provided input on various study documents including the final draft of the protocol. All authors reviewed and approved the final manuscript. CC is overall guarantor.

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**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods and analysis section for further details.

**Patient consent for publication** Not applicable.

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## APPENDIX

### Appendix 1. Data Management

### Appendix 2. FirstCPR Participant Information and Consent form

### Appendix 3. FirstCPR evaluation survey questionnaire

### Appendix 4. Roles and Responsibilities

### Appendix 5. Audit and Monitoring of study

#### **Appendix 1. Data Management**

Majority of the data will be collected via surveys via RedCap™. The study Standard Operating Procedures (SOP) manual and a more specific RedCap™ SOP has been drafted to document all necessary steps in data entry and validation. Any data collected as paper copies will be scanned and uploaded onto the electronic platforms. Data and reports extracted from RedCap™ will be stored in de-identified form on a secure web-based platform and limited to be accessed by authorised study personnel- thus maintaining confidentiality throughout the study period and after the trial. Focus group discussions and in-depth interviews will be recorded on a digital recorder with consenting participants. The recording will be transferred onto the University of Sydney's Research Data Storage (RDS) which is a centralised secure data storage platform. The discussions will then be transcribed following which all the recordings will be destroyed.



## Appendix 2. FirstCPR Participant Information and Consent form



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***FirstCPR study: Education and training of community members in responding  
to an Out-of-Hospital Cardiac Arrest (OHCA)***

### **PARTICIPANT INFORMATION STATEMENT**



#### **What is this study about?**

You are invited to take part in the FirstCPR study, led by Professor Clara Chow at the Westmead Applied Research Centre, University of Sydney. The information in this document will explain what the research is about, why it is being done, and what is involved if you choose to participate. You have been invited to participate in this study because your club/organisation has agreed to work with us to raise awareness and knowledge of what to do when people see a cardiac arrest in the community. This means we are inviting all members (18 years and older) to participate in the educational campaign mainly related to cardiopulmonary resuscitation (CPR). This program is supported by a National Health and Medical Research Council (NHMRC) research grant.

This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the research. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

#### **Providing your consent to participate:**

Participation in this research study is voluntary. Taking the FirstCPR survey will mean that you consent to take part in this study. This means you are telling us that you:

- ✓ Understand what you read in this sheet.
- ✓ Agree to take part in the research study as outlined below.
- ✓ Agree to the use of your personal information as described (name, email, phone number).
- ✓ Agree that you are 18 years or older
- ✓ Are happy to be contacted in the future about the project

**What will happen if I say I want to be in the study?**

If you wish to participate there will be a 5-minute questionnaire at the start about cardiac arrest in the community. Then you will be asked if you would like to receive information and reminders about cardiac arrest and CPR via text message and/or email for a period of 10 to 12 months. Some messages will include links to additional information on websites, videos or factsheets which have been selected by the First CPR research team. At the end of the study period, there will be another short questionnaire. Some of you will be invited to continue to receive less frequent reinforcement messages for an additional 12month period and be asked to complete a similar 5-minute questionnaire at the end of this second period. You can opt out of receiving messages at any time by replying 'STOP.'

During the study period you may be contacted about participating in an interview or group discussion about your views on cardiac arrest, CPR education and training. If you are selected for these, you will be sent more information on these closer to the time and can decide if you wish to join at that stage.

Your organisation will also be provided with materials to share with members and will host a face-to-face information session about basic life-saving skills. These sessions will demonstrate how to do CPR, use a defibrillator, and provide you with the opportunity to ask questions of an instructor. Where a need is identified, arrangements will be made for a multilingual interpreter to be present at the information sessions so translation of the information can be relayed in the language of the audience.

**How long will the study take?**

Your organisation will have access to FirstCPR educational and training material over the next 12 months. However, the time commitment from participants equates to viewing fortnightly short educational and informative messages that we will send via email or text, and these can be viewed in your own time. Participants who enjoy receiving these messages can sign up to receive monthly messages for an additional 12-month period to reinforce learning. You will also be invited to attend a one-hour in-person educational and training session and register to claim one of 30 free vouchers for a 2.5-hour accredited training session that will include hands-on CPR training on a manikin.

**Are there any good things about being in the study?**

By being a part of this research, you will also be given access to training materials and you will contribute to our research to understand whether programs like this can increase awareness and knowledge about CPR. There will also be up to 30 vouchers available to participants in your organisation to attend a free accredited CPR training course that normally costs \$65. All

participants will also go into a draw to win one of ten Coles/Woolworths vouchers valued at \$30 each, drawn at the end of each annual survey rollout.

**Are there any risks or costs associated with being in the study?**

Aside from giving up your time to complete the surveys, we do not expect that there will be any risks or costs associated with taking part in this study.

**What will happen to information about me that is collected during the study?**

Your information will be stored securely, and your identity/information will be kept strictly confidential, except as required by law. Access to this information will only be permitted to authorised researchers directly involved in the study. Study findings may be published, but you will not be individually identifiable in these publications.

**Do I have to be in the study? Can I withdraw from the study once I've started?**

You can decide if you want to take part in this or not. You don't have to, and it is completely up to you. If you decide you want to be in the study and then you change your mind later, that's ok. All you need to do is tell us by text message, email, or telephone call that you want to withdraw. If you decide to withdraw from the study, we will not collect any more information from you. Any information that we have already collected, however, will be kept in our study records and may be included in the study results.

**Will you tell me what you learnt in the study at the end?**

Yes, we will if you want us to. There is a question on the consent form that asks you if you want us to tell you what we learnt in the study (study findings). If you select 'Yes', when we finish the study, we will tell you what we learnt. If you have any questions, you can ask us by calling on [0412 369 519](tel:0412369519) or email us at [warc.firstcpr@sydney.edu.au](mailto:warc.firstcpr@sydney.edu.au).

**What if I am not happy with the study or the people doing the study?**

If you are not happy with how we are doing the study, then you can

- Call the university on +61 2 8627 8176 or
- Write an email to [human.ethics@sydney.edu.au](mailto:human.ethics@sydney.edu.au)



### FirstCPR Participant Consent Form

If you are happy to be in the study, please

- **write** your **name** in the space below
- **sign** your **name** at the bottom of the next page
- put the **date** at the bottom of the next page.

You should only say 'yes' to being in the study if you are 18 years or older, understand what it is about, and you want to be in it.

Yes, I, .....[PRINT NAME], am happy to be in this research study.

In saying yes to being in the study you 1) confirm you have read the participant information sheet, 2) Understand what is involved in participation, 3) understand that by providing contact details and completing the survey you consent to participate in the study and 4) are happy to be contacted in the future about the project.

**Please tick (☐) 'Yes' or 'No' if you would like us to email you a summary report at the end of the study to tell you what we learnt in the study.**

☐ **YES**

☐ **NO**

*If, yes please let us know your email so we can send you the report*

**Email**.....

**Signature** .....

**Date** .....



### Appendix 3. FirstCPR evaluation survey questionnaire

<b>FirstCPR Baseline survey</b>	
<b>Question</b>	<b>Options</b>
<b>1. Kindly tell us some information about yourself</b>	
Please enter your age (in years) ...	..... (Eligible to participate if 18years or older)
Please select your Gender	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Another term: ..... <input type="checkbox"/> Prefer not to answer
What is the highest level of schooling you have completed?	<input type="checkbox"/> Primary/Grade School <input type="checkbox"/> Some high school <input type="checkbox"/> High school graduate <input type="checkbox"/> Technical college or some University <input type="checkbox"/> University diploma or degree <input type="checkbox"/> Postgraduate
In which country were you born?	<input type="checkbox"/> Australia <input type="checkbox"/> China <input type="checkbox"/> England <input type="checkbox"/> India <input type="checkbox"/> Italy <input type="checkbox"/> Malaysia <input type="checkbox"/> New Zealand <input type="checkbox"/> Philippines <input type="checkbox"/> South Africa <input type="checkbox"/> Sri Lanka <input type="checkbox"/> Vietnam <input type="checkbox"/> Other, please specify.....
<b>(If born outside Australia),</b> Approximately how many years have you been living in Australia	..... (if less than a year- e.g., 6 months- please enter 0.5)

What language do you mainly speak at home?	<input type="checkbox"/> English <input type="checkbox"/> Mandarin <input type="checkbox"/> Arabic <input type="checkbox"/> Cantonese <input type="checkbox"/> Vietnamese <input type="checkbox"/> Italian <input type="checkbox"/> Greek <input type="checkbox"/> Hindi <input type="checkbox"/> Spanish <input type="checkbox"/> Punjabi <input type="checkbox"/> Other, please specify.....				
What is your Postcode?	.....				
Which of the following describes your current status?	<input type="checkbox"/> Working for an employer or conducting a business <input type="checkbox"/> Unpaid work in a family business <input type="checkbox"/> Unemployed, looking for work <input type="checkbox"/> Studying <input type="checkbox"/> Homemaker / Stay-at-home parent <input type="checkbox"/> Retired <input type="checkbox"/> Other, please specify.....				
<b>(If selected working / studying / looking forwork):</b> Can you indicate if your current occupation (or field of study) fits into any of the following industry categories – if not, please select ‘Other’ and specify industry category	<input type="checkbox"/> Medical or Health <input type="checkbox"/> Law Enforcement <input type="checkbox"/> Fitness Instructor / Coach <input type="checkbox"/> Social worker <input type="checkbox"/> Aged care worker/Carer <input type="checkbox"/> Jail or correctional staff <input type="checkbox"/> Transport worker <input type="checkbox"/> Flight attendant <input type="checkbox"/> Firefighter <input type="checkbox"/> Lifeguard <input type="checkbox"/> Construction worker <input type="checkbox"/> Electrician <input type="checkbox"/> Teacher <input type="checkbox"/> Childcare provider or staff <input type="checkbox"/> Security personnel <input type="checkbox"/> Other, please specify.....				
<b>(if category other than medical or Health selected above):</b> Have you ever worked or been trained in a medical or health-related field?	<input type="checkbox"/> Yes <input type="checkbox"/> No				
In general, would you say that your health is	Very Poor	Poor	Fair	Good	Excellent
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>2. The next few questions are related to CPR (Cardiopulmonary resuscitation). Please select the option that best reflects your response to the statements below</b>					
I would rate my overall knowledge of CPR as	Very Poor	Poor	Fair	Good	Excellent
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Have you heard of Hands-only or Compression-only CPR?	<input type="checkbox"/> Yes <input type="checkbox"/> No				
<b>Standard CPR involves chest compressions and mouth-to-mouth breathing and is performed on a person who is suspected to be in cardiac arrest. Hands-only or compression-only CPR involves resuscitation with chest compressions only and no mouth-to-mouth breathing.</b>					
<b>I feel confident in my ability to perform</b>					
	Not confident	Somewhat confident	Confident	Very confident	
Standard CPR					
Hands-only	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
CPR	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>I would be willing to perform CPR (either standard or hands-only) on a person collapsed and not breathing normally if they were a...</b>					
	Definitely not	Probably not	Maybe	Yes, probably	Yes, definitely
Family member	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Friend	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Stranger	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>If Definitely Not, Probably Not or Maybe (for FAMILY MEMBER)</b> which of these statements best describes your reasons for why you would not be prepared to perform CPR on this person? ( <i>You can select more than one response</i> )	<input type="checkbox"/> Don't know how to do CPR <input type="checkbox"/> Don't feel confident <input type="checkbox"/> Concerned about hurting the person <input type="checkbox"/> Concerned about being sued <input type="checkbox"/> Concerned about not performing CPR properly <input type="checkbox"/> Physically unable to perform CPR <input type="checkbox"/> Concerned about infection <input type="checkbox"/> Other, please specify .....				
<b>If Definitely Not, Probably Not or Maybe (for FRIEND)</b> which of these statements best describes your reasons for why you would not be prepared to perform CPR on this person? ( <i>You can select more than one response</i> )	<input type="checkbox"/> Don't know how to do CPR <input type="checkbox"/> Don't feel confident <input type="checkbox"/> Concerned about hurting the person <input type="checkbox"/> Concerned about being sued <input type="checkbox"/> Concerned about not performing CPR properly <input type="checkbox"/> Physically unable to perform CPR <input type="checkbox"/> Concerned about infection <input type="checkbox"/> Other, please specify .....				

<p><b>If Definitely Not, Probably Not or Maybe (for STRANGER)</b> which of these statements best describes your reasons for why you would not be prepared to perform CPR on this person? <i>(You can select more than one response)</i></p>	<input type="checkbox"/> Don't know how to do CPR <input type="checkbox"/> Don't feel confident <input type="checkbox"/> Concerned about hurting the person <input type="checkbox"/> Concerned about being sued <input type="checkbox"/> Concerned about not performing CPR properly <input type="checkbox"/> Physically unable to perform CPR <input type="checkbox"/> Concerned about infection <input type="checkbox"/> Other, please specify .....
<b>3. Training related questions</b>	
<p>Have you ever been trained in CPR?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p><b>(If Yes),</b> When did you last receive training?</p>	<input type="checkbox"/> Less than 12 months ago <input type="checkbox"/> 1 to 5 years ago <input type="checkbox"/> More than 5 years ago <input type="checkbox"/> Can't recall
<p><b>(If Yes),</b> Was your most recent training led by a qualified trainer/instructor?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p><b>(If Yes),</b> Why did you undertake your most recent CPR training?</p>	<input type="checkbox"/> Requirement of my job <input type="checkbox"/> Requirement of a community or sporting club <input type="checkbox"/> Self-initiated <input type="checkbox"/> Other, please specify.....
<p><b>If (No- to ever trained),</b> Which of these statements best describes your reasons for not receiving CPR training? <i>(You can select more than one response)</i></p>	<input type="checkbox"/> Never thought about it <input type="checkbox"/> Cost <input type="checkbox"/> Time <input type="checkbox"/> Didn't know where to go to learn <input type="checkbox"/> Other, please specify .....
<p><b>4. The next few questions are about AED (Automatic External Defibrillator) also simply known as Defibrillator. An AED is a portable device that can potentially save the life of someone having a cardiac arrest. It checks the heart's rhythm and sends a shock to the heart to restore a normal rhythm. It is easy-to-use and can guide anyone to use it through simple voice commands</b></p>	
<p><b>Please select the option that best reflects your response to the statements below</b></p>	
<p>I would rate my overall knowledge of a defibrillator (AED) as</p>	<input type="checkbox"/> Very Poor <input type="checkbox"/> Poor <input type="checkbox"/> Fair <input type="checkbox"/> Good <input type="checkbox"/> Excellent <input type="checkbox"/> Not Applicable as I had never heard of an AED/Defibrillator

<b>Please select the option that best reflects how confident you would feel to</b>					
I would feel confident to use an AED in an emergency	<input type="checkbox"/> Not confident <input type="checkbox"/> Somewhat confident <input type="checkbox"/> Confident <input type="checkbox"/> Very confident <input type="checkbox"/> Not Applicable as I have never heard of an AED/Defibrillator				
<b>If an AED/Defibrillator were available, I would be willing to use it in an emergency if they were a ....</b>					
	Definitely not	Probably not	Maybe	Yes, probably	Yes, definitely
Family member	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Friend	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Stranger	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>If Definitely Not, Probably Not or Maybe (for FAMILY MEMBER)</b> selected, which of these statements best describes your reasons for why you would not be prepared to use an AED on this person? ( <i>You can select more than one response</i> )	<input type="checkbox"/> Don't know how to use an AED <input type="checkbox"/> Don't feel confident <input type="checkbox"/> Concerned about hurting the person <input type="checkbox"/> Concerned about being sued <input type="checkbox"/> Concerned about not being able to operate it properly <input type="checkbox"/> Other, please specify.....				
<b>If Definitely Not, Probably Not or Maybe (for FRIEND)</b> selected, which of these statements best describes your reasons for why you would not be prepared to use an AED on this person? ( <i>You can select more than one response</i> )	<input type="checkbox"/> Don't know how to use an AED <input type="checkbox"/> Don't feel confident <input type="checkbox"/> Concerned about hurting the person <input type="checkbox"/> Concerned about being sued <input type="checkbox"/> Concerned about not being able to operate it properly <input type="checkbox"/> Other, please specify.....				
<b>If Definitely Not, Probably Not or Maybe (for STRANGER)</b> selected, which of these statements best describes your reasons for why you would not be prepared to use an AED on this person? ( <i>You can select more than one response</i> )	<input type="checkbox"/> Don't know how to use an AED <input type="checkbox"/> Don't feel confident <input type="checkbox"/> Concerned about hurting the person <input type="checkbox"/> Concerned about being sued <input type="checkbox"/> Concerned about not being able to operate it properly <input type="checkbox"/> Other, please specify.....				
<b>Thank you for completing the survey questions.</b>					

*Note: Survey items on training, willingness and confidence have been adapted from validated surveys used in Australia [Refs: 10,17]*



## Appendix 4. Roles and Responsibilities

### Committees

Members of the investigating team as well as partner organisations formed the steering committee and continue to participate and provide guidance in various discussions and decisions related with the project. In addition, three subcommittees or working groups have been set up based on members' expertise and interest to oversee and provide regular input and support in three key areas of (i)intervention development, (ii)implementation plan and (iii)scientific/ statistical advice.

### Subcommittees:

**Intervention(development) committee:** oversees the development of educational tools and materials for the intervention. Broadly, key tasks involved discussion on key messages that need to be conveyed in the intervention campaign, and identification, collation and reviewing of all intervention material aligned with these key messages.

**Implementation(planning) committee:** deliberates on planning the delivery of the intervention and implementation of the project as per the study protocol. Key discussions involved - the approach to selecting and recruiting community groups, planning of study areas, recruitment approaches for urban versus regional areas, examination of feasibility or rolling interventions in organisations within a select timeframe, review, and comment on study timeline, and advise on the process evaluation component.

**Scientific(advisory) committee:** reviewed and provided advice on the development and amendments to the scientific protocol and included deliberation over the design and methodology, survey items, analysis and evaluation plan, data management and addressing any issues raised by the ethics committee.

**Operations committee:** The study will be coordinated and managed by the Westmead Applied Research Centre (WARC), The University of Sydney. A core committee of investigators, project officers have been meeting regularly to organise and facilitate the working groups, set up the project, develop key documents and contracts and troubleshoot issues related with intervention development and implementation of the project.

## **Appendix 5. Audit and Monitoring of study**

The research team has established quality control procedures for data collection. Through regular audits of study implementation, data collection procedures will further assure that any issues including will be picked up and attended to in time. All data entry will be completed via RedCap<sup>TM</sup>, which will allow for real time data query generation for values entered outside of pre-set valid ranges and consistency checking. Only authorised research staff will have access. All entered data forms will be electronically signed (by use of the unique password) by authorised study staff. All changes made following the initial entry will have an electronically dated audit trail. Centralized coding of outcomes will be performed by a trained researcher and reviewed by the team statistician, to confirm accuracy of coding and correct reporting of outcomes by the sites. Data monitoring will thus be conducted throughout the study, but no interim analysis is planned. Monitoring of data will ensure any adverse or unintended events are picked up in time and reported as outlined in the ethics and governance documents. While an independent audit is not planned, an internal audit by the sponsor may occur during the trial.