ISRCTN90350842 https://doi.org/10.1186/ISRCTN90350842

Facilitating access to cardiopulmonary resuscitation training in high-risk areas study

Submission date
30/09/2022

Recruitment status
No longer recruiting

Registration date
28/03/2023

Overall study status
Completed

Last Edited
09/10/2024

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Cardiac arrest is when someone's heart stops beating and they stop breathing. People who see cardiac arrests are called bystanders. They can help save the person's life by doing cardiopulmonary resuscitation (CPR) and using a heart restarter machine before an ambulance arrives. Heart restarter machines are also known as publicly accessible defibrillators (PADs). In some areas, people are more likely to have cardiac arrest. In some of these areas not many bystanders do CPR either. These are called high-risk areas. High-risk areas are usually deprived areas with a higher number of people from diverse communities living there. The study from King's College London and the University of Warwick will work with people with South Asian and Black Caribbean or African heritages, who know what life is like in these high-risk areas in different parts of England. The study wants to find out what stops people from helping someone having a cardiac arrest. The study also aims to come up with some activities to help people overcome the things that stop them from doing CPR or using a heart restarter.

Who can participate?
In WP1, adults will be recruited from a diverse range of communities who are familiar with life in these marginalised, high-risk areas in the West Midlands. The team would especially like to hear from people from Black African, Caribbean, South Asian or mixed heritages.

In WP2, some people from WP1, and representatives from communities and organisations involved in CPR training and campaigning for improvements in CPR, will be invited to help decide which solutions should be tried out in WP3.

WP3 will start by building on the networks established for WP1 and with people involved in WP2 to identify individuals from locations known to be high-risk (e.g. the West Midlands, London, the North East) who are willing to host CPR workshops and find people in their local communities who might like to take part in these workshops. Workshop hosts then send people who might be interested in taking part a video to watch, which has a link to register for the workshop. Posters are also used to advertise locally. The research team contacts people who registered to talk about the workshop and, if interested, they will be allocated a space.

What does the study involve?
The study is in four parts:
1. The study team will look at information from other studies that have looked at this problem in similar areas. The team will discuss the problem with people from high-risk areas at about 4 workshops in the West Midlands to see what they think about the problem. The team will see if what the other studies say is similar to or different from these experiences. The team will then discuss ideas about activities that might help make things better.
2. The study team will look at all the information from the discussions and work out what sort of activities might work to improve things. They will also work out what it is about the activities that seem to make a difference. At another workshop, the researchers will discuss their ideas with local people and people from organisations interested in improving the number of bystanders doing CPR, like the Resuscitation Council UK. The people taking part will decide which activities could work in the local high-risk areas and decide which are the best ones to try out in the next part of the study.
3. These activities, will be tried out in two places in the West Midlands to see how they work. Information will be collected from people taking part in the test activities to see what they thought. This information will be used to decide if any changes need to be made to the activities before trying them out in a few other areas in England. People taking part will be asked for their thoughts on the activities to see if the activities work for most people or don't work for most people in the way they should.
4. Using information gathered in the first two places, the final activities will be selected. These activities involve four community CPR awareness and training workshops for up to 15 people in various parts of England with characteristics of high-risk areas. The workshops have 2 parts: first, talking about what a cardiac arrest is and how members of the public can feel more confident to help someone having a cardiac arrest. Second, training people how to do CPR and use a heart restarter machine. The workshop will take about two and a half hours, including time to complete a questionnaire. In the two weeks after the workshop, some interviews will take place with a few people, to speak to them in more detail about how they think it went. A researcher will ask if people would be interested in doing an interview. However, people can still take part in the workshop if they don't want to do an interview.

Members of the public will take part in this study in different ways. Two will be members of the study team. Other people will take part in the workshops in WP1 and WP2 of the study. Others will take part in the events run to test out the chosen activities in WP3. This study will help organisations trying to improve the number of bystanders doing CPR in the areas that need it the most to know what activities could help improve things.

What are the possible benefits and risks of participating?
There is unlikely to be a direct benefit to people taking part in WP1 and WP2. However, taking part will help the team learn about why not many people do bystander CPR in certain parts of the country and may help in the work to improve this. In WP3, people will receive training on how to provide CPR and use a heart-restarter machine. In addition, taking part in research to help understand how to improve things may benefit other people in the future. Talking about cardiac arrest and bystander CPR can be hard and may be upsetting. The researcher will check to see if participants are OK during the session and stop if the conversation is upsetting them. Participants will be able to take a break at any time.

Where is the study run from?
King's College London (Lead University) (UK) and Warwick Clinical Trials Unit at the University of Warwick (UK) are running the study on a day-to-day basis

When is the study starting and how long is it expected to run for?
November 2021 to January 2025

Who is funding the study?
National Institute for Health Research (NIHR) Health and Social Care Delivery Programme (NIHR131623) (UK)

Who is the main contact?
Dr Louisa Edwards (Study Coordinator), facts@warwick.ac.uk

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 51238

Study information

Scientific Title
Facilitating Access to Cardiopulmonary resuscitation Training in high-risk areas (FACT) study

Acronym
FACT

Study objectives
We have overall study aims and research questions as opposed to a hypothesis:
The overall study aims are:
In collaboration with people from areas with characteristics of high risk for cardiac arrest, we aim to:
1. Identify reasons for low bystander resuscitation rates in communities living in high-risk areas through literature and primary evidence synthesis
2. Develop, implement and evaluate theoretically informed interventions.

The research questions are:
1. What factors influence performing bystander resuscitation for people who have an out-of-hospital cardiac arrest in areas where there is a higher-than-average incidence of cardiac arrest

combined with a lower-than-average rate of bystander CPR in England?
2. What is the evidence base that could inform the development of interventions to address identified barriers or promote identified facilitators?
3. What factors should be prioritised and have theoretically informed interventions developed to address them?
4. Do the developed interventions work, and if so how, for whom, and in what circumstances, to produce the intended (or any unintended) outcomes?

Ethics approval required
Old ethics approval format

Ethics approval(s)
WP 1 & 2:
1. Approved 29/04/2022, University of Warwick Biomedical and Scientific Research Ethics Committee (University of Warwick, Kirby Corner Road, Coventry, CV4 8UW, UK; +44 (0)24 765 73123; BSREC@warwick.ac.uk), ref: BSREC 101/21-2.
2. Approved 14/07/2022, King's College London Research Governance Office agreed to accept the previous ethical approval on behalf of King's College London's College Research Ethics Committee (King's College London Research Governance Office, Franklin Wilkins Building, 4.19 Waterloo Bridge Wing, Waterloo Road, London, SE1 9NH, UK; +44 (0)20 7848 1239/3323; rgo@kcl.ac.uk), ref: TS-21/22-32518.

WP3:
Approved 15/09/2023, King's College London Health Faculties (Blue) Research Ethics Sub-Committee (King's College London Research Ethics Office, 3rd Floor, 5-11 Lavington Street, London, SE1 0NZ, UK; Tel: not provided; rec@kcl.ac.uk), ref: HR/DP-23/24-34656.

Study design
Collaborative-realist-enquiry realist-evidence-synthesis intervention-development implementation-evaluation with embedded feasibility study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Cardiovascular health

Interventions
This study is a collaborative realist enquiry, informed by the Theoretical Domains Framework (TDF) and associated Behaviour Change Wheel (BCW), consisting of a realist evidence synthesis, intervention development and implementation evaluation with embedded feasibility in three work packages (WPs).

Our key objectives are to:
1. To establish a community-based public involvement advisory group to co-produce key aspects of the study (WP1)
2. To identify barriers and facilitators to performing CPR or defibrillator use in high-risk areas through realist evidence synthesis and develop theoretically informed interventions (WP1)

3. Prioritise interventions with community partners and other stakeholders for evaluation (WP2)
4. Develop a realist-informed evaluation framework and associated data collection tools, including assessment of locally made intervention changes (WP2).
5. Conduct an implementation evaluation of the prioritised interventions with an embedded feasibility study (WP3).

The first two Work Packages are using the following methods:
WP 1 - Realist synthesis, informed by the Theoretical Domains Framework, of published cross-disciplinary literature and primary data from workshops with people from communities with characteristics of high-risk areas.
WP2 – Theoretically informed intervention development building on WP1 findings.

Work Package 3 will be a realist-informed evaluation of the implementation of the interventions developed in WP2. The details will be finalised once the interventions are developed. We will update this information in due course.

Updated 04/09/2024:
WP3 - A mixed-methods realist evaluation of the intervention(s) implementation with an embedded feasibility study. The intervention is designed from the work in WP1 and 2 and has three parts. It will be conducted in up to six high-risk areas in England (two in the embedded feasibility study and the remaining four in the main study).

Intervention Type
Behavioural

Primary outcome(s)
Work package 1 (WP1) is an evidence synthesis using realist principles. It explored factors that help or hinder the participation of members of the public from poorer communities with south Asian or Black African of Caribbean heritage in providing bystander CPR. Data to identify factors and associated interventions will be collected from published literature, 5 workshops discussions with people from the communities of interest and a meeting with the study Public Advisory Group.

Work package 2 (WP2) will produce a theoretically based intervention or interventions that can be evaluated in work package 3 (WP3). To ensure the interventions have a sound theoretical underpinning, the outputs of WP1 will be mapped to behaviour change theory and techniques and then developed into potential interventions. At a stakeholder meeting, the interventions will be discussed and prioritised and the final ones selected to be taken forward for evaluation in WP3. We will use the theoretical basis of how the interventions are intended to work, for whom and in what circumstances to create an evaluation framework for use in WP3.

In WP3, the evaluation framework will allow the conduct of a realist evaluation to establish whether and how the intervention(s) work as intended or not, for whom, and in what circumstances. The framework will inform the development of data collection tools and the analysis. Data will be collected through qualitative interviews after the intervention and, if appropriate, using a study-developed measure (questionnaire) for intervention participants to provide feedback on their experiences of how the intervention worked. The evaluation framework will inform qualitative data analysis and synthesis of findings from the different data collection methods to evaluate how the interventions worked (or didn’t work), in what contexts and for whom to produce the intended (or unanticipated) outcomes of the interventions.

Key secondary outcome(s))

There are no secondary outcome measures

Completion date
31/01/2025

Eligibility

Key inclusion criteria
1. WP1: Adult members of the public from Black African and Caribbean, South Asian or mixed heritages who live in or are knowledgeable about high-risk areas
2. WP2: Stakeholder organisations that represent public/patient views related to CPR or organisations involved in developing, providing or campaigning for public resuscitation skills training, policymakers. Some participants from WP1 will also be invited to this workshop.

Added 04/09/2024:
3. WP3: For parts 1 and 2 of the intervention, eligible participants for inclusion will be trusted members of Black African and Caribbean or South Asian communities or working with those communities in poorer areas. For Part 3, this will be adults from the communities the trusted person works with.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
17 years

Sex
All

Total final enrolment
146

Key exclusion criteria
1. People aged 17 years old and under
2. People who do not live in or are knowledgeable about high-risk areas (WP1)

Date of first enrolment
01/07/2022

Date of final enrolment
22/05/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Warwick Clinical Trials Unit
University of Warwick
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Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available, as stated in the current study protocol (v3.0), there are challenges with sharing qualitative data that will inform decisions. For example, it may be possible to identify participants or participating organisations through contextual data contained in the transcripts, even after names and places have been removed or pseudonyms have been removed.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		15/06/2023	27/06/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes