PROTOCOL

Facilitating Bystander Cardiopulmonary Resuscitation Training in high-risk areas (FACT) study

Sponsor:	University of Warwick
Funding Body:	NIHR HS & DR programme (project number NIHR 131623)
ISRCTN Number:	TBA
Ethics Approval:	University of Warwick BSREC Ref: 101/21-22
Ethics Approval: date:	29 Apr 2022
Version Number:	2.0
Date:	05 August 2022

Protocol Amendments:

Amendment	*Date of Amendment*	*Date of Approval*
1	05 Aug 2022	19 Aug 2022

WARWICK
CLINICAL TRIALS UNIT

FUNDED BY
NIHR | National Institute for Health Research

CONTACT NAMES AND NUMBERS

Sponsor:

University of Warwick, Research & Impact Services

University House

Kirby Corner Road, Coventry, CV4 8UW

Tel: 024 765 22746

Email: sponsorship@warwick.ac.uk

Chief Investigator:

Dr Claire Hawkes

Senior Research Fellow

Warwick Clinical Trials Unit

University of Warwick, Coventry, CV4 7AL

Tel: 024 761 50156

Email: c.a.hawkes@warwick.ac.uk

Co-Investigators:

Mr Deska Howe – West Bromwich African Caribbean Resource Centre, Public Co-investigator

Mr Elyas Kahlifa – Public Co-investigator

Dr Yassar Mustafa – Public Co-investigator

Professor Ivo Vlaev – University of Warwick

Professor Sophie Staniszewska – University of Warwick

Professor Jo Rycroft-Malone – Lancaster University

Professor Gavin Perkins – University of Warwick

Dr Nicholas Parsons – University of Warwick

Senior Project Manager: Dalbir Kaur

Senior Project Manager

Warwick Clinical Trials Unit

University of Warwick, Coventry, CV4 7AL

Tel: TBC

Email: dalbir.kaur@warwick.ac.uk

Senior Research Fellow: Dr Yin-Ling Lin

Senior Research Fellow

Warwick Clinical Trials Unit

University of Warwick, Coventry, CV4 7AL

Tel: TBC

Email: Yin-Ling.Lin@warwick.ac.uk

Trial Manager: Lauren Betteley

Clinical Trial Manager

Warwick Clinical Trials Unit

University of Warwick, Coventry, CV4 7AL

Tel: 024 765 75849

Email: FACTs@warwick.ac.uk

Contents

LIST OF ABBREVIATIONS/GLOSSARY

Abbreviation	***Explanation***
AED	Automated External Defibrillator
APEASE	Affordability, Practicality, Effectiveness/Cost-Effectiveness, Acceptability, Side-effects/safety, & Equity criteria
ASSIA	Applied Social Sciences Index and Abstracts
BCPR	Bystander Cardiopulmonary Resuscitation
BLS	Basic Life Support
BCT	Behaviour Change Technique(s)
BCW	Behaviour Change Wheel
BSREC	Biomedical and Scientific Research Ethics Committee
CI	Chief Investigator
CMO	Context, Mechanism and Outcome
CPR	Cardiopulmonary Resuscitation
CRN	Clinical Research Network
DMC	Data Monitoring Committee
EMS	Emergency Medical Services
FACT	Facilitating Bystander Cardiopulmonary Resuscitation Training in high-risk areas
GCP	Good Clinical Practice
IPT	Initial Programme Theory
ISRCTN	International Standard Registered Clinical/soCial sTudy Number
NHS	National Health Service
OHCA	Out of hospital cardiac arrest
PAD	Publicly accessible defibrillator
PAG	Public Advisory Group
PIL	Participant Information Leaflet
PPI	Patient & Public Involvement
SMG	Study Management Group
SOP	Standard Operating Procedure
SSC	Study Steering Committee

TDF	Theoretical Domains Framework
WCTU	Warwick Clinical Trials Unit
WP	Work Package

1. BACKGROUND

Help given by members of the public to people experiencing an out-of-hospital cardiac arrest (OHCA) varies by area and can lead to inequity of survival. Survival can be improved by bystander cardiopulmonary resuscitation (CPR)[1 2] and use of publicly accessible defibrillators (PADs) before paramedics arrive.[3 4]

Measuring the direct impact of interventions to improve bystander CPR and defibrillator rates and survival outcomes is challenging. It is not possible to know when and where cardiac arrests are going to happen and have specific interventions at the ready. The chain of survival is well recognised in the cardiac arrest field, usually presented as a series of interlinking, equal sized circles with depictions of the stages of resuscitation and a version exists which identifies the relative importance of different links in the chain in improving survival by depicting larger circles for the most important stages (Figure 1).[5] Actions taken by members of the public have the greatest potential to improve outcomes (recognition of an arrest and calling for help, performing CPR and using a defibrillator before the ambulance arrives).

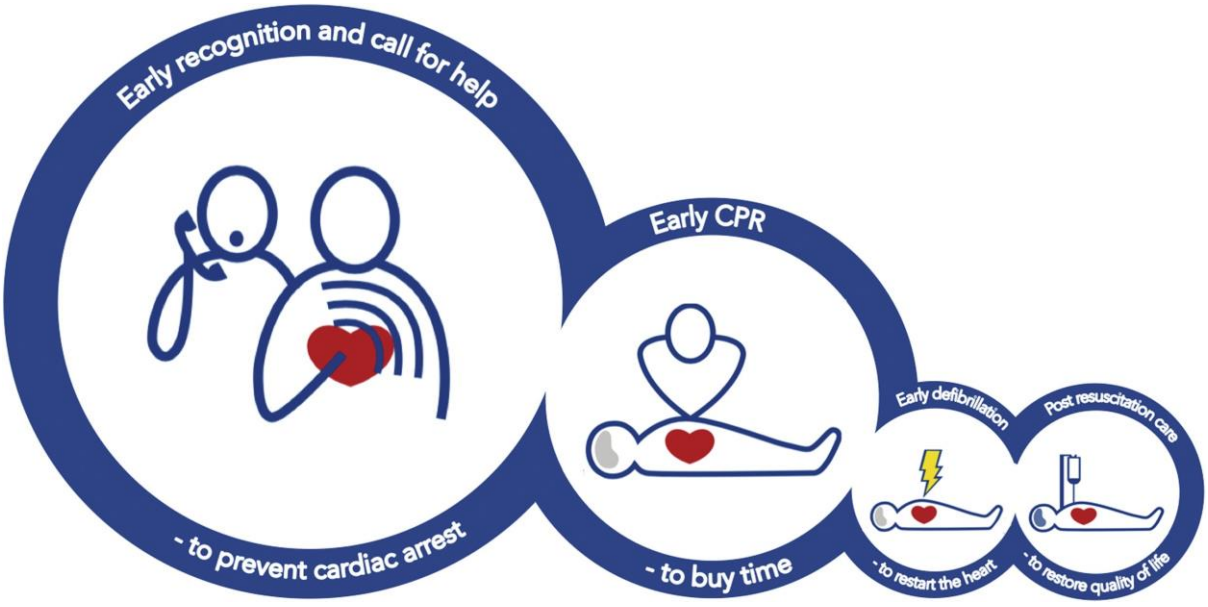


Figure 1 - The chain of survival, Deakin 2018

The impacts on survival from OHCA of individual interventions, which occur in the different links of this chain, are difficult to measure because the chain is complex. Outcomes can be affected by actions in any link, as well as by the individual person's characteristics and subsequent variation in hospital treatment.[6] In response to these challenges, research into improving outcomes from OHCA

has focused on strengthening the elements in the chain of survival and monitoring associated improvements through regional or national registries over time.[7] There is evidence that combinations of public health interventions targeting the first three links in the chain (see Figure 1 above) do result in greater proportions with resuscitation skills and higher bystander intervention rates, which are associated with improved survival outcomes observed in registry data.[4]

English NHS Ambulance Services treat almost 30,000 out-of-hospital cardiac arrest patients a year. Average survival rates have been improving (7.8% in 2014 – 9.4% in 2018).[8] The world's best performing emergency services (EMS) report higher survival rates (e.g. 21% in King County Seattle, USA),[9] so there is still room for improvement. Recent UK initiatives such as the annual Restart a Heart campaign[10 11] are associated with the rising English Bystander CPR rate (from 55.2% in 2014 to 61.4% in 2018).[8] In King County Seattle, in 2016 73% of out-of-hospital cardiac arrest cases received Bystander CPR.[12] Out-of-hospital cardiac arrest survival rates are highest in the 20-25% of out-of-hospital cardiac arrest patients found in a heart rhythm, which benefits from a shock delivered by a defibrillator (29.7% in 2018).[8] In addition to increasing bystander CPR rates, we need to increase defibrillator use rates, which although improving remains low (2.3% in 2014 to 5.8 In 2018).[8] Using a defibrillator before EMS arrival has been associated with significantly increased survival (odds ratio:1.75 CI 1.23 to 2.50).[13]

Variation by area exists in the figures for England. Some areas, characterised by greater than the England average for deprivation, ethnic mix, population density and proportion of people in routine occupations have a higher incidence of cardiac arrest combined with lower than average bystander cardiopulmonary resuscitation rates.[14] These areas can be described as high-risk and were observed in the West Midlands, Yorkshire, the North East and South East.[14] Our recent evaluation of Restart a Heart event locations indicated that events run by ambulance services in England were held in 29% of high-risk areas.[15] Improving survival from out-of-hospital cardiac arrest in high-risk areas is needed to help address this health inequity.

We conducted a scoping review of the literature to assess the evidence base about the phenomenon of high-risk areas and their characteristics. We then conducted a separate search for evidence on initiatives developed to increase bystander CPR and/or defibrillator use targeted to high-risk areas or for characteristics associated with high-risk areas, in particular minority ethnic populations and socioeconomic status. We used OVID to search MEDLINE and EMBASE from 1980 to 8 January 2021. We used the terms in Table 1 below and combined them variously to identify studies about associations between ethnicity and socioeconomic status and cardiac arrest, ethnicity

and socioeconomic status and lay bystander resuscitation rates, and ethnicity and socioeconomic status and training in resuscitation skills. Ethnicity was viewed as incorporating race and culture and all focused on minority groups where the study country's dominant ethnicity was white. Abstracts of the articles identified for each search were scanned for relevance to rates of bystander resuscitation skills in areas that have the characteristics of high-risk areas, contribution to understanding the nature of the problem and any research into and evaluation of initiatives to address the issues. We summarised the results narratively.

Table 1 - Search Terms

Terms to identify out of hospital cardiac arrest,	Cardiac arrest, out of hospital, OHCA, OOCHA, Out-of-hospital Cardiac arrest, Heart arrest
Term to identify lay bystanders and lay organisations	Community Networks, Voluntary Health Agencies, Volunteers, witness*, Bystander*, volunteer*, voluntary, layperson, laypeople, lay person, lay-person, lay-rescuer*, nonprofessional*, unskilled, untrained, (lay person* or lay responder* or layperson* or bystander* or layman or laywoman or laymen or laywomen or first responder).
Terms to identify resuscitation skills	Cardiopulmonary Resuscitation, Cardio-pulmonary resuscitation, CPR, Resuscitation, Basic life support, BLS, First aid, mouth-to-mouth, mouth to mouth, cardiac massage, heart massage, chest compression, automated external defibrilat*, external defibrilat*
Terms to identify resuscitation education and training	Resuscitation/ed [Education], Education, Nonprofessional, Education Health Education Teaching, Learning, Training, First Aid/ed [Education], BLS training, Basic life support training
Terms to identify minority groups	Asian Continental Ancestry Group, African Continental Ancestry Group, Ethnic, british asian*, british African*, (race or racial or ethnic* or native american* or native canadian* or native alaskan* or american indian* or canadian indian* or amerind* or negro* or afro* or african* or black or blacks or arab* or asian* or chinese or japanese or oriental* or thai* or philipino* or filipino* or taiwanese* or indian* or bengali* or kashmiri* or gujarati* or tamil* or bangladeshi* or pakistani* or sri lankan* or hispanic* or latino* or nonwhite* or nonwhite* or multiracial or multi-racial), Indians, North American, native American, Hispanic Americans, Mexican Americans, Minority Groups, (culture or cultural or faith*

	or relig* or sikh* or hindu* or muslim* or islam* or christian* or catholic* or judaism or jew* or buddhis* or jehovah* or evangelical or evangelist* or adventist* or pentacostal)
Terms to identify locations that are deprived/have health inequalities	Health Services Accessibility, Health Status Disparities, Residence Characteristics, Socioeconomic Factors, class demographic, deprivation, deprive*, disadvantage*, disparit*,Economic, education*, employed, employment, income, inequalit*, occupation*, post-code*,postcode*, (postal adj code*), zipcode*, (zip adj code*), Poverty, Socioeconomic status, SES, (social adj1 (class or factor or factors)), socioeconomic, socio-economic, unemploy*

We identified 195 papers in the two searches focusing on out-of-hospital cardiac arrest bystanders training and socioeconomic status and ethnicity. Thirty seven were selected for further review. Of these, eight were conference abstracts with insufficient detail available to include. Of the remaining 29, 13 were epidemiological studies, two were reviews of bystander interventions in general and their association with improving out-of-hospital cardiac arrest patients outcomes, four were about knowledge of and willingness to perform CPR among people form minority ethnic groups or deprived communities, three were about perceptions of CPR, three reported investigations of barriers and facilitators in deprived or ethnic minority communities, three reported specific interventions for ethnic minority or deprived communities, two were consensus papers about the evidence base for resuscitation guideline which included acknowledgement of the lack of evidence in this area.

Internationally epidemiological studies of out-of-hospital cardiac arrest have identified similar high-risk areas in Canada,[16] USA,[17-20] Australia,[21] Taipei,[22] New Zealand,[23] Scotland.[24] However, reasons for the phenomenon and associated intervention development have not been fully explored.

A 2019 systematic review investigated the mediating factors of bystander CPR and socioeconomic status on survival from out-of-hospital cardiac arrest. The incidence of out-of-hospital cardiac arrest in lower socioeconomic status areas was also found to be higher. It reported an association with lower bystander CPR rates and (from one study) lower defibrillator use in areas of lower socioeconomic status. Survival from out-of-hospital cardiac arrest that occurred in lower socioeconomic status areas was also found to be lower.[25]

A systematic review published in 2014 conducted a meta-analysis of observational data comparing out-of-hospital cardiac arrest process and survival outcomes for black and white out-of-hospital cardiac arrest patients. Included studies came from the United States. They found that black patients were less likely to receive bystander CPR (OR=0.66, 95% CI = 0.55 to 0.78), to survive to hospital admission (OR.0.59, 95% CI.0.48–0.72) and survive to hospital discharge (OR.0.72, 95% CI.0.60–0.86) compared to white patients.[26]

Reasons for lower bystander resuscitation intervention rates (CPR and/or defibrillator use) have been suggested with a focus on training, assuming that if fewer people in the high risk areas are trained in resuscitation skills then the pool of people ready to provide CPR in these areas is lower than average and could account for lower bystander intervention rates. There is evidence that people from lower socioeconomic grades, who are more likely to live high risk areas, report lower CPR training rates than those from higher grades.[20 27] A recent review of barriers to performing CPR identified only three studies that specifically covered deprived communities[28]. Access to training could be a reason, but there is no published research into whether this or any other issues account for the lower rates in England.

There is increasing evidence that combinations of interventions including training in CPR and AED use, dispatcher assisted CPR, and the use of technologies that direct nearby lay rescuers to suspected out-of-hospital cardiac arrest cases as part of a co-ordinated EMS response improve bystander CPR rates and survival to hospital discharge.[29] Reviewers reported weak evidence that identified some potential barriers and facilitators to bystanders using defibrillators including knowledge and awareness, willingness to use them, training and accessibility[30]. Apps sending first responders or lay rescuers to assist out-of-hospital cardiac arrest patients used by some ambulance services are a relatively new technology. Our recent study suggests opportunity barriers prevent even capable and motivated volunteer first responders from using defibrillators, and suggested interventions such as highlighting the location of publicly accessible defibrillators, providing access codes to locked cabinets and displaying route distance and time estimates to the nearest defibrillator and to the patient. Arriving at the patient after the ambulance was a demotivating factor and reducing the time between the emergency call and first responder activation and providing the first responder with expected ambulance arrival times could improve this aspect[31]. Apps such as GoodSam (https://www.goodsamapp.org) evaluated in this study, are not yet used by all English ambulance services, however understanding people from high-risk communities' knowledge and views of such apps would be valuable.

For dispatcher (999 ambulance service call handler) assisted CPR, language barriers between the dispatcher and the lay responder can hinder assistance or even ability/willingness to call for help. One US study reported the development of a graphic novella to show how to call the EMS and perform CPR. The novella impacted positively on participants' intentions to call the EMS, but those trained in CPR remained more likely that those not trained to report an intention to attempt CPR.[32]

Accessing training is a key component in these public health initiatives but little is known about English high-risk communities' views about accessing training or indeed using or responding to other interventions. Research into these issues will help stakeholders' decision making about how to engage such communities in efforts to improve bystander CPR and AED use rates.

Outside England, a few studies have identified barriers and facilitators to accessing resuscitation training. Incentives to train in some US high-risk areas have been identified including child-care provision, food/grocery cards for participants, free full certification classes, and transportation cards. Identified barriers included accessibility, costs, distrust of Police/EMS/Fire services, knowledge about why CPR is important.[33 34] Barriers identified in Scotland were lack of confidence, elements of the physical environment, e.g. concerns for personal safety and fear of reprisal from gangs or the police. This study in disadvantaged communities in central Scotland recommending tailoring activities aimed at increasing bystander CPR rates to the needs of individual communities. Six of its 61 focus group participants were from minority group backgrounds.[35] Whether these findings would be the same for other UK locations is unknown.

An exception to the paucity of theoretically informed intervention development research targeting high-risk areas is the identifying High Arrest Neighbourhoods to Decrease Disparities in Survival (HANDDS) programme in Denver USA which uses the Health Beliefs Model of behaviour change.[33] A qualitative focus group study informed the HANDDS programme identifying four considerations for designing community-based CPR interventions; (1) identifying lay people to serve as motivated leaders while targeting both senior citizens and school children to increase reach; (2) finding appropriate community-based locations for CPR training; (3) incentivising participation, and (4) identifying and addressing barriers to participation.[34] The Scottish team's "Let's be CPR Ready" intervention has Bystander Supporters raising awareness in their local communities to increase people's belief that they can and should perform CPR, demonstrating it, encouraging them to plan to act if necessary and sign posting to online resources and training.[28]

While research in both the UK[14] and US[18] has shown high-risk neighbourhoods are characterised by deprivation and lower proportions of white residents, significant societal, cultural and ethnic differences between US and England exist. Understanding whether US findings are relevant in England and comparing the findings from the ongoing Scottish research will be valuable for UK stakeholders.

These studies happened before the coronavirus pandemic which has seen decreases in BCPR rates[36] [37] and has impacted on training opportunities. This study provides an opportunity to explore these impacts and develop interventions addressing COVID-19 related challenges as well as pre-existing ones.

The FACT study will synthesise primary and secondary data, with academics collaborating with members of communities in the West Midlands, to address the lack of evidence about the issues involved. The health literature reviewed in preparation for this study demonstrates that it is an under researched area. For our evidence synthesis, we will draw on interdisciplinary literature on areas and communities that have similar characteristics to those identified as high-risk for out-of-hospital cardiac arrest. Our focus will be on the impacts these characteristics have on volunteer participation in activities similar to bystander interventions in cardiac arrest and on initiatives that have been designed to address these characteristics to increase such volunteer participation. of these areas and communities have on, or have been tackled by, other initiatives that share similarities with increasing volunteer participation in resuscitation for out-of-hospital cardiac arrest. This has the potential to produce new insights into potential reasons for and ways of improving participation. While some issues will go on to be addressed by our intervention development plans, the others we discover will be reported, contributing to knowledge by, potentially identifying areas for further research or as suggestions for ways of intervening. We will prioritise issues identified in the evidence synthesis and develop and evaluate interventions that can be used by stakeholders at the end of the study.

The study will build on the small evidence base, especially in the UK. Characteristics of deprived areas in different parts of the UK vary, e.g. proportions of people from minority group backgrounds.[38] [39] Given the Scottish study only included six participants from minority group backgrounds in their focus groups,[35] FACT will give greater voice to views of people from minority group backgrounds by targeting communities in high-risk areas. It will generate new knowledge by adding evidence from people from high-risk communities and by co-creating theoretically informed

and evaluated interventions addressing issues prioritised by members of the communities themselves for use at the end of the study.

International evidence points to inequalities in survival from out-of-hospital cardiac arrest in high-risk areas, characterised by deprivation and higher proportions of people from a minority group background. Lower survival rates are associated with lower rates of bystander CPR. There is very little evidence about interventions to improve bystander intervention rates in such areas. We found no published research on the topic in England and one ongoing study in Scotland. One initiative in the US has published research, but whether its approach would work in England is unknown.

The NHS England Long Term Plan prioritises reducing health inequalities, recommends partnership working with communities experiencing inequities and sets a target to save 4,000 more lives of people sustaining an OCHA each year by 2028.[40] Improving out-of-hospital cardiac arrest survival is a policy imperative in all four UK nations.[41-44] All emphasise increasing bystander CPR rates and defibrillator use. Increasing public awareness of cardiac arrest and willingness to attempt CPR; increasing the number of people trained in CPR; and increasing the use of defibrillators are steps needed to improve early CPR and defibrillation.[42] The Out-of-hospital Cardiac arrest Outcomes Registry hosted by the University of Warwick, recognised in the Long Term Plan, has been used to identify the issue of high-risk areas in England and provides opportunity for monitoring long term progress towards these policy goals. There is room for improvement in bystander interventions for out-of-hospital cardiac arrest with the greatest potential for impact in high risk areas.

The COVID-19 pandemic has amplified health inequities and a recently published study from the London Ambulance Service reported an 81% increase in the number of out-of-hospital cardiac arrest cases at the height of the first wave compared to the same time the year before. They reported cautiously, because of data quality issues, that the proportion of those who were minority group patients during March and April 2020 had increased compared with data from the same period in 2019.[45] The proposed study has potential to investigate barriers to bystander resuscitation interventions specifically resulting from the pandemic as well as pre-existing ones.

There is therefore an urgent need to address a lack of knowledge for stakeholders and the policy imperative of addressing a health inequality by clearly identifying the issues, designing and evaluating interventions that could be used by stakeholders from the end of the study to help reach out-of-hospital cardiac arrest survival targets set for 2028 by NHS England.[40]

2. STUDY SUMMARY

This section presents an overview of the study, and its three work packages (WP). Details of the individual WPs follow in sections 5 (WP1), 6 (WP2) and 7 (WP3).

2.1 Study summary

2.1.1 Study Research questions

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?

What is the evidence base that could inform the development of interventions to address identified barriers or promote identified facilitators?

What factors should be prioritised and have theoretically informed interventions developed to address them?

Do the developed interventions work, and if so how, for whom, and in what circumstances, to produce the intended (or any unintended) outcomes?

2.1.2 Overall Study Aims

In collaboration with people from areas with characteristics of high-risk 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.

2.1.3 Overall Study Objectives

1. To establish a community based public involvement advisory group to co-produce key aspects of the study
2. To identify barriers and facilitators to performing CPR or defibrillators use in high-risk areas through realist evidence synthesis and develop theoretically informed interventions
3. Prioritise interventions with community partners and other stakeholders for evaluation.
4. Develop a realist informed evaluation framework and associated data collection tools, including assessment of locally made intervention changes.
5. Conduct an implementation evaluation of the prioritised interventions with embedded feasibility study.

2.1.4 Study design

This study is collaborative realist enquiry, informed by the Theoretical Domains Framework (TDF)[50] and associated Behaviour Change Wheel (BCW),[51] consisting of a realist evidence synthesis, intervention development and implementation evaluation with embedded feasibility in three work packages (WPs).

Benefits of community-based collaborative research are; to make research possible, produce credible data, recruit participants, make research and interventions more culturally acceptable and relevant to the local context, increase the likelihood of community action, increase sustainability of projects, and increase the quality of outcomes.[46-48]

Realist informed enquiry is particularly useful for investigations of complex interventions where different contexts into which an intervention is introduced may produce different outcomes. Realist research seeks to answer the question "what works (or does not work) for whom under what circumstances, how and why?"[49] By identifying the contexts and understanding how different potential interventions impact different contexts and what the resulting outcomes are will be essential to inform our evidence synthesis and intervention development. Using realist informed methods in conjunction with behaviour change theory we will develop realist conjectured context mechanism outcome (CMO) theories of how our selected interventions should work to inform an evaluation framework for the implementation evaluation.

2.1.5 Theoretical/conceptual framework

We will use the Theoretical Domains Framework (TDF)[50] and the associated Behaviour Change Wheel (BCW)[51] as a lens through which to view the evidence reviewed, the realist programme theories developed in the evidence synthesis and to inform our intervention development. It has been suggested that frameworks incorporating existing formal psychological theories could be used more to inform the development of realist programme theories.[52 53] The TDF and BCW will facilitate identifying important relationships between common features of interventions from a diverse range of programmes designed to promote change with populations relevant to our research. They are also useful tools to evaluate the outcomes our future interventions might address.

Using the TDF provides a structure for exploring the mechanisms of action in change programmes/interventions identified in the evidence synthesis and the different aspects of their contexts that are activated by mechanisms to produce outcomes of interest. The TDF and the BCW are useful because they break down a number of behavioural theories into component parts

facilitating identification of behaviour change techniques and mechanisms and allow consideration of these within contexts that influence individuals' behavioural choices. In this study we are interested in both behaviour change and contextual influences on peoples' choices around training in and using resuscitation skills. As a framework of constructs from different theories the TDF is flexible. The TDF, a synthesis of 128 constructs from 33 theories of behaviour change frequently used in implementation research, describes the determinants of behaviour change. It includes the following 14 domains: *Knowledge*; *Skills*; *Social/professional role and identity*; *Beliefs about capabilities*; *Optimism*; *Beliefs about consequences*; *Reinforcement*; *Intentions*; *Goals*; *Memory, attention and decision processes*; *Environmental context and resources*; *Social influences*; *Emotions*; and *Behavioural regulation*.

Our realist evidence synthesis will combine published evidence with primary evidence from workshops. We will integrate the primary evidence from the evidence synthesis workshops using realist analysis informed by the TDF. We will draw in relevant theories underpinning how interventions we identify work and will assess whether and how they sit with the TDF and BCW to inform the subsequent stages of the study. We anticipate that the BCW will be helpful with diagnosing the behavioural problem(s) associated with encouraging more members of the public in high-risk areas to provide CPR and use defibrillators on out-of-hospital cardiac arrest patients by using the determinants described by the TDF. This approach should help us develop initial programme theories, using the lens of the TDF and associated BCW, but without excluding other relevant theoretical perspectives from our evidence synthesis.

To develop our interventions, we will use the BCW to map the TDF concepts identified in the realist initial programme theories developed from the evidence synthesis onto the Behaviour Change Techniques (BCT) Taxonomy.[54] The BCT contains techniques (active ingredients in interventions) to mitigate the diagnosed behavioural problems.[(41)] These active ingredients will inform the intervention design. Such a theoretical approach to intervention design and implementation promotes interventions' effectiveness and sustainability.[55] The TDF will therefore also inform our evaluation framework for the intervention implementation study.

2.1.6 Study Methods

The study consists of three work packages (WP) using the following methods:
WP 1 - Realist synthesis, informed by the Theoretical Domains Framework, of published and primary cross-disciplinary literature and data from workshops with people from communities with characteristics of high-risk areas.

WP2 – Theoretically informed intervention development building on WP1 findings.

WP3 – Realist implementation evaluation with embedded feasibility in up to six English high-risk areas.

The flow diagram (Figure 2) summarises the study and timeline.

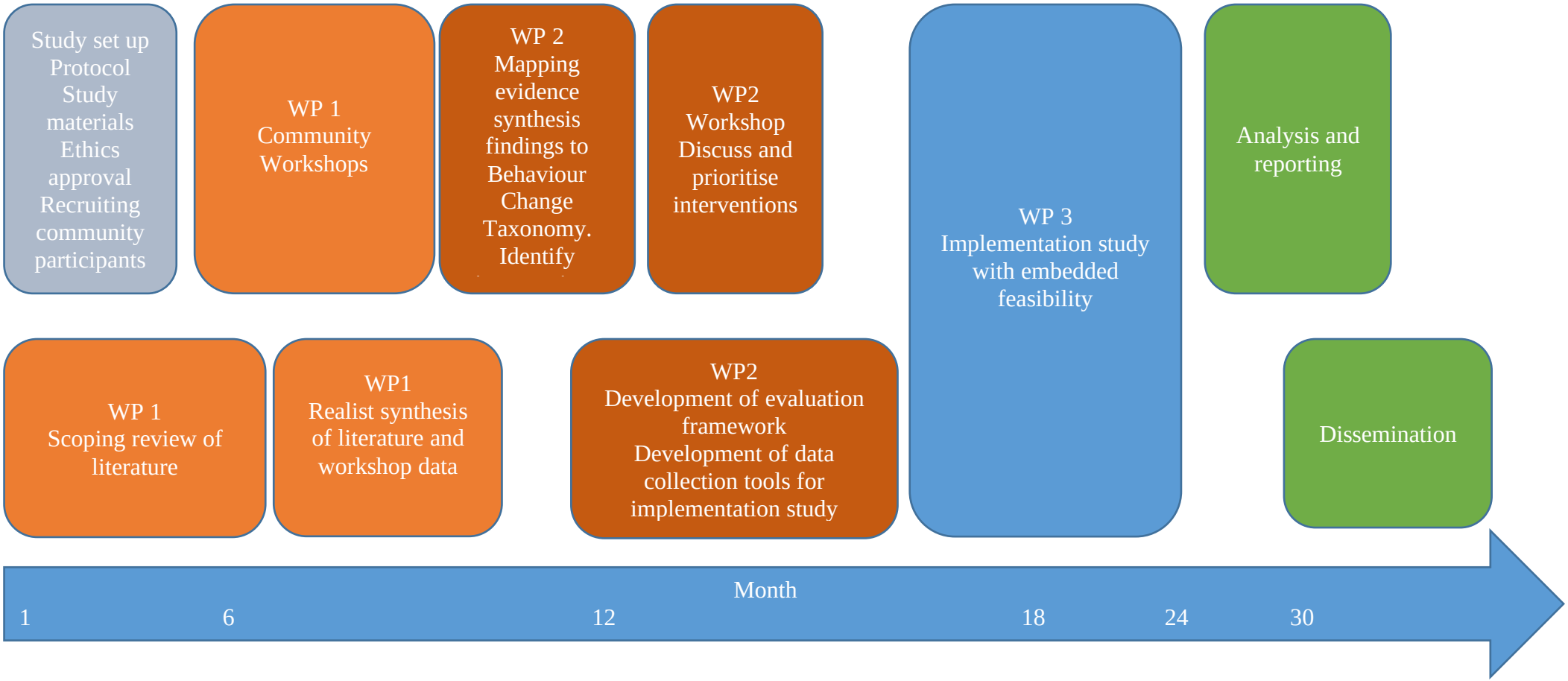


Figure 2 - FACT flow diagram

3. RESEARCH GOVERNANCE AND ETHICAL CONSIDERATIONS

The study will be conducted in accordance with the NHS Research Governance Framework and the principles of Good Clinical Practice. The study will comply with relevant Warwick CTU Standard Operating Procedures (SOPs) and all data will be stored securely and held in accordance with the Data Protection Act (2018).

Ethical approval for the study will be sought from the University of Warwick Biomedical and Scientific Research Ethics Committee (BSREC).

Informed consent: informed consent will be given by study participants. The study team will provide study information leaflets, appropriate to the research activity, to potential participants who will be given the opportunity to ask the researchers questions before deciding whether or not to consent to participation. Written informed consent will be taken at the beginning of the workshop where possible, and witnessed verbal consent will be available for those unable to write. Language support will be made available through information leaflets provided in different languages and provision of interpreters and members of the study team at research activities.
We will also offer the opportunity to participants to complete informed consent over the telephone or via a Microsoft Teams call prior to attending the workshop, to streamline the process and use participants' time more efficiently. If consent is taken over the phone, all elements of the consent form can be verbally agreed to by the participant. The form will be signed by the researcher at this time. The participant will be asked to provide their wet-ink signature at the workshop itself to finalise consent.

Confidentiality: All results and findings reported will be anonymised, to ensure no individuals can be identified in the study.

The study participants will be healthy volunteers, however the topic of cardiac arrest and using resuscitation techniques has the potential to cause distress to participants. Working with community contacts where we hold research activities, we will identify and ensure participants are aware of sources of support following participation. We will inform participants that they can take a break from participation in research activities or withdraw completely from the study at any point. A Withdrawal Form will be completed by the study team to record the details and level of withdrawal.

We will develop a support structure for members of the study team. Exploring the topic and hearing about people's experiences has the potential to be distressing or concerning to the researchers and other members of the team. We will consider a buddying system, where a member of the team has an identified buddy they can talk to following data collection. The CI will be available to members of the research team to debrief after data collection, should they wish, and the University of Warwick has welfare support available to all members of staff should team members need or prefer such confidential support. We will develop proportionate approaches with our research partners on how researchers will respond to sensitive disclosures made by study participants.

We will follow WCTU guidance and risk assessment templates with regards to lone working for the study team.

4. PATIENT AND PUBLIC INVOLVEMENT (PPI)

4.1 Involvement in the grant application

At the outline application we discussed the project with a local cardiac patient support group and members of our PPI co-applicant(s)' communities. The patient group suggested approaching community groups to recruit for the study e.g. faith organisations, community centres. Following this advice, we contacted faith groups thorough our PPI team members. The PPI contributors considered the study valuable for:

- understanding barriers and intervention development as some had experience of organising CPR training that had not been well attended.
- complementing ongoing work to reduce higher incidences of diabetes and cardiac disease in the South Asian communities. They advised we explore the impact of COVID-19 on bystanders
- Potential interventions were discussed and have been costed (e.g. awareness raising video).

At the second stage application we discussed the application with our PPI team members and particularly sought advice on recruitment in response to the outline stage committee's recommendation for researchers themselves developing contacts and to avoid reliance on third sector organisations. We decided that using our co-applicants', especially the PPI co-applicant's networks was the best approach to take in the first instance for recruitment because trust is such a crucial feature for successful involvement and they already have this trust within their networks. They advised that recruiting through their networks and their contacts will result in recruitment of

diverse groups of people, of different ages, genders, from different minority group backgrounds, and from deprived areas. They highlighted the importance of equitable opportunity to participate for people from different cultures and traditions and the value of using neutral venues for mixed workshop meetings in maintaining good will and trust. They thought including professional medical organisations with good representation from minority groups, such as the British Islamic Medical Association Lifesavers group, as stakeholders that have organized CPR training for the community in the past, would be valuable because they have laid some groundwork in raising awareness of CPR and their experiences could contribute to intervention development and they would likely be interested in disseminating successful interventions. They advised research participants should be compensated to facilitate participation. This advice is reflected in the stage 2 detailed project plan recruitment sections and will be valuable when planning to carry out the various study work packages. Our PPI applicants commented on drafts of the second stage application.
We have recruited a third PPI study team member from the African-Caribbean community on the advice of the funding committee.

A Public Involvement Fund grant from NIHR RDS West Midlands supported this grant development work for the outline and stage 2 application.

4.2 Involvement in the research

We will draw on NIHR guidance on co-production to frame our study, with its focus on the development of high quality relationships, reciprocity and the valuing of different forms of knowledge.[56] PPI involvement is essential for the study purpose and design to collaboratively produce interventions that are acceptable to and relevant for use by the communities they are intended for. Our PPI lead will work with our PPI co-applicants, PPI advisory group and research team to ensure that we maintain this collaborative approach and maximise the PPI contribution in the research. The 3 PPI co-applicants have previous experience of working with research teams including research into cardiac arrest and with minority communities. They will support and advise university researchers when working with the communities in their networks. The whole research team will develop and agree ways of working and raising concerns. The PPI-co-applicants will help with and advise on accessing and supporting members of communities to participate in the research. They will contribute to all stages of the research including reporting and dissemination.

A Public Advisory Group will be formed from individuals in the high-risk communities and from other relevant organisations. We will work together with the Public Advisory Group to identify the key points of co-production in the study. The group will consist of up to 8 members. They will meet

flexibly, approximately 5 times a year, depending on when their work is most needed. They will receive study progress reports, advise on participant recruitment and workshop design and facilitation as needed, be involved with the realist review, be involved in intervention selection, advise on any challenges the team encounters, (e.g. managing researcher and community expectations of how any outputs or interventions developed should be used and how any conflicting opinions should be managed and resolved) provide advice on analysis, the final report and other outputs and be involved in dissemination.

We will have 2 PPI members of the independent study steering committee which will monitor study progress and provide advice to the study team as required on behalf of the funder.

PPI contributors will receive time/travel expenses. We will have options for joining the meetings face to face, online or by telephone. Researchers will work with PPI members to assess training and support needs. Warwick CTU runs training days which members will be able to access, we will consider using Centre for Engagement and Dissemination resources as appropriate and seek out other sources of training. The research team will also provide support and facilitate an inclusive approach in meetings and in other study activities. Co-applicant and PPI lead Sophie Stanisewska has extensive experience and expertise in involving members of the public in health related research.

PPI involvement and impact evaluation: We will record our Public Advisory Group meetings in order to capture and report the contribution public contributors make to the study. We will ask PPI partners the best way to facilitate a discussion about what they felt went well and what could be improved at one of the meetings towards the end of the study. These data sources will facilitate a PPI paper reporting the contribution of the public voice, with public contributors as co-authors.

We will report involvement using GRiPP2 reporting checklist in the final report.

5. WORK PACKAGE 1 – REALIST SYNTHESIS OF PUBLISHED AND PRIMARY EVIDENCE

5.1 Overall Study Objectives relevant for WP1

Work package 1 will address the study's main objectives 1 and 2.

1. To establish a community based public involvement advisory group to co-produce key aspects of the study

2. To identify barriers and facilitators to performing CPR or defibrillator use in high-risk areas through realist evidence synthesis to provide evidence to inform the development of theoretically informed interventions

5.2 Research Questions and Objectives for WP1

5.2.1 Research questions

What are the experiences and views of people in areas with high-risk characteristics about barriers and facilitators to performing CPR or defibrillator use?
What interventions do people in areas with high-risk characteristics think might address these and how, why and for whom do they think they would work and in what circumstances?

What evidence is there in the multi-disciplinary literature to inform understanding of barriers and facilitators and associated improvement initiatives that can be synthesised with data from workshops with people from areas with high-risk characteristics (primary evidence) to produce theories of how interventions might work, for whom and in what circumstances?

5.2.2 Objectives

To develop a theory driven understanding of how, why, in which contexts and with what impacts specifically related or other similar interventions may have on performing CPR or using a defibrillator in high-risk areas,

5.3 Design and Methods.

WP1 is a realist evidence synthesis integrating data from a realist literature review and primary data from workshops.

5.3.1 Step 1

5.3.1.1 Scoping of Literature

An initial review of literature will seek to identify initial theories for performing CPR and other similar activities (e.g. bystander interventions in domestic violence or drowning, taking up positive health behaviours, taking part in community activities to improve the environment, engaging with educational opportunities), for identifying factors influencing whether people perform CPR, and for identifying relevant interventions. Our scoping search for this protocol indicated there is little health literature on our specific topic, hence our intention to widen literature search strategy to scope the

evidence base for identifying factors in deprived and/or ethnic minority community to initiatives that have elements in common with providing resuscitation and associated interventions across disciplinary boundaries including health and public health, public engagement, psychology, sociology, and education. Elements such as what encourages or hinders people getting involved and different perceptions of risk are likely to be of relevance in this search, as are considerations of ethical, spiritual and moral aspects of interventions that deal with life and death situations and the potential impacts of such interventions on participants. The TDF will inform how we structure this search, by considering interventions related to CPR and defibrillator use that we identify in the literature and through workshops through the lens of behaviour change components and whether particular TDF determinants, or constructs would prove useful in focusing the searches in the wider literature.

5.3.1.2 Community participatory workshops

We will hold 1-2 workshops in each participating area to seek participants' views on facilitators and barriers to performing CPR or using defibrillators, and for ideas about interventions relevant to their communities – i.e. elicit their theories or hunches.

Participating areas will be in the West Midlands with characteristics associated with high-risk areas. The West Midlands is identified as one of the four English regions with high-risk areas.[14] Participants will be recruited through the study team's networks and by snowballing. These networks consist of personal contacts, contacts in social media groups, contacts with members of community groups, contacts with professional organisations and contacts from previous research work. Between them our Patient and Public Involvement (PPI) study team members have networks across Nuneaton and Coventry, Birmingham, and West Bromwich and have experience of working as PPI representatives in research and research with ethnically diverse communities. Their networks include people with South Asian, Black African, Black Caribbean and Arabic heritages. The team will consider advertising (as advised by PPI members) or directly contacting community groups if necessary, in addition to using existing networks.

We will consult with our PPI partners about the best way to run the workshops and the best approach to making participants likely to attend and comfortable to fully engage. For example, we may be advised that single sex groups or groups of people from similar cultural backgrounds, with appropriate language support would be better than groups with people from mixed backgrounds, or that finding a neutral venue would facilitate a group from mixed backgrounds. Whether workshops

are held face to face or virtually will be decided considering the COVID-19 situation, which by the time the study commences should be greatly improved. Workshop participants may be invited to take part in future workshops i.e., the second workshop in the evidence synthesis work package (WP1) which aims to test the relevance of the conjectured CMO theories (see step 6) developed, and to the WP2 stakeholder workshop.

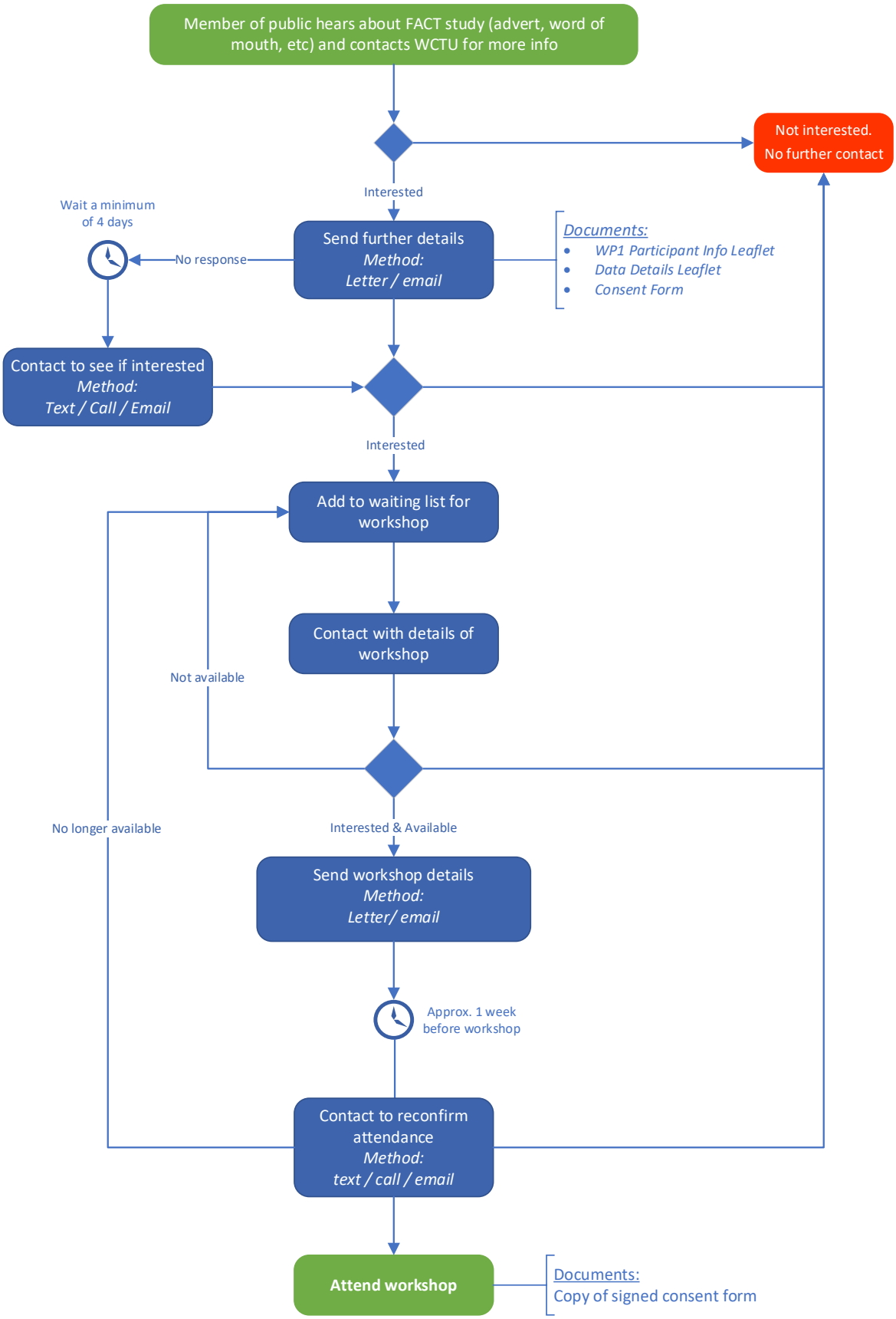
If recruited through the study team's contacts in various organisations, potential participants will be asked if they are happy to leave their contact details for a researcher to contact them or to contact the research team directly. Once the contact with a potential participant is established, the research team will get in touch to provide information about the study and answer any questions they may have. The most likely 8 languages for the participating areas have been identified by our PPI team. We have set aside funds for PIL, 'details about my data' leaflet and ICF to be translated in up to 8 languages. The research team will explain that an interpreter can be arranged for the workshop if needed. If the participant expresses their interest in taking part in the study, the research team will email or post Participant Information Leaflet (PIL), 'details about my data' leaflet, and Informed Consent Form (ICF) to the potential participant, whichever way they prefer. The research team will identify how the potential participant would like to be contacted for a follow up to establish whether they would like to attend or not. The research team will follow up at least 4 days after the PIL is sent to find out if the potential participant wants to attend the workshop or not. They will follow up by phone, email or text according to the potential participant's preference. Those who express their initial willingness to participate in the workshops will be added to our register. The time and the venue of the workshops will then be arranged. These details about the workshop will be communicated to potential participants either via mobile phone text, email, letter or landline, whichever means they prefer. Once they agree to participate in one of the workshops offered, their name will be put down for the workshop of their choice. For those with a mobile phone, text message will be sent to participants who agree to attend workshops the day before the workshop as a reminder.

Written informed consent will be taken at the beginning of the workshop. The research team will take informed consent individually so that there is opportunity for questions and to make sure they fully understand what is involved in taking part, the ICF and 'details about my data' leaflet. Their demographic information will also be collected verbally at this point. We will also offer the opportunity to participants to complete informed consent over the telephone or via a Microsoft Teams call prior to attending the workshop, to streamline the process and use participants' time more efficiently. If consent is taken over the phone, all elements of the consent form can be verbally agreed

to by the participant. The form will be signed by the researcher at this time. The participant will be asked to provide their wet-ink signature at the workshop itself to finalise consent. The participant will be given a later arrival time to the workshop. All participants will be paid for the same length of time to not financially disadvantage those who chose the telephone consent process.

Please see Figure 3 for a diagram of when, and how potential participants will be contacted.
If the COVID-19 restrictions do not allow face-to-face workshops, virtual workshops will be hosted via Microsoft Teams. Similar informed consent procedures will be followed. The research team will establish contact with potential participants and PIL and 'details about my data' leaflet will be sent

Figure 3: Contact Flow – WP1 Participants



to them via either email or post. The research team will follow up potential participants at least 4 days afterwards to see if they are interested in taking part in the study and whether they have the facilities and support they need to take part online. The option of an interpreter will be offered. Once they agree to take part, the research team will email the ICF or post it with a prepaid return envelope. At least two days after the ICF is posted, the research team will contact them to go through the consent process and collect their demographic information. They will be asked to return the completed and signed ICF using the prepaid return envelope or return a signed copy by email. They will be asked to keep a copy for their own records. A text message and an email will be sent to participants who agree to attend workshops the day before the event with a link to the meeting. For those who do not have a mobile phone, email or a landline will be used instead. The meeting will be video recorded.

There will be 2 copies of the consent form- one will be given to the participant and one for the research team, which will be brought back to WCTU after the face-to-face workshops. Consent forms will be stored securely in a lockable filing cabinet in a locked office when it is unattended.

Workshops will consist of discussions with participants about their views and experiences of bystander interventions for people having an out-of-hospital cardiac arrest and associated challenges and difficulties bystanders may have. We will develop activities that will support discussion, e.g. small group discussion with feedback and further discussion in the whole group. The discussions will be widened to include broader issues participants identify as relevant and to discuss potential solutions. We will also discuss things that already work well, and why that is and how they could be built on. We will introduce interventions or issues identified in the literature in the discussion to seek views of their relevance for participants' communities. Researchers will seek to summarise and reflect back to participants key points in the discussions focusing on key issues, why they are key issues and how they might be tackled, what are common experiences or views or ones considered important by the group, views of other initiatives relevant to this topic they are aware of and what worked well or did not work well, how and why. Workshop participants will be paid for their time, or receive an equivalent amount in an alternative form such as vouchers should they prefer, and will be reimbursed for their travel expenses. Workshops will be audio-recorded and transcribed, and anonymised quotes may be used in the results.

We will be taking fieldnotes throughout the process of WP1. This may include informal conversations with stakeholders, participants or debriefing interpreters. These conversations maybe spontaneous

and the researcher will be taking notes manually. No personal information will be recorded, the notes will record the main point(s) of interest, the role of the person/people who contribute to the point and the context of the conversation, e.g. on a phone conversation with a stakeholder or an informal chat with a participant after a workshop. Once the researcher recognises the conversation could be interesting to the study, they will inform the contributor(s) that the discussion may be used as part of the data but no personal information would be included. If any contributor(s) decline to be included, they are likely to stop contributing to the subsequent conversation and their previous contribution will be removed from the fieldnotes. After the conversation, the researcher will write a summary or reflection of the relevant conversation, using the handwritten notes as the basis, as soon as possible, while their memory is still fresh.

Working with our Public Advisory Group (PAG), and in combination with the research team expertise, we will combine information, identifying relevant key questions, terms, from the scoping review and workshops to develop initial 'rough' programme theories that will guide the next steps. These will be expressed as conjectured context-mechanism-outcome. How these conjectured context-mechanism- outcomes, can be seen through the lens of the TDF will be identified at this stage.

5.3.2 Step 2 - Searching

The search terms and the initial theories identified in step 1 will be used to search databases from medicine and health care, psychology, education and social sciences (e.g. Medline, CINAHL, Embase, PsycInfo, Sociological Abstracts, Applied Social Sciences Index and abstracts (ASSIA) and Web of Science). We will search from 2000. Survival outcomes from cardiac arrest have been of increasing interest since the 1980s with associated work on identifying factors associated with worse outcomes. This includes identification of health disparities associated with outcome. The first calls for action to address such issues we are aware of came from the American Heart Association in 2013[33] and associated investigation in the mid 2010s [34]. A date of 2000 should therefore enable us to find literature related any previous work around the world we have not yet identified and will included searching related multidisciplinary literature. Extending the years if the search yields little relevant literature will be considered, especially if the multi-disciplinary literature searches indicate this would be useful. Citation searches on key articles will be conducted as will hand searches of their reference lists. We will include grey literature (e.g. information from organisations or research groups involved in developing interventions for or promoting CPR training). We will seek the support

of our institution's librarian to assist with the search strategy development. We will use Booth et al's suggestions for practice to guide our searches and inform our reporting.[59]

5.3.3 Step 3 – Selection of evidence

Documents will be selected based on relevance to testing the initial programme theories. Search results will be saved as text files into Endnote (or similar reference manager software).
Titles and abstracts of search results will be screened for relevance to the theory area and full texts of selected papers will be retrieved. Inclusion in the review will be determined by the researcher determining whether the evidence is good and provides relevant data for the theory area. The WP team will discuss and resolve any issues concerning inclusion of particular papers.

5.3.4 Step 4 - Data Extraction

Bespoke data extraction proforma will be developed based on the initial programme theories. Data will be extracted by two researchers for two or three articles to ensure a consistent approach and to test the usability of the extraction form, revising it as necessary. The first researcher will complete extraction for the remaining articles, referring to the WP team to resolve any queries. Included studies will likely provide information on contextual aspects of the issue (e.g. the target population, the level at which the change is supposed to happen, environmental factors that may mediate the intervention), the behaviours interventions are designed to address and that identify the mechanisms by which the interventions work (or do not work) and the observed outcomes related to the mechanisms.

Consistent with realist review principles, quality will be assessed for relevance and rigour [57.]

5.3.5 Step 5 – Data synthesis

We will follow the process developed by Rycroft Malone et al [58] , which has been tested in a number of realist reviews for data synthesis. We will organise extracted data in evidence tables organised around the initial programme theories. From the evidence tables researchers will identify themes emerging from across the evidence tables (i.e. patterns). We will seek confirming and disconfirming evidence and build up explanations of that test the initial programme theories. The output from this stage will be a set of refined programme theories.

5.3.6 Step 6 - Initial programme theory testing

The final iterative stage in the realist review will be the testing of the programme theories. We will do this by seeking the view of key stakeholders who will provide a reality check on whether the programme theories align with their experience. We will conduct a further one to two workshops, recruiting further participants if necessary.

The output from this WP will make a significant contribution to literature in this area; in particular, to a greater theoretical and conceptual understanding of what contributes to the issue of low bystander rates in high-risk areas.

6. WORK PACKAGE 2 – INTERVENTION DEVELOPMENT

6.1 Study Design

6.1.1 Overall Study Objectives relevant for WP2

The overall study objectives addressed in the work package are:

1. To establish a community based public involvement advisory group to co-produce key aspects of the study
3. Prioritise interventions with community partners and other stakeholders for evaluation.
4. Develop a realist informed evaluation framework and associated data collection tools, including assessment of locally made intervention changes.

6.1.2 Work package 2 Research Questions

What interventions are there to address issues identified linked to the mechanisms and contexts identified in WP 1?

Which interventions do stakeholders consider are acceptable and feasible and should be prioritised for further development and evaluation?

6.1.2.1 Work package 2 Objectives

The study team and Public Advisory Group will

1. Map evidence synthesis (WP1) outputs to the BCT Taxonomy using the BCW and TDF.
2. Identify/develop interventions based on the mechanisms identified and ideas from WP1.
3. Develop the interventions for evaluation in WP3

4. Develop an evaluation framework and associated data collection tools for WP3

6.1.3 Approach

This work package will consist of four steps building on the work of developing conjectured CMOs in WP1. We will have identified intervention mechanisms and the contexts in which they work from interventions that show promise in WP1. In WP2 we will continue to use our study's theoretical framework, the TDF through its associated Behaviour Change Wheel (BCW), to map information from WP1 onto a taxonomy of behaviour change techniques also associated with the TDF. This will help us identify behaviour techniques we could incorporate into our interventions. It will also provide clear links to the theoretical underpinnings of the developed interventions. This will be important when we evaluate the interventions in WP3. It is difficult to directly measure impacts of interventions on CPR and defibrillation use rates, so evaluating the interventions against the theory of how they should work is important.

Since evidence shows that training in resuscitation skills increases people's self-reported likelihood of performing CPR or using a defibrillator[27], and, that increasing the proportions of people in a population with these skills is associated with improving bystander interventions,[29] we anticipate that training will form a significant component in interventions. The public report that raising awareness of cardiac arrest and the need to intervene was an issue they considered important. We anticipate awareness raising activities will also be a component in the interventions. Techniques for CPR and defibrillation use are standardised and follow national guidelines and we would use organisations who provide such training (e.g. the Red Cross or St John's Ambulance) to provide this in our interventions as appropriate. This would ensure the training given is up to date and delivered by experienced providers.

In the Background section 1, we highlighted the difficulty of measuring direct impact of interventions on bystander intervention and survival rates and the usual approach is to monitor the impact public health intervention programmes on these outcomes through regional or national out of hospital cardiac arrest outcome registries. Evidence already exists that interventions such as training members of the public, when used at scale and over time, are associated with improvements in bystander intervention rates. Evidence is however lacking about interventions designed for people from high-risk areas. Consequentially, the focus of our evaluation will be on assessing whether the interventions we develop can be implemented successfully in a variety of settings in communities known to be high-risk. Success will be assessed by evaluating whether the interventions 1) can be run in different settings; 2) work as intended to produce the outcomes they were designed to produce, by evaluating

them against the conjectured CMOs 3) if we find they do not work to produce expected outcomes, can the evidence generated be used to further refine them.

Having relevant training or awareness raising interventions available to training providers and communities could eventually impact on bystander intervention rates, but uptake, use of the interventions, numbers of people trained in different areas would need to be monitored over a long period of time to try and measure associations with bystander CPR rates and survival outcomes from OHCA, which will require a different study. The ongoing monitoring of these outcomes by the University of Warwick hosted Out of Hospital Cardiac Arrest Registry, provides an opportunity for future research.

6.1.3.1 Step1: Identify theoretically informed active ingredients to include in potential interventions.

The study team will identify and map the relevant elements of the CMOs from WP1 to the TDF domains, using the Behaviour Change Wheel (BCW) onto the Behaviour Change Techniques (BCT) Taxonomy. The taxonomy will help us identify potential techniques (active ingredients in interventions) to inform the intervention design. Should a large number of potential interventions be identified we will work with our Public Advisory Group to decide which ones to take to the stakeholder workshop at the next stage of this work package.

6.1.3.2 Step 2 Workshop to discuss and prioritise intervention(s)

WP2 Workshop participants

Stakeholders (e.g. leaders of the Restart a Heart initiative, first aid training organisations engagement leads, community leaders from high risk areas or representatives from WP1 workshops, professional organisations involved in raising awareness of cardiac arrest and providing or promoting resuscitation skills training in high risk or underserved populations).

We will invite some WP1 workshop participants to the workshop in WP2. In addition, stakeholders from the research team's existing networks and by snowballing will be invited to the workshop in WP2. This will include leaders of the Restart a Heart initiative, engagement leads of first aid training organisations, community leaders from high-risk areas, representatives of professional organisations involved in raising awareness of cardiac arrest and providing or promoting resuscitation skills training in high risk or underserved populations.

The study team will invite potential participants to the workshop and include the participant information leaflet for WP2 which will include information about what it involves and how the data generated will be used. They will be given the opportunity to contact the research team to ask any questions. Previous WP1 workshop participants will have already consented to future workshops when their informed consent was taken. For stakeholder attendees, by agreeing to attend and turn up we will assume they have given their implicit consent to take part.

Please see Tables 3 and 4 and Figures 4 and 5 for more information about how and when potential participants will be contacted.

Contact Points: Public participants					
Type	Initial study information provision	WP1 Workshop	WP1 Follow-Up Workshop	Invitation Letter (WP2)	WP2 Workshop
Content	(PIL, Consent form)	Consent taken. Group discussion	Group discussion	PIL	Group discussion
Who?		All initial participants	Some initial participants	Some initial participants	Some initial participants

Table 2: Contact points for public participants (across WP1 & WP2)

Contact Points: Stakeholder participants					
Type	Initial study information provision	WP1 Workshop	WP1 Follow-Up Workshop	Invitation Letter (WP2)	WP2 Workshop
Content	n/a	n/a	n/a	PIL	Group discussion
Who?				Stakeholder participants	Stakeholder participants

Table 3: Contact points for stakeholder participants (across WP1 & WP2)

Figure 4: Contact Flow – WP1 Follow-Up Workshop & WP2 Workshop: Public Participants

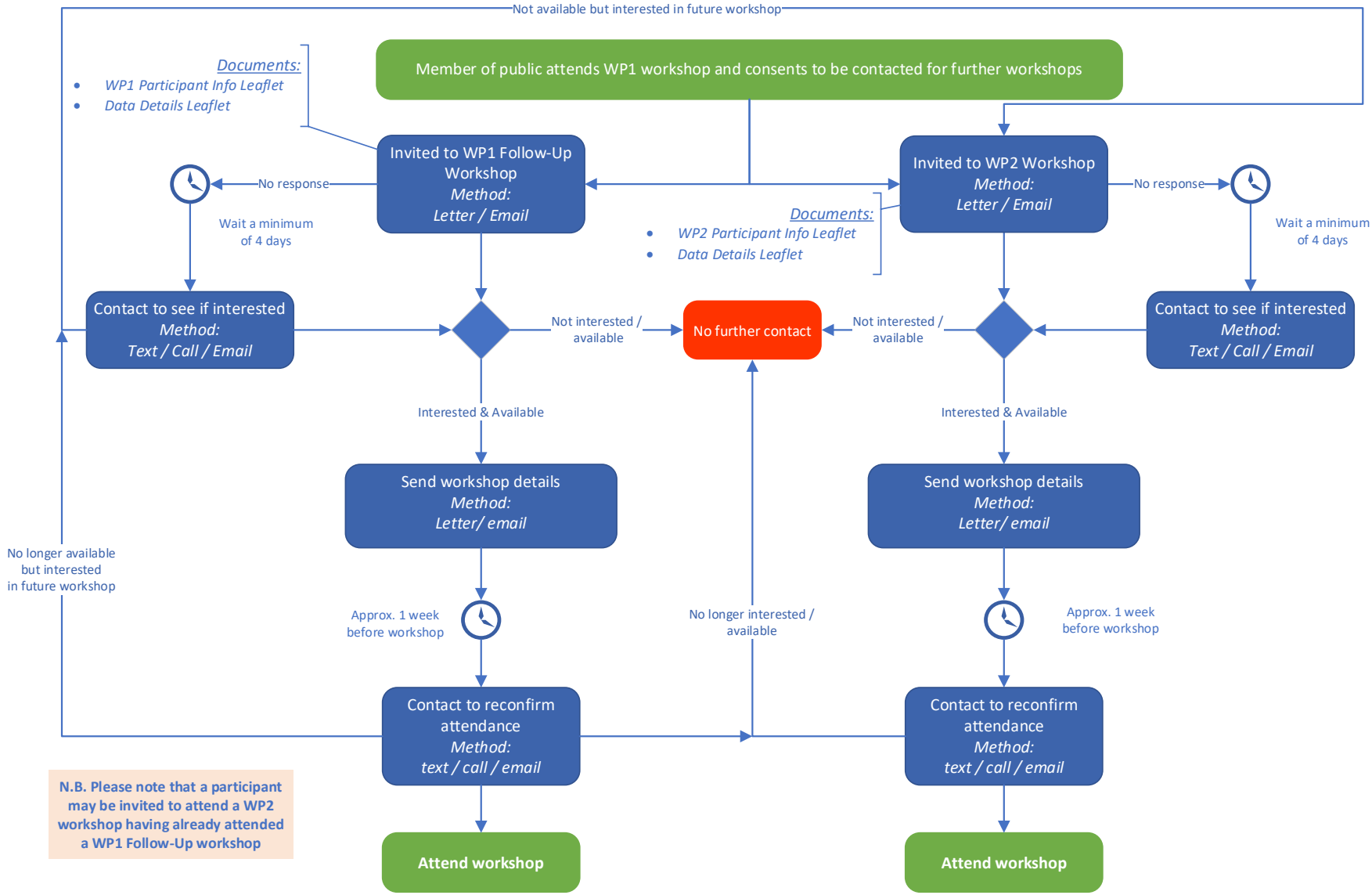
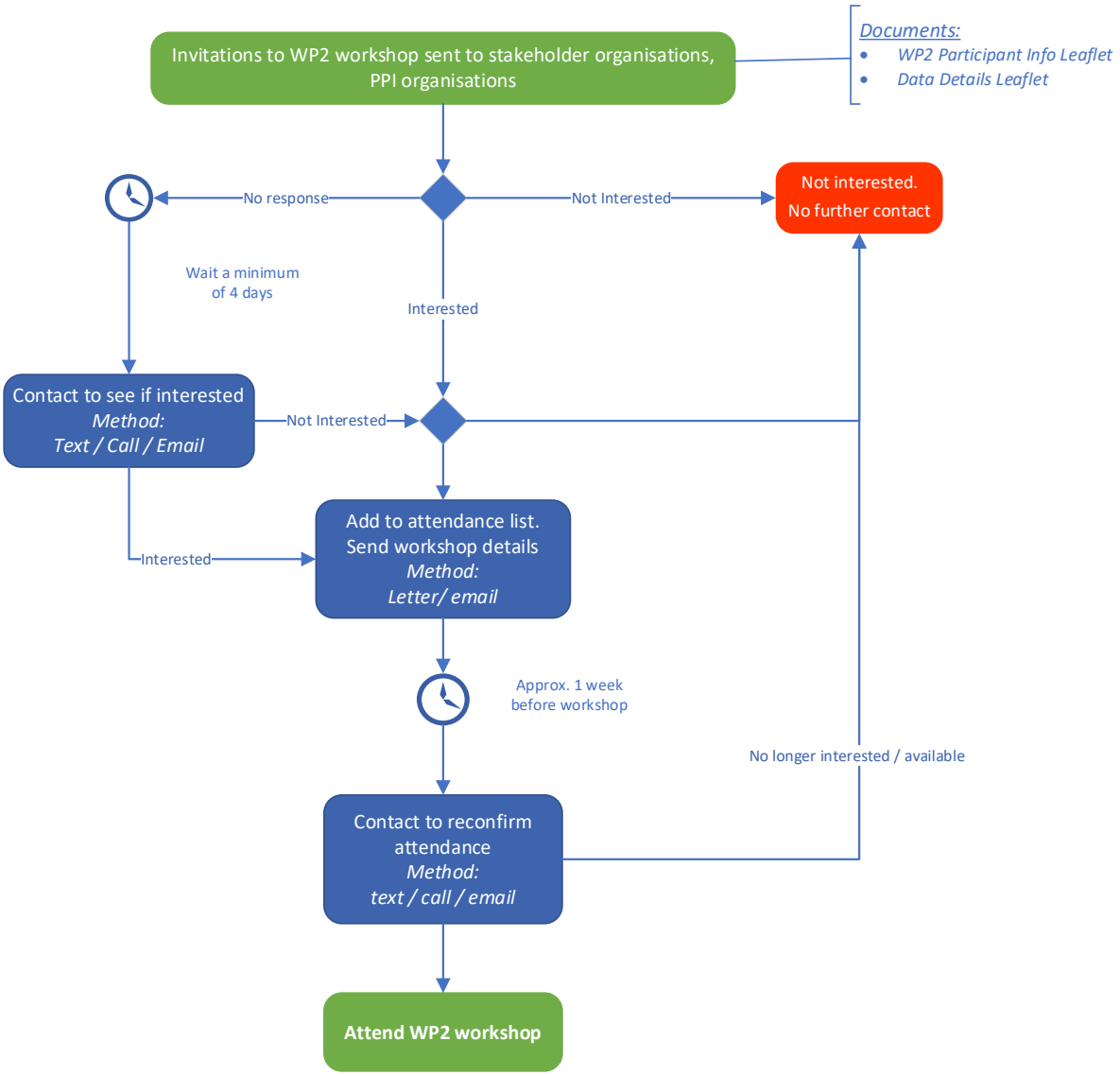


Figure 5: Contact Flow – WP2 Stakeholder Participants



Workshop approach

During the workshop, participants will learn about, discuss, and offer up their questions, comments and concerns regarding the most promising interventions. The participants will also be asked to complete a survey in which they rate their impressions of each selected intervention according to the APEASE criteria (Affordability, Practicality, Effectiveness/cost-effectiveness, Acceptability, Side-effects/safety, & Equity). [40]

During the workshop, participants will be assigned a table to facilitate smaller group discussions. Participants at each table will select a person to record their table's thoughts, and a person to speak on their table's behalf. Members of the research team or PAG will provide overall facilitation for the groups. Participants will be asked to individually rate their first impressions of each intervention according to APEASE criteria and to write additional comments. Next, each intervention proposed by the study team will be considered in greater depth. After considering all the interventions, participants will individually rate each intervention according to the APEASE criteria again and to write additional comments. Then participants at each table will rank order the interventions together from the one most likely to change the target behaviour to the one least likely to do so.

The results of each table's intervention ranking will be presented to all the workshop participants and their overall recommendation for interventions to be taken forward sought. Participants will be asked to provide feedback on which behaviours and influences are critical and to identify additional factors that should be included. We will invite participants to reflect and make suggestions about interventions that could be used to improve performing CPR or publicly accessible defibrillator use.

Workshop discussions will be recorded, relevant sections transcribed and analysed using retroductive realist analysis informed by TDF, Behaviour Change Technique Taxonomy (BCTT)v1,[54] and the constructs of COM-B to identify additional influences, relationships, and opportunities for interventions.

We will be taking fieldnotes throughout the process of WP2. This may include informal conversations with stakeholders, participants or debriefing interpreters. These conversations maybe spontaneous and the researcher will be taking notes manually. No personal information will be recorded, the notes will record the main point(s) of interest, the role of the person/people who contribute to the point and the context of the conversation, e.g. on a phone conversation with a stakeholder or an informal

chat with a participant after a workshop. Once the researcher recognises the conversation could be interesting to the study, they will inform the contributor(s) that the discussion may be used as part of the data but no personal information would be included. If any contributor(s) decline to be included, they are likely to stop contributing to the subsequent conversation and their previous contribution will be removed from the fieldnotes. After the conversation, the researcher will write a summary or reflection of the relevant conversation, using the handwritten notes as the basis, as soon as possible, while their memory is still fresh.

Public Advisory Group advice

The research team will take advice from the PAG on the best way to run the workshop discussions to enable members of the public (e.g. workshop participants from WP1) to feel confident to give their views and experiences. Members of the research team and PAG will advise on facilitating the workshop and support the small table discussions.

6.1.3.3 Step 3 - The research team will use the recommendations from the workshop and decide with the PAG the intervention(s) to develop for testing in WP3.

The interventions will be developed for use by the research team.

6.1.3.4 Step 4 - Development of evaluation framework and research tool(s) for WP3

The purpose of this step is to specify the process by which we will evaluate the success of the intervention(s) in WP3. As mentioned above our measures of success will be whether the interventions 1) can be run in different high-risk community settings; 2) work as intended to produce the outcomes they were designed to produce, evaluated against the conjectured CMOs and 3) if we find they only work partially or mostly do not work, can the evidence generated be used to further refine them.

In order to provide a robust evaluation that can provide evidence for our measures of success we will design an evaluation framework and tools to collect data to evaluate whether the interventions work as intended (how, for whom and in what circumstances) and provide evidence to further refine the theories underlying them.

The mapping process at step 1 of this WP will enable us to identify the theories underpinning how the selected interventions should work and link them to the TDF. We should also be able to express the

theory of how the interventions work in conjectured realist CMO theories i.e. how do they work, for whom and in what circumstances to produce outcomes. Using this information, the research team will develop a theoretically informed evaluation framework for WP3. The framework will be used to inform data collection and data analysis (of qualitative data) and the synthesis of findings. The research team will develop tools designed to collect data appropriate to evaluating the interventions against the evaluation framework. These are likely to include questionnaires, interview topic guides.

PLEASE NOTE THAT THE BELOW SECTION (7) IS INCLUDED FOR BSREC REVIEWERS' INFORMATION ONLY TO UNDERSTAND HOW WP1 & WP2 OUTPUTS WILL BE USED – THIS WP3 WILL BE THE SUBJECT OF A LATER LINKED APPLICATION FOR ETHICS APPROVAL ONCE INTERVENTIONS HAVE BEEN DEVELOPED.

7. WORK PACKAGE 3 –IMPLMENTATION EVALUATION

7.1 Overall study objectives relevant for WP3

The overall study objectives addressed in this work package are

1. To establish a community based public involvement advisory group to co-produce key aspects of the study
5. Conduct an implementation evaluation of the prioritised interventions with embedded feasibility study.

7.2 Work Package 3 Research Question, Aims and Objectives

How do the intervention(s) work when implemented in a variety of communities in different areas of the country?

7.2.1 Work Package 3 Aim

To assess whether the interventions can be implemented and work as intended in communities from three/four high-risk areas, selected for diversity of geographic location.

7.2.2 Work Package 3 Objectives

1. To evaluate and assess the feasibility of delivering the intervention(s) and collecting evaluation data at the two implementation events.

2. Using data from the first two events, identify any changes needed to refine interventions and inform evaluation methods for the remaining events.
3. To evaluate the interventions (with any necessary refinements identified in objective 2) in a further four events.

7.3 Design

A mixed-methods realist evaluation of the intervention(s) implementation with embedded feasibility study.

7.3.1 Recruitment

We will build on the networks established for WP1 and through stakeholders invited to the WP2 workshops to identify potential WP3 contacts who would be willing to host intervention events and identify potential participants in locations known to have high risk areas in England (e.g. the West Midlands, London, the North East).

Intervention(s): The research team and members of the PAG will run about six events at participating sites using the interventions selected in WP2. Two will be used for feasibility testing to assess needed refinements, before events are held at the remaining sites. Interventions are likely to encourage raised awareness of and engagement with resuscitation skills training, advertise and provide a training opportunity for up to 25 people. It is likely that interventions may include CPR and defibrillator training use. If this is the case we will work with a training provider (e.g. the British Red Cross or St John Ambulance) to deliver up to date core training in CPR and defibrillation skills.

Language support will be provided, e.g. training provided in a language spoken by the majority of participants, or with the use of interpreters. Whether interventions are delivered face to face or virtually will be decided considering the findings of WP1 and 2 and the COVID-19 situation.

7.4 Key Outcomes

1. Whether the interventions can be run in different high-risk settings. This will be measured by
    a. the proportion of places filled at the intervention events
    b. the proportion of participants from lower socioeconomic groups
    c. the proportions of participants from the event's target ethnic or cultural groups

d. assessing these measures across the different settings where intervention events are held to identify whether the success criteria were met across all, some (and if so which) or none of the event settings.

2. Whether the interventions work as intended in all, some or none of the settings. This will be evaluated by analysis of data collected:
    a. on expected the outcomes of the interventions (e.g. impact of awareness raising interventions on decision to attend training event, knowledge of how to recognise a cardiac arrest, knowledge of CPR and defibrillation skills, intent to use skills in the future if required, acceptability of the intervention for participant and whether they would recommend it to friends and family)
    b. on how the interventions worked and in what contexts to produce the outcomes (expected and unexpected)

7.5 Data Collection for WP3

7.5.1 Language support for data collection:

We will aim to provide quantitative tools, such as questionnaires in languages appropriate to the participants or language support (e.g. interpreters, members of the study team, including PAG members) for completion for those who may not feel comfortable with written language. Where possible interviews will be conducted in the language of the participants choice by the research team members themselves or through an interpreter.

7.5.2 Embedded feasibility study (first two events) data collection

Quantitative data

The proportion of places at the intervention event filled, including assessment of number of places booked and number of people with booked places attending.
The rates of completion of data collection tools (e.g. questionnaire).

Qualitative data

Post event qualitative face to face/telephone/online semi-structured interviews with event organisers and participants (up to eight) to explore the feasibility of running the events, the influence of interventions to advertise event on attendance, views of how the interventions worked including suggestions for intervention improvement, whether participants would recommend

interventions to others, whether moral, spiritual and ethical aspects were considered sufficiently in interventions, and acceptability of data collection methods.

7.5.3 Main study events (up to four events) data collection

Quantitative data

Proportion of places at the intervention event filled.
Participant questionnaire(s) covering topics on the impact of event on participants resuscitation knowledge and skills, impact of event on people's intent to use skills in the future, satisfaction with the way ethical, spiritual and moral aspects of resuscitation were covered.

Quantitative assessment of attendance, influence of advertising interventions on attendance at event, and impact of event on participants' resuscitation knowledge and skills.

Qualitative data

Post event qualitative face to face/telephone/online semi-structured interviews with event organisers and participants (up to eight) to explore the feasibility of the interventions (after the first two events), suggestions for intervention improvement, views of how the interventions worked, whether participants would recommend interventions to others, and the influence of interventions to advertise event on attendance and views of how moral, spiritual and ethical aspects were covered. Interviews will also explore participants views of the most important impacts of the intervention on themselves, their families and communities. Qualitative follow up semi-structured interviews at about three months with event organisers/participants will explore medium term intervention impacts of the intervention on themselves their families and communities.

Interviews will be digitally recorded and transcribed for analysis. Where interviews have been conducted in a language other than English transcripts will be translated into English.

7.6 Analysis WP3

7.6.1 Feasibility study (first two events)

Descriptive statistics will be used to analyse data to produce results for the proportions of places filled, proportions of questionnaires completed.

We will conduct a realist analysis of the qualitative data focusing on the feasibility of running the interventions, the participants' views of the interventions and their acceptability and suggestions for

improvement. The analysis will result in a summary of findings. Qualitative analysis framed by the conjectured CMOs developed in WP2 be used to refine the intervention.

7.6.2 For data from all events (feasibility and main)

To assess how the interventions worked, interviews will be analysed using the conjectured programme theories underpinning the interventions. The results will be used to refine the conjectured programme theories resulting in final programme theories for the intervention that have been tested in this study. This process will identify whether the interventions worked as intended or not, how they worked and in what circumstances. Suggested improvements may also emerge.

A realist analysis will be conducted to explore participants views of the interventions, and their impacts on them, their families and communities. Data from sections of the qualitative interviews covering impacts on individuals, families and communities will be used to develop an intervention evaluation instrument (e.g. a self-completion questionnaire). Items will be included for recurring or insightful impacts identified in the interviews and from key intended intervention outcomes. We will work with our PAG to refine the tool. It will provide future users of the intervention(s) with an evaluation tool.

A descriptive statistical analysis will summarise the characteristics (e.g. age, sex, ethnicity) of event participants, and assess the influence of these characteristics on the participants views of the intervention; regression analysis will be used if sufficient data are available. The proportion of places filled will be used to assess the overall feasibility of the intervention. The statistical analysis will also be used to refine the conjectured CMO theories, where appropriate.

Results and findings from both quantitative and qualitative data will be synthesised using the CMOs to assess whether the interventions can be run in different high risk settings and whether the interventions work as intended in all, some or none of the settings.

8. EQUALITY, DIVERSITY AND INCLUSION FOR STUDY PARTICIPANTS:

We are investigating an area of health inequality, so our study design is such that we intend to prioritise recruitment of participants who are likely to be from lower socioeconomic backgrounds and specific minority ethnic backgrounds. This is because of the lack of research into bystander

resuscitation within these populations, the higher incidence of cardiac and cardiovascular disease in some South Asian English and some Black English populations and the higher proportions of people from such backgrounds living in high risk areas, which means geographical location may necessarily be restricted to such areas. However, our plans to compensate participants time and travel expenses and provide language support, should help give them the opportunity to take part. We intend to hold workshops in WP1 and events in WP3 close to where participants live. We will provide compensation for travel to these events and the WP2 workshop which is likely to be some distance for some participants, so those living at a distance should not be disadvantaged. We will consider use of technology available through Warwick University Conferences to enable participants who are unable to travel for WP2 to attend on line. We will be mindful of providing access, training and identifying support for those who are not familiar with such technology to facilitate their participation. Venues will be chosen that have disabled access and facilities. Members of the public and those working for charities will be recompensed for their time and all participants will receive travel expenses. We intend to provide language support for those who need it as outlined above. Although some research participants may be recruited through community faith based organisations we will ensure that our recruitment information is clear that membership or having the same beliefs as the organisation are not a prerequisite for participation.

Our design means we are not aiming to recruit a representative sample, but rather ensure a diversity of opinion from people for WP1, opinions from stakeholders with an interest in improving bystander CPR and defibrillator use, as well as participants from WP1 for WP2. For WP3 we will record characteristics of those who attend with their consent to report whether the event reached the diversity of participants it was intended for.

9. DATA MANAGEMENT PROCEDURES

9.1.1 Data Collection

Several modalities will be used for the collection of research data across the different work packages (Table 1). Full information is provided in the detailed description covering each work package.

Table 1 - summarises the main approaches by each work package

	Literature review	Workshops	Qualitative Interviews	Questionnaires
WP 1	x	x		

WP 2		x		
WP 3			x	x

9.1.2 Data Management

Data collected during the study will be handled and stored in accordance with the UK GDPR and University of Warwick Standard Operating Procedures (SOPs). The University of Warwick will be the Data Controller for this study.

Personal data (contact details) will be held prior to the workshop following verbal consent. Written informed consent will be given at the workshop to allow for the continued use of this data for both WP1 and WP2. The data will be kept securely and stored in a secure area of the computer with access restricted to staff working on the study. Study team members will check that consent forms are completely correctly at the time of consent.

In WP1, we will need to collect personal information such as name and contact details of research participants to provide details of where workshops and events will take place and to keep a record of participation. We will also be collecting demographic information including age, gender, religion, ethnic group, highest education attainment and socioeconomic status from workshop participants to create a descriptive summary of these characteristics. This data will be collected anonymously, although we will record which workshop it was collected at. We will keep personal identifiable details separate from data in electronic and paper records, using separate files. Participants will be allocated a unique study ID which will be used on data sources except the demographic information. A file linking participants names and study ID, for university and regulatory audit purposes will be kept separately from data and other identifiable information. All electronic files will be password protected and saved on the secure servers hosted by University of Warwick. Paper copies will be kept in lockable filing cabinets in WCTU, where all rooms are protected by a secure access control system that are only accessible to authorised personnel. No personal data will be collected in WP2.

The anonymous demographic data and any handwritten field notes will be stored with the ICF at the time of collection, both of which will be brought back to WCTU after the face-to-face workshops. ICF forms and demographic data will be stored separately, and will be stored securely in a lockable filing cabinet in a locked office when it is unattended. All rooms in WCTU are protected by a secure access

control system that are only accessible to authorised personnel. The data will be destroyed once the study has concluded, final report completed and papers published

Further details are provided in the detailed descriptions covering each work package.

9.1.3 Data storage

All essential documentation and study records will be stored by WCTU in conformance with the applicable regulatory requirements and access to stored information will be restricted to authorised personnel. Any paper data forms, field notes, meeting notes, or other documents will be stored in a lockable filing cabinet in a secure room, to which access is restricted to authorised personnel. Electronic data will be stored in a secure area of the University computer system with access restricted to staff working on the study with access managed by the study manager. Interview and workshop data may be audio recorded on audio devices. Recordings will be downloaded as soon as possible to encrypted university laptops and subsequently to the secure study area on the university servers. Any data that are transferred out of the secure environment (for example audio files of interviews for transcription) will adhere to University of Warwick SOPs. Any transcription service used will be subjected to the University of Warwick's approved supplier review processes.

9.1.4 Data access and quality assurance

Study participants will be assigned a unique study identifier. The study team will maintain a separate confidential and secure list of patient identifiable information (name, date of birth, identification number and contact details) for the purposes of research (e.g. organising interviews), audit / quality assurance. This will be securely held on the University of Warwick servers.

Once the study has been completed the records will be destroyed according to University of Warwick SOPs. The CI and the WCTU administrator (or staff they delegate this role to) will have access to the final study data set from all three work packages. Access requests from both co-investigators and external parties will be considered by the CI. A formal process will be developed by the study team to facilitate such requests and decisions in line with WCTU processes. 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. Any data shared will be anonymised and transferred as per University of Warwick SOPs with data sharing agreements in place.

9.1.5 Archiving

Study documentation and data will be archived for at least ten years after completion of the study following University of Warwick policy and SOPs.

10. END OF THE STUDY

The study will officially end on the last day of funding, although dissemination of results will continue beyond that date.

Since this study is not implementing any intervention, it is unlikely to be stopped prematurely, unless funding is ended early. If several or all of the recruited organisations supporting participation in the research withdraw their support replacement organisations will be identified within the time constraints of the study. The independent Study Steering Committee will oversee the progress of the study and will advise the funder of any serious concerns that could lead to a premature end to the study. The BSREC will be notified in writing if the study has been concluded or terminated early.

11. OUTPUTS, DISSEMINATION AND PUBLICATION

11.1 Outputs

The overall outputs of the study will include

- A realist evidence synthesis of interventions to promote bystander CPR and defibrillator use in high risk areas.
- Theoretically informed interventions (including an evaluation tool) co-produced with public contributors from affected communities and evaluated in 3-4 high risk areas in England.
- Contribution to the knowledge base for working with people from high-risk areas to improve bystander resuscitation rates.
- Contribution to knowledge of and theory about improving bystander resuscitation intervention rates in high risk areas.

11.2 Final Report

The results of the study will be reported to study collaborators. The main report will be drafted by the study co-ordinating team, and the final version will be agreed by Public Advisory Group and the Study Steering Committee before submission to the NIHR HS&DR programme (the funder).

11.3 Dissemination and anticipated Impact

The study team and PPI partners will develop a dissemination plan and materials targeted to members of the public in high-risk areas. Findings will inform key dissemination messages. PPI partners will play key roles at an event to share findings and seek advice on next steps at a dissemination event for participating community groups and stakeholders.

Stakeholder dissemination meeting(s) will review findings and views on next steps will be sought in particular whether the findings of this study are sufficient to show that the interventions are sufficiently developed for use. If ready for use, stake holders will be asked to contribute to ideas for disseminating them for use and this will be fed into the team's plan. Stakeholders at the event(s) will include organisations involved in training in resuscitation skills and campaigning to encourage members of the public to train, such as organisations working with minority group communities to improve CPR skills and providing training, organisations involved in the national Restart a Heart Initiative and other similar regional initiatives, including ambulance services, the BHF, RCUK, St John's Ambulance, British Red Cross and policy makers.

We will make study results, intervention tools and implementation advice available on a website. We will use social media, engaging with our PPI partners networks and other PPI groups (e.g. Health Watch) having both written and visual (e.g. YouTube video, infographics) links to summary results.

Dissemination for academics, clinicians, managers, stakeholders, and policy makers will include the study report, papers, conference presentations. GP is a leading expert in resuscitation science and co-chair of the international liaison committee on resuscitation (ILCOR) who oversee revisions to international resuscitation guidelines through review of evidence. He also leads working groups with the Resuscitation Council UK (RCUK) for translating these guidelines for into national guidance. GP sits on various groups involved in developing and delivering out-of-hospital cardiac arrest policy, including NHS England's Expert Advisory Group for cardiac arrest. He is well placed to ensure evidence from this study influences national and international guidance as appropriate and national policy initiatives. GP is a member of the RCUK executive committee and CH works closely with colleagues at the RCUK, including those involved in Restart a Heart. The CEO, Director of Engagement and Vice President of the RCUK are supportive of this study and will be in a position to help disseminate any successful interventions resulting from this study.

12. STUDY ORGANISATION AND OVERSIGHT

12.1 Sponsor and governance arrangements

University of Warwick is the research sponsor.
University of Warwick will manage the financial aspects of the grant.

12.2 Regulatory authorities/ethical approval

The University of Warwick requires all research with human subjects to be reviewed either through national health and social care processes or through its own research ethics committees. All participants in this study are healthy volunteers and there are no medical/health service interventions or use of NHS facilities involved, so we will seek approval from the University of Warwick's Biomedical and Scientific Research Ethics Committee (BSREC) and sponsorship approvals from the University of Warwick within the first six months of the study, and prior to any study activities commencing. Should any amendments be required, these will be submitted for consideration by the BSREC following consideration by the Study Management Group.

The discussion of cardiac arrest and CPR may cause participants distress, for example if participants have related personal experience. We will ensure those conducting research activities are aware of the potential and be able to create space for participants affected to withdraw from or take time out of activities. We will seek to provide information about further support available at workshops and events.

12.3 Study Registration

The study will be eligible for inclusion on the CRN Portfolio and will be registered on the ISRCTN.

12.4 Indemnity

The University of Warwick provides indemnity for any harm caused to participants by the design of the research protocol.

12.5 Study timetable and milestones

Table 4 - Plan of investigation and timetable

Year	1				2				3			
Quarter	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Months	1 to 3	4 to 6	7 to 9	10 to 12	13 to 15	16 to 18	19 to 21	22 to 24	25 to 27	28 to 30	31 to 33	34 to 36
Study management group meetings	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Co-applicants meetings	x	x	x	x	x	x	x	x	x	x	x	x
Public Advisory Group. To meet 5 time a year flexibly according to work required	x	x	xx	x	x	xx	x	x	x	x	x	xx
Study steering group (6 monthly)	x		x		x		x		x		x	
Study set up, ethics, governance	1-6											
Community participants recruitment and identification of potential “sites” for WP3 interventions	1-17											
WP1 Evidence synthesis	1-11											
WP2 Intervention development				12-17								
WP3 - feasibility interventions events data collection and evaluation, remaining intervention events data collection and final analysis						18-32						
Stakeholder event and report writing											33-36	

Milestones:

1. Ethics approvals in place – 6 months
2. Evidence synthesis complete and conjectured CMO theories finalised, Interventions identified and developed (WP1 & 2) - 18 months
3. Implementation evaluation events completed (WP3) - 31 months
4. Data analysis complete and findings presented to stakeholder meeting - 34 months
5. Final report - 36 months

12.6 Administration

The study co-ordination will be based at WCTU, University of Warwick.

12.6.1 Essential Documentation

A Study Master File will be set up according to the relevant University of Warwick SOP and held securely at the coordinating centre.

12.7 Study Management Group (SMG)

The Study Management Group, consisting of the CI, study manager, researcher and senior project manager will meet regularly (approximately monthly) with other co-applicants invited as needed depending on the stage of the research. The purpose of this group is to coordinate work and monitor progress with project, deal with operational and research issues and report to the co-investigators and Public Advisory Group meetings on progress. Significant issues arising from management meetings will be referred to the Study Steering Committee or co-investigators, as appropriate.

12.8 Work package team meetings

Work package leads and associated team members (researcher, study manager, PPI co-applicants and CI) to meet regularly to deliver the work package and provide updates to the Study Management group

12.9 Public Advisory Group (PAG)

Public Advisory Group will meet flexibly as determined by the need for their input, approximately five times a year. For example, they are likely to meet more frequently during the intervention development and dissemination phases. They will receive progress updates from the SMG and to work on aspects of the project where the need for their input has been identified in the sections above. The study team will invite between five and eight people to form a Public Advisory Group and two people as PPI members of the study steering committee. We will use our study PPI and other team members' networks to recruit people

12.10 Co-investigators

Three monthly update meetings or reports will be provided by the study team. The purpose of the group is to oversee progress and provide specialist input and contribute to Study Steering Committee progress updates and meeting content as appropriate.

12.11 Study Steering Committee (SSC)

The SSC will meet regularly determined by need by not less that once a year. The SSC will have an independent Chairperson and representation from members of the public (2 members) stakeholder groups as well as experienced researchers. Face to face meetings will be held at regular intervals determined by need. Routine business will be conducted by email, post or online meetings/teleconferencing. Members of the Steering Committee will complete and adhere to the University of Warwick's Steering Committee Charter.

The Steering Committee, working on behalf of the funder will:

- Inform and advise on all aspects of the study
- Review, advise on and agree major decisions such as a major change in the protocol
- Monitor the progress of the study and make progress related recommendations to the study team and the funder where necessary.
- Review relevant information from other sources that could impact on or inform the study

13. MONITORING AND QUALITY ASSURANCE OF STUDY PROCEDURES

All research team staff from the co-ordinating centre involved in data collection will have had GCP training as part of their role.

The study administrator will develop a system to check the quality of participant records (e.g. completion of consent forms and storage of study documentation and data). They will work with the researcher to ensure secure transfer processes of data from sites to the University (e.g. use of secure storage case for transfer of consent forms, encryption of laptops where qualitative data may be temporarily stored). Periodically check paper documentation matches electronic records and personal identifiable data is not stored with research data.

A Risk Assessment and Monitoring plan will be drawn up with the Quality Assurance team. The study will also be added to the WCTU audit scheduling tool which may lead to an audit by the Quality Assurance team.

Quality assurance realist evidence synthesis and realist evaluation: Consistent with realist review principles, quality will be assessed for relevance and rigour [57] by the WP! research team.

Quality assurance qualitative data: For thematic analyses, coding will be developed/checked by 2 researchers independently for a proportion of transcripts and any inconsistencies identified will be discussed to ensure consistency, plausibility and credibility of the resulting analyses.

Quality assurance quantitative data: A proportion of questionnaires (if used) will be double data entered to identify and correct any errors. A proportion of other quantitative data entered into the database will be checked and corrected in a similar way.

14. REFERENCES

1. Riva G RM, Jonsson M, Svensson L, Herlitz J, Claesson A, et al. Survival in Out-of-Hospital Cardiac Arrest After Standard Cardiopulmonary Resuscitation or Chest Compressions Only Before Arrival of Emergency Medical Services: Nationwide Study During Three Guideline Periods, . *Circulation* 2019;139(23):2600–9. doi: 10.1161/CIRCULATIONAHA.118.038179
2. Sasson C, Rogers MA, Dahl J, et al. Predictors of survival from out-of-hospital cardiac arrest: a systematic review and meta-analysis. *Circ Cardiovasc Qual Outcomes* 2010;3(1):63-81. doi: 10.1161/circoutcomes.109.889576 [published Online First: 2010/02/04]
3. Hasselqvist-Ax I, Riva G, Herlitz J, et al. Early cardiopulmonary resuscitation in out-of-hospital cardiac arrest. *N Engl J Med* 2015;372(24):2307-15. doi: 10.1056/NEJMoa1405796 [published Online First: 2015/06/11]
4. Wissenberg M, Lippert FK, Folke F, et al. Association of national initiatives to improve cardiac arrest management with rates of bystander intervention and patient survival after out-of-hospital cardiac arrest. *JAMA,* 2013;310(13):1377-84. doi: 10.1001/jama.2013.278483 [published Online First: 2013/10/03]
5. Deakin CD. The chain of survival: Not all links are equal. *Resuscitation* 2018;126:80-82. doi: 10.1016/j.resuscitation.2018.02.012 [published Online First: 2018/02/23]
6. Couper K, Kimani PK, Gale CP, et al. Patient, health service factors and variation in mortality following resuscitated out-of-hospital cardiac arrest in acute coronary syndrome: Analysis of the Myocardial Ischaemia National Audit Project. *Resuscitation* 2018;124:49-57. doi: https://doi.org/10.1016/j.resuscitation.2018.01.011
7. McNally B. The importance of cardiac arrest registries. *Scand J Trauma Resusc Emerg Med* 2014;22(Suppl 1):A3-A3. doi: 10.1186/1757-7241-22-S1-A3
8. OHCAO Project Team. Out-of-Hospital Cardiac Arrest Outcomes Registry Epidemiology Report, 2018: University of Warwick, 2018.
9. Flemming D, Fogarty J,. Public health—Seattle and Kings County Division of Emergency Medical Services 2013 Annual Report to the King County Council,, 2013.
10. Perkins GD, Lockey AS, de Belder MA, et al. National initiatives to improve outcomes from out-of-hospital cardiac arrest in England. *Emergency Medicine Journal* 2016;33(7):448-51. doi: 10.1136/emermed-2015-204847
11. Resuscitation Council UK. Restart A Heart Day 2020 [Available from: https://www.resus.org.uk/get-involved/restart-heart-day accessed 10.08.2020.
12. Hayes P P, M,. Public Health - Seattle & King County Division of Emergency Medical Services 2017 Annural Report to the King County Council, 2017.
13. Weisfeldt ML, Sitlani CM, Ornato JP, et al. Survival after application of automatic external defibrillators before arrival of the emergency medical system: evaluation in the resuscitation outcomes consortium population of 21 million. *J Am Coll Cardiol* 2010;55(16):1713-20. doi: 10.1016/j.jacc.2009.11.077
14. Brown TP, Booth S, Hawkes CA, et al. Characteristics of neighbourhoods with high incidence of out-of-hospital cardiac arrest and low bystander cardiopulmonary resuscitation rates in England. *Eur Heart J Qual Care Clin Outcomes* 2019;5(1):51-62. doi: 10.1093/ehjqcco/qcy026 [published Online First: 2018/07/03]
15. Hawkes CA, Brown T, Noor U, et al. Characteristics of Restart a Heart 2019 event locations in the UK. *Resuscitation Plus* 2021;6:100132. doi: https://doi.org/10.1016/j.resplu.2021.100132
16. Vaillancourt C, Lui A, De Maio VJ, et al. Socioeconomic status influences bystander CPR and survival rates for out-of-hospital cardiac arrest victims. *Resuscitation* 2008;79(3):417-23. doi: 10.1016/j.resuscitation.2008.07.012
17. Fosbøl EL, Dupre ME, Strauss B, et al. Association of neighborhood characteristics with incidence of out-of-hospital cardiac arrest and rates of bystander-initiated CPR: implications for community-based education intervention. *Resuscitation* 2014;85(11):1512-7. doi: 10.1016/j.resuscitation.2014.08.013 [published Online First: 2014/09/03]

18. Sasson C, Keirns CC, Smith D, et al. Small area variations in out-of-hospital cardiac arrest: does the neighborhood matter? *Ann Intern Med* 2010;153(1):19-22. doi: 10.7326/0003-4819-153-1-201007060-00255 [published Online First: 2010/06/03]
19. Mitchell MJ, Stubbs BA, Eisenberg MS. Socioeconomic Status Is Associated with Provision of Bystander Cardiopulmonary Resuscitation. *Prehospital Emergency Care* 2009;13(4):478-86. doi: 10.1080/10903120903144833
20. Blewer AL, Ibrahim SA, Leary M, et al. Cardiopulmonary Resuscitation Training Disparities in the United States. *J Am Heart Assoc* 2017;6(5):e006124. doi: 10.1161/JAHA.117.006124
21. Straney LD, Bray JE, Beck B, et al. Regions of High Out-Of-Hospital Cardiac Arrest Incidence and Low Bystander CPR Rates in Victoria, Australia. *PLOS ONE* 2015;10(10):e0139776. doi: 10.1371/journal.pone.0139776
22. Chiang W-C, Ko PC-I, Chang AM, et al. Bystander-initiated CPR in an Asian metropolitan: Does the socioeconomic status matter? *Resuscitation* 2014;85(1):53-58. doi: 10.1016/j.resuscitation.2013.07.033
23. Dicker B, Garrett N, Wong S, et al. Relationship between socioeconomic factors, distribution of public access defibrillators and incidence of out-of-hospital cardiac arrest. *Resuscitation* 2019;138:53-58. doi: 10.1016/j.resuscitation.2019.02.022
24. Dobbie F, Angus K, Uny I, et al. Protocol for a systematic review to identify the barriers and facilitators to deliver bystander cardiopulmonary resuscitation (CPR) in disadvantaged communities. *Systematic Reviews* 2018;7(1):143. doi: 10.1186/s13643-018-0807-5
25. van Nieuwenhuizen BP, Oving I, Kunst AE, et al. Socio-economic differences in incidence, bystander cardiopulmonary resuscitation and survival from out-of-hospital cardiac arrest: A systematic review. *Resuscitation* 2019;141:44-62. doi: 10.1016/j.resuscitation.2019.05.018
26. Shah KS, Shah AS, Bhopal R. Systematic review and meta-analysis of out-of-hospital cardiac arrest and race or ethnicity: black US populations fare worse. *Eur J Prev Cardiol* 2014;21(5):619-38. doi: 10.1177/2047487312451815 [published Online First: 2012/06/14]
27. Hawkes CA, Brown TP, Booth S, et al. Attitudes to Cardiopulmonary Resuscitation and Defibrillator Use: A Survey of UK Adults in 2017. *J Am Heart Assoc* 2019;8(7):e008267. doi: 10.1161/jaha.117.008267 [published Online First: 2019/03/29]
28. Uny I AK, Duncan E, Stead M, Critchlow N, Eadie D, MacInnes L, Hasseld L, Clegg G, Dobbie F. Let's be CPR Ready: a development study: Chief Scientific Officer Scotland, 2019.
29. Blewer Audrey L HAFW, Shahidah Nur, White Alexander Elgin, Pek Pin Pin, Ng Yih Yng, Mao Desmond Renhao, Tiah Ling, Chia Michael Yih-Chong, Leong Benjamin Sieu-Hon, Cheah Si Oon,Tham Lai Peng, Kua Jade Phek Hui, Arulanandam Shalini, Østbye Truls, Bosworth Hayden B, Ong Marcus Eng Hock,. Impact of bystander-focused public health interventions on cardiopulmonary resuscitation and survival: a cohort study. *The Lancet Public health* 2020;5(8):e428-e36. doi: 10.1016/s2468-2667(20)30140-7
30. Smith CM, Lim Choi Keung SN, Khan MO, et al. Barriers and facilitators to public access defibrillation in out-of-hospital cardiac arrest: a systematic review. *Eur Heart J Qual Care Clin Outcomes* 2017;3(4):264-73. doi: 10.1093/ehjqcco/qcx023 [published Online First: 2017/10/19]
31. Smith CM, Griffiths F, Fothergill RT, et al. Identifying and overcoming barriers to automated external defibrillator use by GoodSAM volunteer first responders in out-of-hospital cardiac arrest using the Theoretical Domains Framework and Behaviour Change Wheel: a qualitative study. *BMJ Open* 2020;10(3):e034908. doi: 10.1136/bmjopen-2019-034908
32. Eisenberg D SL, Meischke H, Tu S-P, Turner AM, Ike B, Painter I, and Yip M-P. Development of a Culturally-Adapted Graphic Novella about Emergency Communication: Collaborations with a Limited English Speaking Chinese Immigrant Community. *Journal of Health Care for the Poor and Underserved* 2016;27(3):1199-210. doi: 10.1353/hpu.2016.0116

33. Sasson C, Haukoos JS, Eigel B, et al. The HANDDS program: a systematic approach for addressing disparities in the provision of bystander cardiopulmonary resuscitation. *Acad Emerg Med* 2014;21(9):1042-49. doi: 10.1111/acem.12455
34. King R, Heisler M, Sayre MR, et al. Identification of factors integral to designing community-based CPR interventions for high-risk neighborhood residents. *Prehosp Emerg Care* 2015;19(2):308-12. doi: 10.3109/10903127.2014.964889
35. Dobbie F, Uny I, Eadie D, et al. Barriers to bystander CPR in deprived communities: Findings from a qualitative study. *PLOS ONE* 2020;15(6):e0233675. doi: 10.1371/journal.pone.0233675
36. Baldi E, Sechi GM, Mare C, et al. Out-of-Hospital Cardiac Arrest during the Covid-19 Outbreak in Italy. *New England Journal of Medicine* 2020;383(5):496-98. doi: 10.1056/NEJMc2010418
37. Marijon E KN, Jost D, Perrot D, Frattini B, Derkenne C, Sharifzadehgan A, Waldmann V, Beganton F, Narayanan K, Lafont A, Bougouin W, Jouven X. Out-of-hospital cardiac arrest during the COVID-19 pandemic in Paris, France: a population-based, observational study. *Lancet Public Health* 2020 doi: https://doi.org/10.1016/S2468-2667(20)30117-1 [published Online First: May 27 2020]
38. Scottish Government. Scotlands Census, Ethinicity, Identity Language and Religion [Available from:
https://www.scotlandscensus.gov.uk/ethnicity-identity-language-and-religion#:~:text=In%202011%2C%2084%25%20of%20Scotland's,'White%3A%20Other%20British'.&text=The%20Asian%20population%20is%20the,point%20(69%2C000)%20since%202001.
accessed 24.08.2020 2020.
39. UK Government. Regional ethnic diversity [Available from:
https://www.ethnicity-facts-figures.service.gov.uk/uk-population-by-ethnicity/national-and-regional-populations/regional-ethnic-diversity/latest
accessed 24.08.20 2020.
40. NHS England. The NHS Long Term Plan, 2019.
41. Department of Health. Community Resuscitation Strategy for Northern Ireland, 2014.
42. OHCA Steering Group England. Resuscitation to Recovery; A National Framework to improve care of people with out-of-hospital cardiac arrest (OHCA) in England. 2017
43. The Scottish Govenment. Out-of-Hospital Cardiac Arrest: A Strategy for Scotland: The Scottish Government, 2015.
44. Out-of-Hospital Cardiac Arrest sub-gtoup of the Heart Conditions Implementation Group. Out of Hospital Cardiac Arrest Plan: Improving the care of people with and out of hospital cardiac arrest (OHCA) in Wales, 2017.
45. Fothergill RT, Smith AL, Wrigley F, et al. Out-of-Hospital Cardiac Arrest in London during the COVID-19 pandemic. *Resuscitation Plus* 2021;5:100066. doi: https://doi.org/10.1016/j.resplu.2020.100066
46. Cook WK. Integrating research and action: a systematic review of community-based participatory research to address health disparities in environmental and occupational health in the USA. *J Epidemiol Community Health* 2008;62(8):668-76. doi: 10.1136/jech.2007.067645 [published Online First: 2008/07/16]
47. Salimi Y, Shahandeh K, Malekafzali H, et al. Is Community-based Participatory Research (CBPR) Useful? A Systematic Review on Papers in a Decade. *Int J Prev Med* 2012;3(6):386-93. [published Online First: 2012/07/12]
48. Jagosh J, Macaulay AC, Pluye P, et al. Uncovering the benefits of participatory research: implications of a realist review for health research and practice. *Milbank Q* 2012;90(2):311-46. doi: 10.1111/j.1468-0009.2012.00665.x [published Online First: 2012/06/20]
49. Wong G, Greenhalgh T, Westhorp G, et al. RAMESES publication standards: realist syntheses. *BMC Medicine* 2013;11(1):21. doi: 10.1186/1741-7015-11-21

50. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implementation Science* 2012;7(1):37. doi: 10.1186/1748-5908-7-37
51. Michie S AL, West R. The Behaviour Change Wheel: A Guide to Designing Interventions. London: Silverback Publishing 2014.
52. Shearn K, Allmark P, Piercy H, et al. Building Realist Program Theory for Large Complex and Messy Interventions. *International Journal of Qualitative Methods* 2017;16(1):1609406917741796. doi: 10.1177/1609406917741796
53. Kantilal K, Hardeman W, Whiteside H, et al. Realist review protocol for understanding the real-world barriers and enablers to practitioners implementing self-management support to people living with and beyond cancer. *BMJ Open* 2020;10(9):e037636. doi: 10.1136/bmjopen-2020-037636
54. Michie S, Richardson M, Johnston M, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. *Ann Behav Med* 2013;46(1):81-95. doi: 10.1007/s12160-013-9486-6 [published Online First: 2013/03/21]
55. Michie S, Prestwich A. Are interventions theory-based? Development of a theory coding scheme. *Health Psychol* 2010;29(1):1-8. doi: 10.1037/a0016939 [published Online First: 2010/01/13]
56. Hickey DG. The potential for coproduction to add value to research. *Health Expectations* 2018;21(4):693-94. doi: https://doi.org/10.1111/hex.12821
57. Wong G. Data Gathering in Realist Reviews: Looking for needles in haystacks. In: Emmel N GJ, Manzano A, Monaghan M, & Dalkin S, , ed. Doing Realist Research. London: SAGE Publications Ltd, 2018:131-46.
58. Rycroft-Malone J, McCormack B, Hutchinson AM, et al. Realist synthesis: illustrating the method for implementation research. *Implementation Science* 2012;7(1):33. doi: 10.1186/1748-5908-7-33
59. Booth A, Wright, J, & Briscoe S. (2018). Scoping and searching to support realist approaches. In: Emmel N GJ, Manzano A, Monaghan M, & Dalkin S, , ed. Doing Realist Research. London: SAGE Publications Ltd, 2018:147-166.