PROTOCOL

DIspatcher REsusCitation Terminology study (The DIRECT study)

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Table of contents

LIST OF TABLES PAGE

LIST OF FIGURES PAGE

LIST OF ABBREVIATIONS/GLOSSARY

Abbreviation	Explanation
AE	Adverse Event
CI	Chief Investigator
CONSORT	*Con*solidated *S*tandards *o*f *R*eporting *T*rials
CRF	Case Report Form
CTU	Clinical Trials Unit
GCP	Good Clinical Practice
ICF	Informed Consent Form
IRAS	Integrated Research Application System
ISRCTN	International Standard Randomised Controlled Trial Number
MRC	Medical Research Council
PI	Principal Investigator
PPI	Patient & Public Involvement
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
R&D	Research and Development
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
TSC	Trial Steering Committee
WCTU	Warwick Clinical Trials Unit

1. BACKGROUND

1.1 Epidemiology and burden of the condition

Out-of-hospital cardiac arrest (OHCA) is an important cause of morbidity and mortality in the UK. Of the 28,000 treated OHCA events in the UK each year, less than 10% of patients survive to leave hospital.[1] The Government has established a high-level strategic target to reduce OHCA mortality by 1,000 patients per year.[2]

Following cardiac arrest, immediate treatment with cardiopulmonary resuscitation (CPR) is essential to optimise the likelihood of survival.[3] Prior to ambulance arrival, CPR may be delivered by a member of the public. If that bystander has not previously received training in CPR, instructions on how to perform CPR may be provided by the ambulance dispatcher over the telephone.

The quality of CPR, defined by the depth, rate and pauses in chest compressions, is an important determinant of survival following OHCA, but even in trained rescuers, the delivery of CPR often fails to adhere to evidence-based guidelines.[4-12] Chest compression depth is a key CPR quality metric.[5, 6, 13] In a large North American observational of over 9,000 OHCA patients found that each 5-mm increase in chest compression depth was associated with improved hospital survival (odds ratio 1.05 (95% confidence interval 1.00 to 1.08, p=0.045).[5] However, it is also recognised that a chest compression depth should not exceed 6cm as compressions deeper than this provide no additional benefit, whilst increasing the risk of injury.[5, 14]

Across international guidelines, there is variation as to the terminology used in relation to the target depth of chest compressions. Most international guidelines (e.g. UK, European, USA, Australian), as shown in table one.

Table 1: Summary of terminology differences in international resuscitation guidelines

European	“chest compressions should be at least 5cm but not more than 6cm”[15]
UK	“press down on the sternum to a depth of 5–6 cm” [16]
USA	“Perform chest compressions to a depth of at least 2 inches or 5 cm for an average adult, while avoiding excessive chest compression depths (greater than 2.4 inches or 6 cm)”[17]
Australia	“The lower half of the sternum should be depressed approximately one third of the depth of the chest with each compression. This equates to more than 5cm in adults”[18]
Asia	“The depth of compression should be approximately 5 cm”[19]

Previous work has highlighted that the terminology used in the instruction to deliver CPR may affect performance. In a randomised controlled trial of 332 lay persons using a model of dispatched-assisted CPR on a manikin, participants instructed to “push as hard as you can” delivered deeper chest compressions than those instructed to “push down firmly two inches” (36.4 mm (SD 11.6) v 29.7 mm (SD 10.2), p<0.001).[20] In a similar study using a paediatric model, the instruction to “push as hard as you can” resulted in deeper chest compressions, compared with “push down approximately 2 inches” (43 mm (SD 1) v 36 mm (SD 1), p<0.01).[21]

Other chest compression depth terminology has been described in public-facing documents. In particular, the British Heart Foundation's campaign led by footballer Vinnie Jones encouraged rescuers to "compress hard and fast."

1.2 Research question

In adults delivering CPR, does the use of a specific terminology (at least v approximately v hard and fast) to instruct CPR instructions affect CPR quality?

1.3 Need for a trial

There is current uncertainty regarding the most effective terminology to use when instructing bystanders to deliver CPR, with evidence of variability in terminology across international guidelines. There is the opportunity to optimise delivery of bystander through more effective instruction.

In 2015, the International Liaison Committee on Resuscitation published a review of resuscitation science. This study will help to answer two key identified knowledge gaps, namely the optimal instruction sequence for coaching callers in telephone-assisted CPR and the impact of language barriers to telephone-assisted CPR performance.

The DIRECT study will address these knowledge gaps in a three-armed (approximately v at least v hard and fast) randomised controlled manikin trial, in which lay people will be instructed as to how to deliver CPR to a manikin. The specific terminology selected for the trial is based on that described in international guidelines and CPR publicity campaigns.

1.4 Ethical considerations

The trial will be conducted in conformance with the principles of the Declaration of Helsinki and to MRC Good Clinical Practice (GCP) guidelines. It will also comply with all applicable UK legislation. All data will be stored securely and held in accordance with Data Protection Act 1998.

This trial does not raise any significant ethical issues. Participants will give informed consent prior to participation and there is minimal risk associated with participation.

1.5 CONSORT

The trial will be reported in line with the Consolidated Standards of Reporting Trials statement.[22]

1.6 Assessment and management of risk

The trial intervention consists of participants performing 2-minutes of CPR whilst kneeling on the floor. Some people may find this tiring and it may cause discomfort in the upper limbs and knees, but such effects will be short-term. We will exclude potential participants that have a physical

disability that prevents delivery of CPR for 2 minutes while kneeling on the floor. As such, there is minimal risk associated with study participation.

2. TRIAL DESIGN

2.1 Trial summary and flow diagram

The DIRECT study is a three-armed single-centre randomised controlled manikin trial which will evaluate the effect of CPR delivery instruction terminology on CPR quality delivered by people without recent practical CPR training.

Following informed written consent, participants will be randomised in a 1:1:1 ratio to receive one of three CPR instructions and deliver two minutes of chest compressions to a manikin. There will be no follow-up.

The primary outcome is chest compression depth. Secondary endpoints will include other CPR quality metrics.

A trial summary is shown as figure one

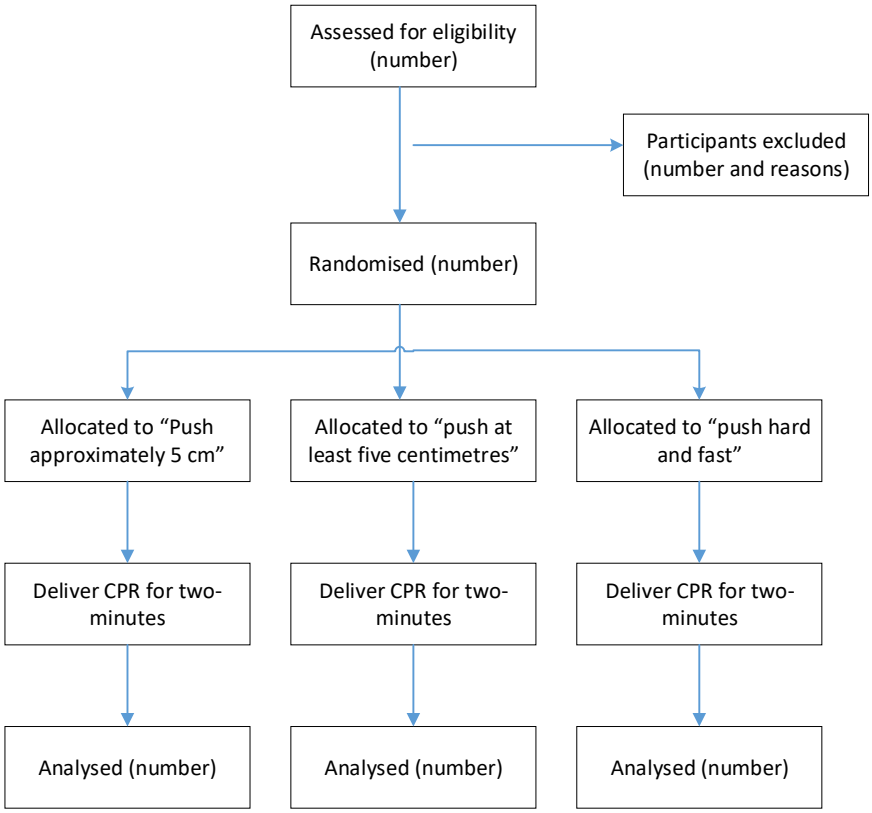

Figure 1 Trial flow diagram

2.2 Aims and objectives

2.2.1 Primary objective

The primary objective of this trial is to assess the impact of CPR instruction terminology on chest compression depth.

2.2.2 Secondary objective

The secondary objectives of the trial are to assess the impact of CPR instruction terminology on other CPR quality metrics.

2.3 Outcome measures

The outcome measures selected for this study are key CPR quality metrics that are associated with outcome in cardiac arrest. We will also record other outcomes that may influence any choice of terminology in international guidelines.

2.3.1 Primary efficacy outcomes

The primary outcome is mean chest compression depth measured during the CPR quality assessment.

2.3.2 Secondary efficacy outcomes

The secondary outcomes are:

- Chest compression rate (min^{-1})
- Chest compression count
- % of chest compessions in target rate range (100-120 compressions per minute)
- % of chest compressions in target depth range (50-60mm)
- % delivery of good quality CPR over two-minute study period (defined as mean CPR depth in target range (50-60mm), chest compression rate in target range (100-120 compressions per minute, and with full recoil)

2.4 Eligibility criteria

Persons at NHS hospital sites are eligible to be included in the trial if they meet the following criteria:

2.4.1 Inclusion criteria

1. Provision of written informed consent

2. Aged over 18 years

2.4.2 Exclusion criteria

1. Physical disability that prevents delivery of CPR for 2 minutes while kneeling on the floor,

2. Previous participation in DIRECT study,

3. Received practical CPR training in the last 2-years,

4. Non-English speaking (to ensure that the information is standardised between groups)

5. NHS employee working in a clinical role.

2.5 Participant identification / Screening

Potential participants will be identified and approached at research sites. Potential sources of participants include NHS administrative and ancillary staff, patients waiting for outpatient appointments, and hospital visitors.

Different approaches are envisaged for different groups of people.

Trust staff will be informed that the study is taking place by email, and administrative offices will be visited to provide study information. Staff will be notified when they can undertake the CPR quality assessment. On arriving to undertake the CPR quality assessment, eligibility will be assessed and they will be asked to sign the informed consent form.

For other groups, research staff will identify an appropriate location to undertake the CPR quality assessment on recruitment days. People passing by or waiting in the nearby area will be approached and informed that the study is being undertaken. Staff may also be recruited by this route.

Any member of research staff that has delegated authority by the principal investigator may assess participant eligibility.

2.6 Informed consent

Potential participants will be provided with a brief verbal explanation of the study by a member of the research team at the hospital site. A copy of the written participant information sheet will be provided. The potential participant will be given adequate time to review the information and ask questions. In view of the nature of the study, it is anticipated that this decision will be made quickly. If the participant is willing to participate, they will complete a signed consent form.

Written consent will be obtained prior to undertaking any study procedure.

The participant may withdraw at any time without giving reasons and without prejudice to any NHS treatment.

The receipt of written informed consent may be undertaken by any member of research staff that has been delegated authority by the principal investigator. The principal investigator retains overall responsibility for informed consent at their site and must ensure that any person delegated responsibility to participate in the informed consent process is duly authorised, trained and competent.

2.7 Randomisation

2.7.1 Randomisation

Participants will be individually randomised in a 1:1:1 ratio to receive one of the following terminologies:

1. Press at least 5cm
2. Press approximately 5cm
3. Push hard and fast

Participants will be randomised strictly sequentially as participants are eligible for randomisation.

An internet-based randomisation system will be used to randomly assign participants to groups. Details of how to access the service will be provided to sites in a trial specific working instruction

2.7.2 Post-randomisation withdrawals

Participants may withdraw from the study at any time without giving a reason. In view of the nature of the study (no follow-up), we expect such events to be rare.

Where a participant withdraws from the study, research staff will discuss with the participant whether they agree to the retention of data already collected.

2.8 Trial treatments / intervention

2.8.1 Trial treatment(s) / intervention

Randomisation and the CPR quality assessment will take place as soon as possible after written informed consent has been obtained.

The CPR quality assessment will consist of a simulated cardiac arrest. On entering the simulation area, participants will be presented with a standardised scenario. They will be informed that they have entered a room at their local community centre and found a 70-year old male collapsed on the floor. They will be informed that they have phoned 999 and provided the location of the event and that the ambulance in en-route. The 999 operator will then guide the participant as to how to commence CPR using a standardised script. We will use a standardised script, based on that used by UK Ambulance Services to direct the dispatcher-assisted CPR. The only difference between the scripts will be the wording to describe the target chest compression depth. All participants will be directed to deliver compression-only CPR.

The instructions will be delivered using a pre-recorded audio recording. The participant will not have the opportunity to ask questions. If a question is asked, the researcher in the room will respond that the participant should follow the instructions on the audio recording

Each participant will deliver chest compressions for approximately two minutes following the delivery of the first chest compression.

After the scenario, the researcher will provide feedback on the participant's performance, based on their subjective assessment of performance.

2.8.2 Compliance/contamination

In view of the nature of the trial, we expect high compliance.

Participants will be asked to not discuss details of the study with other potential participants to minimise the risk of contamination.

2.9 Blinding

2.9.1 Methods for ensuring blinding

It will not be possible to blind research staff or participants to the CPR instruction terminology. Researchers extracting CPR quality data (i.e. outcome assessors) will be blinded to study intervention.

2.9.2 Methods for unblinding the trial

Only the outcome assessor will be blinded to study allocation. As such, a mechanism for unblinding the participant or any other person is not required.

2.10 End of trial

The trial will end when all required participants have completed the CPR quality assessment.

The trial will be stopped prematurely if:

- Mandated by the Ethics Committee, or,
- Funding for the trial ceases.

The Research Ethics Committee will be notified in writing on completion of the trial.

3. METHODS AND ASSESSMENTS

3.1 Schedule of delivery of intervention and data collection

The schedule of delivery of the intervention and data collection is detailed in table one.

Table 2: Schedule of events

Visit	1	2
Visit Window		**Immediately after randomisation**
Informed consent	✓	
Inclusion/exclusion criteria	✓	
Demographic information*	✓	
CPR quality assessment		✓
Adverse events	✓	✓
*- Demographic information will include key variables, such as age, gender, height, weight, previous CPR training, previous resuscitation use.		

3.2 Study equipment

A standard adult manikin will be used in scenarios. CPR quality will be measured using a CPRmeter device (Laerdal Medical, Stavanger, Norway), or similar accelerometer-based CPR measurement device. Any device visual or audio CPR quality feedback will be disabled during the scenario. Data will be extracted using manufacturer software.

4. ADVERSE EVENT MANAGEMENT

4.1 Definitions

4.1.1 Adverse Events (AE)

An AE is: "Any untoward medical occurrence in a patient or clinical investigation participant taking part in health care research, which does not necessarily have a causal relationship with the research".

The reporting periods for adverse events is from the time of written consent to completion of the CPR quality assessment. All adverse events that occur between these time-points should be recorded in the case report form.

In view of the nature of the trial, adverse events should only be recorded if the event may be associated with study participation.

4.1.2 Serious Adverse Events (SAEs)

A Serious Adverse Event is a recordable AE that fulfils one or more of the following criteria:

- Results in death
- Is immediately life-threatening
- Requires hospitalisation or prolongation of existing hospitalisation

- Results in persistent or significant disability or incapacity
- Is a congenital abnormality or birth defect
- Is an important medical condition.

4.2 Reporting SAEs

All **SAEs** occurring from the time of **written informed consent** until the completion of the CPR quality assessment must be recorded on the study Searios Adverse Event Form and faxed to the Sponsor **within 24 hours** of the research staff becoming aware of the event.

For each **SAE** the following information will be collected:

- full details of the event,
- event duration (start and end dates, if applicable),
- action taken,
- outcome,
- seriousness criteria,
- causality (i.e. relatedness to intervention), and,
- whether the event would be considered expected or unexpected.

Any change of condition or other follow-up information should be faxed to the Sponsor as soon as it is available or at least within 24 hours of the information becoming available. Events will be followed up until the event has resolved or a final outcome has been reached.

SAEs will be reported using the SAE form in the participant's CRF. The Principal Investigator in each centre must report any SAEs to the study sponsor within 24 hours of them becoming aware of the event. The SAE form should be completed and faxed to the dedicated fax at Heart of England NHS Foundation Trust. The trial team will liaise with the investigator to compile all the necessary information. The trial coordinating centre is responsible for reporting any related and unexpected SAEs to the sponsor and REC within required timelines.

The principal investigator at the research site is responsible for the recording of AEs and reporting of SAEs in line with the requirements of the protocol.

5. DATA MANAGEMENT

Personal data collected during the trial will be handled and stored in accordance with the 1998 Data Protection Act.

Participants will be identified using a unique trial number and their initials. Details of the management of personal data will be described in the participant information sheet.

5.1 Data collection and management

Case Report Forms (CRFs) will be developed to collect all required trial data.

Demographic data will be recorded at the time of consent through direct questioning of the participant by research staff by a member of research staff.

CPR quality assessment will be collected using a CPR qualiy measurement device (see section 3.2).

5.2 Database

A trial database will be developed, which will be used to store inputted study data.

5.3 Data storage

All essential documentation and trial records will be stored by Heart of England NHS Foundation Trust in accordance with local policy. Access to stored information will be restricted to authorised personnel.

5.4 Data access and quality assurance

Participant data will be recorded in an anonymised format by referring to participants as initials and participant number. Personal information will be retained with explicit consent, only for the purpose of sending out study results (if requested by the participant) or to send out details of CPR training, which will be offered to participants. Personal identifiable information will be stored separately to study results.

A screening log will be used to capture anonymised details of the number of people approached to participate and reasons for people not participating in the study, based on the exclusion criteria.

Study data will be stored securely. Written records will be stored in locked offices, accessible only to study personnel. Electronic data will be stored on password protected computers accessible only to study personnel.

5.5 Archiving

Trial documentation and data will be archived for at least ten years after completion of the trial, in accordance with sponsor policy.

6. STATISTICAL ANALYSIS

6.1 Power and sample size

We will recruit a total of 330 participants. We require 102 participants in each study arm to reliably detect a 5 mm difference in chest compression depth between groups with 90% power and a

significance level of 0.05. In making this sample size calculation, we have made a conservative estimate of the standard deviation (11), as described in the study by Mirza et al.[20] The difference of 5mm is considered clinically important based on large observational studies of the association between chest compression depth and survival following OHCA.[5, 6, 13]

We have included an additional 24 participants to account for drop-outs and data loss.

6.2 Statistical analysis of efficacy and harms

6.2.1 Statistics and data analysis

Data will be analysed using SPSS statistical software.

Continuous data will be assessed for normality. Normally distributed continuous will be described as mean and 95% confidence, Non-normally distributed continuous data will be described as median and interquartile range. Categorical data will be described as number and percentage.

Baseline demographics for each treatment group will be reported using descriptive statistics.

For the analysis of outcomes, we will conduct two groups of analyses:

1. The first analysis will compare each of the outcomes with another outcome (i.e. “at least” v “approximately”; “approximately” v “hard and fast”; “hard and fast” v “at least”). For continuous data, we will report the mean difference, 95% confidence interval, and p-value (t-test). For dichotomous outcomes, we will report the odds ratio, 95% confidence interval, and p-value (chi-squared test or similar).
2. The second analysis will compare all three groups, using an ANOVA test, Kruskal-Wallis test, or Chi-square test, depending on the type of data.

All analyses will be on an intention-to-treat basis. We do not plan to undertake any adjusted analyses. All tests will be two-tailed with a p-value cut-off for significance of 0.05.

7. TRIAL ORGANISATION AND OVERSIGHT

7.1 Sponsorship arrangements

The trial will be sponsored by Heart of England NHS Foundation Trust.

7.2 Ethical approval

An approval application will be made for NHS Research Ethics and Health Research Authority review via the Integrated Research Application System. The trial will be conducted in accordance with all relevant regulations.

The chief investigator will submit a final report to the required authorities with the results, including any publications within one year of the end of the trial.

7.3 Trial Registration

We plan to register the trial with the International Standard Randomised Controlled Trial Number (ISRCTN) Register.

7.4 Protocol deviation

Any incident of study participants not receiving their allocated group treatment as allocated by randomisation will be recorded.

Study and protocol deviations will be documented in the patients CRF and reported to the Study Sponsor via the Trial Office. Patients will be analysed according to group allocation, by intent-to-treat analysis.

7.5 Notification of serious breaches to GCP and/or trial protocol

A "serious breach" is a breach which is likely to effect to a significant degree –

(a) the safety or physical or mental integrity of the subjects of the trial; or
(b) the scientific value of the trial

In the event of a serious breach occurring, the site research team will immediately notify the sponsor that a serious breach has occurred, who will investigate the breach in accordance with local policy.

7.6 Indemnity

NHS indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the trial. NHS bodies carry this risk themselves or spread it through the Clinical Negligence Scheme for Trusts, which provides unlimited cover for this risk.

7.7 Administration

The trial co-ordination will be based at Heart of England NHS Foundation Trust.

7.8 Trial Management Group (TMG)

The Trial Management Group, consisting of the project staff and co-investigators involved in the day-to-day running of the trial, will meet regularly throughout the project.

7.9 Trial Steering Committee (TSC) and Data Monitoring Committee (DMC)

In view of the nature of the trial, it is not considered necessary to convene a TSC or DMC.

7.10 Essential Documentation

A Trial Master File will be set up and held securely at the coordinating centre.

7.11 Financial Support

The trial has been funded by a grant from Resuscitation Council (UK).

8. MONITORING, AUDIT AND INSPECTION

This study may be audited and monitored by the Sponsor to ensure adherence with Good Clinical Practice and the Department of Health Research Governance Framework for Health and Social Care.

9. PATIENT AND PUBLIC INVOLVEMENT (PPI)

The proposed study has been discussed with the Heart of England NHS Foundation Trust Clinical Research Ambassador Group, who support the trial and its proposed methodology.

10. DISSEMINATION AND PUBLICATION

The results of the trial will be reported first to trial collaborators. The main report will be drafted by the trial co-ordinating team and published in a peer-reviewed journal.

The success of the trial depends on the collaboration of doctors, nurses and researchers from across the UK. Equal credit will be given to those who have wholeheartedly collaborated in the trial.

The trial will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines (www.consort-statement.org).

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