WARWICK
THE UNIVERSITY OF WARWICK

POSED
Prehospital Optimal Shock Energy for Defibrillation

A feasibility study of Prehospital Optimal Shock Energy for Defibrillation (POSED)

STATISTICAL ANALYSIS PLAN

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Contents

1. ADMINISTRATIVE INFORMATION

Title: A feasibility study of Prehospital Optimal Shock Energy for Defibrillation (POSED)

ISRCTN Trial registration number: 16327029

SAP Version: 0.2, dated 24 June 2022

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SAP revisions:

Version no.	Changes	Rationale for changes	Timing of change w.r.t. analyses

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2. INTRODUCTION

2.1 Background and rationale

Cardiac arrest, the cessation of the pumping action of the heart, is one of the primary causes of premature death across the world. (1) One fifth of patients sustaining a cardiac arrest in the out-of-hospital environment displays a shockable heart rhythm, i.e. one that may be treated with defibrillation. (2) . There is currently no clear consensus on the optimal shock energy for delivery by a defibrillator. European Resuscitation Council (ERC) guidelines advising both to treat with an initial energy of at least 150J for biphasic waveforms, escalating after a failed shock if the defibrillator is capable, and to base shock energy on manufacturers' guidance. (3) There is an urgent need for a large-scale randomised controlled trial to identify optimal shock energy for first and subsequent shocks. POSED is a stand-alone feasibility study addressing key unknowns that would inform a main trial. The main research question is:

Is it feasible to conduct a randomised, pragmatic clinical effectiveness trial in UK ambulance services to identify the optimal energy for defibrillation?

2.2 Objectives

Primary Objective

- To establish whether it is feasible to conduct a large-scale definitive trial by establishing the number of eligible patients and the number recruited.

Secondary Objectives

- To measure the rate of adherence to the allocated treatment
- Identify the best outcome measures in terms of ease and reliability of recording by reviewing data completeness.
- Explore what affects treatment adherence and data completeness by eliciting the views and experiences of paramedics via focus groups.

3. STUDY METHODS

3.1 Trial design

POSED is a single-centre, cluster-randomised multi-arm study. Defibrillators will be randomised to deliver one of three shock strategies:

Group	First shock	Second shock	Subsequent shocks	Strategy
1	120	150	200	Escalating
2	150	200	200	Escalating
3	200	200	200	Fixed

These three shock strategies represent current standard of care in UK Ambulance Services. This feasibility study aims to recruit 90 patients, ideally 30 in each arm.

3.2 Randomisation

POSED is a cluster randomised study and the unit of randomisation is the defibrillator. Defibrillators will be allocated to one of the three treatment groups in a 1: 1: 1 ratio using simple randomisation. The randomisation will be stratified by ambulance station and by vehicle type (ambulance/response car/team leader vehicle).

3.3 Sample size

This feasibility study aims to recruit 90 patients, ideally 30 in each arm. It is popularly believed that a sample size should be at least 30, based on the central limit theorem whereby as a population becomes large it achieves an approximately normal distribution.(4) Although these is no statistical proof that 30 is a 'large' number in this context, my sample size of 30 in each treatment arm will be sufficiently large to inform discussion around secondary outcomes whilst allowing for missing data and loss to follow up.

3.4 Framework

This is a feasibility study and as such is not testing statistical hypotheses.

3.5 Blinding

This is an open-label study. It is not possible to blind ambulance staff to treatment allocation as they will see the shock energy when they charge the defibrillator. Patients and hospital staff will be blind to the treatment allocation. Those assessing outcomes at discharge/30 days will be blind to allocation although those assessing short term outcomes (cardiac electrical outcomes) will not be blind as the data will be taken from defibrillator data downloads which contain details of the shock energy delivered (the intervention).

3.6 Statistical interim analyses and stopping guidance

As this is a feasibility study there will be no interim analyses. The study will end when all participants have completed their 30 day follow-up or after 24 months of patient recruitment, whichever is sooner.

The study will be stopped prematurely if:

- Mandated by the Ethics Committee
- Following recommendations from the Study Oversight Committee (SOC)
- Funding for the study ceases

3.7 Timing of outcome assessments

	Cardiac arrest	Hospital	Day 30
Inclusion/exclusion criteria	✓	x	x
Cardiac arrest data	✓	x	x
Patient identifiers	✓	✓	x

Adverse event reporting	✓	✓	x
National data opt-out check	✓		x
Survival checks	✓	✓	x
Survival status	✓	✓	✓
Hospital stay data	x	✓	x
Notification of enrolment and invitation to take part in follow up	x	✓	x
Informed consent	x	✓	x
Neurological outcome (mRS)	x	x	✓

4. STATISTICAL PRINCIPLES

4.1 Confidence intervals and P values

There will not be a formal statistical analysis as the study has not been powered to assess difference in interventions. The analyses will be based on summary statistics, namely mean, standard deviation, median, interquartile ranges and missingness in the data. Where possible 95% confidence intervals will also be given.

4.2 Adherence and protocol deviations

From Gamble, JAMA 2017;318(23) supplementary info: *"A protocol deviation is defined as a failure to adhere to the protocol such as the wrong intervention being administered, incorrect data being collected and documented, errors in applying inclusion/exclusion criteria or missed follow-up visits."*

4.2.1 Delivery of intervention

Adherence to the intervention will have been achieved when shocks have been delivered according to the allocated energy level. Patients may need one or more shocks. The protocol determines first, second and subsequent shock energies. It is possible that a protocol deviation may occur when delivering any or all shocks.

Treatment adherence rate will be assessed in terms of how many patients received the allocated first shock energy and, where more than one shock was delivered, how many received the correct subsequent shock energies. These will be reported as one of the secondary feasibility outcomes in the study report.

Short term post-shock outcomes (post-shock rhythms and return of spontaneous circulation (ROSC)) for only the first (up to) three shocks are being reported. Protocolised shock energies must be delivered for these shocks in order to be considered adherent. Where any energies deviate from the protocolised shock energies, this will be considered as non-compliant. Treatment adherence for each of the first three shocks will be reported via a table in the study report.

4.2.2 Data collection and documentation

Where errors in data collection and documentation are identified, these will be rectified where possible. Where these cannot be rectified, data will be reported as missing and displayed in the data tables of the study report.

4.2.3 Eligibility errors

Data will not be collected for ineligible patients. Any data collected relating to a patient who is subsequently deemed ineligible will be deleted.

4.2.4 Missed follow up visits

The proportion of missed follow up visits will be reported in the data tables in the study report.

4.3 Analysis populations

This feasibility study aims to describe the study population in terms of:

- All-treated population: Any subject randomised and eligible for the study that received at least one part of the intervention
- Protocol-compliant population: Any subject who was eligible, randomised and received the protocol required intervention

5. TRIAL POPULATION

5.1 Screening data

Screening data will be collected and reported in terms of the proportion of eligible patients recruited. This forms the primary outcome of this feasibility study.

5.2 Eligibility

Patients are eligible to be included in the study if they meet the following criteria:

Inclusion criteria

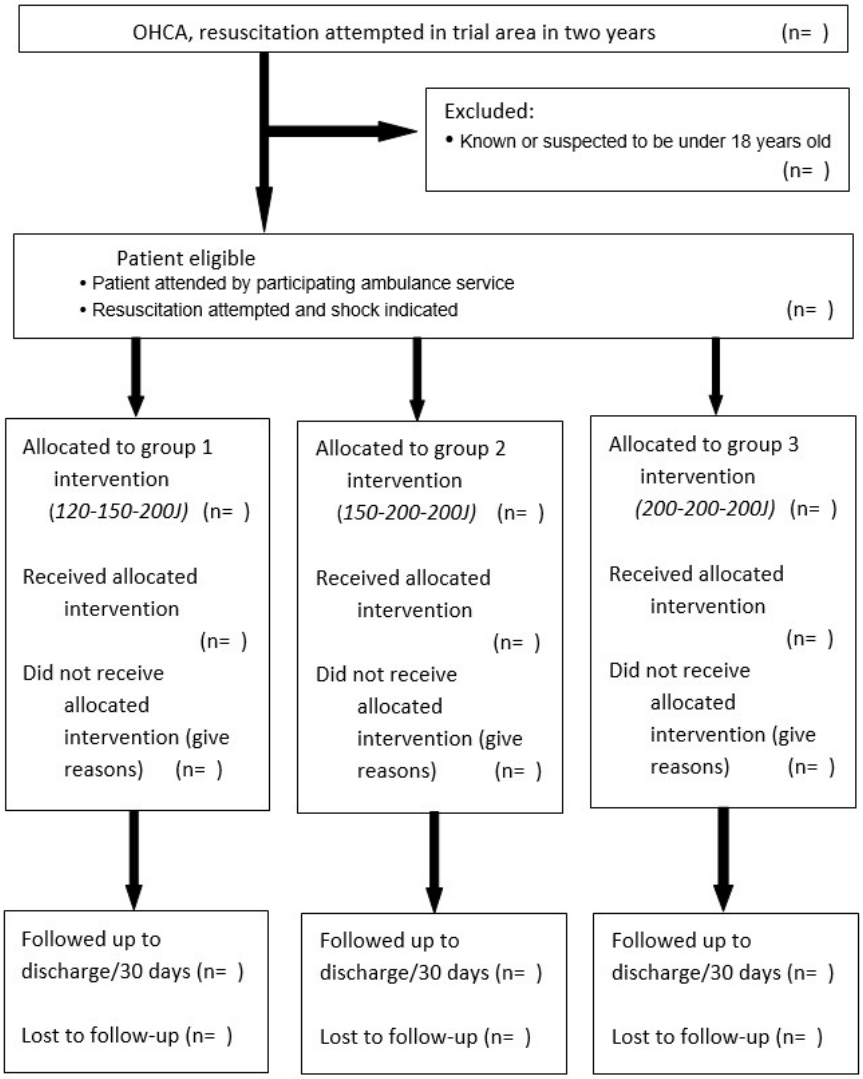
1. Patients sustaining OHCA attended by a crew from participating ambulance service
2. Resuscitation attempted and shock delivered as per Resuscitation Council UK and JRCALC guidelines

Exclusion criteria

1. Patients known or suspected to be under 18 years old

5.3 Recruitment

Figure 1 Study flow diagram



5.4 Withdrawal/follow-up

It will not be possible for patients to withdraw from the intervention since this will have been delivered at a time when they were unconscious. Patients may withdraw from follow up. There are two levels of withdrawal – withdrawal from remote data collection and withdrawal from all data collection (remote and face to face). Both of these will be reported as well as timing of, and reasons for, withdrawal. Numbers of patients lost to follow up will be reported in the study flow chart, broken down for each longer-term follow up assessment in the data tables. Reasons for loss will also be reported.

5.5 Baseline patient characteristics

Baseline comparability of the randomised groups will be assessed using the following variables:

- Age (median and range)
- Sex (% male)
- Location of arrest (% private residence/ public place/ other)
- Witnessed vs. unwitnessed event (% witnessed and % bystander/ EMS or other healthcare provider/ unwitnessed)
- Bystander CPR vs. no bystander CPR (of those not EMS-witnessed, % provided BCPR prior to EMS arrival)
- Type of initial rhythm (% in VF/pVT, PEA or asystole)
- Time from call to application of defibrillator (median and range)
- Aetiology of cardiac arrest (% cardiac vs. non-cardiac cause)

6. ANALYSIS

6.1 Outcome definitions

6.1.1 Primary outcome

The proportion (%) of eligible patients who are randomised to receive the intervention will be reported.

6.1.2 Secondary outcomes

- Treatment adherence rate. This will be assessed in terms of how many patients received the allocated first shock energy and, where more than one shock was delivered, how many received the correct subsequent shock energies. These will be reported as proportions for each treatment arm and overall.

- Data completeness of clinical outcomes below:

    - Neurologically intact survival at 30 days (mRS score)
    - Return Of Organised Rhythm capable of sustaining a pulse (ROOR) 2 min post shock
    - Resulting rhythm (VF/pVT/PEA/asystole) 2 min post shock
    - Re-arrest rate (re-fibrillation)
    - Survived event (return of spontaneous circulation (ROSC) at hospital handover)
    - Survived to hospital discharge

  These will be reported in terms of the proportion of patients for whom each of these outcomes was collected.

- Data completeness of process outcomes below:

    - Quality of CPR (chest compression rate, chest compression depth, chest compression fraction, pre-shock pause, post-shock pause)
    - Number of shocks
    - Advanced airway applied (% advanced airway applied and % supraglottic airway or endotracheal tube)
    - Intravenous medicines administered (% cases where medicines administered and % adrenaline, amiodarone)

- Transported to hospital (% transported)

These will be reported in terms of the proportion of patients for whom each of these outcomes was collected.

6.2 Analysis methods

As this is a feasibility study no statistical analysis will be undertaken. Note that the intracluster correlation (ICC) between allocated shock groups will be calculated for consideration in future studies.

6.3 Missing data

All reasonable attempts will be made to prevent missing data. Since this is a feasibility study, only the proportion of missing data will be reported. No imputation or other techniques will be employed to minimise the impact of missing data.

6.4 Additional analyses

No additional analysis is required.

6.5 Harms

Few if any SAEs are expected since many of the criteria of an SAE are conditions normally associated with cardiac arrest or attempted resuscitation. Summary data for each SAE will be reported including information on severity, expectedness and causality.

6.6 Sub-groups

In relation to initial shock (VT/pVT) as our outcome, we will conduct sub-group analyses of:

1. Hospital handover (ROSC, CPR ongoing, not conveyed);
2. 30 days survival (died/alive);
3. Survival at discharge (died/alive).

We will assess the interaction of the treatment arm, with each of the sub-groups.

6.6 Statistical software

No statistical software is required.

6.7 References

1. Nolan, J.P., G.D. Perkins, and J. Soar, *Improving survival after out-of-hospital cardiac arrest.* British Medical Journal, 2015.
2. Hawkes, C., Booth, S., Ji, C., Brace-McDonnell, S.J., Whittington, A., Mapstone, J., Cookes, M.W., Deakin, C.D., Gale, C.P., Fothergill, R., Nolan, J.P., Rees, N., Soar, J., Siriwardena, A.N., Brown, T.P., Perkins, G.D. on behalf of OHCAO collaborators, *Epidemiology and outcomes from out-of-hospital cardiac arrests in England.* Resuscitation, 2017. **110**: p. 133-140.
3. Soar, J., et al., European Resuscitation Council Guidelines for Resuscitation 2015: Section Adult advanced life support. *Resuscitation*, 2015. **95**: p. 100-147.
4. Chakrapani C. Statistical Reasoning vs. Magical Thinking. *Vue*. 2011: 12-18.

The electronic Trial Master File can be found at:
M:\WMS\CTU\Emergency Care\POSED

The POSED Data Management Plan can be found at:
M:\WMS\CTU\Emergency Care\POSED\11. Data Collection

The following SOPs should be read in conjunction with the POSED SAP, they are found in the SOPs section of the WCTU website found here:
https://warwick.ac.uk/fac/sci/med/research/ctu

SOP Number	SOP Name
9	Randomisation in Research Studies
15	Information Handling – Part 1 / Part 2 / Part 3 / Part 4
16	Case Report Forms
17	Safety Reporting – Part 2 / Part 3 / Part 4
18	Risk Assessment & Monitoring
31	Deviations Violations, Misconduct and Serious Breaches of GCP and/or study Protocol

7. TEMPLATE TABLES

Baseline characteristics

	Group A (n=)	Group B (n=)	Group C (n=)	All cases (n=)
Age – N				
Mean	μ	μ	μ	μ
SD	σ	σ	σ	σ
Median (IQR)	Median (Q1:Q3)	Median (Q1:Q3)	Median (Q1:Q3)	Median (Q1:Q3)
Missing - n (%)	n (%)	n (%)	n (%)	n (%)
Gender – n (%)				
Male	n (%)	n (%)	n (%)	n (%)
Female	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
Location of arrest - n (%)				
Private residence	n (%)	n (%)	n (%)	n (%)
Public place	n (%)	n (%)	n (%)	n (%)
Other	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
Witnessed event – n (%)				
Witnessed	n (%)	n (%)	n (%)	n (%)
Unwitnessed	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
Bystander CPR (B-CPR) – n (%)				
Non-EMS witnessed events receiving B-CPR	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
Prior shocks delivered by non-study defibrillator	n (%)	n (%)	n (%)	n (%)
Initial rhythm – n (%)				
VF/pVT	n (%)	n (%)	n (%)	n (%)
PEA	n (%)	n (%)	n (%)	n (%)
Asystole	n (%)	n (%)	n (%)	n (%)

Missing	n (%)	n (%)	n (%)	n (%)
Time from call to application of defibrillator – N				
Mean	μ	μ	μ	μ
SD	σ	σ	σ	σ
Median (IQR)	Median (Q1:Q3)	Median (Q1:Q3)	Median (Q1:Q3)	Median (Q1:Q3)
Missing - n (%)	n (%)	n (%)	n (%)	n (%)
Aetiology of cardiac arrest – n (%)				
Cardiac	n (%)	n (%)	n (%)	n (%)
Non-cardiac	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)

Process outcomes

Quality of CPR

	Group A (n=)	Group B (n=)	Group C (n=)	All cases (n=)
Chest compression rate				
Median (IQR)	Median (Q1:Q3)	Median (Q1:Q3)	Median (Q1:Q3)	Median (Q1:Q3)
Missing - n (%)	n (%)	n (%)	n (%)	n (%)
Chest compression depth				
Median (IQR)	Median (Q1:Q3)	Median (Q1:Q3)	Median (Q1:Q3)	Median (Q1:Q3)
Missing - n (%)	n (%)	n (%)	n (%)	n (%)
Chest compression fraction				
Median (IQR)	Median (Q1:Q3)	Median (Q1:Q3)	Median (Q1:Q3)	Median (Q1:Q3)
Missing - n (%)	n (%)	n (%)	n (%)	n (%)
Pre-shock pause				
Median (IQR)	Median (Q1:Q3)	Median (Q1:Q3)	Median (Q1:Q3)	Median (Q1:Q3)
Missing - n (%)	n (%)	n (%)	n (%)	n (%)
Post-shock pause				
Median (IQR)	Median (Q1:Q3)	Median (Q1:Q3)	Median (Q1:Q3)	Median (Q1:Q3)
Missing - n (%)	n (%)	n (%)	n (%)	n (%)

Defibrillation attempts

	Group A (n=)	Group B (n=)	Group C (n=)	All cases (n=)
Number of prehospital shocks delivered				

Median (IQR) Missing - n (%)	Median (Q1:Q3) n (%)	Median (Q1:Q3) n (%)	Median (Q1:Q3) n (%)	Median (Q1:Q3) n (%)
Total number of shocks delivered – n (%)				
1 only	n (%)	n (%)	n (%)	n (%)
1 - 3	n (%)	n (%)	n (%)	n (%)
> 3 shocks	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
Rhythm preceding 1st shock – n (%)				
VF	n (%)	n (%)	n (%)	n (%)
pVT	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)

Treatment adherence

	Group A (n=)	Group B (n=)	Group C (n=)	All cases (n=)
1st shock energy				
Delivery of allocated energy	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
2nd shock energy				
Delivery of allocated energy	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
3rd shock energy				
Delivery of allocated energy	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)

Other treatments

	Group A (n=)	Group B (n=)	Group C (n=)	All cases (n=)
Advanced airway adjunct - n (%)				
iGel	n (%)	n (%)	n (%)	n (%)
Endotracheal tube	n (%)	n (%)	n (%)	n (%)
Not used	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
IV medications administered				

Adrenaline given (yes)	n (%)	n (%)	n (%)	n (%)
Amiodarone given (yes)	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)

Out-of-hospital outcome

	Group A (n=)	Group B (n=)	Group C (n=)	All cases (n=)
Out-of-hospital outcome				
Died on scene	n (%)	n (%)	n (%)	n (%)
Died in ambulance	n (%)	n (%)	n (%)	n (%)
Transported to ED	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)

Sub-group analysis: Out-of-hospital outcome for patients with initially shockable rhythm (VF/pVT)

	Group A (n=)	Group B (n=)	Group C (n=)	All cases (n=)
Out-of-hospital outcome				
Died on scene	n (%)	n (%)	n (%)	n (%)
Died in ambulance	n (%)	n (%)	n (%)	n (%)
Transported to ED	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)

Clinical outcomes

Electrical outcomes

	Group A (n=)	Group B (n=)	Group C (n=)	All cases (n=)
Rhythm post 1st shock				
ROSC	n (%)	n (%)	n (%)	n (%)
pVT	n (%)	n (%)	n (%)	n (%)
VF	n (%)	n (%)	n (%)	n (%)
PEA	n (%)	n (%)	n (%)	n (%)
Asystole	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)

Rhythm post 2nd shock				
ROSC	n (%)	n (%)	n (%)	n (%)
pVT	n (%)	n (%)	n (%)	n (%)
VF	n (%)	n (%)	n (%)	n (%)
PEA	n (%)	n (%)	n (%)	n (%)
Asystole	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
Rhythm post 3rd shock				
ROSC	n (%)	n (%)	n (%)	n (%)
pVT	n (%)	n (%)	n (%)	n (%)
VF	n (%)	n (%)	n (%)	n (%)
PEA	n (%)	n (%)	n (%)	n (%)
Asystole	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
ROOR 2 min post shock - n (%)				
Within 1 shock	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
Within 2 shocks	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
Within 3 shocks	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
Refibrillation rate – n (%)				
Before 2nd shock	n (%)	n (%)	n (%)	n (%)
Before 3rd shock	n (%)	n (%)	n (%)	n (%)
Before 4th shock	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
Time from app. of defibrillator to prehospital ROSC – N				
Mean	μ	μ	μ	μ
SD	σ	σ	σ	σ
Median (IQR)	Median (Q1:Q3)	Median (Q1:Q3)	Median (Q1:Q3)	Median (Q1:Q3)
Missing - n (%)	n (%)	n (%)	n (%)	n (%)

Sub-group analysis: Electrical outcomes of patients with initially shockable rhythm (VF/pVT)

	Group A (n=)	Group B (n=)	Group C (n=)	All cases (n=)
Rhythm post 1st shock				
ROSC	n (%)	n (%)	n (%)	n (%)
pVT	n (%)	n (%)	n (%)	n (%)
VF	n (%)	n (%)	n (%)	n (%)

PEA	n (%)	n (%)	n (%)	n (%)
Asystole	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
Rhythm post 2nd shock				
ROSC	n (%)	n (%)	n (%)	n (%)
pVT	n (%)	n (%)	n (%)	n (%)
VF	n (%)	n (%)	n (%)	n (%)
PEA	n (%)	n (%)	n (%)	n (%)
Asystole	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
Rhythm post 3rd shock				
ROSC	n (%)	n (%)	n (%)	n (%)
pVT	n (%)	n (%)	n (%)	n (%)
VF	n (%)	n (%)	n (%)	n (%)
PEA	n (%)	n (%)	n (%)	n (%)
Asystole	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
ROOR 2 min post shock - n (%)				
Within 1 shock	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
Within 2 shocks	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
Within 3 shocks	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
Refibrillation rate – n (%)				
Before 2nd shock	n (%)	n (%)	n (%)	n (%)
Before 3rd shock	n (%)	n (%)	n (%)	n (%)
Before 4th shock	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
Time from app. of defibrillator to prehospital ROSC – N				
Mean	μ	μ	μ	μ
SD	σ	σ	σ	σ
Median (IQR)	Median (Q1:Q3)	Median (Q1:Q3)	Median (Q1:Q3)	Median (Q1:Q3)
Missing - n (%)	n (%)	n (%)	n (%)	n (%)

Survival

	Group A (n=)	Group B (n=)	Group C (n=)	All cases (n=)
At hospital handover – n (%)				

ROSC	n (%)	n (%)	n (%)	n (%)
CPR ongoing	n (%)	n (%)	n (%)	n (%)
Not conveyed	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
At 30 days– n (%)				
Alive	n (%)	n (%)	n (%)	n (%)
Died in hospital	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
At discharge – n (%)				
Alive	n (%)	n (%)	n (%)	n (%)
Died in hospital	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)

Neurological outcome at 30 days

	Group A (n=)	Group B (n=)	Group C (n=)	All cases (n=)
mRS score at discharge – n (%)				
0	n (%)	n (%)	n (%)	n (%)
1	n (%)	n (%)	n (%)	n (%)
2	n (%)	n (%)	n (%)	n (%)
3	n (%)	n (%)	n (%)	n (%)
4	n (%)	n (%)	n (%)	n (%)
5	n (%)	n (%)	n (%)	n (%)
6	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
mRS score at 30 days – n (%)				
0	n (%)	n (%)	n (%)	n (%)
1	n (%)	n (%)	n (%)	n (%)
2	n (%)	n (%)	n (%)	n (%)
3	n (%)	n (%)	n (%)	n (%)
4	n (%)	n (%)	n (%)	n (%)
5	n (%)	n (%)	n (%)	n (%)
6	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
Neurological outcome - n (%)				
Good (mRS ≤ 3)	n (%)	n (%)	n (%)	n (%)
Death/poor (mRS = 4-6)	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)

Sub-group analysis: Neurological outcome of patients with initially shockable rhythm (VF/pVT)

	Group A (n=)	Group B (n=)	Group C (n=)	All cases (n=)
mRS score at discharge – n (%)				
0	n (%)	n (%)	n (%)	n (%)
1	n (%)	n (%)	n (%)	n (%)
2	n (%)	n (%)	n (%)	n (%)
3	n (%)	n (%)	n (%)	n (%)
4	n (%)	n (%)	n (%)	n (%)
5	n (%)	n (%)	n (%)	n (%)
6	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
mRS score at 30 days – n (%)				
0	n (%)	n (%)	n (%)	n (%)
1	n (%)	n (%)	n (%)	n (%)
2	n (%)	n (%)	n (%)	n (%)
3	n (%)	n (%)	n (%)	n (%)
4	n (%)	n (%)	n (%)	n (%)
5	n (%)	n (%)	n (%)	n (%)
6	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)
Neurological outcome - n (%)				
Good (mRS ≤ 3)	n (%)	n (%)	n (%)	n (%)
Death/poor (mRS = 4-6)	n (%)	n (%)	n (%)	n (%)
Missing	n (%)	n (%)	n (%)	n (%)

Withdrawals

Patients eligible – N Patients recruited – N	

	Group A (n=)	Group B (n=)	Group C (n=)	All cases (n=)
Patients randomised – N	n (%)	n (%)	n (%)	n (%)
Patients withdrawn prior hospital discharge – N	n (%)	n (%)	n (%)	n (%)
Patients withdrawn after hospital discharge – N	n (%)	n (%)	n (%)	n (%)
Patients lost to follow up – N	n (%)	n (%)	n (%)	n (%)