# Randomized clinical trial of machine learning assisted recognition of Out-of-Hospital Cardiac Arrest during emergency calls versus non-assisted recognition of Out-of-Hospital Cardiac Arrest during emergency calls. The study protocol.

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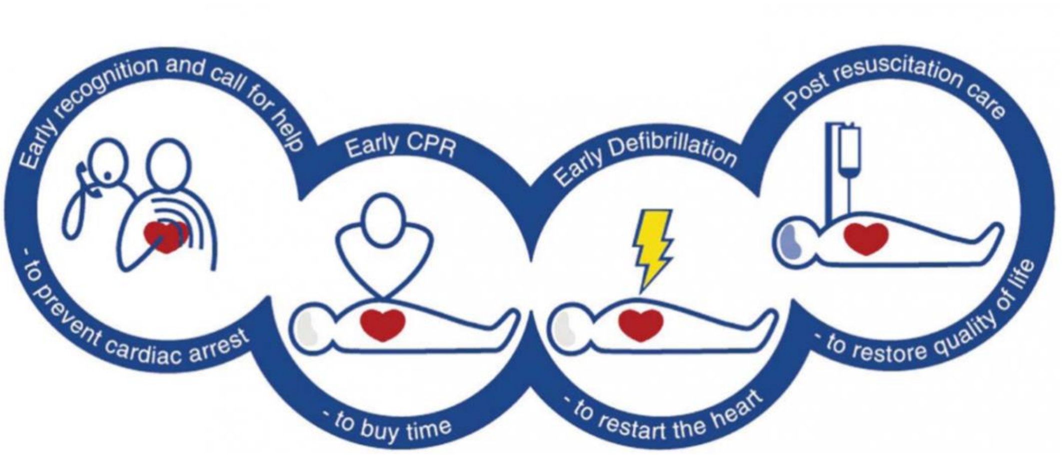
## Background

Survival from Out-of-Hospital Cardiac Arrest (OHCA) depends on four links in the chain of survival: Recognition of the event, cardiopulmonary resuscitation (CPR), defibrillation and post resuscitation care[1,2].




Early recognition and intervention are critical for patient survival. High quality CPR and defibrillation by automated external defibrillator (AED) prior to Emergency Medical Services (EMS) arrival improves survival after OHCA[3-5]. Therefore, the chance of surviving OHCA is highly correlated with bystander and medical dispatchers' recognition of the condition during the emergency calls.

Previous studies have investigated patterns in medical dispatchers' recognition of OHCA[6-10].

However, still not all OHCAs are recognised on the telephone when incorporating these patterns in the algorithms used by medical dispatchers[11]. In two recent studies, the recognition rate of OHCA in mergency medical dispatch centre Copenhagen (EMDC Copenhagen) was established to be 70 % and 81 %[12,13]. While this is considered a high accuracy, it still leaves room for improvement.

Bystanders recognise about 30 % of OHCA before calling the emergency number. The remaining OHCA are recognised during the interview with the medical dispatcher[13]. Medical dispatchers often have special training in identifying cardiac arrest, however, OHCA constitutes only few percentages of the total call volume. The individual medical dispatcher thereby gets little experience in recognising OHCA. To support the medical dispatcher in decision-making, most dispatch centre have included algorisms in their dispatch system to guide the medical dispatcher. Some dispatch centres supply with systematic ongoing feedback as quality assurance. However, the combination of human experiences and use of algorithm does not nearly identify all cardiac arrests.

Although improvements have been made during the past few decades, survival after OHCA remains low[3,14-16]. The period immediately after OHCA is critical; each instance that passes in which the patient does not receive resuscitation, greatly decreases their chance of survival[17,18]. The time from collapse to EMS arrival is often more than 5 minutes; this delay, coupled with the need for immediate resuscitative support, emphasises the critical importance of having early interventions performed by bystanders with guided assistance from medical dispatchers.

At the EMDC-Copenhagen, the medical dispatcher will by the use of 'Danish Index', and basic algorithms "No-No-Go" usually recognise OHCA. The "No-No-Go" approach is a potential tool for improving OHCA recognition. This method is a two-question approach, where the medical dispatcher in every emergency call asks the caller if the patient is conscious and if the patient is breathing normally. If the answer for both questions is "No", then relevant EMS units are dispatched, and medical dispatcher-assisted CPR protocols are initiated ("Go"). A novel approach to improve recognition of OHCA is to apply machine learning directly to the dialogue.

In a previous project "Can a computer through machine learning recognise of Out-of-Hospital Cardiac Arrest during emergency calls" (supported by TrygFoundation), we found, it was possible to create a Machine Learning (ML) model, which could recognise OHCA with higher precision than medical dispatchers at the EMDC-Copenhagen.

We now wish to test and document the effect of the model in the EMDC-Copenhagen. For this purpose, we have built a computer server running the ML-model. This server is integrated in the network at EMDC-Copenhagen, making it possible to push alerts to the medical dispatcher, when a cardiac arrest is recognised by the model.

With aid of machine learning, the hypothesis is, that recognition of OHCA is improved, and happen both more frequent and faster than present.

An instruction for the medical dispatchers is developed, which guides the medical dispatcher in instance of an alert from the machine.

## Aim

1. To investigate whether a potential increase in recognitions is due to machine alerts or the increased focus of the medical dispatcher on recognizing OHCA when implementing the machine
2. To investigate if a machine learning model based on neural networks, when alerting medical dispatchers will increase overall recognition of OHCA and increase dispatch of citizen responders.

3. To investigate increased use of AEDs, CPR or dispatch of citizen responders in cases of OHCA on machine recognised OHCA vs. medical dispatcher recognised OHCA.

## Methodology

The study has been designed as a prospective, blinded, randomized clinical trial (RCT). Each call where the machine learning model suspects a cardiac arrest is by lot (1:1) randomized to either alert on dispatchers' screen or no alert on dispatchers' screen.

This trial will comply with the CONSORT 2010 Statement[19] and the SPIRIT guidelines[20] and a Statistical Analysis Plan (SAP)[21] will be included.

### Participants

800 participants/calls will be included consecutively in the study, from EMS-Copenhagen covering all the capital region.

**Inclusion/exclusion** criteria are listed in Table 1.

Table 1

Inclusion and Exclusion Criteria

| Inclusion Criteria | Exclusion Criteria: |
|---|---|
| - Call regarding a cardiac arrest registered in the national Danish Cardiac Arrest Registry<br>- OHCA is recognized by machine-learning model<br>- Call originates from 1-1-2 | - OHCA EMS-witnessed<br>- Call is from another authority (police or fire brigade)<br>- Call is a repeat call<br>- Call has been on hold for conference |

### Flow

All calls to 1-1-2 EMS-Copenhagen are analysed by the machine-learning model. When the model recognizes a suspected OHCA, lot is drawn (1:1), and an alert will be shown on screen for the intervention group. For the control-group call is answered following usual guidelines and routines.

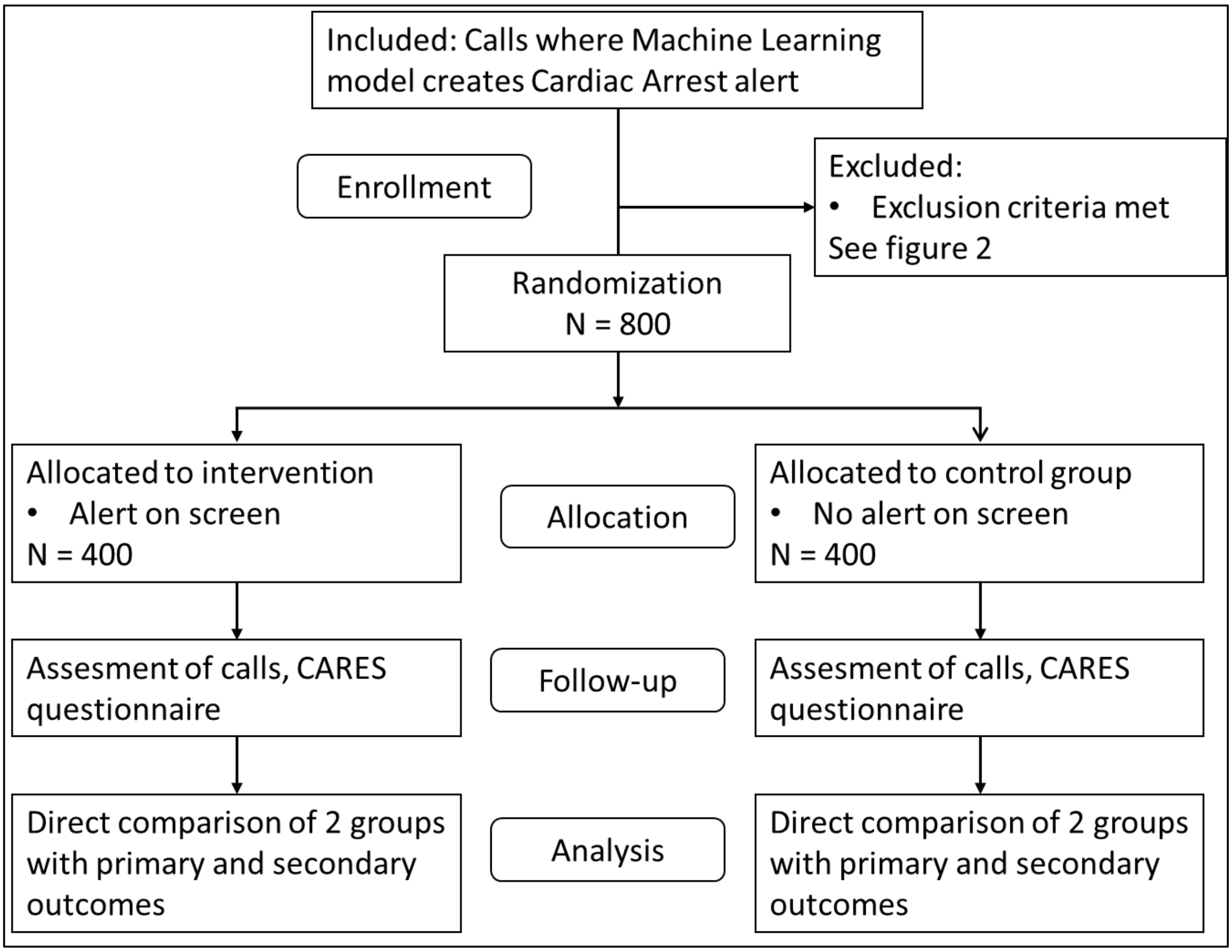



Fig. 2

## Intervention

Based on the randomization of the patient/call, the dispatcher/call taker will either have 1) alert on the screen, 2) no help from the machine learning model, and the dispatcher will proceed along the usual guidelines.

All dispatchers from EMS-Copenhagen will participate, and all dispatchers are medically trained call takers, and either trained as paramedics or nurse.

## Primary outcome measure

Dispatcher recognition of out-of-hospital cardiac arrest is the primary outcome. Recognition is reported by a questionnaire filled in by a group of auditors listening to recordings of all included calls. The questionnaire is a modified CARES protocol for the calls and consists of 21 questions whereby the quality of the call is evaluated. The questionnaire is validated and has been used in other studies.

### Secondary outcome measures

Secondary outcomes measures are derived from the CARES-question are.

Time to recognition

Dispatcher assisted CPR initiated

Time of CPR / first compression

### Sample size

Based on our previous study[22], the difference in recognition between machine learning model and dispatcher is 10 %. Setting the significance level (alpha) at 5 % and the power (1-beta) at 95 %, 356 calls is needed in each group, resulting in a total study population of 712 calls. This number has been rounded up to 800 by the research-group.

### Randomization

Simple randomization with a 1:1 allocation between intervention and control group. Randomization is done at time of (machine) recognition of cardiac arrest.

The random allocation sequence is made digitally by the machine learning model picking a random number between 0 and 1, allocating to the two groups depending on value being more or less than 0.5.

### Blinding

Randomization is blinded to dispatchers, who will not know whether a call is in the control-group.

### Statistical analysis plan

Following analysis are performed at the end of the trial for both intervention and control group

- All OHCA are identified with data from the Prehospital Patient Journal to confirm whether there was an actual OHCA
- Was OHCA recognized by medical dispatcher
- Was Cardiopulmonary resuscitation (CPR) initiated
- How many seconds before OHCA is recognised
- How many seconds before CPR is initiated
- Follow up on whether the medical dispatcher followed the alert

- How did medical dispatchers with alerts react upon false alerts?
- Was the alert correct

Analysis is done by comparing

- Recognition of OHCA
- Time of CPR initiation
- Time (seconds) before OHCA is recognized
- Follow up on whether the medical dispatcher followed the alert
- How did medical dispatchers with alerts react upon false alerts?

Analyse will cover

1. Median unrecognised time – machine compared to medical dispatchers
2. Percentage of OHCA recognised – machine compared to medical dispatcher
3. Characterise machine recognition
    a. False positives
    b. False negatives
4. Characterise medical dispatcher recognition
    a. False positives
    b. False negatives

### Timeline and ethics

Recruitment of calls/patients started September 2018. Based on expected incidence of OHCA, inclusion is expected to last between 9 and 11 months as a conservative estimate.

The trial protocol has been approved by the Regional Ethics Committee of the Capital region of Denmark.

## List of abbreviations

AED — Automated external defibrillator

CPR — Cardiopulmonary resuscitation

EMDC — Emergency medical dispatch centre

EMS — Emergency Medical Services

OHCA — Out-of-Hospital cardiac arrest

## Project organisation

**Primary investigator**

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In this project, the primary investigator is responsible for data collection, data analysis, first-drafts of papers and publications. In the first year of the study, he has validated data for the algorithm, planned and executed the entire project, and made interim analysis. Prior to this, he has through his work in EMS Copenhagen extensive knowledge on the mechanisms and processes in a call to EMDC-Copenhagen. He has years' experience as data manager, and an extensive knowledge on the data structure of the EMDC. He also has statistical knowledge with respect to both methods and statistics in prehospital research.

The Co-investigators are from different universities and contribute with interdisciplinary skills. The combined group of skills within the project covers project leadership, emergency medicine, anaesthesiology, register-based research, register-based epidemiology, statistics,

**Co-investigators:**

Freddy K. Lippert, M.D. Associate professor, The Faculty of Health and Medical Sciences, Department of Clinical Medicine, University of Copenhagen, Denmark. CEO, Emergency Medical Services, Copenhagen, The Capital Region of Denmark. Contribute with guidance and review.

Helle Collatz Christensen, M.D. Ph.D., Emergency Medical Services, Copenhagen, The Capital Region of Denmark. Contribute with guidance and review.

Frederik Folke, M.D. Ph.D., Associate professor, Emergency Medical Services, Copenhagen and the Faculty of Health and Medical Sciences, Department of Clinical Medicine, University of Copenhagen, Denmark. Contribute with guidance, methodological and clinical counselling and review.

Annette Kjær Ersbøll, MSc, Professor, PhD, National Institute of Public Health, University of Southern Denmark. Contribute with guidance, statistical analysis and review.

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