

RACE-CARS Synopsis

What is RACE-CARS?

The **R**andomized Cluster Evaluation of **C**ardiac **A**rrest **S**ystems. (RACE-CARS) trial was funded by the National Heart, Lung, and Blood Institute (NHLBI) starting July 2020 to evaluate whether community-based strategies can improve outcomes for out-of-hospital cardiac arrest (OHCA) victims. The trial will test whether a set of customized community-based interventions can improve survival to hospital discharge with good neurologic function in out-of-hospital cardiac arrest (OHCA) relative to usual care. RACE-CARS is a 7-year pragmatic, cluster randomized (1:1) trial to be conducted in 50 counties in North Carolina. The intervention strategy will consist of 4 main elements: (1) optimized medical 911-dispatch performance with rapid recognition of cardiac arrest and dispatch of emergency response, (2) enhanced 911-dispatch telephone coaching of bystander CPR, (3) improved first responder performance, and (4) comprehensive public training of CPR and AED use. RACE-CARS will use the ongoing data collection of qualifying cardiac arrest cases in the NC Cardiac Arrest Registry to Enhance Survival (CARES) registry and is projected to enroll ~20,000 patients with cardiac arrest over the 4-year intervention period.

Prior collaborative work by the RACE-CARS team that focused on rapid identification and triage of ST elevation MI in NC has resulted in a major improvement in the standards of care and outcomes for acute MI across the state. RACE-CARS aims to achieve the same eventual objective for OHCA.

Who is conducting RACE-CARS?

The RACE-CARS trial is led by a team of researchers at the Duke Clinical Research Institute in partnership with EMS agencies, hospitals, 911-dispatch, fire, rescue, law enforcement agencies, and communities throughout North Carolina. The principal investigator of the clinical coordinating center is Dr. Christopher Granger, MD, Professor of Medicine, and the PIs of the data coordinating center are Dr. Hussein Al-Khalidi, PhD, Professor of Biostatistics and Bioinformatics and Dr. Daniel B. Mark, MD, Professor of Medicine. Other DCRI investigators include Dr. Jamie Jollis; Dr. Monique Starks; and Lisa Monk.

What are the trial outcomes?

The primary outcome that will be used to judge the success of the intervention strategy is survival to hospital discharge with good neurologic function (cerebral performance category [CPC] score of 1 or 2). Secondary outcomes are 1) rates of bystander CPR and 2) defibrillation prior to EMS arrival (by bystander or first responder). Other secondary outcomes include rate of 911-dispatch recognition of cardiac arrest, survival to hospital discharge with CPC score of 1, survival to hospital discharge, and quality of life and neurological functional status at 6 and 12 months following hospital discharge.

How long is the trial?

The trial will last for 7 years with several phases.

Study Start-Up

For the first 6 months, we will plan the trial and recruit EMS agencies to participate in our study. At the end of this 6 months, participating counties will be randomized to either the intervention strategy or usual care.

Intervention Design and Training

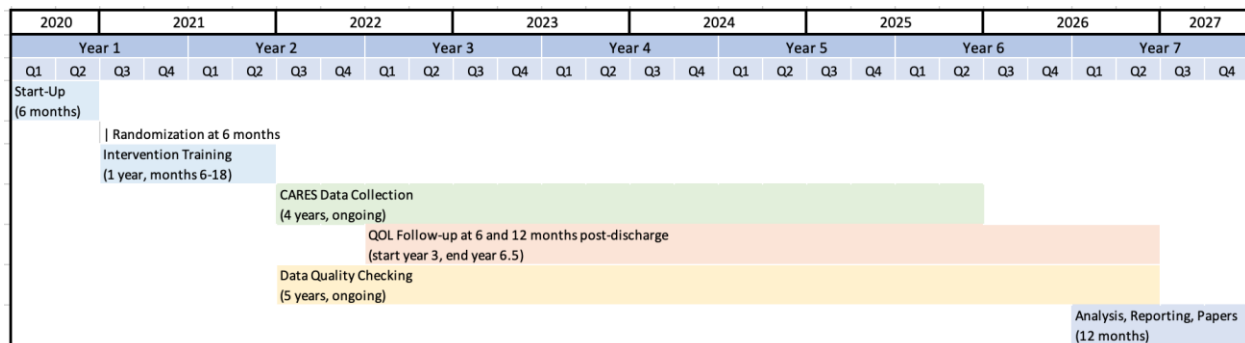
For counties randomized to the intervention strategy, the next 12-month period will be devoted to designing a strategy and training 911-dispatchers, first responders, and community partners in the implementation of each selected intervention element. Each county randomized to the intervention strategy will first work with RACE-CARS investigators to develop a customized intervention strategy unique to the needs and resources of the county and EMS agency. Next, intervention counties will work to implement the customized training plans for each level of the prehospital chain of survival.

Data Collection, Feedback, and Improvement

The training phase will be followed by a 4-year period of OHCA enrollment and CARES data collection. Investigators will evaluate basic metrics to inform, advise, and assist EMS teams in intervention counties to achieve performance goals established in the training phase. All EMS agencies will collect contact information of survivors during this period for the long-term quality of life study.

Close Out, Analysis, and Publication

During the final phase of the trial, investigators will analyze data and prepare manuscripts.



What is required of participating EMS agencies?

CARES Data Entry

Each EMS agency will have a primary responsibility for timely CARES data entry, including pursuing hospital data, for the RACE-CARS clinical trial.

Recruitment of Strategic Partners

Each EMS agency will be responsible for coordinating the participation of 911 dispatch center, first responder, and community leaders in the trial. In conjunction with the RACE-CARS team, EMS agencies will work with each community partner to implement

and carry out consistent interventions. EMS agencies will help to ensure that implementation has occurred with each emergency agency.

Recruitment of Cardiac Arrest Survivors for Long-Term Follow-Up

EMS agencies will typically identify a RACE-CARS champion in their county who will approach the patient within 30 days of hospital discharge to discuss the long-term follow-up study, provide study materials, and obtain patient contact information. This contact information will be used by the RACE-CARS study team to contact the patient by telephone at 6 and 12 months post-hospital discharge to ask a brief set of questions about the survivors quality of life and functional ability.

Intervention Conduct

Participating EMS assigned to the intervention will work with dedicated RACE-CARS implementation staff to carry out details of the intervention throughout the trial conduct period.

Each EMS agency will be compensated for participating in the RACE-CARS clinical trial according to the level of work involved.

How will county-level CARES data be used?

Each county interested in participating in RACE-CARS will be asked to allow the RACE-CARS coordinating center to access their county-level data for the duration of the trial. These data will be used to serve 4 basic objectives:

Customization of Intervention

We will initially use the CARES data to help EMS agencies determine the best interventions to apply based on its historical benchmarked performance for each planned intervention.

Primary Data Collection for the Trial

We will be using the Cardiac Arrest and Dispatch Modules of the CARES registry as our primary data collection tool. Each patient will be considered “enrolled” in the trial at the time of the cardiac arrest. Data collection for the trial will include all CARES data elements from each module from the standard data collection forms.

Feedback and Intervention

The RACE-CARS team will work with each intervention county to set achievable goals for the 4 components of the intervention (above). The RACE-CARS coordinating center will then provide regular feedback to counties on target performance versus observed performance.

Primary Contact for Long-Term Follow-up

Each CARES patient enrolled in the trial will be approached by an EMS agency coordinator within 30 days of hospital discharge to discuss the long-term study, provide study materials, and obtain contact information that is then passed on to the study team for follow-up at 6 and 12 months.

It should be emphasized that RACE-CARS public reports, presentations, and papers will present only aggregate data. No individual county data will ever be released or made public in any way by the RACE-CARS team.