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Early neurologically-focused follow-up after cardiac arrest improves quality of life at one year: A randomised controlled trial☆

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ABSTRACT

Background: Survivors of a cardiac arrest frequently have cognitive and emotional problems and their quality of life is at risk. We developed a brief nursing intervention to detect cognitive and emotional problems, provide information and support, promote self-management, and refer them to specialised care if necessary. This study examined its effectiveness.
Methods: Multicentre randomised controlled trial with measurements at two weeks, three months and twelve months after cardiac arrest. 185 adult cardiac arrest survivors and 155 caregivers participated. Primary outcome measures were societal participation and quality of life of the survivors at one year. Secondary outcomes were the patient's cognitive functioning, emotional state, extended daily activities and return to work, and the caregiver's well-being. Data were analysed using 'intention to treat' linear mixed model analyses.
Results: After one year, patients in the intervention group had a significantly better quality of life on SF-36 domains Role Emotional (estimated mean differences (EMD) = 16.38, p = 0.006), Mental Health (EMD = 6.87, p = 0.003) and General Health (EMD = 8.07, p = 0.010), but there was no significant difference with regard to societal participation. On the secondary outcome measures, survivors scored significantly better on overall emotional state (HADS total, EMD = −3.25, p = 0.002) and anxiety (HADS anxiety, EMD = −1.79, p = 0.001) at one year. Furthermore, at three months more people were back at work (50% versus 21%, p = 0.006). No significant differences were found for caregiver outcomes.
Conclusion: The outcomes of cardiac arrest survivors can be improved by an intervention focused on detecting and managing the cognitive and emotional consequences of a cardiac arrest.
Trial registration: Current controlled trials, ISRCTN74835019.

1. Introduction

Of those people who survive a cardiac arrest, about half suffer cognitive impairments and quality of life can be at risk for all of them [1–3]. The cognitive impairments arise from hypoxic–ischaemic brain injury [4]. Emotional problems, such as anxiety and depression, are also frequently seen, as well as a reduced level of participation in society and a low return to work rate [5,6]. Caregivers may also feel highly burdened and they often have emotional problems, including symptoms of post-traumatic stress [7,8]. Because a cardiac arrest can affect patients and caregivers on all these domains, there is an urgent need for an effective intervention that guides patient and caregiver after survival of a cardiac arrest.

Although cognitive impairments are common after cardiac arrest and affect quality of life, these problems often remain undetected by health care professionals [9,10]. We therefore developed a new early intervention service for survivors and their caregivers called 'Stand still …, and move on'.

☆ All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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This brief intervention is directed at screening for cognitive and emotional problems, provision of information and support, promotion of self-management, and referral to specialised care if necessary [11].

The goal of this study was to evaluate the effectiveness of this new intervention for cardiac arrest survivors and their caregivers. We expected that the intervention would primarily result in a higher level of participation in society and better quality of life for the survivors and, in addition, would also improve the well-being of caregivers, compared with those who had only received usual care. We did not expect the intervention to affect cognitive impairments, as it did not include cognitive training.

2. Methods

2.1. Design overview

This study, named 'Activity and Life after Survival of a Cardiac Arrest' (ALASCA), was a multicentre single blind randomised controlled trial in which we compared the effect of receiving the new intervention alongside usual care to care as usual only. The study was registered in a trial register [ISRCTN74835019], and the protocol has been published [12]. There were only minor deviations from the protocol, which are reported in the following text.

2.2. Setting

Patients were recruited from the coronary care units and intensive care units of five hospitals in the southern part of the Netherlands, between April 2007 and December 2010. The participating hospitals serve approximately one million inhabitants. All the hospitals had protocols for care of resuscitation patients in line with international guidelines and performed therapeutic hypothermia and pacemaker implantations [13]. In addition, two of the hospitals undertook percutaneous coronary interventions, implantable cardioverter defibrillator (ICD) implantations, catheter ablations, and coronary artery bypass grafts. Throughout the study period, medical care for cardiac arrest patients in the participating hospitals remained unchanged.

2.3. Participants

Inclusion criteria for the study were survival more than two weeks after an in-hospital or out-of-hospital cardiac arrest, living within 50 km of one of the participating hospitals, age 18 years or older and sufficient knowledge of the Dutch language. Exclusion criteria were a life expectancy of less than three months (as estimated by the treating physician) and living in residential or institutional care prior to the cardiac arrest.

In this study, we defined caregiver as a partner, spouse or significant other who was closely related to the patient. There were no additional inclusion or exclusion criteria for the caregivers. If a patient had a partner or a spouse, that person was asked to participate in the trial together with the patient. If the patient did not have a partner or a spouse, we asked the patient to assign another person as the caregiver, but this was not obligatory.

2.4. Procedure

Newly admitted survivors of cardiac arrest were assessed for study eligibility and potential participants were approached between three and ten days after their cardiac arrest. Patients and caregivers who decided to participate signed an informed consent form. If the patient did not have the capacity to consent, the caregiver was asked for provisional consent until the patient had the capacity to decide.

Baseline measurements were planned two weeks after the cardiac arrest, with follow-up at three and twelve months (main study end point). At baseline, we also assessed the patient's level of daily functioning and participation in society prior to the cardiac arrest. Research assistants visited the patients at their homes to perform the measurements. The Medical Ethics Committee of Maastricht University Medical Centre approved the study protocol.

2.5. Randomisation

Participants were randomly assigned to either the intervention group or the control group, with a 1:1 allocation ratio. Randomisation took place after the baseline measurements. The randomisation procedure was performed centrally by the project leader using a computerised block randomisation containing blocks of 15. The randomisation scheme included stratification on two variables: hospital site and location of the cardiac arrest (in-hospital versus out-of-hospital).

Research assistants administered the assessments and were blinded for group allocation. To check the success of the blinding, they were asked to indicate group allocation for all participants who completed the trial, choosing one of the following options: 'Intervention group', 'Control group' or 'I don't know'.

2.6. Intervention

In addition to usual health care, patients in the intervention group received an early intervention named 'Stand still …, and move on'. This intervention is a short, individualised, semi-structured intervention for survivors of cardiac arrest and their caregivers. Table 1 describes the content and characteristics of the intervention. More details about the rationale and content of the intervention, as well as training of the nurses, have been published previously [11]. Furthermore, a process evaluation has found the intervention to be feasible [14].

2.7. Standard care

This new early intervention was set in the context of and added to standard care. All participating hospitals had general outpatient cardiac rehabilitation programmes in which patients could enrol at their cardiologists' discretion [20]. However, there were no specific programmes for cardiac arrest survivors and standard care did not include any specific attention to cognitive impairments.

2.8. Outcomes and follow-up

Table 2 describes the measurement instruments that were used. Primary outcome measures were the patient's participation in society and quality of life one year after the cardiac arrest. Secondary outcome measures were the patient's level of cognitive functioning, emotional state, extended daily activities and return to work, as well as the caregiver's quality of life, strain and the emotional state. We assessed all the outcome measures for the effect evaluation three times: at two weeks (baseline), three months and twelve months (endpoint) after the cardiac arrest. More details about the administered measurement instruments can be found in the study protocol [12].

'Work situation' was a socio-demographic variable in the protocol, but since return to work is an important variable reflecting societal participation, it is now reported as a secondary outcome measure. 'Return to work' was defined as partial or complete return to a paid job.

The EuroQol 6D was administered as a cost-effectiveness study parameter and is therefore not included in this effect evaluation.

At baseline, we recorded socio-demographic and medical variables together with some measures of functioning (left ventricular ejection