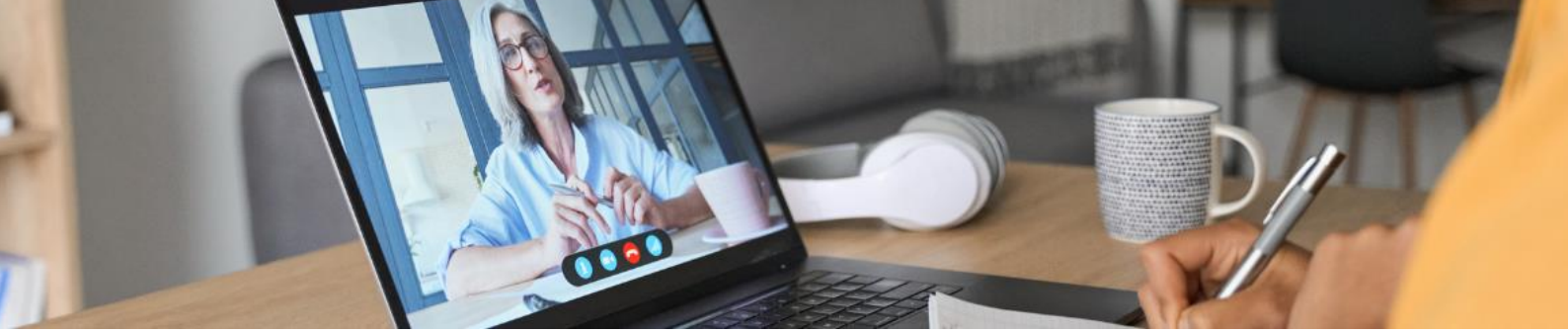

CARESS

Cardiac Arrest Recovery Enablement and Supported Self-management **feasibility** study

Participant Information Sheet

Co-survivors

Warwick Medical School:	Professors Kirstie Haywood, Julie Bruce, Harbinder Sandhu, David Ellard, and Drs Keith Couper, Rebecca Kandiyali, Anower Hossain
University Hospitals Coventry and Warwickshire NHS Trust:	Dr Nathan Pearson, Professor Gordon McGregor
Public Research Partners:	Mr Paul Swindell, Mr Stuart Menzies

We are inviting you take part in a research study funded by the National Institute for Health Research (NIHR), Research for Patient Benefit (RfPB) programme.

This information sheet gives you some detail about the CARESSf study and your involvement should you choose to take part. Thank you for reading this and for thinking about being part of the study. Talk to others about the study if you wish and please feel free to ask any questions. If you want to join the study or have any questions, please contact Professor Kirstie Haywood or Dr Nathan Pearson on the following email CARESS@warwick.ac.uk.

FUNDED BY NIHR | National Institute for Health and Care Research

WARWICK MEDICAL SCHOOL

NHS University Hospitals Coventry and Warwickshire NHS Trust

Why are we doing this study?

A cardiac arrest occurs when someone's heart suddenly stops beating. In the UK, around 5,500 people survive their cardiac arrest each year. For most of these people, life is never the same again. Many cardiac arrest survivors have long-term problems with memory, emotions, fatigue, physical and social difficulties which can reduce their quality of life. People are often anxious about carrying out daily activities.

These changes can also be upsetting for family members and co-survivors, particularly if they were present at the time of the arrest. As well as caring for the survivor and the changes in the survivor, this can include processing the trauma of the event, and emotional concern that there will be a repeat event. They may also experience long-term emotional difficulties and become anxious about day-to-day activities.

However, little is known about how to support survivors and their family members after returning home from hospital. Unlike with other conditions such as stroke and heart attack, a care pathway for cardiac arrest survivors and their families is not available. Some may need specialist care and support. Some survivors attend cardiac rehabilitation, but this may not address their specific physical and emotional needs and attendance is often poor. Family members and co-survivors receive very little support. Survivors and their families have said that they need more help and support on their recovery journey once they have returned home from hospital.

We have worked together with cardiac arrest survivors, their families and co-survivors, and healthcare professionals to develop a new on-line programme of one-to-one and group education, support, and exercise rehabilitation for cardiac arrest survivors, provided soon after they return home from hospital. We have also developed a similar programme of education and support for family members or co-survivors impacted by the cardiac arrest.

We now need to test the programmes with up to 30 survivors and 30 family members or co-survivors to see if they can be delivered in the NHS. Talking to people after they have finished the programme will help us improve it and ultimately improve care for survivors and co-survivors.

Why have I been asked to take part?

We are asking you to take part in this study because you are:

- A family member or co-survivor of someone who has survived a cardiac arrest within the past 12 months.

This means that you have first-hand experience of what life after a cardiac arrest is like, and the challenges that co-survivors may experience. Other people may not know or understand these things.

We will be inviting up to 30 family members or co-survivors from across England to take part. Up to 30 cardiac arrest survivors are also being invited to take part.

Who is eligible for the study?

Cardiac arrest survivors and family members or co-survivors may take part in the study.

As a co-survivor, you can take part if the cardiac arrest survivor:

- Had a hospital stay following their cardiac arrest that was no-longer than 30-days (1 month).
- Has returned to their home or usual place of residence
- Has had their cardiac arrest within the past 12 months.

In addition, you must:

- Be aged 18 years or older.
- Be able to read and communicate in English.
- Have basic computer literacy and access to a smart phone, tablet, laptop or computer.

Do I have to take part?

Participation in this study is voluntary. If you later change your mind, you can withdraw from the study at any time without giving a reason.

If you agree to take part, we will ask you to complete a consent form. Even after completing the consent form, you can withdraw without giving a reason. If you decide not take part, or you withdraw from the study, the standard of care you receive will not be affected.

If you decide to withdraw, we will keep the information about you that we have already collected but no information that personally identifies you will be published.

What does taking part in this study involve?

Taking part in this study involves providing some information about you, completing some questionnaires about your health and wellbeing, and taking part in the care programme. There are three steps to join the study, and we have described these within this information sheet.

Step 1: Registering your interest in learning more about the study

If you are interested in learning more about the study and potentially taking part, then you can register your interest. You can do this through our study website: www.warwick.ac.uk/CARESS or by scanning the QR code in this document with your mobile phone. Registering your interest involves sharing your contact details with the research team. Within five working days, a member of the study team will telephone you to answer any questions that you might have and confirm your eligibility for the study.	

Step 2: Giving consent to take part

Following the initial call, if you want to take part in the care programme, we will send you a weblink to complete an online consent form. Once completed, we will ask you to complete an online questionnaire.

Step 3: Completing an online questionnaire

You will be asked a bit about you, your health, and your wellbeing. Some questions may appear similar, but your answers are really important. The questionnaire should take about 30 minutes to complete. You can take a break and return to the questionnaire at any time. A member of the study team may contact you if any of your responses are unclear or missing. You can contact us via the CARESS@warwick.ac.uk email address if you have any problems with the questionnaire or website.

You will be asked to complete this questionnaire again after you have completed the CARESS programme. This will help us understand if the care programme has helped you. If we have any questions for you during the study, we will get in touch.

With your permission, we will contact your GP to let them know you are taking part in the study. We will also let them know how you answered questions about your mental health and share a copy of your consent form with them. If you do not want us to tell your GP, you will not be able to take part. There may be times when the study team need to act upon confidential information for safety reasons. If our questionnaires or conversations with you highlight any health problems (physical or mental) that may require further treatment, we may refer you to your GP.

What will I have to do next?

Once you have given your consent and completed the online questionnaire, you will be enrolled into the care programme for co-survivor.

Care programme for co-survivors

If you are a family member, friend, or significant other of a cardiac arrest survivor ('co-survivor'), you will be invited to take part in an 8-week CARESS care programme. The CARESS programme is delivered by University Hospitals Coventry and Warwickshire (UHCW) NHS Trust through Atrium Health. The programme consists of two elements.

1. One-to-One online appointment (week 1)

The co-survivor involvement with the CARESS programme will commence with a video or telephone call with a study healthcare specialist who will tell you what to expect from the programme and discuss your wellbeing needs. The videocall will last up to 60 minutes. You will (also) be directed to websites where more information about the survivor's cardiac arrest recovery journey can be found. You will have a chance to ask questions about the recovery journey following a cardiac arrest.

2. Online support group (weeks 2-8)

You will also be invited to attend up to eight online group support sessions with other family members and co-survivors. Some of these sessions will also be held with cardiac arrest survivors. Each session will be led by a CARESS specialist and will last about 60 minutes. During the sessions you will be able to talk with the people in your group who are all recovering from the impact of cardiac arrest in their lives.

You will be provided with a workbook that includes general information about the CARESS study. There will also be guidance on the support sessions, spare pages to

record the dates and times of your sessions, and some worksheets to use during the support sessions.

With your consent, we will observe and record your online appointment and support sessions. This is for quality control purposes and to provide the CARESSf team with an understanding of the topics and issues that generate discussion in the sessions.

OPTIONAL - <u>you do not have to agree to the following:</u>

1. **Interview:** with your consent, we may invite you to take part in an interview to explore your experience of being in the study and how it made you feel. If you are interested in this, we will send you a separate invitation with further information to help you decide.

Sharing your information: The CARESS programme is delivered by University Hospitals Coventry and Warwickshire (UHCW) NHS Trust through Atrium Health, and the University of Warwick. To ensure smooth delivery and monitoring, we will securely share your personal information (for example, your name, contact details, and other relevant data) with teams at UHCW, Atrium Health and the University of Warwick. Your information will remain confidential and will only be shared with authorised personnel for the purposes of the CARESS care programme. It will not be shared outside of these organisations, except when necessary to deliver the intervention or for essential programme coordination and monitoring.

Do I need a computer to take part in the study?

You will need internet access, an email address and use of an electronic device to fill in the questionnaires, and make video calls and receive text messages. This can be a smart phone, tablet, laptop or computer. The device needs to have a camera that faces you, so we can see you during video calls.

We will use videocalls for the appointment and support sessions. The study team will be available to help you with the use of computers, tablets, phones, and other devices for video calls.

What should I expect from an online group support session?

The online group support sessions will take place via a third-party online video platform which uses Zoom. The CARESS specialist will provide you with a link to this website and ask you to register an account. The website will ask you to read and agree to the terms and conditions, then register an account using your name and email address.

During the online group you will be visible on screen to the CARESS specialist and the other people in the group. You can choose to remain anonymous by creating a nickname to be displayed in place of your real name. This will allow the CARESS specialist to collect information on your health. Any data collected in this way will be encrypted and stored safely to NHS Digital and UK Government standards.

How long does the study last?

The care programme lasts for just 8 weeks. Within 3 weeks of completing the programme, we will ask you to complete the study questionnaires again. These are the same questionnaires you will complete at the start of the study.

What are the benefits of taking part?

Although this study may not offer you any direct benefit, you may find the opportunity to speak to others within the care programme helpful. Further, the findings from this study may help people recovering from cardiac arrests, and their co-survivors, in the future.

What are the risks of taking part?

Sometimes, people may find the support sessions upsetting. Our specialist staff are fully trained and will provide appropriate support and assistance if needed.

What if I have concerns about the programme?

If you have any concerns about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you are still not happy, any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of Warwick official entirely independent of this study:

Head of Research Governance
University of Warwick, Research & Impact Services
University House, Kirby Corner Road, Coventry, CV4 8UW
researchgovernance@warwick.ac.uk; Telephone: 024 765 75733

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter: DPO@warwick.ac.uk.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

How will we use information about you?

University Hospitals Coventry and Warwickshire NHS Trust (UHCW NHS Trust) is coordinating and delivering this study in partnership with Warwick Medical School at the University of Warwick (UoW). This means they will act as joint data controllers for the study, and together, are responsible for looking after your information and using it appropriately.

To run the study, we will need to collect some personal information. This will include your name, email address and contact information. If you are eligible to take part and consent, we will also ask you to provide some information about yourself such as your age, ethnicity, education and so forth. This information will support the research, and may be used as part of routine checks to make sure the research is being done properly. Information will only be shared on a need-to-know basis and people outside of the study will not see your name or contact details. Your data will be assigned a unique identifying code to protect your identity where it is shared – this is called pseudonymisation. In this way, we will keep all your personal information safe and secure.

NHS sites will pass your details to UHCW NHS Trust and UoW, along with information collected from you and your medical records. The only people at UHCW NHS Trust and UoW who will have access to information that identifies you, will be people who need to contact you about the study, exercise specialists leading the online groups, people who follow up on your progress or check questionnaires are completed, people who host the database where your information will be stored, or people who will audit the data collection process. If you are interested in taking part in the study but are later deemed ineligible, your contact details will be disposed of securely within 6 weeks.

If you are recruited to the study through an NHS site, only necessary personal information (for example, your name, date of birth, recruitment dates) will be shared with the NHS where necessary. This is for recruitment monitoring purposes and will be recorded at sites as per their recruitment reporting processes. This data will be stored securely, accessed only by authorised staff, and pseudonymised where appropriate.

The people who analyse study information will not be able to identify you and will not have access to your name or contact details. NHS sites will keep identifiable information about you from this study for a minimum of 10 years after the study has finished. If you agree to take part, and with your permission, your GP will be notified that you are taking part in this study and a copy of your consent form will be shared with them.

With your consent, UHCW NHS Trust and UoW will collect information about you for this research study from you and your medical records. This information will include health information which is regarded as a special category of information. If you agree to take part, we may use information collected for future research. Any future research will only proceed if approved by a Research Ethics Committee where necessary.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data that we hold about you. UHCW NHS Trust and University of Warwick have policies and procedures in place to keep your data safe. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

For further information, please refer to the privacy statements by UHCW NHS Trust and UoW, or contact the Legal and Compliance Team at GDPR@warwick.ac.uk.

UHCW privacy statement: www.uhcw.nhs.uk/privacy

UoW privacy notice: https://warwick.ac.uk/services/idc/dataprotection/privacynotices/researchprivacynotice.

Where can you find out more about how your information is used?

You can find out more about how we use your information at:

- www.hra.nhs.uk/information-about-patients/

- Our leaflet available from www.hra.nhs.uk/patientdataandresearch
- By asking one of the research team (CARESS@warwick.ac.uk)
- By sending an email to Warwick Group Data Protection Officer at dpo@warwick.ac.uk

What will happen to the results of the study?

On completion of the study, we will publish the findings in medical journals and at medical conferences. You will not be identified in any reports or publications. Once all participants have been followed up and the results have been analysed, we will make a copy of the study results available on the study website: www.warwick.ac.uk/CARESS.

Thank you considering participating in our study.