The impact of psychological distress on recovery from injuries sustained in a traffic crash

‘The IMPRINT study’

INFORMATION FOR CONTROL PARTICIPANTS

What is this study about?
You are invited to participate in research investigating the psychological and physical impact of road traffic injuries on health and quality of life. The aftermath of a motor vehicle accident can be distressing. This study is designed to assess the extent of distress by measuring the variability of heart rate, known as Heart Rate Variability (HRV), in relation to psychological and physical health following a motor crash injury. HRV assesses time between heartbeats and is a measure of how well physiological and emotional processes are regulated. These results will be compared with the results of people (controls), who have not experienced an injury resulting from a motor vehicle accident within the last 5 years. The objective is to investigate whether HRV may predict higher rates of psychological and physical distress following a motor vehicle crash.

You have been asked to take part in this study because:
- you are aged 18 years or over,
- you have not experienced a land transport accident or serious injury within the last 5 years.

Who is running the study?
This study is being conducted by the John Walsh Centre for Rehabilitation Research in the Faculty of Medicine, The University of Sydney in collaboration with two hospital sites (RPAH and RNSH). The study is funded by a research grant NSW State Insurance Regulatory Authority or SIRA (previously the Motor Accident Authority or MAA), who wish to improve recovery in people who experience injury in a motor vehicle crash. The principal investigators are: Prof. Ashley Craig, a Clinical Psychologist, and Dr. Ilaria Pozzato, a Rehabilitation Physician.

What will the study involve for me?
If you agree to participate in this study, you will be asked to sign the Participant Consent Form. You will be then be asked to undertake a 20 minute electrocardiograph (ECG) recording from which heart rate variability (HRV) is obtained. ECG and HRV are non-invasive techniques involving no pain and are completely safe. The ECG recording session will occur once at the time of your enrolment. This will be conducted in the laboratory of Kolling Building at the Royal North Shore Hospital or alternatively at the Royal Prince Alfred Hospital, and it will not take more than 30 minutes overall.
You will also be asked to complete an online questionnaire. The online website is secure and it allows for rest breaks, if you feel the need for a rest. The website will immediately send an email to you with details of how to log back in and continue the online questionnaire later on. You will be asked questions about your psychological and your physical health status. The survey will take approximately 30 minutes to complete. Following the initial contact, you will be asked to complete the online assessment again at various times (3, 6 and 12 months), for follow-up about your health.

**What are the possible benefits of taking part?**
The information you provide about your health status will help us better understand the processes which contribute to the risk of psychological and physical distress following a motor vehicle crash. Your contribution will enhance medical knowledge to assist the development of innovative interventions and the improvement in compensation schemes in NSW. If you decide to take part in the study, you will receive a reimbursement of $50 for travel cost and time (Gift card).

**What are the possible risks and disadvantages of taking part?**
This is a research study and no treatment is involved. However, answering some of the questions may cause you to become upset or distressed. Please remember that you may decline to answer a question at any time and if you become distressed you can contact us and we will discuss this with you. We will also call you after your involvement to ask whether the assessment caused any distress and if needed, we will provide suggestions for referral to professional counsellor.

**What will happen to information about me that is collected during the study?**
We want to reassure you that no information is shared with third parties other than the researchers involved in the study. All information is de-identified at the end of the study. Maintaining the confidentiality of your information is of upmost importance to us. Computer files storing this information will be password protected at all times and stored on secure servers maintained by The University of Sydney Information and Communication Departments. Paper copies are stored in a locked cabinet at The John Walsh Centre for Rehabilitation Research. Additionally this information will be stored separately from your contact details. After the final follow-up interview and checking of data all identifiers in computer files and paperwork will be destroyed. Information will only be disclosed with your permission except as required by law (in this case, confidentiality cannot be guaranteed). The data gathered for all of the participants will be combined and analysed. Reports that are published will not identify any person in the study. All information collected during the study will be confidential and handled under guidelines set out by the National Health & Medical Research Council (NH&MRC).

**Do I have to be in the study? Can I withdraw from the study once I've started?**
Being in this study is completely voluntary and you do not have to take part. If you decide to take part and later change your mind, you are free to withdraw your participation without reason at any time. You may also refuse to answer any questions in the questionnaire that you do not wish to answer. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine care, or your relationship with any other of your medical and health profession staff. We would like you to consent to participate in this study as we believe that you can make an important contribution to this medical research.

**Further information and who to contact**
If you want to take part into the study or you would like to know more at any stage, please contact Dr Ilaria Pozzato on 02 99264962 or e-mail her at ilaria.pozzato@sydney.edu.au. Dr Pozzato is involved in this study as a doctoral candidate. Her primary investigator colleagues are also highly experienced clinicians and researchers at the Sydney University John Walsh Centre for Rehabilitation Research.
Please leave your name, your telephone number and your email address. Our research team from The University of Sydney will contact you on your preferred contact to schedule an appointment and to provide you with instructions on how access the online questionnaires.

Ethics Approval and Complaints
This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on 02 9515 6766 and quote protocol X15-0312.

Thank you for taking the time to consider this study.

If you wish to take part in it, please sign the attached consent form.

This information sheet is for you to keep.