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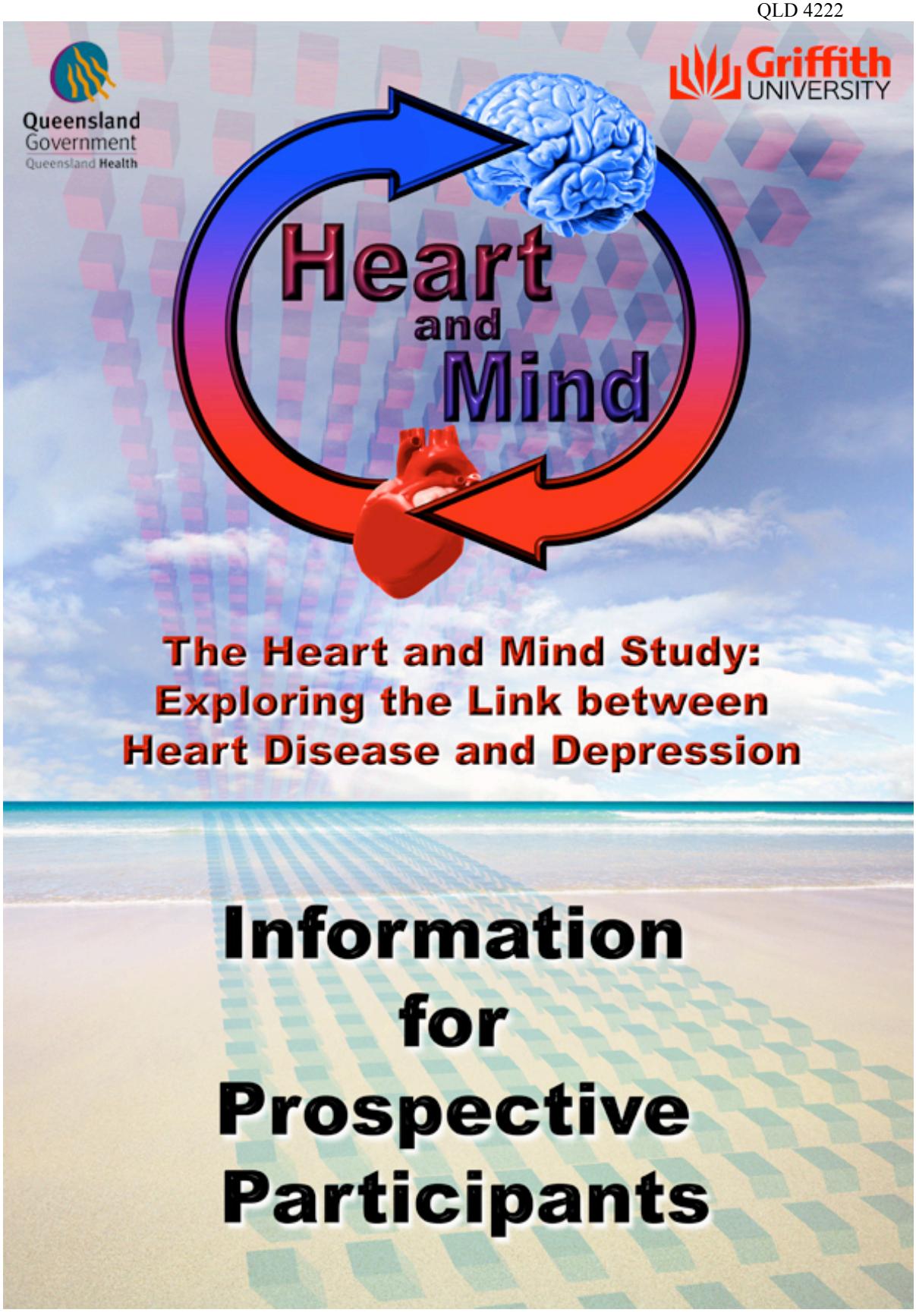

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THE HEART AND MIND STUDY

Quantitative relationships between clinical measures of depression and heart rate variability as measured by linear and non-linear methods.

INFORMATION SHEET

Why is this research being conducted?

The findings of this study are expected to help us learn more about the relationship between heart rate variability and mood changes such as depression. This knowledge is relevant to the practice of psychiatry as well as clinical psychology as it will help us understand how the heart and the mind influence each other and may even lead to a way of using heart rate variability to measure depression.

Who is conducting the research?

The chief investigators are:

Dr Chris Stapelberg (Contact Person) School of Psychology C/o Gold Coast Hospital Ph 0405 015 430 Email: C.Stapelberg@griffith.edu.au	Associate Professor David Neumann School of Psychology Gold Coast Campus Ph: 555 28307 Fax: 555 28291 Email: D.Neumann@griffith.edu.au	Professor David Shum School of Psychology Mt Nathan Campus Ph 373 53370 Email d.shum@griffith.edu.au
Professor Harry McConnell Consultation Liaison Psychiatry Gold Coast Hospital Ph 5519 8211 Email: Harry_McConnell@health.qld.gov.au	Professor Ian Hamilton-Craig Department of Cardiology Gold Coast Hospital Ph 5519 8211 Email: Ian_Hamilton-Craig@health.qld.gov.au	

The co-investigators are:

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The following study is being conducted as part of a PhD research project by Dr Stapelberg. The PhD research project is being supervised by Dr. Neumann and Professors Shum, McConnell, and Hamilton-Craig.

What you will be asked to do.

Your participation will involve the following activities:

- You will undergo a standardised medical examination, particularly a cardiovascular examination. This will be performed by your general practitioner or by another community doctor. Your consent will be sought to provide that examination information to the researchers.
- You will be asked to consent to your general practitioner or another community doctor referring you for Cognitive Behavioural Therapy Treatment if you are found to be suffering from depression.
- You will be asked to attend the cardiology department at the Gold Coast Hospital to undergo a 24 hr Holter monitor assessment. This will involve carrying a cigarette-packet-sized device, with leads, which are attached to the chest above the heart, for one day. The device will be fitted at the Gold Coast Hospital and then you will be free to return home. The next day the device will be removed at the Gold Coast Hospital, having recorded 24 hours of data about your heartbeat.
- You will undergo a formal psychiatric evaluation for about one and a half hours. As part of this process you will be asked to complete a Hamilton Depression Rating Scale, a Beck Depression Inventory and a Hamilton Anxiety Rating Scale.
- After the initial process you will be asked to return every two months for a follow-up appointment. You will be followed up for one year. Therefore, you will have the initial assessment plus six follow-up visits, a total of seven contacts with the research team.
- The follow-up appointments involve a brief mental health review, which includes filling out a Hamilton Depression Rating Scale, a Beck Depression Inventory and a Hamilton Anxiety Rating Scale each time. This will take about 30 minutes. You will also undergo another Holter study as part of each follow-up.
- The follow-up visits will be entirely separate from any treatment you receive for depression or for heart disease, or from any cardiac rehabilitation program.

What will happen if you are found to suffer from a medical condition that was previously undiagnosed?

- If you are found to suffer from depression from this assessment, options for suitable treatment will be discussed with you. One recommended treatment for mild to moderate depression is a talking therapy called Cognitive Behavioural Therapy or CBT. More information on CBT is given below.
- If the Holter study should show any incidental medical conditions such as an arrhythmia (irregular heart beat), options for further testing and treatment will again be discussed with you.
- In the event of the above medical conditions, or any other medical condition, being

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discovered, you will have the option of being referred to your regular general practitioner doctor, your regular specialist doctor, or another doctor or clinician as needed. If this happens, the reasons for this will be discussed with you, and you will then (at that time) be asked to make an informed decision as to whether you want such a referral to occur or not. You should note that consenting to the study is separate from consenting to any medical treatment. Also, just like you have the option to exit out of the study at any time, you also have the option to refuse any further medical testing, medical treatment or medical follow-up.

- If you are found to be suffering from depression and assigned to the Cognitive Behavioural Therapy program linked to the study, you will be asked to consent to your therapist being able to pass important information (for example that your mental health may be deteriorating) to the principal researcher, and *vice versa*. Again, if this needs to happen for any reason, your permission will be asked again at that time.
- If your regular doctor considers that it is important that they pass on certain clinical information about you to the researchers, they will also ask your permission to do so.
- All such clinical information will be subject to strict confidentiality.

What is Cognitive Behavioural Therapy (CBT)?

Cognitive Behavioural Therapy or CBT is a form of psychological talking therapy or counselling that is used by many clinical psychologists, psychiatrists and counsellors. CBT therapy is based around helping people understand, manage and change their thoughts (cognitions) and actions (behaviour), to better cope with stress, depressed feelings and also anxiety. This form of therapy has been shown to be very effective for many mental health problems but is particularly effective for depression and anxiety.

Cognitive behavioural therapy can help people to identify and change negative thinking patterns which are associated with depressed feelings. As part of CBT people can also learn techniques for relaxation or dealing with anxiety attacks. CBT also helps by teaching techniques to focus on the positive things and to think about depressing or anxiety provoking aspects of life in new ways which help people to cope with them better. Cognitive behavioural therapy thus allows people to learn new strategies for managing problems which previously would have seemed overwhelming and would lead to feeling depression or anxious.

Why is Cognitive Behavioural Therapy (CBT) used in this study?

CBT is currently one of the recommended treatments for people who suffer mild to moderate depression. According to the Royal Australian and New Zealand College of Psychiatrists Clinical Practice Guidelines for Depression, psychological treatments are preferred over medication for mild depression, and for moderate depression, treatment with CBT is as good as other alternatives such as Interpersonal Therapy (another form of taking therapy) or some antidepressant medication. Studies thus do suggest that CBT is an effective and appropriate treatment for people with mild to moderate depression, although participants should be aware that there are several ways to treat depression, of which CBT is one option.

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CBT is being used in this study because:

- CBT is a safe and effective treatment which is as good as other treatments for mild to moderate depression, including some antidepressant medication
- CBT is a clinically recommended treatment for mild or moderate depression
- It is a highly standardised treatment which has been widely evaluated and studied. This makes it very good for research purposes as well as being an effective treatment.
- This study cannot follow participants using antidepressant medication, as medications can influence the heart data which is being collected with the Holter monitors, which can artificially change the study results

If participants require or wish to commence antidepressant medication, they will leave the study, but this will in no way affect ongoing treatment.

The basis by which participants will be selected or screened

The following people are not eligible to participate in the study:

- People under the age of 18
- People who do not have the capacity to provide consent for the study for any reason.
- People with chronic medical illnesses like diabetes
- Pregnant women
- People with intellectual impairment or who have suffered a brain injury
- People who are dependent on any substance such as alcohol
- People with longstanding mental illnesses such as bipolar disorder, schizophrenia or chronic depression are not eligible to participate in the study
- People under the Mental Health Act 2000 are not eligible to participate in the study

Risks to you

The experiment will involve a Holter monitor assessment of your heart rate. The Holter monitor is non-invasive (no part of it enters inside your body) and should provide minimal discomfort when worn.

Your confidentiality

Confidentiality of the data will be maintained whereby the consent form and medical and psychiatric interview results will be stored separately from the rest of the data. Numerical codes only will be used for identifying Holter data and data from the depression and anxiety inventories.

Your participation is voluntary

Participation in this research project is voluntary and you may withdraw at any time without penalty or explanation. Refusal to participate or withdrawal will not involve any penalty or loss of benefits to which you might otherwise be entitled.

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Refusal to participate or withdraw will not affect your medical care in any way. If you entered the study as a depressed patient, for example, you will continue to receive appropriate treatment from your doctor or psychologist, who is separate from this study. Your relationship with the School of Psychology and Griffith University will not be affected if you are a student. If you wish to withdraw from the study at any time, please contact Dr Stapelberg at the contact number given above. In the event that you do withdraw from the study, we will ask you to choose what to do with any medical information about you – we can pass the information on to your general practitioner or have it destroyed if you leave the study.

Questions / further information

Any matter or concern regarding the research can be raised with the chief investigator on the contact details provided above.

The Ethical Conduct of this Research

Griffith University conducts research in accordance with the National Statement on Ethical Conduct in Human Research. If you have any concerns or complaints about the ethical conduct of this research project you should contact the Manager, Research Ethics, at Griffith University Human Research Ethics Committee on 3735 5585 (research-ethics@griffith.edu.au) or the Gold Coast Hospital Human Research Ethics Committee on 5519 8010 (GCHEthics@health.qld.gov.au).

Feedback to you

Feedback can be provided at the end of the study to inform you of the results obtained. Participants who would like a summary of the findings e-mailed to them upon completion of this project can indicate this on the consent form. If you would like a summary of the results please indicate this by ticking the box indicated on the consent form. The experimenter will record your e-mail address on an separate sheet so that a summary can be e-mailed to you. The research results are completely de-identified, which means that no personal details will be published or given out, only the statistical findings of the project.

Privacy statement

The conduct of this research involves the collection, access, and / or use of your identified personal information. The information collected is confidential and will not be disclosed to third parties without your consent, except to meet government, legal, or other regulatory requirements. A de-identified copy of this data may be used for other research purposes. However, you anonymity will at all times be safeguarded. For further information consult the University's Privacy Plan at http://www.griffith.edu.au/privacy-plan or telephone (07) 3735 5585.