UNIVERSITY of OTAGO
Te Whare Wānanga o Otago

DEPARTMENT OF PSYCHOLOGICAL MEDICINE

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Targeting Functional Recovery in Mood Disorders
Information for Healthy Participants

Introduction
You are being invited to take part in a research study being conducted by Professor Richard Porter, Professor Marie Crowe, Dr Maree Inder, Dr Jennifer Jordan, Dr Katie Douglas, Professor Roger Mulder, Professor Peter Joyce, Dr Cameron Lacey, Dr Ben Beaglehole, Dr Dave Carlyle, Associate Professor Sue Luty, Dr Chris Frampton, Dr Richard Tranter, Dr Giles Newton-Howes, and Dr Trudy Sullivan.

It is important for you to understand why the research is being done and what it will involve. Please take the time to read over this information sheet carefully and to ask us if there is anything that is not clear or if you would like more information. You are free to discuss this study with others to help you make a decision. You are welcome to ask a support person to join you in asking more questions about the study.

What is the purpose of the study?
People with mood disorders, such as bipolar disorder and depression, often have problems with functioning in everyday life, such as problems in their work and relationships. This may be, in part, because mood disorders are associated with difficulty in areas of brain functioning such as thinking, planning and memory. Talking therapies (psychological therapies) focus on thoughts and feelings to improve mood, but we think adding specific help and practice in the areas of planning, thinking and memory will help to improve brain and everyday functioning in people with mood disorders.

What will I have to do if I take part?
People with mood disorders who are taking part in this study will be asked to complete a cognitive assessment at baseline and at 12 and 18 months in order to find out whether their cognitive functioning (e.g., thinking, planning and memory) is improved by the treatment they are receiving. To be certain that it is the treatment that is improving cognitive functioning in the group with mood disorders, we need to recruit healthy individuals from the general population who are not receiving the treatment to determine if and/how their cognitive functioning changes over the same period of time. Problems with cognitive function might be related to immune system activity in the body. Therefore, we will be taking blood samples to measure substances that may indicate an immune system activity.

Your participation in the study will first involve answering some questions on the phone with one of our research team to check you are eligible to take part in the study. This will include answering questionnaires that assess mental health symptoms. If eligible, you will then complete a cognitive assessment which will take about one and a half hours. During this assessment you will perform tasks on a computer, and using pen-and-paper, that will measure your memory, attention, and organisation. At 12 and 18 months, you will return to the Department to complete the same cognitive assessment.

Blood tests

We are interested in blood tests which indicate that the immune system is active. At the moment, these tests measure a substance called interleukin. However, new tests for immune system activity and new substances which show that the immune system is active are still being discovered. Therefore, other immune system substances may be measured. Blood samples will be identified only with a code and no identifying information will be included with them. Blood samples will be retained for a minimum of 10 years after completion of the study. If you decide to withdraw your consent to the storage of your blood samples during this storage period, you may do so by contacting the Clinical Research Unit, Ph 3726 700, or by writing to the address at the end of this Information Sheet. Samples will be disposed of using standard laboratory procedures for disposal (in accordance with NZS 4304.2002 "Healthcare Waste Management"). If you prefer, your samples will be disposed of with appropriate karakia, in accordance with "Rangahau e pa ana ki te Maori: Research involving Maori - Guidelines for disposal or retention of samples and specimens". Blood samples will be analysed in New Zealand.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are free to withdraw at any time without giving a reason.

What are the risks involved in taking part in the study?
We do not think it is likely that there will be any major risks in participation. There may be discomfort when thinking or talking about personal issues during completion of the questionnaire asking about mental health symptoms.

Will I receive compensation for time taken to be part of this study?
Yes, you will receive $100 in MTA vouchers to compensate you for the time taken.

Will my taking part in this study be kept confidential?
All material that you provide us will be treated in the utmost confidence. We will hold research information about you on a computer in the Department of Psychological Medicine in

Christchurch. The study has a security system which ensures that all information you provide is stored in anonymous form on computer files and that no data that can be linked to an individual can be accessed without knowledge of this security system. Only those directly involved in the study will have access to this information and we will ensure that confidentiality is kept. Your identity will not be revealed in any reports based on this study.

If in the course of the research we discover information which is important to your continued health and safety we will discuss this with you and ask your permission to convey this to your GP.

What will happen to the results of the research?
We plan to finish the study by the end of 2020 and to submit the results for publication in science journals. If study findings are positive, we will discuss findings with mental health service providers in the hope of incorporating the psychological intervention under study into standard care. The identity of the participants will not be made public during this discussion.

Where can I get information about the study?
Emily Douglas may be contacted by telephone or email: Phone: 03 3726 700, Email: emily.douglas@otago.ac.nz

*This study has been approved by the **NZ Health and Disability Ethics Committee (Southern Branch).** If you have any concerns about the ethical conduct of the research you may contact the Committee through the Human Ethics Committee Administrator (ph 64-3-479 8256 or gary.witte@otago.ac.nz). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.*