Government of South Australia
SA Health

FLINDERS UNIVERSITY
ADELAIDE • AUSTRALIA

School of Psychology

Reg Nixon, Ph.D.
School of Psychology
GPO Box 2100
Adelaide 5001
South Australia
Telephone: (+61 8) 8201 2748
Fax: (+61 8) 8201 3877
Email: reg.nixon@flinders.edu.au
http://www.ssn.flinders.edu.au/psyc/

PARTICIPANT INFORMATION SHEET

The effectiveness of combining cognitive processing therapy with case formulation in treating PTSD.

This is a research project, and you do not have to be involved. If you do not wish to participate, your medical care will not be affected in any way and we will discuss with you appropriate referrals to access treatment without any prejudice to you.

Aims of the project

You are invited to take part in a study researching a way to make a therapy known to be effective, Cognitive Processing Therapy (CPT), even more effective. CPT was designed to help people recover after experiencing a traumatic event such as a motor accident, industrial accident, physical or sexual assault. It is a manualised form of trauma focused cognitive behavioural therapy which looks at how your beliefs about the trauma can interfere with how you have processed the trauma or cause other symptoms, and provides other ways of thinking. The study is being conducted by Professor Reg Nixon and Ms Marja Elizabeth (registered psychologist and PhD student) from Flinders University.

This letter is to inform you of the aims of the project and outlines what is involved. It also outlines the benefits, risks and confidentiality associated with the project.

Summary of involvement

If you choose to take part in the study, you will be asked to participate in assessments and therapy held in the School of Psychology, Flinders University or Yarrow Place Rape and Sexual Assault Service. There will be three assessments: one before therapy begins, one just after therapy has finished, and another six months after therapy has finished. At these assessments you will participate in an interview with a registered or advanced trainee psychologist (mimumum one year post trainee registration) and you will also be asked to complete questionnaires. The assessment interviews will involve asking about things such as previous life experiences and previous psychological difficulties. You will also be asked about the trauma and your current adjustment to that trauma. The questionnaires will ask about your current reactions to the trauma, your beliefs about the trauma and general questions about your emotions. You do not have to answer all questions, and may skip any that you find too difficult to answer. With your permission, parts of the interview will be voice-recorded. This taping is done so that we can check that the interviewer is asking the questions in the correct fashion. Each interview could take up to 1.5 hours, and it could take up to 1 hour to complete the questionnaires.

The research study uses a randomised controlled design, meaning that participants will be allocated to one of two treatment groups by chance, like flipping a coin. Both groups will be receiving Cognitive Processing Therapy (CPT). CPT involves looking at how your beliefs about the trauma may affect your recovery. The therapy helps you develop different ways of thinking to help you recover from your symptoms. CPT has

been shown to be effective in treating posttraumatic stress. As part of the current study, one of the groups will include adding 'case formulation' to the CPT, which means working with your therapist to individualise therapy to your particular needs. This may mean spending more time working through posttraumatic issues that are particularly important/troublesome for you, adjusting the overall length of therapy (e.g., being shorter if required) and/or including other effective therapies/techniques that may assist with other issues that may be hindering your treatment progress (e.g., sleep problems, depression, general anxiety etc.). Therapy will involve attending one 60-90 minute session each week, for between 12-15 weeks. Therapy will be conducted by registered or advanced trainee psychologists (mimumum two years post trainee registration).

With your permission, therapy sessions will be video recorded so that we can check that the therapists are conducting the treatment the way it should be delivered and to allow for assessment of emotional expression. The tapes may be randomly checked by another researcher (who is not directly involved in the study). Please be assured we will be using a secure method of sending any tapes to researchers to protect your confidentiality. The videos will not be accessed by any one else not directly related to your therapy. Recordings will be stored in a secure and confidential manner and will be destroyed 15 years after the completion of the study. We also seek permission to access your medical files in order to document any injuries you may have sustained in the truama and medications you may be receiving (if applicable).

Benefits

Although we cannot predict whether you will benefit from the treatment offered to you in this study, people who have received similar therapies in the past have reported to have gained at least some benefit. It is hoped that the information gathered in this research will help increase understanding of the best ways to offer treatment to individuals who have been traumatised. At the final interview (6 months after therapy has finished), we will discuss with you possible referrals for additional therapy if you believe this might be useful.

Risks

Although there are no anticipated risks in participating in the research, at times you may think about experiences that are sensitive or distressing. You will be seeing a trained therapist who is experienced in discussing such matters, and who will help you work through any difficult emotions during the course of therapy. Further, Assessment and Crisis Intervention Services (ACIS; 13 14 65) and Lifeline (13 11 14) can be contacted at any time should you experience anxiety or distress out of office hours.

Non Participation and/or Withdrawal

Your participation in the study is entirely voluntary and you have the right to not participate or withdraw from the study at any time. If you decide not to participate in this study or if you withdraw from the study, you may do this freely without prejudice to any treatment at the School of Psychology, Flinders University or at Yarrow Place. In that event we will make appropriate referrals within Yarrow Place or to an alternative service who will discuss treatment options with you.

Confidentiality

All records containing personal information will remain confidential and no information that could lead to your identification will be released, except as required by law. All information gathered through your interviews and questionnaires will be coded with a number so that it cannot be linked to you. The recordings of your interview and therapy sessions will be labelled with a code and will not contain any identifying information. It is also your right to obtain copies of certain parts of information gathered during

the research should you wish. Please be aware that certain materials or information cannot be released if you do not possess the appropriate professional qualifications required for their interpretation.

You should be aware that data gathered through this research may be published or presented at conferences, but you will not be able to be identified in any manner in these publications/presentations.

Complaints and questions

If you would like more information about the project or have concerns, either before, during or after the study, please contact the Chief Investigator, Professor Reg Nixon, School of Psychology, Flinders University, GPO Box 2100, SA 5001, phone: 8201 2748, or email: reg.nixon@flinders.edu.au.

This study has been reviewed by the Women and Children's Health Network Research Ethics Committee. Should you wish to discuss the study with someone not directly involved, in particular in relation to matters concerning policies, your rights as a participant, or should you wish to make a confidential complaint, you may contact the Administrative Officer – Research, Brenda Penny on 8161 6521.

Thank you for your attention and assistance.
Yours sincerely,

Professor Reg Nixon