PATIENT INFORMATION SHEET

A DESCRIPTIVE STUDY OF BREAKTHROUGH PAIN IN CANCER PATIENTS RECEIVING PALLIATIVE CARE

You are invited to take part in a study that looks at breakthrough pain, what it means to you and the ways that you manage this pain.

Breakthrough pain refers to pain that flares up temporarily when your normal level of pain has been controlled or reduced to a mild or moderate level. It may occur as a result of something you have done, eg. a more active day, or it may flare up for no apparent reason.

Purpose and Duration of the Study

This study will describe the frequency, duration and intensity of breakthrough pain and also look at any patterns in the pain episodes of cancer patients receiving palliative care. It will also look at the ways people manage their pain and what breakthrough pain and their illness means for them. There is still a lot that we do not know about breakthrough pain and this study will attempt to provide information that may be of assistance in managing breakthrough pain in the future.

This study will take place over a period of seven consecutive days, preceded by a short interview (approximately one hour) shortly before the first day.

Description and procedure of the study

Approximately 200 people will be involved in this study. We would like you to take part in an interview about your pain and the ways that you manage it. This interview will be a face-to- face interview, lasting approximately 60 minutes, either at your home, or if you prefer, at some other venue. During this interview you will be asked to complete three questionnaires: one about the meaning breakthrough pain and your illness has for you, one about your pain management strategies and another about how you are adapting to pain. You are allowed to skip any questions that you are unable or are uncomfortable about answering. We would also like you to advise us if you are participating in any other research at this time. We would like you to complete a breakthrough pain diary for a period of seven days, starting from 6 am on the day after the researcher gives you the diary. A researcher will deliver your breakthrough pain diaries to your home, when she conducts your interview. The researcher will also arrange suitable times for us to contact you or your carer by telephone, to see how you are managing, to discuss any issues that you may have with the diary and to collect your diary information. If daily phone contact is inconvenient, a suitable frequency of contact will be negotiated. These daily phone calls (or other method of contact, if special arrangements have been made) will take no more than 10 minutes.

Confidentiality

The information you provide will be treated as confidential. You will not be personally identifiable in any of the records. All the patient documents produced during the study will
contain unique numbers to identify the patients. Your name will not appear in any materials produced from this study. However direct access to your medical records will be required by the researchers, for the purpose of verifying the medications and treatments that you are receiving. Your phone number and address will also be needed so that we are able to contact you for your interviews. Two researchers will have access to this information, as well as members of the Repatriation General Hospital Research and Ethics Committee, who may monitor our work.

Voluntary Participation

Your decision to participate in this study is entirely voluntary and refusal to participate will involve no penalty or loss of benefits to which you would otherwise be entitled, including your veteran entitlement. In addition, you may withdraw from the study at any time, or elect not to participate on any day, without penalty or loss of benefits. Your medical care will not be affected by your decision to withdraw from the study.

If during the course of this study, you have questions concerning the nature of the research or your rights as a subject, you should contact:

Susan Page
School of Psychology
Flinders University of South Australia
Bedford Park SA

Work: 08 82751057 (message)
Mobile: 0414 806 212

This study has been approved by the Research and Ethics Committee at the Repatriation General Hospital, Daw Park. Should you wish to discuss the study with someone not directly involved, in particular in relation to matters concerning policies, information about the conduct of the study, or your rights as a participant, you may contact Sarah Moulds, the Executive Officer of the Research and Ethics Committee at the Repatriation General Hospital, Daw Park, Telephone 08 82751876.