

PATIENT INFORMATION SHEET

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

Protocol Number

15/2002

You are invited to take part in a study that is being conducted at Flinders University, Southern Adelaide Palliative Services and Lyell McEwin Palliative Care Service. It 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. However, there will be no direct benefits patients who participate in the study.

Participation in this study does not affect your medical treatment in any way. Your continuing care by the Palliative Care Service will be the same, whether you participate in this study or choose not to.

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 about 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 breakthrough pain. You are allowed to skip any questions that you are unable or uncomfortable about answering. We would also 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 diary 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. Only the researcher and her supervisor at Flinders University and Southern Adelaide Palliative services will have access to this information. However, you will not be personally identifiable in any of the records. All the patient documents produced during the study will contact unique numbers to identify the patients. Your name will not appear in any materials produced from this study.

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. 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 continuing care by the Palliative Care Service will not be affected in any way by your decision to withdraw from the study.

If you have any questions before, during or after the study, you may contact:

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

Work: 08 8201 2251 (message)
Mobile: 0414 806 212

The research described in this paper has been approved by the Ethics of Human Research Committee of the North Western Adelaide Health Service. As part of its professional responsibility, this committee may need to access medical records from time to time. Any such access will be made in a manner that respects and protects your privacy.

Should you wish to speak to a person not involved with the project, you can contact Paul Miller, Executive Officer, Ethics of Human Research Committee on 8222 6841.