

PARTICIPANT INFORMATION SHEET

**Study Title:** Understanding the factors of suffering (predisposing, precipitating, perpetuating and protective) for palliative care patients; and the effectiveness of gratitude journaling in the amelioration of suffering.

**Version No: 1.0**

**Version Date: 18 October 2017**

We would like to invite you to take part in a research study. Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

***Attention to the investigator: Please fill in simple layman language as you would speak to research subjects.***

1. **What is the purpose of this study?**

To explore the experiences of suffering in the palliative care patients and to understand whether keeping a gratitude journal can ease suffering

1. **Why is this study important?**

Despite suffering being the most commonly feared symptom in people who are near the end of their lives, very little research has been done to measure suffering let alone develop identify treatment that reduce suffering. This study will allow us to understand suffering better.

1. **What type of study is this?**

This study has two parts: the first part is an observation study, where we are measuring suffering and the second part involves an intervention to see if we can relief suffering.

1. **What is the procedure that is being tested? (If applicable)**

If you agree to take part in this study, you will be required to provide some information about yourself. We will be measuring your level of anxiety and depression and asking a few questions about the difficulties you could be experiencing. Following that we will be asking you about how much suffering you feel you are experiencing by using a special pictogram developed at the University of Malaya by our Palliative Medicine specialists. We will be helping you chart your level of suffering using this method over seven days. You will also be asked to write down descriptions of your suffering.

We will then be assigning you into one of two groups. One group is called the control group and one group is called the intervention group. The control group will be charting your suffering on Day 1 and Day 7, additionally you will be required to write down the things that happen around you on a daily basis for 7 days in a diary. It can be as simple as news headlines, or a joke you heard from the nurse. If you are assigned to the intervention group, we will ask you to keep a special diary which records your gratitude. It’s a simple procedure which will only take a few minutes a day. You will be randomly assigned to control or intervention groups. You need to understand that you will not be able to choose which group you will be in. We will not reveal to you which group you are in either, as this could potentially influence your answers in the final test.

1. **Does the investigatory product contain cultural sensitive ingredients eg: bovine or porcine? (if applicable)**

Not applicable

1. **Why have I been invited to participate in this study?**

We are looking for patients receiving treatment from Palliative Medicine Specialists aged 18 years and over.

1. **Who should not participate in the study?**

You should not participate if you have not been referred to Palliative Medicine or if you are not willing to talk about your illness.

1. **Can I refuse to take part in the study?**

You can refuse to take part in the study, and even if you agreed to take part you may choose to withdraw at any time. Your treatment at the hospital will not be affected in any way if you decide not to take part.

1. **What will happen to me if I take part?**

You will be visited by a member of the research team each day to assist with the seven-day suffering scoring initially. After that you will be assigned to either the intervention or control group. The researcher will show you how to fill in your daily diaries, and will contact you again at the end of seven days to repeat the suffering scores and other questions. There are no blood tests or drugs tested in this study.

1. **How long will I be involved in this study?**

7 days

1. **What are the possible disadvantages and risks?**

It may take up some of the your time. You may feel more distressed when talking about the difficulties you have been experiencing.

1. **What are the possible benefits to me?**

Taking part in the study will allow you to talk about your symptoms more which may help you take control of your illness better.

1. **Who will have access to my medical records and research data?**

Only the researcher personally.

1. **Will my records/data be kept confidential?**

Yes

1. **What will happen to any samples I give? (If applicable)**

Not applicable.

1. **What will happen if I don’t want to carry on with the study?**

You can request to withdraw from the study any time.

1. **What if relevant new information about the procedure/ drug/ intervention becomes available? (If applicable)**

Not applicable.

1. **What happens when the research study stops? (If applicable)**

Not applicable

1. **What will happen to the results of the research study?**

The results of the study will be published in top scientific journals. Once published, we will also be sharing the results with our local media through the radio and newspapers and will patient groups through the Malaysian Hospice Council.

1. **Will I receive compensation for participating in this study?**

We will not be incurring any expenditure from your part in this study, which is why we are not planning any compensation.

1. **Who funds this study?**

There is currently no funding for this study.

1. **Who should I contact if I have additional questions/problems during the course of the study?**

Name of investigator 1 **Tan Ting Ting**

Affiliation **Pusat Perubatan Universiti Malaya**

Telephone number (Mobile number) **0129130109**

1. **Who should I contact if I am unhappy with how the study is being conducted?**

Medical Research Ethics Committee

University of Malaya Medical Centre

Telephone number: 03-7949 3209/2251

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