Research Information Sheet

Research Project Title: The Effect of using Weighted Blanket on anxiety, stress, depression and comfort level among patients with cancer Undergoing Chemotherapy; a Randomized controlled study.

Sponsor: Sultan Qaboos Comprehensive Cancer Care and Research Center

Researchers: Aida Al Kindy and Fatma AlFarsi

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1. Purpose of the study:

You have been invited to take part in this study because you are scheduled to receive your first cycle of chemotherapy. The purpose of this study is to find out if the use of a weighted blanket will help reduce your anxiety, depression and stress during the treatment session. Studies have shown that a weighted blanket, which is a special kind of blanket that provide a cocooning (hugging) effect to patients can reduce anxiety and can improve your mental wellbeing.

2. Procedures to be followed:

You will be approached in the clinic and the study will be offered to you. You will be randomized to either receive the weighted blanket or the regular blanket should you need one. The ratio of randomization is 1:1. The researchers have no control over the group that you will be assigned to.

If you are assigned to the WB group, you will be provided with the blanket at the beginning of your chair time. Vital signs will be taken at the start, halfway through your treatment and at the end of your treatment. The researchers will also provide you with a questionnaire to ask about your level of anxiety and depression and assess other symptoms. The same procedures will be repeated in the 2nd cycle. In the 3rd cycle, you will not be provided with a weighted blanket but the researcher will ask you if you would agree to receive one should it become available under standard of care.

If you are assigned to the experimental arm, you will be provided with the regular blanket if you requested for one and vital signs will also be taken at the start, midway through and at the end of the chemotherapy session. The same process will be repeated for the 2nd and 3rd cycle.

3. Risks:

This study has minimal risks as the intervention is non-pharmacological. You will not be approached to participate unless you fit the criteria of the study including your safety. If you are in the WB group, you will be provided with the needed education and training as well as the safety measures of use. Please ask the nurse for help and guidance.

4. **Benefits:**

Weighted blanket has shown evidence in many settings of reducing psychological distress in patients and participating in the study will help the researchers evaluate if the WB will be useful for the population in Oman. If there is high evidence of usefulness in reducing stress, anxiety and depression in patients receiving chemotherapy for the first time, then WB can be added to the practice and all patients who can benefit from WB can be provided with one.

5. **Statement of confidentiality:**

Your participation in this research is confidential. The consent forms will be stored and secured at SQCCCRC in a locked filing cabinet. Your name will only be associated with the code number on the signed consent form. This code will not be linked to your name or family information in any data file. In the event of any publication or presentation resulting from this research, no personally identifiable information will be shared.

6. **Right to ask questions:**

Please contact Fatma AlFarsi @72727307 for any questions about this research project.

7. **Voluntary participation:**

Your decision to be in this research is voluntary. You can stop at any time. Refusal to take part in or withdraw from this study will involve no penalty and will not affect you as a patient at SQCCCRC. Should you decide to withdraw from the study at any point in the future, please contact Fatma AlFarsi @72727307.

Thank you for your participation in this research.

My agreement to be enrolled in this study

- The nature of this research and content has been explained to me in details.
- My involvement in this research is voluntary without any pressures.
- I can withdraw my involvement in this research at any time without the need of specifying any reasons or causes and without affecting the services I receive at Sultan Qaboos Comprehensive Cancer Care and Research Center. (SQCCCRC)
- I am not earning any personal gain from my participation in this research or have been given any fees or gifts.
- I have received sufficient information on the benefits expected from this research.
- I have been informed that my personal information will be managed with complete confidentiality.
- I have been informed that I can communicate with the research investigators anytime in case I want to know more about the research or withdraw from participation at any time.
- No identifiers will be collected; participants will be assigned a code e.g. WB001 or SOC001 etc.

Participant	Full Name: Signature:	Date: DDMMMYYYY
Person obtaining consent	Full Name: Signature:	Date: DDMMMYYYY
Subject code/ number		