Research Information Sheet

Protocol Title: The Effect of Using Weighted Blanket on anxiety, stress, depression, and comfort level among Patients with cancer undergoing chemotherapy and its burden on daycare nurses; a Randomized controlled study.

Sponsor: Sultan Qaboos Comprehensive Cancer Care and Research Center

Investigators	Aida Al Kindy and Fatma AlFarsi

1. **Purpose of the study:**

Anxiety, stress and depression is considered to be one of the major issues facing patients diagnosed with cancer and who are going to receive their first cycle of chemotherapy. Weighted blankets (WB) is a special type of blanket that offers deep touch pressure (DTP) providing patients with a hugging and cuddling effect. This is believed to help the patient feel calm and reduce their anxiety.

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.

Patients who are consented on this study will either be randomized to using the weighted blanket or getting the standard of care option which is the regular blanket.

You have been invited to participate in this study as the nurse who have provided care to patients who were randomized to the Weighted Blanket arm.

2. **Procedures to be followed:**

You will be asked to answer a survey about nurses' burden after caring for a patient using weighted blankets. Your responses will be anonymous. The approximate time that you may take in answering the questions is 5 to 10 minutes.

3. **Risks:**

There is no identified risk if you choose to take part in this survey.

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 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.

Your feedback about the burden you experience when providing care to patients assigned to the weighted blanket arm can affect the decision on nurse patient ration and quality improvement.

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 withdrawing 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. RN001, RN002 etc.

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

Demographic data:

Gender: Male ☐ Female ☐

Nationality: Omani ☐ Non-Omani ☐ Specify: _____

Age group:

- ☐ 20-25 years
- ☐ 26-30 years
- ☐ 31-35 years
- ☐ 36-40 years
- ☐ 41-45 years
- ☐ Above 45 years

Years of experience in nursing:

- ☐ Less than 1 year
- ☐ 1–3 years
- ☐ 4–6 years
- ☐ 7–10 years
- ☐ 11–15 years
- ☐ More than 15 years

Years of experience administering chemotherapy:

- ☐ Less than 1 year
- ☐ 1–3 years
- ☐ 4–6 years
- ☐ 7–10 years
- ☐ 11–15 years
- ☐ More than 15 years

Education level:

- ☐ Diploma in Nursing
- ☐ Associate Degree in Nursing (ADN)
- ☐ Bachelor of Science in Nursing (BSN)
- ☐ Master of Science in Nursing (MSN)
- ☐ Doctor of Nursing Practice (DNP)
- ☐ PhD in Nursing

Worked with patients on WB before: Yes ☐ No ☐

Nurses' feasibility to use Weighted Blanket (WB) for patients' survey

Nurse code: Date:

Patients' codes:

Assessment of the feasibility of using the weighted blankets on patients receiving chemotherapy for nursing staff. Please choose the option that best reflects your experience.

Based on your experience today: Please indicate your level of agreement with the following statements by selecting one option per row.

Statement	Disagree (0)	Not Sure (1)	Agree (2)
The weighted blanket (WB) was easy to apply.	☐	☐	☐
The WB was convenient and did not interfere with patient care.	☐	☐	☐
I have no safety concerns regarding patients using WBs (e.g., risk of fall).	☐	☐	☐
Patients using WBs did not require additional care (increased patients' calls, questions, etc.).	☐	☐	☐
Patients using WB looked comfortable	☐	☐	☐
I would recommend WBs to patients.	☐	☐	☐