Protocol Title: The Effect of using Weighted Blanket on anxiety, stress, depression and comfort level among Patients with cancer Undergoing Intravenous anticancer therapy and its feasibility of use by nurses compared to routine care; a Randomized controlled study.

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SQCCCRC-UMC

A Nursing Clinical Trial

Version number: 2.0

Version Date: 01MAR2026

Sponsor	Investigator-Initiated Trial (SQCCCRC)
Protocol Title	**Protocol Title: The Effect of using Weighted Blanket on anxiety, stress, depression and comfort level among Patients with cancer Undergoing intravenous anticancer therapy and its feasibility of use by nurses compared to routine care; a Randomized controlled study.**
Protocol Name	WB Chemo
Protocol Version Date	V 2.0 – 01MAR2026
Summary of Changes:	Main Changes Removed restrictions on patients on weekly anti-cancer therapy regimens, as there is no supportive evidence that anxiety is affected by the frequency of anticancer therapy. Added to exclusion criteria: Patients on daily anticancer infusions.
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1. Glossary of Terms

	Abbreviation	**Term**
1	DASS-21	Depression, Anxiety, and Stress Scale-21
2	DCU	Day Care Unit
3	DTP	Deep Touch Pressure
4	ESAS- R	Edmonton Symptom Assessment Scale-Revised
5	IV	Intravenous
6	OPD	Outpatient Department
7	VAS-A	Visual Analogue Scale- Anxiety
8	VS	Vital signs
9	WB	Weighted Blankets

2. Summary

Protocol Title: Protocol Title: The Effect of using Weighted Blanket on anxiety, stress, depression and comfort level among Patients with cancer undergoing intravenous (IV) anticancer therapy and its feasibility of use by nurses compared to routine care; a Randomized controlled study.
Study Tools: VAS-A, ESAS-R, DASS-21 and comfort level scale will be used to study the patients' population. A survey will be used to assess the feasibility of using the weighted blankets on patients receiving IV anticancer therapy.
Methodology: Consented patients will be stratified per gender then randomized to either ARM1: The interventional arm, Weighted blanket, or ARM2: The control arm, Standard of care. (Regular blanket). The weighted blanket will be administered in the two cycles of IV anticancer therapy for the interventional arm, exploring the temporal trajectory of anxiety, depression, and psychological distress, and investigating the potential of a weighted blanket intervention to mitigate these symptoms. The tools will be administered according to the study protocol. Day Care Unit nurses will be assessed on how feasible they think the blankets are for patients. **Expected Outcome:** WB is expected to reduce the anxiety in patients undergoing IV anticancer therapy and reduce the nurses' burden when caring for those patients.

3. Background

According to the annual report by Ministry of Health (2020), cancer ranks as the 4th most common cause of death in the Sultanate of Oman. The crude incidence rate for all cancers among Omanis was 68.3 per 100,000 for males and 79.4 per 100,000 for females. Overall, breast cancer is the most common cancer with 35% of cases diagnosed in the 3rd or 4th stage, followed by thyroid cancer and then colorectal cancer (MOH, Oman 2020).

There are different treatment modalities for cancer including surgery, radiotherapy, and anticancer medications. There are different drugs used to treat cancer including chemotherapy, biological molecules, immune medicated therapies and hormonal therapies. Chemotherapy is the most used treatment either alone or in combination with surgery or radiotherapy or even with other cancer medications. Despite being the most used anti-cancer medication, chemotherapy is well known for its side effects which affect patients physical and mental health (Afroze et al. 2018). Patients with cancer undergoing chemotherapy experience a set of symptoms like anxiety, depression and psychological distress (Garcia 2014).

Anxiety is reported to be the most common symptom. It is caused by the anticipation of treatment-induced adverse events, changes in body image, strained relationships, and affected social interaction (Charalambous, et al. 2017). Heightened anxiety levels were reported in several studies in women receiving their first cycle of chemotherapy, with levels subsiding over time. Leaving anxiety without management can lead to poor comfort level and dissatisfaction (Kroenke et al. 2007).
Anxiety fluctuates throughout treatment, with specific periods of heightened distress due to various factors. The initial diagnosis and treatment planning are often overshadowed by uncertainties surrounding treatment outcomes, potential side effects, and the future, leading to

significant anxiety (Kroenke et al. 2007). Age and pre-existing anxiety traits can further exacerbate these concerns (Singh et al, 2015). During Treatment stage, the ongoing treatment process itself, riddled with uncertainties and potential side effects, can contribute to sustained anxiety. Chemotherapy, while lifesaving, significantly impacts mental well-being, with anxiety being a prevalent and debilitating concern (Baltussen, et al, 2023).
While some studies suggest lower anxiety during initial cycles, the occurrence of symptoms like nausea, fatigue, and pain can intensify anxiety throughout treatment, not just in later stages. Individual coping mechanisms, specific chemotherapy regimen, and treatment-related side effects all play a role in this fluctuation. Beyond Cycles, distinct time points like treatment milestones, symptom flare-ups, and treatment fatigue can further exacerbate anxiety, typically later in the process but potentially earlier for some individuals (Subbiah, 2015).

On the other hand, there are many studies that report the effect of chemotherapy on the psychological well-being of patients. A study found that among patients undergoing chemotherapy, 25.5 % experienced anxiety and depression. Add to that, a quarter of the patients participated in the study were burdened with psychological distress (Zainal et al. 2007). Psychological distress is a multifactorial unpleasant emotional experience of a psychological (cognitive, behavioral, emotional), social, or spiritual nature that may interfere with the patient's ability to cope with the disease. The psychological impact caused by chemotherapy is but not limited to psychological effects such as fear stemming from uncertainty regarding treatment results and disease recurrence, anxiety, depression, and sadness commonly associated with perceived loss such as losing hair (Elkhair et al. 2019). There are many studies that have reported the relationship between psychological distress and poor outcomes, recurrence, and decreased survival in patients with cancer (Satin et. al 2009, Sotelo et al. 2014). Literature suggests various non-pharmacologic interventions to alleviate anxiety, depression and psychological distress during chemotherapy, including guided imagery, art therapy, music therapy, muscle relaxation, psychoeducation, cognitive-behavioral therapy, and deep touch pressure (DTP) (Lim et al, 2011; Charalambous et al. 2017, Vinson et al. 2020).
DTP involves tactile sensory input like holding, stroking, hugging, swaddling, and squeezing. It acts as a calming method, improving coping behaviors and adaptation to stressful situations, ultimately reducing anxiety (Chen et al. 2011). DTP has several components to ensure effectiveness including conformation, compression and constant contact to the nerve. It is also suggested that DPT can influence parasympathetic and sympathetic activities (Field et. al. 2010). Parasympathetic activities are assessed through the increase in vagal tone, and sympathetic activity is assessed through the reduced activation of the stress response (Kimball et al. 2007).
DTP can be provided by several methods such as swaddling, deep massage, compression sleeves, compression vests and use of weighted blankets (WB) (Miller et al. 2003). WBs are manufactured using plastic pellets or glass microbeads that add pressure to the body when used. The material used provides warmth and is usually heavier than regular duvets and comforters. Many are made to have a cover that is removable for easy cleaning. WB is believed to stimulate the production of happy hormones and allows the body to enter though the state of relaxation that enhances calmness and is conducive of sleep (Noyed 2023).

A systematic review that looked into 8 studies concluded that the use of WB had been demonstrated to be an appropriate therapeutic tool that alleviated anxiety (Eron et. al, 2020). The application of DTP through the use of WB was found to produce a calming effect in many conditions, including autism spectrum disorder (ASD), attention deficit hyperactivity disorder (ADHD), and a number of developmental disorders through providing a "cocooning" feeling to all age groups. It was also shown to reduce anxiety levels in adults and children with high anxiety levels and bipolar disorder. Studies have also found that DTP application through WBs given in nursing homes gave relief to elderly who suffered from anxiety and dementia in nursing homes (Eron et. al, 2020; Ackerley, et al. 2015). The use of WBs had also been found to significantly reduce the physiological burden and anxiety for patients going through dental procedures using WBs (Chen et al. 2013).

In regard to evaluating the effect of WBs on cancer patients, Vinson et al (2020) conducted a randomized controlled trial using a cross-over study design to evaluate the effect of the use of WBs on patient's anxiety levels. Patients on chemotherapy were randomly assigned to use WB in the first or second cycles. Based on the study results, Vinson et al (2020) concluded that patients using the WB during chemotherapy experienced significantly less anxiety overall.

A recent study conducted by Hermann et al (2024) on the use of WBs in outpatient oncology in the US found that they effectively reduced anxiety in patients receiving their first two infusion treatments. Most patients reported feeling comforted and soothed, with over 90% finding the WB comfortable, appropriately weighted, and easy to put on.

On another hand, some studies evaluated the feasibility and practicality of using the WBs and its effect on nurse's workload. Hermann et al (2024) reported that that nurses who administered the WBs thought they were easy to use and compliant with infection control standards. Add to that, Vinson et al. (2020) claimed that WB gives nurses one additional option to provide an intervention that can reduce anxiety.

At the center, there are limited non-pharmacological nursing interventions available to alleviate anxiety, stress, and depression experienced by cancer patients. Despite growing recognition of the need for holistic care, many oncology settings still lack structured, evidence-based psychosocial support programs led by nurses. Interventions such as use of WBs show promise in reducing psychological distress, yet there is limited evidence about their use in cancer patients in Arab and Muslim countries.

4. Study Aims/ Objectives

4.1 Primary aim: To examine the effectiveness of using Weighted Blankets (WB) on anxiety, stress, and depression in patients diagnosed with cancer during their first and 2nd cycle of IV anticancer therapy.

Objectives for the primary aim:

- **Objective 1:** To correlate the level of anxiety with the use of WB. (Pre and Post) (VAS-A).
- **Objective 2:** To study the effect of the use of WB on the symptoms in the ESAS-R.
- **Objective3:** To study the effect of WB on depression, anxiety and stress using DASS-21.

4.2 Secondary aims:

- Measure the patients' satisfaction and comfort level when using the WBs.

- Compare the changes in Vital sings pre and post IV anticancer therapy between the interventional and control arms.
- Investigate the feasibility of using the WBs by the nurses assigned to patients using the blankets.

5. Methodology

5.1 Study Design

This study is an open label randomized clinical trial 2 arms study, before patients receive their first line of IV anticancer therapy, they will be randomized to either getting the WB applied or receive standard of care blanket if requested by the patient. Data will be collected through validated assessment tools, comfort and satisfaction survey and vital signs. (Refer to appendix 11 for study schema)

5.2 Study settings

Patients will be recruited from the outpatient clinics (OPD) prior to their treatment and then after consenting patients will be randomized to either the interventional arm or the control arm. All patients will receive their intervention/control in the Daycare unit (DCU).

5.3 Participants Selection

5.3.1 Eligibility Criteria: the study patients' population

5.3.1.1 Inclusion criteria for patients:

- Newly diagnosed cancer patients aged 18 years and older.
- Receiving first-line intravenous anticancer therapy (chemotherapy or immunotherapy or a combination of both) in the daycare unit (adjuvant, neoadjuvant, or palliative).
- Weighting at least 55 kg during obtaining the informed consent. (At least 54 kg before the intervention).
- Able to complete study assessments.
- Speaks Arabic or English.
- Signs Informed consent.

5.3.1.2 Exclusion Criteria for patients

- Prior psychological treatment or psychotherapy (confirmed psychological diagnosis, history of psychotropic medications and previous psychotherapy).
- Currently hospitalized in inpatient units.
- Patients on daily anticancer infusions.
- Positive fall risk assessment.
- Open wounds and recent surgeries/ stoma.
- Enrolled in any other device study or clinical trial during data collection.
- History of:
    - Diabetes mellitus
    - Respiratory disorders,
    - Claustrophobia (Miller et al 2003) Because of the possibility for altered sensory perception,

- Patients who had a diagnosis of peripheral neuropathy or fibromyalgia (Vinson et al. 2020)
- Cognitive impairment

5.3.2 Eligibility criteria for the nurse's population:

DCU nurses will be recruited by convenient sampling and feedback will be sought per patient per visit. The reason to this is because the same nurses maybe caring for multiple patients using the WBs and each patient will provide a different experience for the nurses caring for those patients. Only nurses who agree to complete the study questionnaire will be included.

6. Clinical Trial Procedures

6.1 Informed Consent: Written informed consent will be obtained from the patient following discussion about the aim and purpose of the clinical trial. Informed consent process is voluntary, and patients may choose to withdraw from the study at any point without the need to provide justification.

6.2 Stratification: Patients will be stratified according to gender i.e. males and females, as this is identified as a strong confounding variable for reported anxiety. A systematic review/ meta-analysis done by Vitale et al. 2024 found that in cancer patients, females reported higher depression and anxiety rates than males, as males face difficulties in expressing anxiety and exhibit different symptoms compared to females. (For example: anger, obsession and hostility) which may lead to under reported anxiety levels in men.

6.3 Randomization: Consented participants will be randomly assigned to one of the two arms (1:1 ratio) using a clinical trial randomization tool. Each stratum (male, female) will have its randomization list. Participants will be assigned to either the interventional arm of the control arm through a validated method which is a computer-generated random assignment (NIH tool) (Kroenke et al. 2007).

Participants will be coded by the research nurse coordinator as: WB-PI-0X for the intervention arm; WB-PC-0X for the control arm. Only the research nurse will know the code and be able to assign the patients to their codes in every visit.

6.4 Interventions

Patients on the interventional arm will be provided with a WB. WBs selection was done to ensure the weight is below 10% of the participants' average weight. For the purpose of this study, researchers will use the 12 lbs (equivalent to 5.44 kg) blankets to account for less than 10% of the patients' average weight. The blankets do not come in free size (Field et. al. 2010). The manufacturer selected was Sommerfly, mainly because of suitability of the product for clinical use (infection control recommendations) and ease of shipping of the products.

Care instructions for the WBs will be conducted before applying to the patients in the intervention arm, while the control arm will be provided with regular blankets as per the standard of care. The nurses will be trained in how to care for the WBs. The research team will ensure that WBs are cleaned after each patient's use, following the manufacturer's guidelines. The Sommerfly weighted blankets are waterproof, breathable, tear-resistant, antimicrobial, flame-resistant and non-toxic. According to the manufacturer, cleaning involves wiping the

surface with approved cleaning wipes or mild soap and water, followed by rinsing and air-drying. If disinfection is required, a 10% bleach solution may be used. Machine washing, drying, or dry cleaning is not permitted (Appendix: 9).

6.4.1 ARM1: Intervention Arm:

Cycle 1:

- Fitness assessment is conducted by the research nurse to ensure patient safety the use of the WBs (eligible weight, negative fall risk, etc.).
- Pre-treatment assessment (ESAS-R, VAS-A, VS) and WB provision by research nurse at the time of administering of the premedication.
- Mid treatment: round on the patients to ensure usage of the WB and patient's comfort.
- Post-treatment assessment (ESAS-R, VAS-A, VS and patient's satisfaction and comfort survey) and WB removal.

Cycle 2:

- Fitness assessment by the research nurse to ensure patient safety for continued participation (weight, fall risk, etc.). Refer to Appendix 3.
- If patient is fit to continue with the intervention, repeat the Cycle 1 process.

Cycle 3:

- At the beginning of cycle 3: WB will not be provided. Patients in the interventional arm will be asked if they want to use WB again with reasons for refusal optional. "Would you like to use the WB again?" with yes/no and optional reason selection. Reasons include uncomfortable, heavy, movement restriction, breathing difficulty, no difference from the regular blanket, and others (specify). Refer to Appendix 10.
- Vital signs will be collected pre and post treatment.
- DASS-21 will be administered.

6.4.2 ARM 2: Control Arm:

Cycle 1, 2

- The patient receives a regular blanket (if requested) before IV anticancer therapy.
- Pre-treatment assessment (ESAS-R, VAS-A, VS) will be done.
- Post-treatment assessment (ESAS-R, VAS-A, VS) will be done.

Cycle 3

- Vital signs will be collected pre and post treatment.
- DASS-21 will be administered.

7 Schedule of Activities

Time point / Event /Data to be collected	Screening Baseline [1]	Before the C1D1 & C2D1 infusion (Including Pre-meds)	End of C1D1 & C2D1 IV anticancer therapy	During infusion	C3D1
Informed Consent	**X**				
Demographic and medical data [2]	**X**				
Eligibility Criteria	**X**				
Randomization	**X**				
Fitness to proceed with WB		**X**[3]			
Apply the WB		**X**[3]			
Fall risk	**X**	**X**			
Weight	**X**	**X**			
VAS-A		**X**	**X**		
ESAS-R		**X**	**X**		
DASS-21	**X**				**X**
Patient comfort surveys			**X**[2]		
WB feasibility of use, nurses' survey			**X**[2]		
Interest in using the WB					**X**[2]
Vital Signs (HR, BP, Temp, RR, SPO2)		**X**	**X**		**X**[5]
Round to check patient's comfort and WB usage				**X**[2]	

1. Can be done on the same day as the C1.
2. Demography includes gender, age, educational level, nationality, religion, region, and support system. Medical history includes diagnosis, stage of disease (curative/ palliative), and IV anticancer therapy protocol. (Appendix 8)
3. Interventional arm only.
4. Prior to C1D1 and C2D1 of interventional arm only.
5. Pre and Post the IV anticancer therapy.

8 Study Tool

The tools used in this study are:

8.1 Demographic Data and medical history survey: A survey tool of study participants demographic and medical history variables. This will be done while recruiting the participants by the research team. Patients' physical symptoms including vital signs of participants will be checked and recorded for all participants, pre- mid and post IV anticancer therapy.

8.2 Visual Analogue Scale for Anxiety (VAS-A): This simple, single-item measure allows patients to easily rate their anxiety on a scale of 0 (no anxiety) to 10 (significant anxiety). While it has limitations like subjectivity, its strengths lie in its speed, convenience, and strong correlation with other anxiety measures. This valuable tool helps to gain insights into anxiety levels. Studies have shown significant correlations between VAS-A scores and other validated anxiety measures, such as the State-Trait Anxiety Inventory (STAI) and the Hospital Anxiety and Depression Scale (HADS). Studies using Cronbach's alpha have shown good internal consistency of VAS-A scores, indicating that different items on the scale measure the same underlying construct (anxiety) reliably. Studies have shown that VAS-A scores remain relatively stable over short periods, demonstrating good test-retest reliability (Facco et. al. 2011; Ward, 1985). The VAS-A will be administered to participants pre and post-IV anticancer therapy with or without WBs.

8.3 Edmonton Symptom Assessment Scale-Revised (ESAS-R)- this scale be used for capturing the patients' level of anxiety and related symptoms pre and post IV anticancer therapy in both study arms. The Edmonton Symptom Assessment Scale-Revised (ESAS-R) is a tool used to assess the severity of common symptoms in people with advanced illness. It is a simple and easy-to-use tool that can be used by patients themselves, family caregivers, or healthcare professionals. The ESAS-R assesses 10 symptoms: Pain, Tiredness, Nausea, Lack of appetite, Shortness of breath, Depression, Anxiety, Well-being, Drowsiness, Constipation. For each symptom, the patient is asked to rate the severity of the symptom on a scale of 0 to 10, where 0 is no symptom and 10 is the worst possible symptom. The ESAS-R can be used to: track the severity of symptoms over time, identify symptoms that need to be treated and monitor the effectiveness of treatment (Subbiah et al, 2021). The ESAS-R is used as a standard of care for all cancer patients at the center. Therefore, the research team would only utilize the results to track any differences in symptoms reported by patients over time.

8.4 Depression, Anxiety, and Stress Scale-21 (DASS-21): The Depression, Anxiety, and Stress Scale-21 (DASS-21) is a concise, 21-question self-assessment tool used to measure the intensity of symptoms commonly associated with these three emotional states. This highly reliable scale, validated for use with cancer patients, demonstrates strong internal consistency within each of its three subscales: depression, anxiety, and stress. Taking the DASS-21 involves reflecting on the past week and rating the frequency or severity of each symptom on a four-point scale ranging from 0 ("Did not apply to me at all") to 3 ("Applied to me very much or most of the time"). Individual scores are then calculated for each subscale by summing the item ratings. The depression subscale focuses on symptoms like

lack of motivation, diminished pleasure, low mood, disinterest, self-criticism, negative thoughts about life, and feelings of hopelessness. The anxiety subscale assesses physical symptoms linked to nervous system activation (e.g., increased heart rate, muscle tension), anxieties related to specific situations, and subjective feelings of worry or unease. Finally, the stress subscale evaluates difficulties with relaxation, nervous energy, irritability, and feelings of impatience or overreaction to situation (Ali et al. 2017).

8.5 Patient's satisfaction and comfort survey. The patient's satisfaction and comfort will be assessed by a survey developed by the research team based on recent literature. The survey tool was reviewed by the team for validity. Participants in the intervention arm will be asked to complete this survey at the end of each intervention in C1 and C2. The tool was translated by the research team to Arabic language. The tool then was validated by Arabic speaking administrative Omani staff for readability and clarity of questions. (Appendix 1)

8.6 WB feasibility of use, nurses' survey: The nurses' perspective of the feasibility of using the WB will be assessed using a tool developed by the research team. The tool was developed based on the literature available (Hermann et al. 2024). The tool was reviewed by the research team and expert nursing staff for readability and clarity. An informed consent will be obtained from the nurses who care for patients on WB. The nurses will fill in a short demographic questionnaire, then they will be asked to answer a few questions within a survey to assess the effect of WBs on their workflow, patients and patients' care. The survey will be collected on the same day of the patient's intervention, following the patient's discharge (Appendix 2).

9 Statistical Plan

9.1. Primary endpoints analysis:

In the primary analysis, we will compare interventional arm (WB) with the control arm (No WB) using the Wilcoxon rank sum test. The statistical tests will be two-sided. A p-value ≤ 0.05 will be considered statistically significant.

The primary endpoints are the following:

- Visual Analogue Scale- Anxiety (VAS) score
- Depression Anxiety and Stress Scale 21 (DASS-21) score
- Edmonton Symptom Assessment System – Revised (ESAS-r) score
- Vital signs (Heart rate, respiration rate and blood pressure relevant to anxiety)

9.2 Secondary endpoints analysis:

To analyze the secondary endpoints:

- We will use the Chi-square test or Fisher exact test for analyzing the binary endpoints.
- We will use the ordinal logistic regression for analyzing the ordinal endpoints.
- We will use the Wilcoxon signed-rank test to examine differences in the vital signs between pre- and post-treatment measurements, in each arm.

- The statistical tests will be two-sided. A p-value ≤0.05 will be considered statistically significant.

9.3 Sample size:

If we aim to detect a medium effect size (Cohen's d=0.5) at 5% significance level with 80% statistical power, 67 patients per arm is required. Accounting for approximate ~10% missing data or dropping-out rate, the total required sample size is 152 patients (76 per arm)-(The study will have even numbers in each arm to have equal numbers for strata) . The results of the power analysis are shown in the Table below. Each arm will include two strata (male and female) with 38 patients recruited in each.

Table: Sample size requirement for 5% significance level and 80% statistical power using the G*Power software (1:1 allocation, a priori analysis, 2-sided Wilcoxon Rank-Sum test)

Effect size d	Effect size	N per arm	Total sample size
0.2	Small difference	412	824
0.5	Medium difference	67	134
0.8	Large difference	27	54

10 Expected Outcomes:

10.1 **Main outcomes:** This study aims to provide valuable insights into the complex relationship between IV anticancer therapy and mental well-being. It is anticipated that the WB intervention will demonstrate effectiveness in reducing anxiety and improving overall mental health during the initial stages of treatment. This could lead to developing evidence-based supportive interventions for cancer patients undergoing IV anticancer therapy, ultimately optimizing treatment outcomes and improving quality of life.

10.2 Strengths of proposal:

- Focus on early nonpharmacological nursing intervention, addressing anxiety, stress and depression before it escalates.
- Novel use of a WB intervention in the context of IV anticancer therapy.
- Rigorous RCT design with pre-and post-test assessments.
- Incorporation of different methods of data collection to gain a deeper understanding of patient experiences.

This proposal offers a promising approach to addressing the significant mental health challenges faced by IV anticancer therapy patients. By investigating the effectiveness of a readily available and potentially cost-effective/ nonpharmacological intervention like WB, this study can contribute to improved supportive care practices and enhance the overall well-being of cancer patients.

10.3 Potential risks

Minimal risk has been identified in literature for adults using WBs. Children, on the other hand, who are not eligible for this trial may suffer from suffocation as a result of using a WB that is not suited for their weight (Singh et al, 2015; Whisenant et al, 2020). This study will include adults of 18 years of age and older.

Using the wrong weight of WB, i.e., more than 10% of the body weight, can lead to discomfort and possible suffocation (Champagne, et al, 2010; Hjort Telhede, 2022). Therefore, participants' weight will be checked on every visit to ensure patients safety to use the WB. Furthermore, to prevent suffocation, nurses and patients will be trained to ensure that WBs will not be folded twice at the chest level and will not be folded tight around the patients' bodies (Whisenant et al, 2020). Add to that, for this study, WBs will be used during the day in open nursing bays under the supervision of the nursing staff and research nurses.

Another identified risk in literature is discomfort when using the WB, expressed by verbalizing discomfort or nonverbal gestures such as facial grimaces (Whisenant et al, 2020).

Researchers will assess the patients' comfort when the WB is applied. If the patient is uncomfortable, participation in the trial will be halted, and a regular blanket will be provided, if requested. Therefore, to ensure patients' safety, there are specific inclusion criteria to ensure patients' weight is within acceptable limits based on the weight of the WB provided. We will also exclude patients with a positive fall risk assessment to ensure their safety.

10.3.1 Safety and reporting of adverse events

10.3.1.1 Adverse events

An adverse event (AE) is any untoward medical occurrence in a patient or clinical investigation of a subject who has been enrolled in a clinical study and who may have been administered an investigational product, regardless of whether or not the event is assessed as related to the study drug treatment. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of an investigational product, regardless of whether or not the event is assessed as related to the investigational product.

10.3.1.2 AE assessments:

The PI/Co-PI must use their best clinical judgement to evaluate the AEs/SAEs based on the following criteria: Seriousness, Causality, Severity and Expectedness.

10.3.1.3 Seriousness:

The serious adverse event (SAE) definition and reporting requirements are in accordance with the International Conference of Harmonization (ICH) Guideline for Clinical Safety Data Management, Definitions and Standards for Expedited Reporting, Topic E2A. An SAE is defined as any untoward medical occurrence that at any dose:

- Results in death.
- Is immediately life-threatening (i.e. in the opinion of the investigator, the AE places the subject at immediate risk of death; it does not include a reaction that, had it occurred in a more severe form, might have caused death).

- Requires inpatient hospitalization or results in prolongation of an existing hospitalization.
- Results in persistent or significant disability or incapacity

10.3.1.4 Severity:

Assessment severity of toxicities and adverse events will be graded according to the Common Toxicity Criteria (CTC), version 5.0

10.3.1.5 Reportability of SAEs to the Institutional Review Board (IRB SQCCCRC)

SAEs are unlikely to occur during the application of the weighted blanket, given the safety precautions followed by the study team to ensure safe application. However, should SAEs occur due to the application of the WB, the Principal Investigator (PI) and/or designated co-investigators are responsible for identifying, documenting, and recording any events that meet the criteria for adverse or serious adverse events. They also remain accountable for the follow-up of serious adverse events, particularly those that are related to the application of the WB.
This study will report SAEs to the local institutional IRB as per the SQCCCRC-UMC center policy SOP as per the following criteria:

- All SAEs must be reported within 24 hours of awareness.
- Other non-serious AEs related to the application of the WB that are grade 2 unexpected, grade 3 and grade 4 should be reported to IRB on continuing review quarterly per calendar year.
- Grade 1 and expected grade 2 AEs are not required to be reported to IRB; however, those will be assessed, managed and documented as data in the CRF. Interventions will be applied as per the standard of care.

Adverse events and serious adverse events will continue to be collected for a duration of the study which is 3 treatment cycles.

10.4 Measures of Success and Potential Barriers

Measures of success is the selection of WB that is within the acceptable weight for the majority of the cancer patients at the center. Add to that, the purchased WBs are approved for clinical use with clear cleaning instructions. They are also easy to carry and store.

Conducting this study in the Day care unit which operates during official working hours. This will allow the research nurse to oversee the study procedure ensuring the study is conducted as per the study protocol. The research nurse will be able to pre-assess study participants before applying the WB, provide the patients with blankets, taking the time to administer the questionnaires and assessing the patients' vital signs at the required time points during the process. Add to that, the research nurse will be able to assess patients comfort level and ensure nurses complete the feasibility survey.

Nurses working in the daycare unit may find it overwhelming to care for standard of care patients as well as research patients. This can be solved by assigning a special nurse to take

care of the research component of the patient care while allowing the DCU nurse to focus on administering the IV anticancer therapy and provide the standard of care nursing care.

Another barrier that the research team may face is that the research team is not sure how patients will react to participating in the study. This is mainly as patients might be overwhelmed with the cancer diagnosis and the treatment plan. Add to that, this might also affect the completion of the initial and pre-intervention study assessments.

On another hand, the research team is not sure how nurses will react to providing care and reassuring patients on the intervention arm. Contingencies to this is to provide nurses with appropriate in-service education to orient them to reduce their anxiety in dealing with patients participating in a research study.

10.5 Study progress and project planning:

The idea for this clinical trial was conceptualized in May 2023 and was developed and approved by the IRB at SQCCCRC in November 2024. Blankets were secured in Oct2025. Second amendment with new available literature was submitted to IRB in Nov2025. Recruitment will start in Nov 2025. Potentially, 13

to 25 weeks will be required to recruit patients if 6 patients were recruited on the experimental arm every week, provided approximately the same number is recruited on the control arm. Recruitment and data collection will be finalized by June 2026. Statistical analysis will follow, and manuscript writing will be started in November 2026 and publication/ conference presentation in January 2027.

11 Ethical Consideration and confidentially

This study has gained Ethical Approval from the Institutional Review Board (IRB) at SQCCCRC with an approval number **CCCRC-56-2024.** Patient's confidentiality will be protected and by used codes for each patient and the database will be password protected. Patients and nurses' identity will not be disclosed to any person outside the research team and upon dissemination of knowledge.

12 Declaration of conflict of interest

This clinical trial is entirely academic in nature. The researchers do not endorse the use of WB from Sommerfly. Neither did the researcher receive funds from the manufacturers to use the WB for the purpose of clinical research. The researchers promote the concept of using non-pharmacological nursing intervention in the form of deep pressure stimulation delivered by WB to alleviate anxiety and other variables that will be assessed during the conduct of this study. Fundings were sought and was from Rakeeza, a non-profit governmental organization which has purchased the blankets for SQCCCRC to be used for patients and patients' research. The total cost for six blankets was USD 1,853.48 (approximately OMR 713.59).

13 References

Ackerley, Rochelle & Olausson, Håkan & Badre, Gaby. (2015). Positive effects of a weighted blanket on insomnia. Journal of Sleep Medicine and Disorders. 2. 1022. Retrieved on 09APR2023 from 2015_Ackerley_etal_JSleepMedDisord.pdf

Afroze Alam, U Farooq, Ruchi Singh, VP Dubey, Shailendra Kumar, Rashmi Kumari, Kamlesh Kumar Naik, BD Tripathi and KL Dhar (2018) Chemotherapy Treatment and Strategy Schemes: A Review. Open Access Journal of Toxicol. 2 (5) DOI : 10.19080/OAJT.2018.02.555600.

Ali, A. M., Ahmed, A., Sharaf, A., Kawakami, N., M Abdeldayem, S. and Joseph, G. (2017) The Arabic Version of The Depression Anxiety Stress Scale-21: Cumulative scaling and discriminant-validation testing, Asian journal of psychiatry, 30: 56–58. https://doi.org/10.1016/j.ajp.2017.07.018

Baltussen, J.C., de Glas, N.A., van Holstein, Y., et al. (2023). *Chemotherapy-Related Toxic Effects and Quality of Life and Physical Functioning in Older Patients*. JAMA Network Open, 6(10), e2339116. doi:10.1001/jamanetworkopen.2023.39116. Available at: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2810982. [jamanetwork.com]

Clinical Trial Randomization Tool - Clinical Trial Randomization Tool (cancer.gov)

Champagne, T., (2010) The weighted blanket competency training program: Adult mental health populations, Boston University ProQuest Dissertations Publishing. 3411717. Retrieved from The weighted blanket competency training program: Adult mental health populations – ProQuest

Charalambous, A., Kaite, C. P., Charalambous, M., Tistsi, T., & Kouta, C. (2017). The effects on Anxiety and quality of life of breast cancer patients following completion of the first cycle of chemotherapy. *SAGE open medicine*, *5*, 2050312117717507. Retrieved on 06JUN2023 from The effects on Anxiety and quality of life of breast cancer patients following completion of the first cycle of chemotherapy (sagepub.com)

Chen, H., Yang, H., Chi, H., & Chen, H. (2013). Physiological Effects of Deep Touch Pressure on Anxiety Alleviation: The Weighted Blanket Approach. Journal of Medical and Biological Engineering, 33, 463-470. Retrieved on 05JUN2023 from Abstract (shopify.com)

CTCAE V 5.0 V5.0 (CTCAE): publish date November 27, 2017: https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_5x7.pdf

El Kheir DYM, Ibrahim AHM. Epidemiological assessment of distress during chemotherapy: who is affected? J Taibah Univ Med Sci. 2019 Oct 8;14(5):448-453. doi: 10.1016/j.jtumed.2019.08.004. PMID: 31728143; PMCID: PMC6838912.

Eron, K., Kohnert, L., Watters, A., Logan, C., Weisner-Rose, M., & Mehler, P. S. (2020). Weighted blanket use: A systematic review. *The American Journal of Occupational* Facco E, Zanette G, Favero L, Bacci C, Sivolella S, Cavallin F, Manani G. Toward the validation

of visual analogue scale for anxiety. Anesth Prog. 2011 Spring;58(1):8-13. doi: 10.2344/0003-3006-58.1.8. PMID: 21410359; PMCID: PMC3265269. Retrieved from https://pubmed.ncbi.nlm.nih.gov/21410359/

Field, T., Diego, M., & Hernandez-Reif, M. (2010). Preterm infant massage therapy research: A review. Infant Behavior and Development, 33, 115–124. http://dx.doi. org/10.1016/j.infbeh.2009.12.004

Garcia, S. (2014). The effects of education on anxiety levels in patients receiving chemotherapy for the first time: an integrative review. *Clinical Journal of Oncology Nursing*, *18*(5).

Hermann, C., Corbett, M., Chicko, L., Cole, V., Arcieri, C., & Jabaley, T. (2024). Weighted Blanket: An Anxiety Reduction Tool in the Outpatient Oncology Infusion Setting. Clinical Journal of Oncology Nursing, 28(3).

Hjort Telhede E, Arvidsson S, Karlsson S. (2022) Nursing staff's experiences of how weighted blankets influence resident's in nursing homes expressions of health. Int J Qual Stud Health Well-being. 2022 Dec;17(1):2009203. doi: 10.1080/17482631.2021.2009203. PMID: 34904541; PMCID: PMC8740773.

Kimball, J. G., Lynch, K. M., Stewart, K. C., Williams, N. E., Thomas,M. A.,& Atwood, K. D. (2007). Using salivary cortisol to measure the effects of a Wilbarger protocol-based procedure on sympathetic arousal: A pilot study. American Journal of Occupational Therapy, 61, 406–413. http://dx.doi.org/10.5014/ajot.61.4.406

Kroenke K, Spitzer RL, Williams JB, et al; Anxiety disorders in primary care: prevalence, impairment, comorbidity, and detection. Ann Intern Med. 2007 Mar 6 146(5):317-25.

Lim, C. C., Devi, M. K., & Ang, E. (2011). Anxiety in women with breast cancer undergoing treatment: a systematic review. *International Journal of Evidence-Based Healthcare*, *9*(3), 215-235. Retrieved on 06JUN2023 from Anxiety in women with breast cancer undergoing treatment: a systematic review - Lim - 2011 - International Journal of Evidence-Based Healthcare - Wiley Online Library

Miller, B.F., & O'Toole, M.T. (2003). Miller-Keane encyclopedia and dictionary of medicine, nursing, and allied health (7th ed.). Saunders.

Ministry of Health: Cancer incidence in Oman 2020, Accessed on 13Mar2024 Retrieved from https://www.moh.gov.om/documents/127157/0/Oman+Cancer+Incidence+Report+2020.pdf/55ebb1e7-19ea-78fe-5674-91a1d89d9504 on 12Mar2024)

Noyed, D., (May, 2023) How Heavy Should a Weighted Blanket Be? Retrieved from How Heavy Should a Weighted Blanket Be? | Sleep Foundation

J.R. Satin et., al., Depression as a Predictor of Disease Progression and Mortality in Cancer Patients, Cancer 2009.

Singh RP, Singh H, Singh CJ, Kaur KT. Screening of Psychological Distress in Cancer Patients During Chemotherapy: A Cross-sectional Study. Indian J Palliat Care. 2015 Sep-Dec;21(3):305-10. doi: 10.4103/0973-1075.164887. PMID: 26600699; PMCID: PMC4617038.

Sommerfly. (2020). Wipe-Clean™ fabric information and care instructions [PDF document].https://cdn.shopify.com/s/files/1/0252/1985/8477/files/Wipe-Clean_Care_Instructions_website_download-fullpage_3_2020_1.pdf?v=1585255098

Sotelo, J. L., Musselman, D., & Nemeroff, C. (2014). The biology of depression in cancer and the relationship between depression and cancer progression. International Review of Psychiatry, 26(1), 16-30.

Subbiah, V. (2015). *Cognitive Changes During Chemotherapy*. JAMA Oncology, 1(9), p.1353. doi:10.1001/jamaoncol.2015.4142. Available at: https://jamanetwork.com/journals/jamaoncology/fullarticle/2469340.

Vinson J, Powers J, Mosesso K. Weighted Blankets: Anxiety Reduction in Adult Patients Receiving Chemotherapy. Clin J Oncol Nurs. 2020 Aug 1;24(4):360-368. doi: 10.1188/20.CJON.360-368. PMID: 32678376. Retrieved on 09APR2023 https://www.ons.org/cjon/24/4/weighted-blankets-anxiety-reduction-adult-patients-receiving-chemotherapy

Vitale, E., Halemani, K., Shetty, A., Chang, Y.-C., Hu, W.-Y., Massafra, R., & Moretti, A. (2024). Sex Differences in Anxiety and Depression Conditions among Cancer Patients: A Systematic Review and Meta-Analysis. *Cancers*, *16*(11), 1969. https://doi.org/10.3390/cancers16111969

William B. Ward, Jr., AJ Dent Res. (1985) Original VAS-A publication: "The Measurement of Anxiety in the Dental Setting" by Aug;64(8):1162-7

Whisenant M, Wong B, Mitchell SA, Beck SL, Mooney K. Trajectories of Depressed Mood and Anxiety During Chemotherapy for Breast Cancer. Cancer Nurs. 2020 Jan/Feb;43(1):22-31. doi: 10.1097/NCC.0000000000000670. PMID: 31805023; PMCID: PMC6901090.

Zainal N., Hui K., Hang T. Prevalence of distress in cancer patients undergoing chemotherapy. *Asia Pac J Clin Oncol.* 2007;3:219–223 –

14 Appendices

Appendix 1: Patient satisfaction and comfort survey.

Patient Satisfaction and Comfort Survey on the Use of the Weighted Blanket/ استبيان رضا وراحة المريض عند استخدام البطانية الثقيلة

Date: _____ Patient's codes: _____

Please indicate your level of agreement with each statement by ticking the appropriate box.
يرجى تحديد مدى موافقتك على كل عبارة عن طريق وضع علامة في المربع المناسب.

Statement / العبارة	Disagree (0) لا أوافق	Not Sure (1) غير متأكد	Agree (2) أوافق
I felt comfortable using the weighted blanket (WB). شعرت بالراحة عند استخدام البطانية الثقيلة	☐	☐	☐
The weighted blanket did not feel very heavy. لم تكن البطانية ثقيلة الوزن	☐	☐	☐
The weighted blanket was easy to put on. كان من السهل استخدام البطانية الثقيلة	☐	☐	☐
The weighted blanket did not interfere with healthcare providers' ability to care for me. لم تعيق البطانية الثقيلة مقدمي الرعاية الصحية عن تقديم الرعاية لي	☐	☐	☐
I would like to use the weighted blanket again. أود استخدام البطانية الثقيلة مرة أخرى	☐	☐	☐
I would recommend the weighted blanket to other patients. أوصي باستخدام البطانية الثقيلة للمرضى الآخرين	☐	☐	☐

Appendix 2: WB feasibility of use, nurses' survey

Nurse code: _____ Date: _____

Patient's codes: _____

Assessment of the feasibility of using the weighted blankets on patients receiving IV anticancer therapy 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)	Comments
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.	☐	☐	☐	

Appendix 3: Fitness to proceed to study intervention (WB) Checklist (Interventional Arm)

Patient's Initial: _____ Study ID: _____Date: _____

Treatment Cycle: Cycle 1 ☐ / Cycle 2 ☐ Date of Cycle 1 Day 1: _____

Treatment Regiment: _____

Does the patient meet the following criteria?

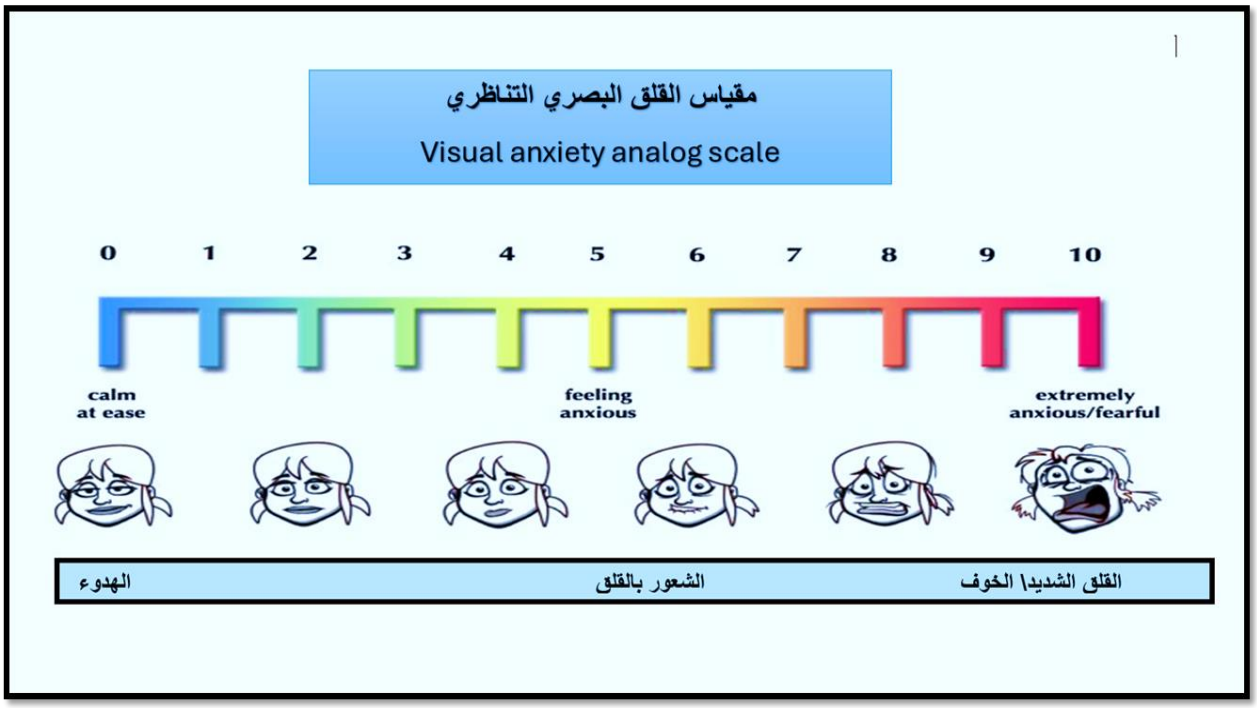
	Criteria	**Conditions Met**
1	The patient wishes to proceed with the WB provision	Yes☐ No☐ N/A☐
2	The patient's weight is within the safe range to use WB (55 kg and more)	Yes☐ No☐ N/A☐
3	The patient does not have a fall risk	Yes☐ No☐ N/A☐
4	The patient is not hospitalized	Yes☐ No☐ N/A☐
5	Has the patient smoked before the treatment session?	Yes☐ No☐ N/A☐
6	Has the patient had alcohol, drugs or herbs before the treatment session? (State if any) _____	Yes☐ No☐ N/A☐
7	The patient withdrew from the study. Reason: _____ _____	

Appendix 4: WB CRNC Manual Checklist

Baseline Assessments in OPD – Date: _____	
Informed Consent: ☐ Randomization ☐	Weight: ☐ DASS-21 ☐
Documentation of the consenting process in HIS ☐	Demographic/ Medical Data ☐
Inclusion/ Exclusion Worksheet ☐ Fall risk ☐	Diagnosis ☐ Stage of disease ☐ Length of Cycle ☐
IV anticancer therapy protocol ☐	
Cycle 1 Before premedication & IV anticancer therapy - Date_____	
Vital Signs ☐ *(BP, HR, Respiration, Body Temp., O_2)*	VAS- A ☐ ESAS-R ☐
Fall risk ☐	Provide the intervention ☐ (WB or SOC)
Cycle 1- During IV anticancer therapy - Date_____	
Weighted blanket usage ☐	Comfort assessment ☐ (Do you feel comfortable?)
Cycle 1 End of IV anticancer therapy **- Date_____**	
Vital Signs ☐ *(BP, HR, Respiration, Body Temp., O_2)*	Patient comfort survey ☐ (WB Arm only)
VAS- A ☐ ESAS-R ☐	WB feasibility of use, nurses' survey ☐ (WB Arm only)
Cycle 2- Before premedication & IV anticancer therapy - Date_____	
Vital Signs ☐ *(BP, HR, Respiration, Body Temp., O_2)*	Fall risk ☐ VAS- A ☐ ESAS-R ☐
Fitness to proceed with WB ☐ (ARM 1 arm only)	Provide the intervention ☐ (WB or SOC)
Cycle 2- During IV anticancer therapy - Date_____	
Weighted blanket usage ☐	Comfort assessment ☐ (Do you feel comfortable?)
Cycle 2- End of IV anticancer therapy - Date_____	
Vital Signs ☐ *(BP, HR, Respiration, Body Temp., O_2)*	Patient comfort survey ☐ (WB Arm only)
VAS- A ☐ ESAS-R ☐	WB feasibility of use, nurses' survey ☐ (ARM 1 only)
Cycle 3 - Date_____	
Vital Signs ☐ *(BP, HR, Respiration, Body Temp., O_2)* (Before and After IV anticancer therapy)	DAS-21 for all patients ☐
Interest – *Ask the patient in WB Arm if he/she would like to get the WB again* ☐	

Appendix 5: VAS-A (English and Arabic)

Visual Analogue Scale- Anxiety



Appendix 6: ESAS R English & Arabic version

Edmonton Symptom Assessment System Revised Tool (ESAS-r)

Please circle the number that best describes how you feel NOW

Pain	*None*	0	1	2	3	4	5	6	7	8	9	10 Worst
Tiredness *(lack of energy)*	*Good*	0	1	2	3	4	5	6	7	8	9	10 *Worst*
Drowsiness *(feeling sleepy)*	*None*	0	1	2	3	4	5	6	7	8	9	10 *Worst*
Nausea	*None*	0	1	2	3	4	5	6	7	8	9	10 *Worst*
Appetite	*Good*	0	1	2	3	4	5	6	7	8	9	10 *Worst*
Shortness of Breath	*None*	0	1	2	3	4	5	6	7	8	9	10 *Worst*
Depression *(feeling sad)*	*None*	0	1	2	3	4	5	6	7	8	9	10 *Worst*
Anxiety *(feeling nervous)*	*None*	0	1	2	3	4	5	6	7	8	9	10 *Worst*
Wellbeing *(how you feel overall)*	*Good*	0	1	2	3	4	5	6	7	8	9	10 *Worst*
Other Problem e.g. *(constipation, epigastric pain, itching):*	*None*	0	1	2	3	4	5	6	7	8	9	10 *Worst*

Edmonton Symptom Assessment System Revised Tool (ESAS-r)

المقياس العددي لتقدير الأعراض

الرجاء اختيار الرقم الذي يصف وضعك الحالي وما تشعر به من اعراض حاليًا:

ألم (صؤلان، وجع)	لا يوجد	0	1	2	3	4	5	6	7	8	9	10	أسوأ ما يمكن
التعب والإرهاق (الوهن، الخمول)	لا يوجد	0	1	2	3	4	5	6	7	8	9	10	أسوأ ما يمكن
النعاس (الشعور بالنوم، الشعور بالنواد)	لا يوجد	0	1	2	3	4	5	6	7	8	9	10	أسوأ ما يمكن
الغثيان (اللوعان، الشعور بالتقيق، الشعور بالزوع)	لا يوجد	0	1	2	3	4	5	6	7	8	9	10	أسوأ ما يمكن
فقدان أو نقص الشهية	لا يوجد	0	1	2	3	4	5	6	7	8	9	10	أسوأ ما يمكن
ضيق في التنفس (ضيق النسم)	لا يوجد	0	1	2	3	4	5	6	7	8	9	10	أسوأ ما يمكن
اكتئاب (الحزن، البؤس، عدم السعادة)	لا يوجد	0	1	2	3	4	5	6	7	8	9	10	أسوأ ما يمكن
قلق (التوتر النفسي، الفزع)	لا يوجد	0	1	2	3	4	5	6	7	8	9	10	أسوأ ما يمكن
العافية والشعور بالصحة العافية = كيف تشعر بشكل عام	أفضل عافية	0	1	2	3	4	5	6	7	8	9	10	أسوأ ما يمكن
أي مشكلة أخرى (مثل الإمساك، حكة، انتفاخ في المعدة، حرقان، حموضة، أرق ومشاكل في النوم أو غيرها ----	لا يوجد	0	1	2	3	4	5	6	7	8	9	10	أسوأ ما يمكن

Appendix 7: DASS-21 English and Arabic version

DASS21

Name: Date:

Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you **over the past week**. There are no right or wrong answers. Do not spend too much time on any statement.

The rating scale is as follows:

0 Did not apply to me at all
1 Applied to me to some degree, or some of the time
2 Applied to me to a considerable degree or a good part of time
3 Applied to me very much or most of the time

1 (s)	I found it hard to wind down	0	1	2	3
2 (a)	I was aware of dryness of my mouth	0	1	2	3
3 (d)	I couldn't seem to experience any positive feeling at all	0	1	2	3
4 (a)	I experienced breathing difficulty (e.g. excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5 (d)	I found it difficult to work up the initiative to do things	0	1	2	3
6 (s)	I tended to over-react to situations	0	1	2	3
7 (a)	I experienced trembling (e.g. in the hands)	0	1	2	3
8 (s)	I felt that I was using a lot of nervous energy	0	1	2	3
9 (a)	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10 (d)	I felt that I had nothing to look forward to	0	1	2	3
11 (s)	I found myself getting agitated	0	1	2	3
12 (s)	I found it difficult to relax	0	1	2	3
13 (d)	I felt down-hearted and blue	0	1	2	3
14 (s)	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15 (a)	I felt I was close to panic	0	1	2	3
16 (d)	I was unable to become enthusiastic about anything	0	1	2	3
17 (d)	I felt I wasn't worth much as a person	0	1	2	3
18 (s)	I felt that I was rather touchy	0	1	2	3
19 (a)	I was aware of the action of my heart in the absence of physical exertion (e.g. sense of heart rate increase, heart missing a beat)	0	1	2	3
20 (a)	I felt scared without any good reason	0	1	2	3
21 (d)	I felt that life was meaningless	0	1	2	3

DASS-21 Scoring Instructions

The DASS-21 should not be used to replace a face to face clinical interview. If you are experiencing significant emotional difficulties you should contact your GP for a referral to a qualified professional.

Depression, Anxiety and Stress Scale - 21 Items (DASS-21)

The Depression, Anxiety and Stress Scale - 21 Items (DASS-21) is a set of three self-report scales designed to measure the emotional states of depression, anxiety and stress.

Each of the three DASS-21 scales contains 7 items, divided into subscales with similar content. The depression scale assesses dysphoria, hopelessness, devaluation of life, self-deprecation, lack of interest / involvement, anhedonia and inertia. The anxiety scale assesses autonomic arousal, skeletal muscle effects, situational anxiety, and subjective experience of anxious affect. The stress scale is sensitive to levels of chronic non-specific arousal. It assesses difficulty relaxing, nervous arousal, and being easily upset / agitated, irritable / over-reactive and impatient. Scores for depression, anxiety and stress are calculated by summing the scores for the relevant items.

The DASS-21 is based on a dimensional rather than a categorical conception of psychological disorder. The assumption on which the DASS-21 development was based (and which was confirmed by the research data) is that the differences between the depression, anxiety and the stress experienced by normal subjects and clinical populations are essentially differences of degree. The DASS-21 therefore has no direct implications for the allocation of patients to discrete diagnostic categories postulated in classificatory systems such as the DSM and ICD.

Recommended cut-off scores for conventional severity labels (normal, moderate, severe) are as follows:

NB Scores on the DASS-21 will need to be multiplied by 2 to calculate the final score.

	Depression	Anxiety	Stress
Normal	0-9	0-7	0-14
Mild	10-13	8-9	15-18
Moderate	14-20	10-14	19-25
Severe	21-27	15-19	26-33
Extremely Severe	28+	20+	34+

Lovibond, S.H. & Lovibond, P.F. (1995). Manual for the Depression Anxiety & Stress Scales. (2nd Ed.)Sydney: Psychology Foundation.

Arabic DASS21

اسم:_____ التاريخ:_____

اقرأ كل من النصوص التالية ثم ضع دائرة حول الرقم ٠،١،٢ أو ٣ الذي يبين درجة انطباق هذا الشعور عليك في الأسبوع الماضي. لا يوجد إجابات صحيحة أو خاطئة. لا تقضي وقتاً طويلاً في أي منها.

استعمل التقديرات التالية:

٠ لا ينطبق عليّ بتاتاً
١ ينطبق عليّ بعض الشيء أو قليلاً من الأوقات
٢ ينطبق عليّ بدرجة ملحوظة أو بعض الأوقات
٣ ينطبق عليّ كثيراً جداً، أو معظم الأوقات

١	وجدت صعوبة في الاسترخاء والراحة	٠	١	٢	٣
٢	شعرت بجفاف في حلقي	٠	١	٢	٣
٣	لم يبدو لي أن بإمكاني الإحساس بمشاعر إيجابية على الإطلاق	٠	١	٢	٣
٤	شعرت بصعوبة في التنفس (شدة التنفس السريع، اللهثان بدون القيام بمجهود جسدي مثلاً)	٠	١	٢	٣
٥	وجدت صعوبة في أخذ المبادرة بعمل الأشياء	٠	١	٢	٣
٦	كنت أميل إلى ردة فعل مفرطة للظروف والأحداث	٠	١	٢	٣
٧	شعرت برجفة (باليدين مثلاً)	٠	١	٢	٣
٨	شعرت بأنني أستهلك الكثير في الطاقة العصبية (شعرت بأنني أستهلك الكثير من قدرتي على تحمل التوتر العصبي)	٠	١	٢	٣
٩	كنت خائفاً من مواقف قد أفقد فيها السيطرة على أعصابي واسبب إحراجاً لنفسي	٠	١	٢	٣
١٠	شعرت بأن ليس لدي أي شيء أتطلع إليه	٠	١	٢	٣
١١	شعرت بأنني مضطرب ومنزعج	٠	١	٢	٣
١٢	أجد صعوبة في الاسترخاء	٠	١	٢	٣
١٣	شعرت بالحزن والغم	٠	١	٢	٣
١٤	كنت لا أستطع تحمل أي شيء يحول بيني وبين ما أرغب في القيام به	٠	١	٢	٣
١٥	شعرت بأنني على وشك الوقوع في حالة من الرعب المفاجئ بدون سبب	٠	١	٢	٣
١٦	فقدت الشعور بالحماس لأي شيء	٠	١	٢	٣
١٧	شعرت بأن قيمتي قليلة كشخص	٠	١	٢	٣
١٨	شعرت بأنني أميل إلى الغيظ بسرعة	٠	١	٢	٣
١٩	شعرت بضربات قلبي بدون مجهود جسدي (زيادة في معدل الدقات، أو غياب دقة قلب، مثلاً)	٠	١	٢	٣
٢٠	شعرت بالخوف بدون أي سبب وجيه	٠	١	٢	٣
٢١	شعرت بأن الحياة ليس لها معنى	٠	١	٢	٣

Appendix 8: Baseline assessment worksheet

University Medical City
Sultan Qaboos Comprehensive Cancer Care & Research Centre

SULTAN QABOOS COMPREHENSIVE CANCER CENTRE

المدينة الطبية الجامعية
مركز السلطان قابوس للتكامل لعلاج وبحوث أمراض السرطان

Weighted Blankets- Baseline assessment worksheet

Subject ID: ---------- Subject initials: ---------- Date: ----------

Eligibility checklist:

Inclusion criteria: (Must Yes for All)		
Newly diagnosed cancer patients aged 18 years and older.	Yes ☐	No ☐
Receiving first-line IV anticancer therapy in DCU (adjuvant, neoadjuvant, or palliative)	Yes ☐	No ☐
Weighting at least 55kg	Yes ☐	No ☐
Able to complete study assessments.	Yes ☐	No ☐
Speaks Arabic or English.	Yes ☐	No ☐
Signs Informed consent.	Yes ☐	No ☐
Exclusion criteria: (Must No for All)		
Prior psychological treatment or psychotherapy	Yes ☐	No ☐
Currently hospitalized in IPUs	Yes ☐	No ☐
Patients on weekly anticancer infusions	Yes ☐	No ☐
Positive fall risk assessment*	Yes ☐	No ☐
Open wounds and recent surgeries/ stoma	Yes ☐	No ☐
Enrolled in any other device study or clinical trial during data collection	Yes ☐	No ☐
History of: • Diabetes mellitus • Respiratory disorders • Claustrophobia • Peripheral neuropathy or Fibromyalgia • Cognitive impairment	Yes ☐	No ☐

Weighted Blankets- Baseline assessment worksheet

Subject ID: ---------- Subject initials: ---------- Date: ----------

***Ambulatory Fall Risk assessment:**

1- Do you have dizziness or vertigo?
Yes ☐ No ☐ Unanswered ☐

2- Do you use ambulatory aids (walker, crutch, artificial limbs)?
Yes ☐ No ☐ Unanswered ☐

3- Have you fallen within the last 6 months?
Yes ☐ No ☐ Unanswered ☐

4- Do you have any visual problem?
Yes ☐ No ☐ Unanswered ☐

Scale Result:

Risk for fall ☐ **No Fall Risk** ☐

Informed consent:

The study participant signed the ICF Version _____ dated _____.

Date of signature _____.

- **If the patient agrees to participate, please complete the following:**

Demographic data:

Gender: Male ☐ Female ☐ **Age:** _____

Educational level: Basic ☐ Secondary ☐
Specialized diploma ☐ Bachelors/Higher studies ☐

Nationality: Omani ☐ Non- Omani ☐ Specify: _____

Religion: Muslim ☐ Non- Muslim ☐ Specify: _____

Region: _____

Weighted Blankets- Baseline assessment worksheet

Subject ID: ---------- Subject initials: ---------- Date: ----------

Smoking: Yes ☐ No ☐ If yes, How many per day? _____

Use of drug or alcohol: Yes ☐ No ☐ If yes, please specify? _____

Medical history:

Diagnosis: _____

Stage of disease: _____

Treatment: Adjuvant ☐ Neoadjuvant ☐ Palliative ☐

Previous Treatments Received (before Anticancer treatment):

Surgery ☐ Radiotherapy ☐ None ☐

Treatment protocol: _____

Estimated Duration of infusion (Including Pre-medications) in hours (hrs):

0.5 – 1 hr ☐ More than 1 – 2 hrs ☐ More than 2 – 3 hrs ☐
More than 3 – 4 hrs ☐ More than 4 – 5 hrs ☐ More than 5 hrs ☐

Weight: _____ kg

DASS-21 (Depression, Anxiety, and Stress Scale-21):

Patient completed DASS-21? Yes No

Version: Arabic ☐ English ☐

Date of completion: _____

Result: _____ **Action if taken:** _____

Participant randomized to: Interventional Arm ☐ **Control Arm** ☐

CRNC /Co-I Name: _____Signature_____ Date: _____

PI/Co-I Name: _____Signature_____ Date: _____

Appendix 9: Care instructions for the weighted blankets

Sommerfly™
Feel the Calm™

NEW

Wipe-Clean™ Fabric Information and Care Instructions:

Sommerfly's NEW Wipe-Clean™ products are Hospital-Grade. Made with our new high tech, ultra durable fabric they are a perfect fit for hospitals, schools or any setting where machine washing is unavailable or inconvenient. Sommerfly™ Wipe-Clean™ products do not require machine laundering!

Our NEW Wipe-Clean™ fabric is waterproof, breathable, tear resistant, anti-microbial and pleasant to touch. Our fabric is flame resistant (class A barrier) and non-toxic.

Cleaning is easy: Use approved cleaning wipes listed below OR wipe down with mild soap suds, rinse with warm water when soilded. Disinfect, if required with 10% bleach and water solution. Air dry or wipe with dry cloth. Do not machine wash or dry or dry clean Sommerfly™ Wipe-Clean™ products.

LIST OF CLEANING AGENTS TESTED BY FABRIC MANUFACTUER:

These agents are noted to be safe when used according to the manufacturer's directions.

- Virox 5 Cleaner (Active Ingredient: 0.5% Hydrogen Peroxide)
- Oxivir® TB Disinfectant Cleaner (Active Ingredient: 0.5% Hydrogen Peroxide)
- CaviWipes Disinfecting Towels (Active Ingredient: 0.28% Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride; 17.2% Isopropanol)
- ProCure V (Active Ingredient: Chlorine Dioxide)
- PDI Sani-Cloth HB Germicidal Disposable Wipe (Active Ingredients: Alkyl dimethyl denzyl ammonium chloride and Alkyl dimethyl ethyl denzyl ammonium chloride)
- Clorox Healthcare Bleach Germicidal Wipes - One-step, ready-to-use disinfectant (Active Ingredient: 0.5% sodium hypochlorite)

Proudly made in the USA with the highest standards in construction and materials.

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Appendix 10: Cycle 3 Visit worksheet (Interventional Arm)

Patient's Initial: _____ Study ID: _____Date: _____

Date of Cycle 1 Day 1: _____ Date of Cycle 2 Day 1: _____

Treatment Regiment: _____

Would you like to use the WB again? هل ترغب في استخدام البطانية الثقيلة مرة أخرى؟	Yes ☐ No ☐ ☐ نعم ☐ لا
If No, please specify the reasons? إذا كانت الإجابة "لا"، يرجى تحديد الأسباب:	☐ Uncomfortable غير مريحة
	☐ Heavy ثقيلة
	☐ Movement restriction تقيّد الحركة
	☐ Breathing difficulty صعوبة في التنفس
	☐ No difference from the regular blanket لا يوجد فرق عن البطانية العادية
	☐ Others (specify)_____ ☐_____ أسباب أخرى (اذكرها)

Appendix 11 Study Schema:

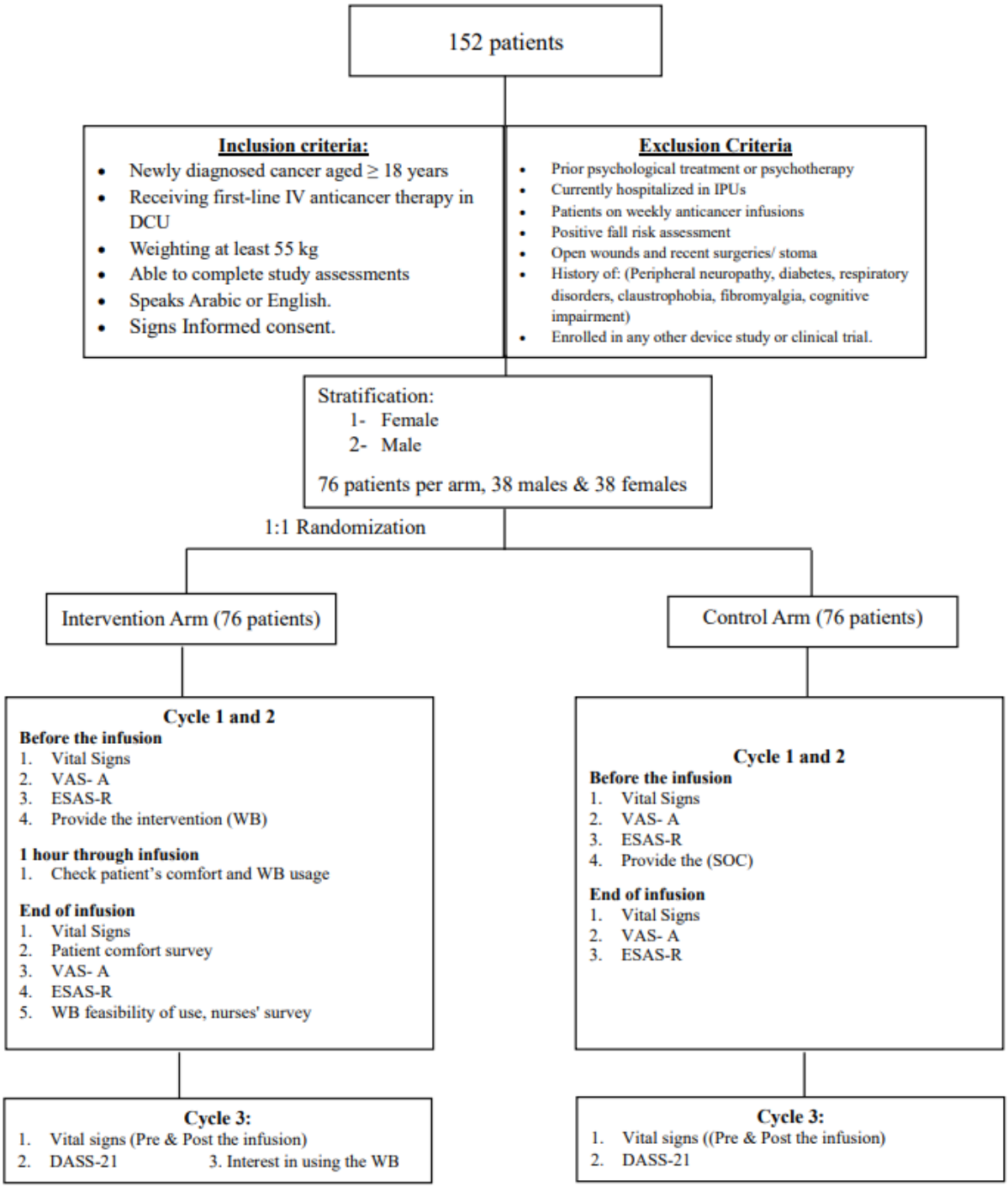


Fig 1: Study Schema