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CLINICAL RESEARCH PROTOCOL

Study Title: **COOLVAS** Study

Exploring the Feasibility and Impact of **Cool**ing Mats on **Vas**omotor Symptoms in Patients Receiving Endocrine Treatment: A Pilot Study

Protocol Number: Version 1

Date: 16th July 2025

Protocol Author:

Breege Farrelly and Moira Maxwell

Principal Investigators:

Breege Farrelly, Advanced Nurse Practitioner Oncology, Sligo University Hospital, Ireland

INVESTIGATOR PROTOCOL AGREEMENT PAGE

I, the undersigned, am responsible for the conduct of the trial at this site and agree to the following:

- I understand and will conduct the trial according to the protocol, any approved protocol amendments, ICH GCP and all applicable regulatory authority requirements and national laws.
- I will not deviate from the protocol without prior written approval from the Institutional Review Board or Independent Ethics Committee, except where necessary to prevent any immediate danger to the subject.
- I have sufficient time to properly conduct and complete the trial within the agreed trial period, and I have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.
- I will ensure that any staff at my site(s) who are involved in the trial conduct are adequately trained regarding the protocol and their responsibilities.

Signed Date

_____ _____

Breege Farrelly, Principal Investigator, Sligo University Hospital

CO-INVESTIGATORS

Moira Maxwell, CNM2, Cancer Research Department, Sligo University Hospital.

Mary O'Brien Staff Nurse, Cancer Services, Sligo University Hospital.

Oliva Grady, Oncology CNS, Sligo University Hospital.

Dr Lore Komanyae, Consultant Medical Oncologist, Sligo University Hospital.

Dr. Michael Martin, Consultant Medical Oncologist, Sligo University Hospital.

CONTENTS

1. SYNOPSIS

Study Title	Exploring the Feasibility and Impact of **Coo**ling Mats on **Vas**omotor Symptoms in Patients Receiving Endocrine Treatment: A Pilot Study. **COOLVAS**
Background	Hot flashes and other vasomotor symptoms (VMS) are common and distressing, affecting up to 75% of women during peri- and post-menopause. These symptoms significantly impair quality of life and increase risks for depression, anxiety, and cardiovascular disease. Management is especially challenging in cancer patients, where hormone replacement therapy is contraindicated. Women undergoing endocrine therapy for breast cancer and men receiving androgen deprivation therapy for prostate cancer often report VMS and rely on non-pharmacological interventions.
Rationale	VMS are highly prevalent among cancer patients on endocrine therapy and are associated with poor treatment adherence, impaired sleep, and psychological stress. Cooling gel pads may offer a safe and effective symptom management strategy, but evidence supporting their use, particularly in Ireland, is limited.
Study Aim	1. Assess the severity of vasomotor symptoms in patients undergoing endocrine therapy following a breast or prostate cancer diagnosis. 2. Evaluate the feasibility and effectiveness of a non-pharmaceutical intervention, which uses thermoregulation materials, designed to keep body temperature in a comfortable range by reducing heat, through a cooling mat, for managing these symptoms.
Objectives	1. To identify the prevalence and severity of vasomotor symptoms in patients receiving endocrine therapy. 2. To determine patient tolerance and satisfaction with the use of a cooling pad, as a non-pharma logical intervention for symptom management. 3. To explore any changes in the frequency and severity of vasomotor symptoms when using a cooling pad. 4. To assess the feasibility of incorporating a cooling pad as a routine non-pharmacological intervention in clinical practice.
Endpoints	**Primary Endpoint** To reduce the severity and frequency of vasomotor symptoms.

	Secondary Endpoint 1. To evaluate patient satisfaction and tolerability 2. Assess feasibility of cooling pad use 3. Assess change in sleep quality 4. Assess impact on quality of life
Study Design	Prospective, single-arm pilot study with 30–40 adult patients with hormone-sensitive breast or prostate cancer receiving endocrine therapy. Recruitment at Sligo University Hospital Oncology Service.
Inclusion Criteria	• Adult aged ≥ 18 years • Diagnosed with breast or prostate cancer • Receiving endocrine therapy cancer treatment • Experiencing vasomotor symptoms, such as hot flushes or night sweats.
Exclusion Criteria	• Prior use of cooling mats for vasomotor symptoms • Allergy to Polyvinyl chloride (PVC) • Patients who are unable to co-operate with the study protocol • Patients who are unable to give informed consent
Intervention & Procedures	Participants receive two Silentnight® cooling gel pads (pillow and mattress) for 8 weeks. Baseline demographic, medical, and social data will be collected. VMS assessment tools include: • Hot Flash-Related Daily Interference Scale (HFRDIS) • NCI CTCAE v5 • PRO-CTCAE® Symptom Terms • 3-Category Daily Hot Flash Diary • Daily cooling pad usage and satisfaction log
Data Collection & Analysis	Descriptive statistics for demographics and VMS characteristics. Pre-/post-intervention comparisons using paired t-tests or Wilcoxon signed-rank tests. Correlation analyses (Pearson's or Spearman's). IBM SPSS v31 for analysis.
Risks & Benefits	Risks: Minimal, potential mild skin irritation or discomfort. Benefits: Identification of a safe, non-drug VMS intervention; potential improvement in therapy adherence and patient well-being.

Ethical Considerations	Ethical approval from Sligo University Hospital. Compliance with GCP and HSE data policies. Participants can withdraw anytime. Adverse events monitored and serious events reported.
Data Protection & Dissemination	Data pseudonymised and stored securely for five years. Results may be published or presented, with confidentiality maintained.

2. INTRODUCTION

2.1 Background Information

Hot flashes are a common and distressing symptom during perimenopause and post-menopause, affecting up to 75% of women. These symptoms, including sudden heat, sweating, and flushing, can last for years and significantly impact quality of life by disrupting sleep and mood, and increasing risks of depression, anxiety, and cardiovascular disease.

For women with a history of breast cancer, managing hot flashes is particularly challenging as hormone replacement therapy is often contraindicated. Non-pharmacological interventions, such as lifestyle modifications, cognitive behavioural therapy, relaxation techniques, mindfulness, physical activity, and acupuncture, are crucial alternatives. Men undergoing endocrine therapy for prostate cancer also experience hot flashes and rely on similar non-pharmacological strategies for relief.

This study aims to identify if another non-pharmacological intervention, a cooling mat, can assist individuals in managing their hot flash symptoms as a consequence of cancer treatment and thus improve their quality of life. This investigation seeks to address a critical gap in the existing evidence base by evaluating a novel and emerging supportive care intervention. The findings from this study are intended to contribute to the development of evidence-based, patient-centred interventions that are practical, accessible, and suitable for integration into routine oncology practice.

In summary, hot flashes remain a significant unmet need in supportive cancer care for both women and men affected by hormonal changes due to cancer therapies. Non-pharmacological interventions, including the potential use of cooling mats, are essential, especially when hormonal treatments are not an option, and should be tailored to individual needs and preferences. This study addresses a key gap in current research by guiding the development of evidence-based, patient-centred supportive care strategies to enhance supportive care in oncology practice.

3. STUDY RATIONALE

Patients undergoing endocrine therapy for hormone-sensitive cancers, such as breast and prostate cancer, frequently experience vasomotor symptoms (VMS), including hot flushes and night sweats. These symptoms are often induced by treatment-related menopause or hormonal suppression and can be distressing, leading to:

- Reduced quality of life
- Disrupted sleep
- Decreased medication adherence
- Increased psychological burden

Pharmacologic options for managing these symptoms (e.g., hormone replacement therapy) are often contraindicated in this population due to the hormone-sensitive nature of their cancer. Cooling gel pads offer a simple, low-risk, and potentially effective non-pharmaceutical approach to manage vasomotor symptoms by maintaining thermoregulation during rest or sleep. Preliminary evidence suggests cooling surfaces can reduce the intensity and frequency of hot flushes, but there is limited data specific to cancer populations, especially in Ireland. This research seeks to fill a critical gap in the current evidence base and inform the development of supportive care interventions that are safe, patient-centred, and practical for implementation in real-world oncology settings.

4. STUDY AIM

1. Assess the severity of vasomotor symptoms in patients undergoing endocrine therapy following a breast or prostate cancer diagnosis.
2. Evaluate the feasibility and effectiveness of a non-pharmaceutical intervention, which uses thermoregulation materials, designed to keep body temperature in a comfortable range by reducing heat, through a cooling mat, for managing these symptoms.

5. STUDY OBJECTIVES

1. To identify the prevalence and severity of vasomotor symptoms in patients receiving endocrine therapy.
2. To determine patient tolerance and satisfaction with the use of a cooling pad, as a non-pharma logical intervention for symptom management.

3. To explore any changes in the frequency and severity of vasomotor symptoms when using a cooling pad.
4. To assess the feasibility of incorporating a cooling pad as a routine non-pharmacological intervention in clinical practice.

6. STUDY ENDPOINTS

6.1 Primary Endpoint

To reduce the severity and frequency of vasomotor symptoms.

6.2 Secondary Endpoint

1. To evaluate patient satisfaction and tolerability
2. Assess feasibility of cooling pad use
3. Assess change in sleep quality
4. Assess impact on quality of life

7. STUDY DESIGN

This is a prospective single arm pilot study to assess the feasibility and effectiveness of cooling mats in reducing the frequency and severity of vasomotor symptoms.

8. STUDY POPULATION

Adult patients diagnosed with hormone sensitive breast or prostate cancer receiving endocrine therapy and experiencing vasomotor symptoms.

8.1 Participant Selection and Recruitment

Purposeful sampling method will be utilised to select patients that meet the eligibility criteria and attend the Oncology Service. Patients will be provided with information about the study and will be enrolled following written informed consent.

8.2 Study Inclusion Criteria

- Adult aged ≥ 18 years
- Diagnosed with breast or prostate cancer

- Receiving endocrine therapy cancer treatment
- Experiencing vasomotor symptoms, such as hot flushes or night sweats.

8.3 Exclusion Criteria

- Prior use of cooling mats for vasomotor symptoms
- Allergy to Polyvinyl chloride (PVC)
- Patients who are unable to co-operate with the study protocol
- Patients who are unable to give informed consent

9. WITHDRAWL FROM STUDY

Participants will be informed of their right to refuse to participate and their right to withdraw from this research study

10. INFORMED CONSENT

Informed consent to take part in the research will be obtained. Patients will be consented by a member of the study team. This will occur in person when they attend their clinic visit. Information about the study may be provided remotely as follows:

- Potential participates identified at the hospital clinic will be provided a hard copy of the Patient Information Leaflet and Informed Consent Form (PIL/ICF).
- Potential participants identified from a virtual clinic will receive a hard copy of the PIL/ICF in the post.
- If the patient is willing to consent to the study they will be asked to attend the hospital clinic to sign the consent form with the research team member who will also sign the consent form.
- The completed ICF (signed by the both the participant and the research team member) will be filed in the study file which is kept securely in the cancer research office. One copy will be placed in the patient's medical notes and one copy will be given to the participant for their own records.
- Participants will be given the opportunity to take their time between receiving the PIL and agreeing to participate in the study, this may mean attending to provide consent at a subsequent clinic.

11. METHODOLOGY

All participants will be assessed with regards to their vasomotor symptoms at baseline along with demographic data collection. They will then be provided with two Silentnight© cooling gel pads:

1. Restore by Silentnight Cooling Gel Pillow Pad.
2. Restore by Silentnight Body Cooling Gel Mattress Pad.

Participants will receive written instructions on their use and maintenance, Appendix II. Participants will use the intervention for eight weeks and complete a daily hot flash and cooling pad utilisation diary. At the end of the intervention phase, vasomotor symptoms, adherence and satisfaction will be assessed.

Schedule of Assessments next page.

Table 1 Schedule of assessments

	Time Point		
	Baseline	8 week Intervention phase	End of Intervention (Virtual Visit)
Procedures			
Screening/Eligibility • Informed Consent • Screening/Eligibility • Enrolment Form	X		
Demographics • Sex • Age • Ethnicity	X		
Medical History • Cancer Diagnosis • Menopausal Status • Endocrine Therapy • BMI	X		
Social History • Employment Status • Smoking Status • Alcohol Intake • Caffeine Intake • Exercise Levels	X		X
Vasomotor symptom management Strategies History	X		X
Vasomotor Assessments • Hot Flash-Related Daily Interference Scale (HFRDIS) • NCI CTCAE v5 Hot Flashes • NCI CTCAE PROM	X		X
Daily Hot Flash Diary		X	
Cooling Pad Usage		X	
Satisfaction with Cooling Pad			X
Adverse Events	X	X	X

12. INTERVENTION

The intervention being evaluated comprises of Silentnight Restore Cooling Gel Mattress Pad and Silentnight Restore Cooling Gel Pillow Pad, a non-pharmacological, non-invasive commercially available cooling aid designed to provide localized body cooling and thermal comfort, particularly during sleep. It is intended for individuals who experience overheating or night sweats, including those with vasomotor symptoms.

The mattress pad measures 60 x 90 cm, approximately the width of a standard pillow and long enough to cover the upper body area where night sweats typically occur. It is composed of 100% PVC outer material with a 100% gel inner core, divided into three gel compartments to help prevent heat dispersion across the mattress and maintain localized cooling. The pad has a depth of 5 mm and features a soft and flexible structure. The pillow pad measures 60 x 40cm and is composed the same material as the mattress pad, divided into two gel compartments.

Participants will be instructed to use the cooling pad daily for a period of 8 weeks, placing it either directly under their body, on top of the mattress, or beneath the fitted sheet or pillow case, based on personal comfort. The pad functions passively by absorbing excess body heat to reduce skin temperature. For enhanced cooling on particularly hot nights, participants may optionally place the pad in the refrigerator prior to use, although refrigeration is not required for efficacy.

The pads are wipe-clean only and must not be bleached, tumble dried, or ironed. They can be folded neatly for travel or storage and must be kept away from fire. While its primary use is during sleep, participants may also use the pad while sitting or reclining, such as on a sofa or during travel. Participants will be provided verbal and written instructions of use, as detailed in appendix II.

13. ASSESSMENTS AND PROCEDURES

13.1 Demographics

At baseline participants will be asked their sex, age and ethnicity.

13.2 Medical History

At baseline, participants will provide information on their cancer diagnosis, menopausal status (for females), endocrine treatment history, height, and weight (for BMI calculation).

13.3 Social History

Participants social history, including employment status, smoking, alcohol and caffeine intake, and exercise levels, will be collected at baseline and at the end of the intervention phase.

13.4 Vasomotor Symptom Assessment

Multiple tools will be used to assess vasomotor symptoms:

- **Hot flash-Related Daily Interference Scale (HFRDIS)**

  The Hot Flash-Related Daily Interference Scale (HFRDIS) is a validated, self-report questionnaire used to measure how much hot flashes interfere with various aspects of daily life, particularly those experiencing menopause or undergoing treatments that cause vasomotor symptoms. It consists of 10 items that assess the impact of hot flashes on areas such as work, social and leisure activities, sleep, mood, concentration, sexuality, and overall quality of life. Each item is rated on a scale from 0 (not at all interfering) to 10 (extremely interfering), with higher scores indicating greater disruption. The total score provides a summary measure of overall interference. The HFRDIS is widely used in clinical and research settings to evaluate the burden of hot flashes and assess the effectiveness of interventions aimed at alleviating them. The HFRDIS demonstrates strong psychometric properties, including high internal consistency (Cronbach's alpha > 0.90) and established construct and convergent validity with other measures of quality of life and symptom burden. It can be completed in approximately five minutes. Permission was sought from Dr Janet S. Carpenter, author of the HFRDIS and a leading expert on menopause symptoms, and granted on 24th September 2024 for use in this study.

- **NCI CTCAE v5 Hot Flashes**

  The NCI Common Terminology Criteria for Adverse Events (CTCAE) version 5.0 includes a standardized grading system for assessing hot flashes as an adverse event in clinical trials. This tool, developed by the National Cancer Institute, is used to classify the severity of hot flashes based on their impact on daily functioning.

  In CTCAE v5.0, hot flashes are defined as sudden, transient episodes of flushing, typically associated with perspiration. The grading is as follows:

  - Grade 1 represents mild symptoms that do not interfere with function.
  - Grade 2 indicates moderate symptoms that limit instrumental activities of daily living (e.g., preparing meals or using the telephone).

- Grade 3 reflects severe symptoms that limit self-care activities of daily living (e.g., bathing or dressing).

This standardized grading system allows for consistent reporting and monitoring of treatment-related hot flashes across studies and supports the evaluation of intervention safety and tolerability.

- **PRO-CTCAE® Symptom terms: Hot flashes and Insomnia**

The Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE®) includes symptom terms such as insomnia and hot flashes, allowing patients to directly report the frequency, severity, and interference of these symptoms in clinical trials. For insomnia, patients typically rate how often they experienced difficulty sleeping, how severe it was, and how much it interfered with daily activities. For hot flashes, patients report on the frequency and severity of episodes, as well as their impact on daily life. This tool complements clinician-reported CTCAE by capturing the patient's subjective experience, enhancing the accuracy and sensitivity of symptom monitoring in cancer and symptom management research.

- **3-Category Daily Hot Flash Dairy adapted from Guttuso et al. (2012)**

The three-category hot flash diary is a standardized patient-reported tool designed to capture the frequency and severity of hot flashes over time. As reviewed by Guttuso et al. (2012), this diary categorizes hot flashes into mild, moderate, or severe episodes, allowing participants to record the number and intensity of occurrences throughout the day.

- Mild hot flashes are those that are noticeable but do not cause discomfort or disruption.
- Moderate hot flashes may cause discomfort and possibly some interference with activities.
- Severe hot flashes are intensely uncomfortable and significantly disrupt daily activities or sleep.

Participants will be asked to complete the diary daily, making it a useful tool for tracking symptom patterns and evaluating the effectiveness of therapeutic interventions. The three-category diary is valued for its simplicity, feasibility, and sensitivity in clinical trials and observational studies involving vasomotor symptom management. It helps quantify symptom burden over time, offering objective data to complement subjective quality-of-life measures.

- **Vasomotor symptom management Strategies History**

Participants will be asked about history what vasomotor symptoms management strategies they have used in the past.

- **Cooling Pad Utilization and Satisfaction**

Participants will record daily cooling pad usage, and satisfaction data will be collected at the end of the intervention phase.

14. STATISTICAL METHODS

14.1 Statistical Analysis

Data analysis will include descriptive statistics will be used to characterise the sample through measurement of central tendency, variability and frequency distribution. Comparative analysis (paired t-test or Wilcoxon signed-rank test depending on distribution of data) will compare the pre/post intervention differences on the dependent variables. Correlation analysis will be used to assess relationship between the variables (Pearson's correlation or Spearman's rank correlation depending on distribution of data).

Data analysis will be done by the research team using IBM SPSS version 31.

14.2 Proposed Sample Size and Calculation

The study team aims to prospectively enrol approximately 40 patients to this study.

Based on last year's combined data for breast and prostate cancer patients at the hospital, 130 individuals were diagnosed and referred for treatment, with approximately 65% of breast cancer patients and all prostate cancer patients receiving endocrine therapy. As a result, the target population size is 95, requiring a representative sample of 77 patients (95% confidence level, 5% confidence interval). However, due to constraints in human resources, time, and financial securement to allow the purchase of the necessary cooling mats, a pilot study is proposed. No previous Irish study available to guide sample size.

A literature review indicates that pilot studies typically require 10–30 participants per group, with at least 30 recommended for estimating effect sizes. Therefore, a sample size of 30–40 participants has been selected for this single-arm pilot study, considering the inclusion of two distinct populations (breast and prostate cancer patients). As this is a pilot study, it is not intended to be representative.

15. STUDY RISKS

The cooling mat is a non-pharmacological, passive strategy. Therefore, risks, if any are expected to be minimal. No serious adverse events are expected from the use of the cooling mat based on its intended design and current evidence.

However potential anticipated adverse events may include and are not limited to:

- Mild skin irritation or rash
- Discomfort during sleep or difficulty adjusting to the device
- Allergic reaction to materials (rare)

16. STUDY BENEFITS

The potential identification of a non-pharmaceutical intervention for vasomotor symptoms in patients receiving endocrine therapy.

17. ADVERSE EVENT REPORTING

An Adverse Event (AE) is any untoward medical occurrence in a participant that arises during the course of the study, regardless of whether it is considered related to the study intervention (cooling pad).

A Serious Adverse Event (SAE) is defined as any AE that:

- Results in death
- Is life-threatening
- Requires inpatient hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability or incapacity
- Is a congenital anomaly/birth defect
- Is deemed medically significant by the investigator Adverse Events (AE) refers to any untoward event or medical occurrence that may not have a causal relationship with the treatment.

17.1 Monitoring and Detection

Participants will be provided with contact information for the study team and instructed to report any symptoms or concerns. Study staff will proactively inquire about potential adverse effects during

scheduled check-ins. Participants will be monitored through routine clinical care and follow-up appointments.

17.2 Documentation of Adverse Events

All adverse events must be documented in the patient's medical records and recorded in the study Adverse Events Log, Appendix VIII, to include:

- Date and time of event onset
- Description of the event
- Severity (mild, moderate, severe)
- Assessment of relatedness to the study intervention (definitely, probably, possibly, unlikely, or unrelated)
- Action taken (e.g., discontinuation of mat, medical treatment)
- Outcome and resolution date

17.3 Reporting of Adverse Events

Non-serious AEs:

- Logged in patient medical records and AE logs
- Reviewed during regular team meetings
- Reported in study summary at conclusion

Serious Adverse Events

- Must be reported to the Principal Investigator and patients medical consultant within 24 hours of awareness.
- Principal Investigator reports to the Research Ethics Committee (REC) within 7 calendar days of awareness (for unexpected and related SAEs)
- Documentation medical records and AE log.

17.4 AE/SAE Follow-up and Management

All AEs will be followed until:

- The event resolves

- The participant returns to baseline health status
- A final outcome is established

If any participant discontinues use of the cooling mat due to an AE, the reason and outcomes must be fully documented.

18. ETHICS AND REGULATORY CONSIDERATIONS

Ethics approval has been obtained for this study from the ethics committee governing Sligo University Hospital. All study procedures will be conducted in line with Good Clinical Practice Guidelines.

19. DATA PROTECTION

Explicit consent will be sought from participants for the processing of their data.

Sligo University Hospital, HSE is both the data controller and data processor for this study.

20. DATA HANDLING

20.1 Data Storage

Data will be retained for a period up to 5 years post completion of study and destroyed as per HSE policy.

20.2 Data Processing

All data collected is for the purpose of achieving the objective of this research study. The data will not be processed in any way that will cause damage or distress to the participant.

Once explicit consent has been obtained from participants their data will be pseudonymised by assigning a unique identifier to their data. Only members of the research team will have access to the identifier key which will be locked in restricted office within Sligo University Hospital.

All study documents and participant data will be stored in a locked and restricted office within Sligo University Hospital. Only study team members will have access to the data. Data analysis will be completed on a HSE computer that is password protected, encrypted and cyber secure per the HSE IT security policy.

20.3 Data Confidentiality

All information regarding the study data or results supplied to the investigator is privileged and confidential information. All research team members who have access to the data are bound to maintain confidentiality in line with their employment contract and professional conduct per their regulatory body.

21. PUBLICATION OF STUDY FINDINGS AND USE OF INFORMATION

Data associated with this study may be used in the context of scientific research and publications or educational material. No participant will be identifiable from the data presented.

22. INDEMNITY

This study is registered with the Clinical Research Development Office and CIS cover obtained where applicable.

APPENDIX I: PATIENT INFORMATION LEFLEAT AND INFORMED CONSENT FORM

Patient Information Leaflet

Study title: Exploring the Feasibility and Impact of Cooling Mats on Vasomotor Symptoms in Patients Receiving Endocrine Treatment: A Pilot Study

Principal investigator's name: Breege Farrelly

Principal investigator's title: Advanced Nurse Practitioner Oncology

Telephone number of principal investigator: 0877918160

Co-investigator's name: Moira Maxwell

Co-investigator's title: Research Clinical Nurse Manager II

Co--investigator's name: Olivia Grady

Co-investigator's title: Clinical Nurse Specialist

Co--investigator's name: Mary O'Brien

Co-investigator's title: Staff Nurse

Data Controller's/joint Controller's Identity: Breege Farrelly

Data Controller's/joint Controller's Contact Details: 0877918160

Data Protection Officer's Identity: Liam Quirke

Data Protection Officer's Contact Details: Email: ddpo.west@*hse*.ie

Introduction

You are being invited to take part in a research study to be carried out at Sligo University Hospital by Principal Investigator Breege Farrelly and nurse colleagues in oncology department, with the full endorsement of both medical oncology consultants, Dr Michael Martin and Dr Lore Komanyane.

Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or doctor. Take time to ask questions – don't feel rushed and don't feel under pressure to make a quick decision.

You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

You don't have to take part in this study. If you decide not to take part it won't affect your future medical care.

You can change your mind about taking part in the study any time you like. Even if the study has started, you can still opt out. You don't have to give us a reason. If you do opt out, rest assured it won't affect the quality of treatment you get in the future.

Why is this study being done?

This research study will investigate whether using a non-drug option, like a cooling mat, made of temperature-regulating materials, can help relieve the discomfort of hot flushes and/or night sweats for people receiving hormone treatment following a cancer diagnosis.

Cooling mats are made from specialised material designed to keep body temperature in a comfortable range by reducing heat. Previous research has shown these materials can be helpful for managing hot flushes during menopause, and we are investigating if the same benefits apply to cancer patients.

Ultimately we hope this information will offer an alternative, non-drug option for managing these symptoms, providing cancer patients with additional approach to improve their quality of life.

Who is organising and funding this study?

The study is being run by nurses in the oncology department, who are employed at Sligo University Hospital.

The pharmaceutical company Novartis is providing some funding for this study. The majority of the funds will be allocated to purchasing cooling mats, while the remaining funds will be used for a statistical analysis package, posters, and other necessary materials.

There is no financial gain for any of the research team. This is solely being done to improve symptom management for patients.

Why am I being asked to take part?

You are invited to participate in this study because you have are experiencing hot flushes and/or night sweats and are prescribed endocrine treatment after a cancer diagnosis.

How will the study be carried out?

We plan to commence the study in early 2025 at Sligo University Hospital for a 3-6 month a period. We aim to recruit 40 patients with a breast or prostate cancer diagnosis who report hot flushes interfering with their quality of life.

We will provide the cooling mat, to help manage your hot flushes and you will also be asked to complete questionnaires and a hot flush diary.

What will happen to me if I agree to take part?

Following your consent, you will be asked to complete a daily questionnaire/scale for a short period to ascertain the impact of the hot flushes on your quality of life prior to an intervention. This should take no longer than 5 minutes each day. Once this information is completed, a cooling mat will be provided to you, with instructions on its use and care. You will be asked to complete a daily questionnaire which again should take no longer than 5 minutes daily. On completion of 8 weeks of use of the cooling mat, you will be asked to reassess if a benefit has been experienced as a result of the intervention.

What are the benefits?

As part of this study, you will be provided with a cooling mat to use. We hope that its use will help reduce the severity of your hot flushes. The results of this study may benefit other cancer patients who experience hot flushes related to cancer treatments.

What are the risks?

We envisage your participation in this study carrying minimal risk. No serious adverse events are expected from the use of the cooling mat based on its intended design and current evidence.

However potential adverse events may include and are not limited to:

- Mild skin irritation or rash
- Discomfort during sleep or difficulty adjusting to the device
- Allergic reaction to materials (rare)

Your oncology team and study team are available to discuss any concerns.

What if something goes wrong when I'm taking part in this study?

If any issue arises during the course of your participation or if you wish to make a complaint, please contact your oncology team or a member of the study team.

If you wish to make a formal complaint please contact:

Patient Advice Liaison Services (PALS) Co-Ordinator

Saolta University Healthcare Group

Sligo University Hospital

Email: pals.suh@hse.ie

Will it cost me anything to take part?

No. It will not cost you anything to take part in this study. The cooling mat will be provided to you for the study.

Is the study confidential?

Yes. The information collected as part of the study will remain confidential. A unique study ID number will be assigned to each participant. This number is linked to the patient identifying information (a process called pseudo anonymization). The information collected for the study will be stored in a secure location in the Hospital by the Principle Investigator.

Research team members who have access to the data are bound to maintain confidentiality in line with their employment contract and will have undertaken GDPR training. Study data will be maintained confidentially in a dedicated database in a secure location within the hospital for 5 years. It will then be destroyed in line with HSE practice.

The findings will be published in a nurse journal and displayed at local and national professional conferences. No identifiable information will be published.

Data Protection

We will be using your personal information in our research to help us gain a greater understanding of a non-drug intervention to manage hot flushes related to cancer treatments for legitimate interests and for scientific research purposes. Researchers involved in this study will have access to the data. All research staff are bound to maintain confidentiality in line with their employment contract and will have undertaken training in data protection law and practice. If any data breach occurs during this study, appropriate measures will be taken. You will be informed and further processes to mitigate the risk of data breach will be reviewed and implemented.

You have the right to withdraw consent to your participation and to your data being used in this study. Please inform your oncology nurse or the principal investigator. This will not affect your care or treatment plan.

Under data protection legislation, it is important to know that as a participant in the study, you have a right to lodge a complaint with the Data Protection Commissioner.

You have the right to request access to your data and receive a copy of it.

You have the right to restrict of object to processing.

You have the right to have any inaccurate information about you corrected or deleted, unless your request would make it impossible or make it very difficult to conduct the research.

You have the right to have your personal data deleted, unless the timing of the deletion would be impossible i.e. just before publication.

You have the right to data portability, meaning you have a right to move your data from one controller to another in a readable format.

Please be assured there is no automated decision making or patient profiling in this study. Data will be used for the reasons stated above.

All study data will remain in Ireland at Sligo University Hospital.

If you have any questions about data privacy and data protection, please contact the Data Protection Officer for the hospital by phone: 091 524222, or email: ddpo.west@hse.ie

Consent to Future Uses

We would like to retain the data for up to five years for the possible future research by the current researcher or colleagues. Any such research will remain in keeping with recognised ethical standards for scientific research.

Where can I get further information?

If you have any further questions about the study or if you want to opt out of the study, you can rest assure it won't affect the quality of treatment you get in the future.

If you need any further information now or at any time in the future, please contact:

Name: Breege Farrelly, ANP Oncology

Address Sligo University Hospital, Rathquarter, F91 H684

Phone No 0877918160

Name: Moira Maxwell, Research Clinical Nurse Manager II

Address Sligo University Hospital, Rathquarter, F91 H684

Phone No 0874526654

PATIENT CONSENT FORM

Study title: Exploring the Feasibility and Impact of Cooling Mats on Vasomotor Symptoms in Patients Receiving Endocrine Treatment: A Pilot Study

I have read and understood the Information Leaflet about this research project. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	Yes ☐	No ☐
I understand that I don't have to take part in this study and that I can opt out at any time. I understand that I don't have to give a reason for opting out and I understand that opting out won't affect my future medical care.	Yes ☐	No ☐
I am aware of the potential risks, benefits and alternatives of this research study.	Yes ☐	No ☐
I give permission for researchers to look at my medical records to get information. I have been assured that information about me will be kept private and confidential.	Yes ☐	No ☐
I have been given a copy of the Information Leaflet and this completed consent form for my records.	Yes ☐	No ☐
I consent to take part in this research study having been fully informed of the risks, benefits and alternatives.	Yes ☐	No ☐
I give informed explicit consent to have my data processed as part of this research study.	Yes ☐	No ☐
I consent to be contacted by researchers as part of this research study.	Yes ☐	No ☐

FUTURE CONTACT [please choose one or more as you see fit]		
I consent to be re-contacted by researchers about possible future research related to the current study for which I may be eligible.	Yes ☐	No ☐

STORAGE AND FUTURE USE OF INFORMATION		
RETENTION OF RESEARCH MATERIAL IN THE FUTURE		
I give permission for material/data to be stored for *possible future research related* to the current study *without further consent being required* but only if the research is approved by a Research Ethics Committee.	Yes ☐	No ☐

I give permission for material/data to be stored for ***possible future research unrelated*** to the current study ***without further consent*** being required but only if the research is approved by a Research Ethics Committee.	Yes □	No □

Patient Name (Block Capitals) Patient Signature Date

--- --- ---

Translator Name (Block Capitals) Translator Signature Date

--- --- ---

Legal Representative/Guardian Name Legal Representative/Guardian Signature Date

--- --- ---

To be completed by the Principal Investigator or nominee.

I, the undersigned, have taken the time to fully explain to the above patient the nature and purpose of this study in a way that they could understand. I have explained the risks involved as well as the possible benefits. I have invited them to ask questions on any aspect of the study that concerned them.

Name (Block Capitals) | Qualifications | Signature | Date

3 copies to be made: 1 for patient, 1 for PI and 1 for hospital records.

APPENDIX II: INSTRUCTIONS FOR CARE AND USE OF RESTORE BY SILENTNIGHT COOLING PADS (as per manufacturer's instructions)

As part of this study, you will be using the **Silentnight Cooling Gel Mattress Pad** and **Silentnight Restore Cooling Gel Pillow Pad** at home each night to help manage symptoms such as hot flashes and night sweats. Please follow the instructions below to ensure safe and consistent use of the cooling pad throughout the study period.

Cooling Pads Composition Materials:

- Cover: 100% PVC
- Filling: 100% Gel

How to Use the Cooling Pad:

1. **Placement Mattress Pad:**
    - Place the cooling pad on your mattress in the area where your upper body typically rests.
    - You can use the pad **on top of your fitted sheet** or **underneath it**, depending on what feels most comfortable to you.
    - Ensure the pad lies flat and does not bunch or fold while in use.

    Placement Pillow Pad:
    - Fits across a standard pillow
    - Insert the pad inside your pillowcase, on top of your usual pillow, or place it directly on top.
2. **Nightly Use:**
    - Use the cooling pad during your normal sleep schedule.
    - If you wake up during the night and need to reposition the pad, do so to maintain comfort.
    - If desired, you may **chill the pad in the refrigerator** for extra cooling, especially on warmer nights. Do **not** place the pad in a freezer.
3. **Other Settings (Optional):**
    - You may also use the pad while sitting or resting during the day (e.g., on a sofa).

Care Instructions:

- The pad is **wipe-clean only**. Use a damp cloth and mild soap if needed.
- Do not machine wash, tumble dry, or iron the pad.
- Store the pad flat or loosely folded in a cool, dry place when not in use.
- Keep away from fire.
- Check the pad daily for any damage or leaks.

During the Study Period:

- **Complete symptom diary daily** to track your experience, including whether you used the pad.

If You Experience Any Problems:

- If the pad causes discomfort, skin irritation, or disrupts your sleep, stop using it and inform the research team immediately.
- If the pad is damaged, discontinue use and notify the research team for a replacement.

Research Team Contact Numbers:

0877918160 or 0874526654 (office hours only)

Clinical Nurse Specialist Contact Numbers:

Breast Care Nurse: 0873331729 or Oncology CNS: 0877589022 (office hours only)

Out of Office hours Contact Number:

0719174399 (haematology/oncology inpatient ward)

In an emergency, please attend your local emergency department or GP.

APPENDIX III: ELIGIBILITY AND ENROLLMENT FORM

COOLVAS STUDY PARTIICIPANT ELIGIBILITY AND ENROLLMENT FORM

Section 1. Eligibility		
Inclusion Criteria	**Yes**	**No**
Adult aged ≥ 18 years		
Diagnosed with breast or prostate Cancer		
Receiving endocrine therapy cancer treatment		
Experiencing vasomotor symptoms, such as hot flushes or night sweats.		
Exclusion Criteria	**Yes**	**No**
Prior use of cooling mats for vasomotor symptoms		
Patients who are unable to co-operate with the study protocol		
Patients who are unable to give informed consent		
Allergy to Polyvinyl chloride (PVC)		

Section 2. Enrolment	
Date of Informed Consent (mm/dd/yyyy)	__ /__ / _____
Participant Enrolment Number	___ ___ ___

Completed by:

_____ _____ _____

Print Name **Sign** **Date**

APPENDIX IV: BASELINE ASSESSMENT FORM

COOLVAS STUDY

BASELINE ASSESSMENT QUESTIONNAIRE Version 1

Study Number:_____ Date:_____

Section 1. Demographics	**Please tick your answer in the box or write in the space provided**
1. What is your gender?	Male □ Female □
2. What is your age?	_____ years
3. What is your ethnicity?	
Section 2. Medical History	**Please tick your answer in the box or write in the space provided**
1. What is your cancer diagnosis?	Breast □ Prostate □
2. What is your menopausal status (female only question)?	Pre-menopausal □ Peri-menopausal □ Post-menopausal □
3. What endocrine/hormone therapy are you taking?	
4. How long have you been taking endocrine/hormone therapy?	
5. What is your weight in kg? 6. What is your height in cm?	_____ kg _____ cm BMI:
Section 3. Social History	**Please tick your answer in the box or write in the space provided**
1. What is your employment status?	Stay at home parent/carer ☐ Unemployed ☐ Self-Employed ☐ Full-time Employment ☐ Part-time Employment ☐
2. Do you currently smoke tobacco products (e.g., cigarettes, cigars, pipe) or vape? 3(a) **<u>If Yes to smoking tobacco products</u>**, how many cigarettes (or equivalents) do you have per day? 3(b) **<u>If Yes to vaping</u>**, what is -the frequency of use -duration of use -time spent vaping per day -amount of e-liquid consumed	Smoke: Vape: Yes ☐ Yes ☐ No ☐ No ☐ Former smoker/vaper ☐ 1–10 ☐ 11–20 ☐ More than 21 ☐ Days per week/month _____ Number of puffs per session _____ Minutes/Hours _____ Millilitres used per week/month _____
4. Do you drink alcohol?	Yes ☐ No ☐

5. If Yes, how often do you drink alcohol?	Rarely (less than once a month) ☐ Occasionally (1–4 times a month) ☐ Weekly (1–3 times a week) ☐ Frequently (4 or more times a week) ☐
6. On a typical drinking day, how many standard drinks do you consume?	1-2 ☐ 3-4 ☐ 5-6 ☐ More than 6 ☐
7. Do you regularly consume caffeine (e.g., coffee, tea, soda, energy drinks)?	Yes ☐ No ☐
8. On average, how many **caffeinated beverages** do you consume per day?	0 ☐ 1 ☐ 2 ☐ 3-4 ☐ More than 4 ☐
9. What types of caffeinated products do you use? (Select all that apply)	Coffee ☐ Tea ☐ Energy drinks ☐ Cola or soft drinks ☐ Caffeine tablets/supplements ☐ Other: _____
10. How often do you engage in physical activity (e.g., walking, cycling, gym, sports)?	Rarely or never ☐ 1–2 times per week ☐ 3–4 times per week ☐ 5 or more times per week ☐
11. What type of physical activity do you usually perform? (Select all that apply)	Walking ☐ Jogging or running ☐ Strength training ☐ Yoga/Pilates ☐ Sports (e.g., tennis, football) ☐ Other: _____
12. On average, how many minutes do you exercise per session?	Less than 15 minutes ☐ 15–30 minutes ☐ 31–60 minutes ☐ More than 60 minutes ☐

Section 6. Vasomotor Assessment

NCI CTCAE v5 symptom term: Hot Flash
Definition: A disorder characterised by an uncomfortable and temporary sensation of intense body warmth, flushing, sometimes accompanied by sweating upon cooling

◯ Grade 1 *Mild symptoms; intervention not indicated*	◯ Grade 2 *Moderate symptoms; limiting instrumental ADL*	◯ Grade 3 *Severe symptoms; limiting self-care ADL*

PRO-CTCAE® Symptom Term: Hot flashes

a. In the last 7 days, how OFTEN did you have HOT FLASHES/FLUSHES?

◯ Never	◯ Rarely	◯ Occasionally	◯ Frequently	◯ Almost constantly

b. In the last 7 days, what was the SEVERITY of your HOT FLASHES/FLUSHES at their WORST?

◯ None	◯ Mild	◯ Moderate	◯ Severe	◯ Very severe

PRO-CTCAE® Symptom Term: Insomnia

a. In the last 7 days, what was the SEVERITY of your INSOMNIA (INCLUDING DIFFICULTY FALLING ASLEEP, STAYING ASLEEP, OR WAKING UP EARLY) at its WORST?

◯ Never	◯ Mild	◯ Moderate	◯ Severe	◯ Very Severe

b. In the last 7 days, how much did INSOMNIA (INCLUDING DIFFICULTY FALLING ASLEEP, STAYING ASLEEP, OR WAKING UP EARLY) INTERFERE with your usual daily activities??

◯ Not at all	◯ A little bit	◯ Somewhat	◯ Quite a bit	◯ Very much

Section 7. Vasomotor Management Strategies

Have you used any treatment or therapys to help control your vasomotor symptoms strategies?

APPENDIX V: Hot flash-Related Daily Interference Scale (HFRDIS)

Hot Flash Related Daily Interference Scale (HFRDIS)

Study Number: _____ Time Point:_____

Please circle one number to the right of each phrase to describe how much DURING THE PAST WEEK hot flashes have INTERFERED with each aspect of your life. Higher numbers indicate more interference with your life. If you are not experiencing hot flashes or if hot flashes do not interfere with these aspects of your life, please mark zero to the right of each question.

		Do not interfere interfere										Completely
		0	1	2	3	4	5	6	7	8	9	10
1	Work (work outside the home and housework)	○	○	○	○	○	○	○	○	○	○	○
2	Social activities (time spent with family, friends, etc.)	○	○	○	○	○	○	○	○	○	○	○
3	Leisure activities (time spent relaxing, doing hobbies, etc.)	○	○	○	○	○	○	○	○	○	○	○
4	Sleep	○	○	○	○	○	○	○	○	○	○	○
5	Mood	○	○	○	○	○	○	○	○	○	○	○
6	Concentration	○	○	○	○	○	○	○	○	○	○	○
7	Relations with others	○	○	○	○	○	○	○	○	○	○	○
8	Sexuality	○	○	○	○	○	○	○	○	○	○	○
9	Enjoyment of life	○	○	○	○	○	○	○	○	○	○	○
10	Overall quality of life	○	○	○	○	○	○	○	○	○	○	○

APPENDIX VI: HOT FLASH DIARY AND COOL PAD USAGE

DAILY HOT FLASH AND COOLING PAD RECORD SHEET

Study Number: _____ Week: _____

Fill in the appropriate circle immediately after you have a hot flash. Keep this sheet with you at all times. Night time hot flashes/night sweats should be recorded no later than that morning.

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
MILD: Sensation of heat without sweating/dampness. If at night, you don't wake up, but later notice damp sheets or clothing.	○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○	○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○	○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○	○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○	○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○	○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○	○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○
MODERATE: Sensation of heat with sweating/dampness, but able to continue current activity. May briefly fan yourself. If at night, you wake up because you are hot and/or sweating, but no action is necessary other than rearranging the bed sheets.	○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○	○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○	○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○	○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○	○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○	○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○	○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○
SEVERE: Sensation of intense heat with sweating causing disruption of current activity. If at night, you wake up hot and sweating and need to take action (e.g., removing layer of clothes, open the window, or get out of bed).	○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○	○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○	○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○	○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○	○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○	○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○	○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○ ○○○○○○
If there were **NO HOT FLASHES** all day and night, fill in this circle.	○	○	○	○	○	○	○
Did you use your **COOLING PAD** to manage your hot flash?	Yes ○ No ○	Yes ○ No ○	Yes ○ No ○	Yes ○ No ○	Yes ○ No ○	Yes ○ No ○	Yes ○ No ○

Daily Hot Flash Dairy adapted from Guttuso et al. (2012) "Review of Hot Flash Diaries", Maturitas, 71, 213-216

APPENDIX VII: END OF INTERVENTION ASSESSMENT

COOLVAS STUDY

END OF TREATMENT ASSESSMENT QUESTIONNAIRE version 1

Study Number:_____ Date:_____

Section 1. Social History	**Please tick your answer in the box or write in the space provided**
1. What is your employment status?	Stay at home parent/carer ☐ Unemployed ☐ Self-Employed ☐ Full-time Employment ☐ Part-time Employment ☐
2. Do you currently smoke tobacco products (e.g., cigarettes, cigars, pipe) or vape?	Smoke: Vape: Yes ☐ Yes ☐ No ☐ No ☐ Former smoker/vaper ☐
3(a) **If Yes to smoking tobacco products**, how many cigarettes (or equivalents) do you have per day?	1–10 ☐ 11–20 ☐ More than 21 ☐
3(b) **If Yes to vaping**, what is -the frequency of use -duration of use -time spent vaping per day -amount of e-liquid consumed	Days per week/month _____ Number of puffs per session _____ Minutes/Hours _____ Millilitres used per week/month _____
4. Do you drink alcohol?	Yes ☐ No ☐
5. If Yes, how often do you drink alcohol?	Rarely (less than once a month) ☐ Occasionally (1–4 times a month) ☐ Weekly (1–3 times a week) ☐ Frequently (4 or more times a week) ☐
6. On a typical drinking day, how many standard drinks do you consume?	1-2 ☐ 3-4 ☐ 5-6 ☐ More than 6 ☐
7. Do you regularly consume caffeine (e.g., coffee, tea, soda, energy drinks)?	Yes ☐ No ☐
8. On average, how many **caffeinated beverages** do you consume per day?	0 ☐ 1 ☐ 2 ☐ 3-4 ☐ More than 4 ☐ Coffee ☐ Tea ☐

9. What types of caffeinated products do you use? (Select all that apply)	Energy drinks ☐ Cola or soft drinks ☐ Caffeine tablets/supplements ☐ Other: _____
10. How often do you engage in physical activity (e.g., walking, cycling, gym, sports)?	Rarely or never ☐ 1–2 times per week ☐ 3–4 times per week ☐ 5 or more times per week ☐
11. What type of physical activity do you usually perform? (Select all that apply)	Walking ☐ Jogging or running ☐ Strength training ☐ Yoga/Pilates ☐ Sports (e.g., tennis, football) ☐ Other: _____
12. On average, how many minutes do you exercise per session?	Less than 15 minutes ☐ 15–30 minutes ☐ 31–60 minutes ☐ More than 60 minutes ☐

Section 2. Vasomotor Assessment

NCI CTCAE v5 symptom term: Hot Flash
Definition: A disorder characterised by an uncomfortable and temporary sensation of intense body warmth, flushing, sometimes accompanied by sweating upon cooling

◯ Grade 1 *Mild symptoms; intervention not indicated*	◯ Grade 2 *Moderate symptoms; limiting instrumental ADL*	◯ Grade 3 *Severe symptoms; limiting self-care ADL*

PRO-CTCAE® Symptom Term: Hot flashes

a. In the last 7 days, how OFTEN did you have HOT FLASHES/FLUSHES?

◯ Never	◯ Rarely	◯ Occasionally	◯ Frequently	◯ Almost constantly

b. In the last 7 days, what was the SEVERITY of your HOT FLASHES/FLUSHES at their WORST?

◯ None	◯ Mild	◯ Moderate	◯ Severe	◯ Very severe

PRO-CTCAE® Symptom Term: Insomnia

a. In the last 7 days, what was the SEVERITY of your INSOMNIA (INCLUDING DIFFICULTY FALLING ASLEEP, STAYING ASLEEP, OR WAKING UP EARLY) at its WORST?

◯ Never	◯ Mild	◯ Moderate	◯ Severe	◯ Very Severe

b. In the last 7 days, how much did INSOMNIA (INCLUDING DIFFICULTY FALLING ASLEEP, STAYING ASLEEP, OR WAKING UP EARLY) INTERFERE with your usual daily activities??

◯ Not at all	◯ A little bit	◯ Somewhat	◯ Quite a bit	◯ Very much

Section 3. Cooling Pad Experience	**Please tick your answer in the box or write in the space provided**
1. How long have you used the cooling pad?	Less than 1 week ☐ 1–2 weeks ☐ 2–4 weeks ☐ 4-5 weeks ☐ 5-6 weeks ☐ 6-7 weeks ☐ 8 weeks ☐
2. How easy was it to use the cooling pad?	Very difficult ☐ Difficult ☐ Neutral ☐ Easy ☐ Very easy ☐
3. Did you experience any discomfort while using the cooling pad?	Yes ☐ (please describe): No ☐
4. How effective was the cooling pad in relieving your symptoms?	Not effective ☐ Slightly effective ☐ Moderately effective ☐ Very effective ☐ Extremely effective ☐
5. How quickly did you notice symptom relief after using the pad?	Immediately ☐ Within 15 minutes ☐ 15–30 minutes ☐ More than 30 minutes ☐ No noticeable relief ☐
6. How often did you use the cooling pad?	As needed ☐ Daily ☐ Several times per day ☐ Only at night ☐ Other: _____
7. What is your overall satisfaction with the cooling pad?	Very dissatisfied ☐ Dissatisfied ☐ Neutral ☐ Satisfied ☐ Very satisfied ☐

8. Would you recommend the cooling pad to others with similar symptoms?	Yes ☐ No ☐ Not sure ☐
9. What did you like most about the cooling pad?	
10. What did you dislike or find challenging about the cooling pad?	
11. Do you have any suggestions for improving the cooling pad or your experience?	
Section 4. Vasomotor Management Strategies	
Have you used any other treatment or therapys to help control your vasomotor symptoms?	

APPENDIX VIII Adverse Event Log

Adverse Event Log

Page ___ of ___

Study: ____________________ **Subject ID:** __________________ Patient Addressograph

#	Adverse Event	Serious Yes / No If yes ensure SAE form submitted	Grade CTCAE version ______	Start Date & Time if needed DD/MM/YYYY	End Date Or Continuing at end of study i.e. last dose DD/MM/YYYY	Action (s) Taken: 0 No action taken 1.Drug dosage adjusted 2 Temporarily interrupted 3 Drug discontinued 4 Con-medication taken 5 Non-drug therapy given 6 Hospitalization/ Prolonged hospitalisation	Researcher sign and date	Relationship To IMP __________	Relationship To IMP __________	Relationship To IMP __________	Relationship To IMP __________	Investigator Sign and Date
							Start: ______ Sign and date End: ______ Sign and date	☐Definitely ☐Probably ☐Possibly ☐Unlikely ☐Not related	☐Definitely ☐Probably ☐Possibly ☐Unlikely ☐Not related	☐Definitely ☐Probably ☐Possibly ☐Unlikely ☐Not related	☐Definitely ☐Probably ☐Possibly ☐Unlikely ☐Not related	Start: ______ Sign and date End: ______ Sign and date
							Start: ______ Sign and date End: ______ Sign and date	☐Definitely ☐Probably ☐Possibly ☐Unlikely ☐Not related	☐Definitely ☐Probably ☐Possibly ☐Unlikely ☐Not related	☐Definitely ☐Probably ☐Possibly ☐Unlikely ☐Not related	☐Definitely ☐Probably ☐Possibly ☐Unlikely ☐Not related	Start: ______ Sign and date End: ______ Sign and date
							Start: ______ Sign and date End: ______ Sign and date	☐Definitely ☐Probably ☐Possibly ☐Unlikely ☐Not related	☐Definitely ☐Probably ☐Possibly ☐Unlikely ☐Not related	☐Definitely ☐Probably ☐Possibly ☐Unlikely ☐Not related	☐Definitely ☐Probably ☐Possibly ☐Unlikely ☐Not related	Start: ______ Sign and date End: ______ Sign and date
							Start: ______ Sign and date End: ______ Sign and date	☐Definitely ☐Probably ☐Possibly ☐Unlikely ☐Not related	☐Definitely ☐Probably ☐Possibly ☐Unlikely ☐Not related	☐Definitely ☐Probably ☐Possibly ☐Unlikely ☐Not related	☐Definitely ☐Probably ☐Possibly ☐Unlikely ☐Not related	Start: ______ Sign and date End: ______ Sign and date

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2. Brook Hervik, J. and Stub, T. (2016) 'Adverse effects of non-hormonal pharmacological interventions in breast cancer survivors, suffering from hot flashes: A systematic review and meta-analysis', *Breast Cancer Research and Treatment*, 160, pp. 223-236.
3. Carpenter, J.S. (2001) 'The Hot Flash Related Daily Interference Scale: A Tool for Assessing the Impact of Hot Flashes on Quality of Life Following Breast Cancer', *Journal of Pain and Symptom Management*, 22(6), pp. 979-989.
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