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# HOW DESIGN FOR WELLBEING CAN AFFECT THE VASOMOTOR SYMPTOMS OF MENOPAUSAL WOMEN THROUGH THE USE OF BIOFEEDBACK TECHNOLOGY

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AUGUST 23, 2023

## Acknowledgements

I am incredibly grateful to the Product Design team at the University of Huddersfield; without their support, I would not have reached the final stages of the research, as their constant support has kept me positive throughout the process. I would especially like to thank my primary supervisor, Dr. Ertu Unver, who has been involved with my work from start to end. I would also like to thank Dr. Omar Ivan Huerta Cardoso, who had been my primary supervisor has since moved on to further his career. I am also thankful to Dr. Caterina Benincasa-Sharman, who helped me through the final stage of the thesis up to completion; whilst also giving me the confidence to originally engage in postgraduate studies at the end of my undergraduate studies.

I would then press my sincerest gratitude to my close family. My mother Pam has always been supportive of my work and was my initial inspiration behind the research topic I have researched throughout this thesis, as I wanted to help her and others who have gone and will go through the same experiences. My father Chris has also always been available to support me through the years of hard work it has taken to complete this thesis. I would also like to mention family members and friends, along with those that have passed since undertaking this research, including my grandparents, aunties, and uncles. I would like to give special thanks to my partner Katie, she has been my rock through the hardest stages of this thesis and has helped me through my worst periods and experienced my best moments.

Lastly, I would like to acknowledge the University of Huddersfield, Lancaster University, and all participants that have helped provide content throughout this thesis to conclude this research.

## Author's Declaration

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## Abstract

Research addressing therapeutic interventions for menopausal vasomotor symptoms has received comparatively less attention than other medical domains, resulting in limited successful outcomes and potential side effects. This study explored the impact of well-being-oriented design, employing biofeedback technology on menopausal vasomotor symptoms. Menopause constitutes a critical phase in a woman's life, often accompanied by vasomotor symptoms that adversely affect well-being. This investigation aimed to assess the viability of utilising biofeedback technology to modulate body temperature, employing a novel framework, thereby enhancing well-being among menopausal women.

Through co-creation workshops, an alternative design approach was developed and subsequently tested to ascertain its potential for improving well-being in menopausal women. The outcomes of these tests were comprehensively evaluated to discern the implications and significance of the results. This research culminated in an examination of whether biofeedback technology could effectively mitigate vasomotor symptoms and consequently enhance the well-being of menopausal women.

Key investigations revolved around refining the utilisation and triggers of biofeedback to alleviate vasomotor symptoms. A connection was established between increased heart rate and impending hot flushes. A novel wearable design, located on the dorsal side of the wrist, was developed to monitor heart rate and initiate cooling, thereby reducing both heart rate and body temperature. Furthermore, the adaptability of this design for nocturnal symptom alleviation was explored, revealing its efficacy in mitigating vasomotor symptoms during both day and night through localised cooling.

This study's contribution to knowledge encompasses the development of a novel methodology that integrates Software Development and Information Design processes to

devise an innovative wearable product. The ID-Agile method, born from a rigorous 4-stage design and evaluation process, yielded a refined conceptual framework that demonstrated the feasibility of localised cooling pre-emptively minimising vasomotor symptoms. The outcome manifested as reductions in both perceived and actual body temperatures, supported by empirical evidence in both physiological and cognitive data.

Ultimately, this research underscores the pivotal role of biofeedback in diminishing vasomotor symptoms and fostering enhanced well-being during the menopausal transition. The implications of this study extend towards ameliorating the quality of life for women throughout the menopausal and post-menopausal phases. The design approach outlined herein holds the potential to redefine wearable technology development and significantly impact women's health during this crucial life stage.

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## Abbreviations

**3D**-Three Dimensional

**AR**-Augmented reality

**BF**-Blood Flow

**BPM**-Beats Per Minute

**CBT**-Cognitive Behavioural Therapy

**FBF**-Finger Blood Flow

**GP**-General Practitioner

**HCI**-Human Computer Interaction

**HR**-Heart Rate

**HRT**-Hormone Replacement Therapy

**ID**- Information Design

**IT**-Information Technology

**NHS**-National Health Service

**NPD**-New Product Development

**REM**-Rapid Eye Movement

**UI**-User Interface

**UX**-User Experience

**VR**-Virtual Reality

## Chapter 1 - Introduction

## 1.1. Introduction To the Thesis

This thesis will cover the transition into menopause, which marks a significant phase in a woman's life. As the body undergoes various hormonal changes, women often find themselves grappling with a range of symptoms that impact their physical, emotional, and psychological wellbeing. One of the most common and disruptive symptoms experienced during menopause are vasomotor symptoms, such as hot flashes and night sweats. These sudden waves of heat can arise at any time, leaving women feeling uncomfortable, self-conscious, and at times even debilitated. However, in this era of technological advancements, new hope in the form of wearable biofeedback technology has the potential to improve menopausal wellbeing.

Women no longer want to feel powerless against the onslaught of vasomotor symptoms. The future could have a world where wearable devices, equipped with sophisticated biofeedback mechanisms, serve as steadfast companions on the journey through menopause. Such devices have the potential to revolutionise the way women experience this life stage, granting them greater control over their bodies and ultimately improving their overall quality of life.

Wearable biofeedback technology refers to a class of devices designed to monitor physiological signals from the body and provide real-time feedback. These devices can range from smartwatches and fitness trackers to innovative patches or even discreet jewellery seamlessly integrated into everyday life. By capturing essential data on bodily functions, such as heart rate, skin temperature, and perspiration levels, these wearables can offer invaluable insights into the patterns and triggers of vasomotor symptoms.

Through their continuous monitoring capabilities, these devices gather data that far surpasses what a woman could discern on her own. These devices become increasingly adept at recognising the early signs of a vasomotor episode, alerting the wearer in advance, and providing effective coping strategies. The true power of wearable biofeedback technology lies not only in its ability to detect

and predict vasomotor symptoms but also in its capacity to empower women to actively manage their wellbeing. Armed with a wealth of real-time data and personalised feedback, women gain a newfound understanding of their bodies. They become partners in their own health, making informed decisions about lifestyle changes, dietary adjustments, and stress management techniques that can significantly mitigate the intensity and frequency of vasomotor symptoms.

Beyond the individual level, the transformative potential of wearable biofeedback technology extends to the realm of therapeutic research and treatment. The vast amount of data collected from wearables can be anonymised and aggregated, fuelling ground-breaking studies on menopausal health. Researchers can delve into this treasure trove of information to identify overarching patterns, refine treatment protocols, and develop innovative interventions. The collaborative efforts between wearables, healthcare providers, and researchers hold the promise of unlocking new horizons in menopausal care, paving the way for tailored treatments that prioritise women's unique needs.

As the journey is about to begin with this thesis, it is essential to acknowledge the potential challenges and considerations surrounding wearable biofeedback technology. However, with thoughtful development and user-centric designs, these obstacles can be overcome, ensuring that wearable biofeedback technology becomes an inclusive and empowering force for women from all walks of life.

In the chapters that follow, we will explore the vast landscape of wearable biofeedback technology, diving deeper into how the technology behind biofeedback could offer menopausal women support, examining the evidence-based benefits they offer, and investigating the outcomes of women who have harnessed their potential. The research will uncover how this revolutionary technology holds the key to unlocking a future where menopausal wellbeing is elevated, vasomotor symptoms are tamed, and women can embrace this transformative phase with grace, confidence, and renewed vitality.

## 1.2 General Overview

This thesis will address how design for well-being can affect vasomotor symptoms of menopausal women using biofeedback technology. In the UK, the government state that roughly 'a third' of women are currently either perimenopausal or menopausal. In addition, menopause can last for an average of 10 years (NHS,2022a). Menopause severely affects a woman's well-being (Gartoulla et al., 2015a).

Women seek relief from menopause by using complementary and alternative medicines such as hormone replacement therapy (HRT) which are thought to improve mood and well-being (Fischer et al., 2014). Side effects of HRT include breast tenderness, headaches, nausea, indigestion, abdominal pain, and vaginal bleeding. In addition, HRT can cause more severe problems such as blood clots and breast cancer, with the National Health Service (NHS) themselves stating that HRT is 'generally felt to outweigh the risks' (NHS, 2019). With women often seeking other alternatives to battle menopause, design for health is a crucial area in which well-being can improve through design (Payne et al., 2014).

Vasomotor symptoms, such as hot flushes and night sweats, are considered the cardinal symptoms of menopause; where '80%' can be affected (Avis et al., 2018). Wellbeing can be improved through the reduction of severity in vasomotor symptoms (Shepherd-Banigan et al., 2017). Wellbeing can also be improved through biofeedback heart rate monitoring (Lehrer et al., 2020). Design for well-being strategies encompasses users at the core of the design process (Marshall et al., 2014). A research methodology assessing the user through co-creation is needed to create a fully functional concept that improves well-being (Pera & Viglia, 2015).

Well-being is heavily linked to User Experience (UX) design as UX becomes increasingly essential through the design stages for wearable health technology (Asimakopoulos et al., 2017). All UX models commonly focus on well-being as the outcome and not the performance of a user's

interaction with a product (Hassenzahl, 2008). Integrating Human-Computer Interaction (HCI) can improve UX through Software Development processes (Joshi et al., 2010). UX Design has continued to grow, primarily emphasising human-computer interactions (Knemeyer & Svoboda, 2018). Recent research has linked HCI to wearable technologies and a human's senses (Bachmann et al., 2018).

Therefore, biofeedback wearable technologies will assess a menopausal woman's body and offer an output that can improve menopausal well-being through this transitional period. Current research can be over-medicalised, where a biofeedback therapy approach to this subject could offer an improved solution. Limited research suggests biofeedback as a useable alternative to medications to improve well-being. Designs are also currently either manually controlled or biofeedback at the onset of a hot flush. This thesis aims to offer cooling prior to the onset of a hot flush to reduce vasomotor symptoms' effects and, in turn, improve well-being.

This research will therefore offer a research-based therapeutic solution to an over-medicalised area. The research will find an outcome by achieving a set of aims and objectives following Information Design and Software Development methodology. The methodology will follow an iterative process where each stage will iterate to offer further insight and design knowledge. Co-creation with menopausal women will be a critical part of this work, as their insight will be invaluable to the overall outcome.

### 1.3 Biofeedback Research for Menopause is Relevant Research

Biofeedback for menopause is a current research topic because it holds the potential to provide non-pharmaceutical alternatives for managing menopausal symptoms. Menopause is a natural phase in a woman's life when her menstrual cycle stops. During this transition, women may experience various physical and psychological symptoms, including hot flashes, night sweats, mood swings, sleep disturbances, and anxiety.



Biofeedback is a technique that enables individuals to learn how to control their bodily functions through self-regulation. It involves the use of electronic devices to monitor physiological processes such as heart rate, muscle tension, and skin temperature. By providing real-time feedback, individuals can become aware of their physiological responses and learn techniques to modify them.

The potential benefits of biofeedback for menopause lie in its ability to address symptoms without the use of medication, which some women may prefer due to concerns about potential side effects or contraindications with other medications. Biofeedback techniques can help women learn relaxation techniques, stress reduction strategies, and control over their bodily responses, which may alleviate menopausal symptoms.

Research on biofeedback for menopause is still in its early stages, and more studies are needed to determine its efficacy and identify the specific techniques that yield the best results. Nonetheless, the potential for non-pharmaceutical interventions to alleviate menopausal symptoms is a compelling area of research, and biofeedback represents a promising avenue for further exploration.

#### 1.4 The Rationale for Researching Biofeedback for Menopausal Women

Through a rationale the researcher hopes to fill gaps of knowledge within current research for this subject area. Addressing the practical significance of this research will help advance the existing knowledge. Improved mixed methodology will be integral to the overall advancement of research practices and can lead to more accurate, reliable, or efficient data collection and analysis. Adding to the body of knowledge within this field can be achieved through generating a new framework that enhances understanding and promotes further research and scholarly discourse.

Researching biofeedback for menopause is driven by several rationales:

- Symptom management: Menopause is accompanied by a range of symptoms such as hot flashes, night sweats, mood swings, sleep disturbances, and vaginal dryness. These

symptoms can significantly impact a woman's quality of life. Biofeedback techniques, which involve using electronic devices to monitor and provide feedback on physiological processes, can potentially help women learn to control their symptoms and improve their well-being.

- **Non-pharmacological approach:** Many women seek non-pharmacological interventions to manage menopausal symptoms due to concerns about the potential risks and side effects of hormone replacement therapy (HRT) and other medications. Biofeedback offers a non-invasive and drug-free alternative for symptom management, reducing the reliance on pharmaceutical interventions.
- **Individualised treatment:** Biofeedback can be tailored to the specific needs of each woman. It provides real-time feedback on physiological parameters like heart rate, skin temperature, and muscle tension, allowing individuals to develop personalised strategies to manage their symptoms. This individualised approach is particularly valuable, considering that menopausal experiences and symptom severity can vary widely among women.
- **Empowerment and self-care:** Menopause is a natural transition in a woman's life, but it can also be a challenging time. Biofeedback empowers women by giving them an active role in their own health and well-being. By learning to regulate their physiological responses, women can gain a sense of control over their symptoms, leading to improved self-care and overall confidence.
- **Long-term benefits:** Biofeedback techniques not only provide immediate relief but also offer the potential for long-term benefits. By learning self-regulation skills, women may acquire lifelong coping mechanisms to manage stress, anxiety, and other physiological responses. This may extend beyond menopause, positively impacting their overall health and resilience.
- **Cost-effectiveness:** Compared to some pharmaceutical treatments, biofeedback can be a cost-effective option for managing menopausal symptoms. While initial investment may be

required for biofeedback equipment or sessions with a trained professional, it can provide long-term benefits without ongoing medication expenses.

Overall, researching biofeedback for menopause aims to explore an effective, personalised, and non-pharmacological approach to symptom management, offering women greater control over their well-being during this significant life stage.

### 1.5 Personal Experience with Menopause

The research topic chosen may seem unusual for a young male researcher to undertake, but for one main reason the research is held in high importance. Mothers are the main inspiration of this research topic. Personally, there are several reasons as to why mothers are an inspiration to investigate this research topic further:

- **Personal Experience:** All mothers go through menopause; her personal experience can inspire children to learn more about this phase of a woman's life. Witnessing her journey, including any challenges she may have faced, this has motivated the conduct of research to better understand menopause and its effects.
- **Empathy and Support:** Seeing a mother navigate the physical and emotional changes that accompany menopause might have sparked a sense of empathy and a desire to support her and other women in similar situations. This has led a pursue of research to find solutions, treatments, or strategies that can alleviate the symptoms and improve the overall well-being of women during menopause.
- **Knowledge Gap:** Personally, there has been a lack of information or misconceptions surrounding menopause during the researcher's mother's experience. This knowledge gap may has inspired the researcher to delve into menopause research to gain a deeper understanding of the subject and help dispel any myths or misunderstandings surrounding menopause.

- **Personal Connection:** A mother holds a special place in a child's life. Her well-being and health are important, which has motivated the researcher to explore menopause research to ensure support can be offered to her and other women going through this phase.

Ultimately, the reasons behind the researcher's inspiration are personal and unique to their relationship with their mother. This research acknowledges the importance and appreciates the role she plays in life and how her experiences can shape personal interests and research focus.

### 1.6 Defining Well-being

“Well-being can be defined as the integration of experiencing positive emotions and attaining optimal functioning. It encompasses the sensations of happiness and contentment, as well as the development of one's abilities, having a certain level of control over life circumstances, possessing a sense of purpose, and nurturing positive relationships” (Huppert,2009).

When considering the wellbeing of menopausal women, it would consider their holistic state of health and satisfaction encompassing various dimensions of physical, mental, emotional, and social well-being during the menopausal transition and beyond (Jaspers et al., 2015). It involves achieving a sense of balance, fulfilment, and optimal functioning across these different aspects of their lives (Jaspers et al., 2015; Boniwell, 2008). When considering the well-being of menopausal women, there are certain aspects that should be considered:

- **Physical Wellbeing:** This dimension focuses on maintaining good physical health and addressing any health concerns that may arise during menopause. It involves managing menopausal symptoms, such as hot flashes, night sweats, sleep disturbances, changes in weight or body composition, vaginal dryness, and bone health (Whiteley et al., 2013). Engaging in regular physical activity, adopting a healthy diet, and seeking appropriate medical care are essential for physical wellbeing (Sternfeld & Dugan, 2011).

- **Emotional Wellbeing:** Emotional wellbeing relates to the management of emotional health and psychological state during menopause. It involves addressing mood swings, irritability, anxiety, depression, or other emotional changes that may occur (Bromberger & Kravitz, 2011). Coping strategies, stress management techniques, seeking emotional support, and engaging in activities that promote emotional wellness, such as relaxation exercises, mindfulness, or therapy, contribute to emotional wellbeing (Zandi et al., 2021).
- **Mental Wellbeing:** Mental wellbeing focuses on cognitive health, memory function, and mental clarity during menopause. It involves addressing any cognitive changes or challenges, such as forgetfulness or difficulties with concentration or focus (Mitchell & Woods, 2011). Mental stimulation, engaging in intellectually stimulating activities, maintaining a healthy lifestyle, and seeking professional help if needed are important for mental wellbeing (Zhang et al., 2022).
- **Social Wellbeing:** Social wellbeing encompasses maintaining healthy relationships, social connections, and a sense of belonging and support during menopause. It involves nurturing existing relationships with family, friends, and the community, as well as fostering new connections (de Salis et al., 2017). Having a strong support network, participating in social activities, and addressing any social challenges or changes in roles or identity contribute to social wellbeing (Umberson & Karas Montez, 2010).
- **Sexual Wellbeing:** Sexual wellbeing focuses on maintaining a satisfying and fulfilling sexual life during menopause. It involves addressing any changes or challenges related to sexual desire, arousal, lubrication, or discomfort. Open communication with a partner, seeking medical advice or therapy when necessary, and exploring new ways of intimacy or sexual experiences contribute to sexual wellbeing (Finley, 2017).
- **Spiritual Wellbeing:** Spiritual wellbeing refers to the sense of meaning, purpose, and connection to something greater than oneself. It involves exploring personal beliefs, values, and engaging in practices that provide a sense of inner peace, reflection, and transcendence

(Hrabe et al., 2018). Activities such as meditation, mindfulness, prayer, or engaging in nature or creative pursuits can contribute to spiritual wellbeing (Greeson et al., 2011).

The overall wellbeing of menopausal women is a multifaceted concept that considers the interplay of various dimensions of health and satisfaction. Women often have to assess their own wellbeing and often have their own definitions. Throughout chapter 4, continuous feedback as to how women assess their own women can be found within initial co-creative sessions. It is important for women to prioritise self-care, seek appropriate support, and adopt strategies that promote their overall wellbeing during this significant life transition. The design of an alternative will aim to improve the physical and emotional aspects of wellbeing. Secondary aspects that may improve through biofeedback technology are the mental, social and potentially spiritual aspects of menopausal wellbeing.

### 1.7 Aims and Objectives

The study aims to design a new solution to improve the vasomotor symptoms of menopausal women through design. By developing further knowledge and understanding from the literature review and research studies; an answer to the main research question, achieving:

- How can design for well-being affect vasomotor symptoms of menopausal women through the use of biofeedback technology?

The research question gathers an answer through some objectives established. Meeting these objectives will set the foundations for designing a new product to improve the well-being of menopausal women. The objectives are as follows:

- To investigate whether biofeedback technology can alter body temperature.
- To define a design framework to improve the well-being of menopausal women.

- To design an alternative in a co-creation workshop to improve the well-being of menopausal women.
- To design and test a prototype to improve the well-being of menopausal women.
- To analyse the results from the testing to see if design has improved the well-being of menopausal women.
- To understand the implications of the test and results for the well-being of menopausal women.
- To analyse and conclude if biofeedback technology can improve the well-being of menopausal women by lessening the effects of vasomotor symptoms.

## Chapter 2 - Literature Review



## 2.1 Overview of the Menopausal Wellbeing Market

### 2.1.1 Design and Development of New Product for Menopausal Treatments

Menopausal treatments can develop at a rate of 6.18% until 2027 to around £11 Billion (Market Research Future, 2020). In addition, Mintel (2020) states that, due to COVID-19, the industry for intelligent technology has become more prominent. Stating innovative technologies like the 'Grace' wristband can positively affect women's lives for menopause.

COVID-19 has had a detrimental impact on the menopausal industry. Demand has lowered, and factories have been closed due to lockdowns meaning manufacturing has been affected. Top manufacturers, such as Pfizer, are trying to overcome their losses since the outbreak, with further efforts seen going into development and research to see problems that have accumulated due to coronavirus. The expected market rise is also since once countries gradually lift lockdowns; the global market will recover in the coming years (Market Research Future, 2021).

The need for effective treatments to combat menopausal symptoms has never been more necessary, where COVID-19 has affected women more than men (Thibaut & van Wijngaarden-Cremers, 2020). Women are seeking relief from not only physical health deterioration but mental health deterioration. The main factor for this is the coronavirus pandemic. Increases in "hot flashes, formication, migraine, anxiety, fatigue, mood swings, irritability and insomnia" are the main areas that research and development are seeking to find solutions for, though research and development are predominantly drug-based (Market Research Future, 2020).

Stress is also a big part of a menopausal woman's life. Women often want to escape their ordinary lives to access another place momentarily to gain peace, if only for a certain amount of time. Due to a lack of sleep down to insomnia in menopausal women, this is a crucial area of rest and peace that women are not able to enjoy due to the symptoms of menopause. These factors and menopausal

women's general incomes lead to a favourable upturn in the market for menopausal treatments (Market Research Future, 2020).

The menopausal market requires different solutions to combat menopausal symptoms. Herbal treatments are a standard method of dealing with menopausal symptoms compared to medicinal-based remedies. Black cohosh and soy isoflavones are the main drivers in this specific market, as menopausal women prefer them to other methods (Market Research Future, 2020). Even though herbal treatments are the prominent alternative, the introduction of wearables can combat specific symptoms to improve well-being.

The cost of bringing a therapeutic new product to market compared to a medical new product vastly benefits therapeutic design. According to Kefalas (2014), Even though the cost can be lower for therapeutic designs, the lack of research-backed data can often be a downfall where the product is exclusive. A therapeutic device can be time-limited but can be viable if there is not a medically licensed design similar. On the other hand, medical devices must go through compliance processes, whereas therapeutic designs are unassessed via the same methods (GOV.UK, 2013). Therefore, assessing whether the device will be a medical or therapeutic design is critical.

### 2.1.2 Therapeutic New Product Development Versus Medical New Product Development

Developing a new wearable product needs consideration as to whether the classification is therapeutic or medical. Summaries have found that it is a fine line between therapeutic and medical devices, also devices that are for lifestyle consumers and rigid medical care (Lievevrouw et al., 2021). The Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) defines the meaning of a medical device as "any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or

therapeutic purposes or both and necessary for its proper application, which is intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment, or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement, or modification of the anatomy or of a physiological process, or
- control of conception" (GOV.UK, 2013)

The classification guidelines for whether this designed wearable falls into any of these categories are debatable. Firstly, menopause is not a disease or health condition; it is a part of every woman's life (Sivarajasingam, 2022). Therefore, this wearable does not interfere with the initial bullet point, as menopause is not a disease. In addition, Menopause is not an 'injury or handicap', so it can not infringe the second bullet point. Menopause can have physiological symptoms and improve well-being; these symptoms are being affected (Peacock & Ketvertis, 2022). Even though this could infringe the third bullet point, the main design of the device is not to alter the physiological process. The device will not be able to investigate, replace or modify the physiological process. It could, however, affect this through secondary feedback, as the initial design to improve vasomotor symptoms may improve other aspects of menopause. Moreover, the last bullet point is invalid for this new product development as control of contraception is not a factor in this research. Therefore, the only possible infringement would be if regulators thought that the wearable was one to have any impact on the physiological process.

If the process of menopause is considered physiological, it can then be considered a borderline product. As some researchers define menopause as a physiological process, the designed wearable must acknowledge the regulatory standards to abide by through this development (Peacock & Ketvertis, 2022). Defined categorisations for borderline products 2021):

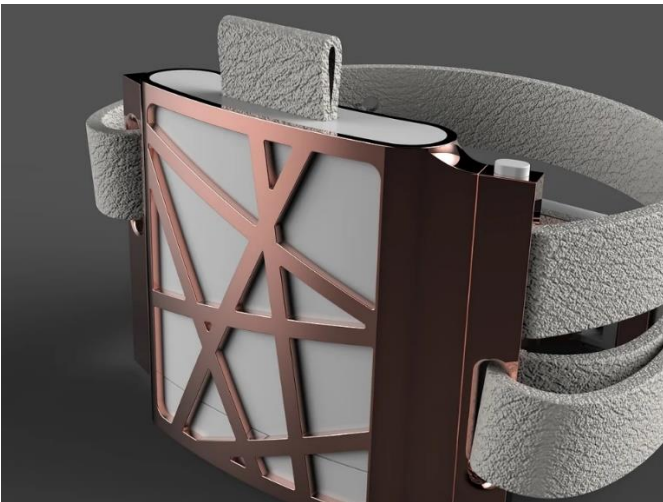
- ‘Cosmetics’
- ‘Food products’
- ‘Herbal products’
- ‘Biocides’
- ‘Machinery and laboratory equipment’

The categories assumed do not accommodate the wearable to be designed as the categories are too specific for the outputs of the new product development. In addition, definitions are stated by the Medical Devices Regulations 2002 for medical devices. The wearable would not infringe on any points made from these regulations. The new product development (NPD) could affect physiological functions, but it would not do this by exerting a pharmacological, immunological, or metabolic action. Therefore, the new design concept could not be defined as it cannot make a medical diagnosis and does not affect physiological functions to the specific aspects mentioned within the Medical Devices Regulations 2002.

The MHRA (Medicines and Healthcare products Regulatory Agency) can decide whether a product is medicinal or therapeutic. They assess what the product does, ingredients and materials, purpose, current market, and branding (GOV.UK, 2021). The development of this thesis will have to assess the current design, which can be considered therapeutic. Products that showcase successful design outcomes, such as the 'Aircon' start-up watch (Figure 1), the 'Grace' wristband (Figure 2) and the 'Embr Wave' cooling bracelet (Figure 3), are likely to be seen as therapeutic concepts due to the non-invasive technologies used (Kickstarter, 2017; Astinno Limited, 2022, Embr Labs, 2022). Therefore, the branding and packaging will also be in line with current products and not infringe on medical devices by stating the therapeutic nature of the design.



*Figure 1 Aircon Start-up Watch (Kickstarter, 2017)*



*Figure 2 Grace Cooling Wristwear (Peter Astbury, 2022)*



*Figure 3 Embr Wave Wristwear (Embr Labs, 2022)*

Therefore, the NPD of wearable can not infringe on medical regulations as the categories stated within this section cannot house the proposed, designed wearable. If consumers were to think the product was an infringement on medical devices, the MHRA would then assess against the criteria stated to deal with infringements. Therefore, if the designed concept were marketed, it would be helpful to gain advice from the MHRA's guidance before committing to marketing the product on a large scale. From the researcher's viewpoint, this product is considered therapeutic and not medicinal, as stated in this section.

### 2.1.3. Seeking Alternative Design Methods to Improve the Wellbeing of Menopausal Women

Seeking an alternative that can improve well-being therapeutically instead of current methods, such as medical-based, could be feasible. Increasing research has explored the links between technology & interaction design for mental health and therapy (Thieme et al., 2012). With user well-being becoming more prominent within design, therapy has improved well-being (Amiri et al., 2017). Wearable technologies in health research are said to potentially improve how data is collected and processed to visualise data (Izmailova et al., 2018). With therapy becoming more commonly trialled within health design, it could be vital to design therapeutically instead of medically.

Therapeutic designs are assumed to be non-invasive, where the user does not have a medical reaction to the use of the device. Previous research has defined humans as multi-sensory, where psychological mechanisms can occur through evoking the five senses (Franco et al., 2017). Firstly, the five senses of sight, sound, touch, smell, and taste need to be defined for their effects on menopause, as offering a non-invasive solution to improve well-being is centred around these areas. To consider designing for menopausal women, menopause also needs to be defined, with clear insight into the main symptoms of menopause and how they may deteriorate well-being through this period.

## 2.2 Menopause

As discussed, the researcher needs to understand menopause. The research will investigate what menopause is and its main symptoms. The main symptoms are assessed for potential design for well-being alternatives using the five senses.

### 2.2.1 What Is Menopause?

Menopause is a natural process within a woman's life. Usually, menopause is classified when a woman has not had a menstrual period for the prior twelve months, meaning they are no longer fertile (Stanford et al., 1987; Peacock & Ketvertis, 2022). With women no longer fertile from menopause, they can no longer become pregnant naturally. According to the NHS, periods start to occur less over months and sometimes years but can sometimes just stop suddenly (NHS, 2022a). This time frame before menopause, where a woman's hormone levels gradually decrease, is called perimenopause. There is also a phase after menopause often referred to as life following menopause or post-menopause (Stanford et al., 1987). Conflating menopause and perimenopause from this stage forward will address both stages under menopause as they transition into one another. Only when explicitly addressing perimenopause will that be stated as a separate entity.

In addition, the NHS states that the average age for menopause in the UK is 51. However, a woman can experience natural menopausal symptoms between the ages of '45 and 55' due to decreased oestrogen levels (NHS, 2022a). Also, around '1%' of women can experience menopause prior to being 40 years old (NHSinform, 2022). If this occurs, it is known as premature menopause or premature ovarian insufficiency. Menopause is a natural biological process with many symptoms affecting a woman's life. Physical and emotional symptoms have different effects depending on severity; and can contribute to the disruption of sleep, energy, and emotional health (Pfizer, n.d.).

### 2.2.2 Symptoms of the Menopause

Nearly all women are subjects of menopausal symptoms. The NHS (2022b) lists the most common and severe of those symptoms that can affect everyday life for women.

The NHS list of common symptoms includes:

- ‘Hot flushes’
- ‘Night sweats’
- ‘Vaginal dryness and discomfort during sex’
- ‘Difficulty sleeping’
- ‘Low mood or anxiety’
- ‘Reduced sex drive (libido)’
- ‘Problems with memory and concentration’

These symptoms can begin months and sometimes years before a woman's last period, last, on average, four years after periods end, and often last much longer.

A woman's well-being through menopause is severely altered due to their mindful state.

Fluctuations in hormones from a perimenopausal stage can lead to somatic and mental changes in women's health, with changes leading to unhealthier lifestyles (Czarnecka-Iwańczuk et al., 2012).

Women during this stage can be both positive and negative about the situation, whereby a woman who is positive about menopause will be more likely to have an improved experience compared to those who are pessimistic about this period (Iwanowicz-Palus et al., 2019). Women who see the positives of menopause can often evaluate life and reconsider their main priorities; whilst having a



more enjoyable experience (InformedHealth.org, 2006). Every woman deals with the menopausal period in their way, with well-being deemed to be affected in some way by most women.

### 2.2.3 Impact of Menopause on a Woman's Wellbeing

Well-being for menopausal women should be the main priority for research in this area. When looking into the well-being of menopausal women, researchers focus on the psychological and psychosocial effects of well-being rather than physical effects (Hunter, 1996; Gartoulla et al., 2015b). Both can be related as one often affects the other. The decline of physical aspects of health and well-being through menopause has limited research (Mishra et al., 2003). When looking at the NHS's list of common symptoms for menopausal women to experience, over half can be said to be physical effects of menopause. It could be hypothesised that the physical aspects have a significant role in the deterioration of well-being. In addition, if the physical aspects of menopause were lessened or eliminated, the other symptoms, seen as psychological, on the NHS's standard list of menopausal symptoms could also be lowered as a result.

Primarily medical research focuses on offering medical interventions to reduce menopausal symptoms, where design interventions are limited for a therapeutic outcome. Due to the loss in oestrogen, during this phase of life, women consequently have many physiological changes (Gurgan et al., 2005). A general practitioner (GP) will offer HRT, vaginal lubricants, creams and moisturisers, cognitive behavioural therapy (CBT), along with diet and exercise (NHS, 2022c; NHS, 2022d). Cumming et al. (2015) conducted a mass study of 1476 menopausal women and found that '7 in 10' have/would use HRT. Significant advantages of HRT are its ability to effectively alleviate the majority of menopause and perimenopause symptoms. These symptoms, which include hot flushes, brain fog, joint pains, mood swings, and vaginal dryness, can be greatly relieved with notable improvements within a few weeks (NHS, 2022d). Therefore, current medicinal treatments

aimed at affecting the psychological and physiological aspects of a menopause, which subsequently affect physical aspects of menopause aiming to improve wellbeing.

In addition, HRT is used to improve a woman's libido through this period but has little effect.

Research has found that the Female Sexual Function Index score decreases for women during the perimenopausal stage. Where, '30%' have increased sexual dysfunction during this period. Sex drive can lower through the menopausal transition, leaving a woman's well-being lower. Well-being is directly related to vaginal symptoms through menopause. Research has found that vaginal symptoms correlate to 'daily living, emotional well-being, sexual function, and self-concept and body image' (Huang et al., 2015). In addition, 'menopausal status has a direct effect on vaginal dryness, but an indirect effect on sexual responsivity via a direct effect of menopausal status on symptoms, which then affect well-being' (Dennerstein, et al., 1999). HRT can help women improve their libido, but research shows that minimal increases in sexual desire are found (Cappelletti & Wallen, 2016). Thus, the quality of life and relationships are affected by menopause, where current solutions offer little support.

Women seek viable alternatives to medicinal therapies due to scepticism about the positives and negatives of physical and mental health. A study conducted from 1992-2009 showed that the use of HRT had decreased (Parkin, 2011). Women are now aware of the risks that HRT poses to the body. The NHS (2019) states that HRT 'can increase your risk of breast cancer'. Over '1/3' of women with breast cancer had used HRT one year before the index date (Vinogradova et al.,2020). Over the last 14 years, women have become heightened to the risks associated with HRT and are therefore uncertain of what is best for themselves (Cumming et al.,2015). Although other methods should not promote breast cancer, they also have individual side effects (Van Patten, 2002). Women should have more options for relief from symptoms, but more importantly, women should not be at risk of cancer for trying to alleviate symptoms from a natural bodily process. Women are aware of their well-being through their menopausal transition but are currently unable to control their bodies to

improve their well-being. Biofeedback wearables would offer menopausal women security as the body naturally adapts to the wearable's outputs.

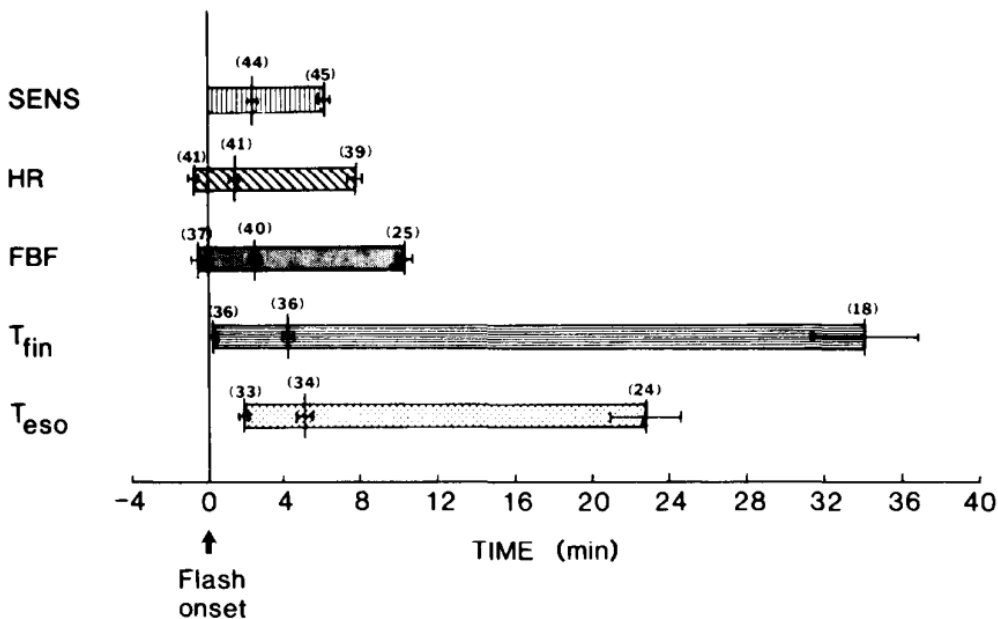
Vasomotor symptoms can also affect a menopausal woman's well-being through stigma. Women can perceive shame and guilt through menopause leading to a lower quality of life (Zivdir & Sohbet, 2017). Other research discusses the distress caused to women surrounding hot flushes as the embarrassment and concern about others' perceptions when a woman is having a hot flush (Reynolds, 1999). Further research also outlines women's social problems during hot flushes and their negative attitudes towards menopause (Ayers et al., 2009). Women can have social anxiety when they feel unable to control their bodies, leading women to either try and cool, avoid others or proceed as usual (Hunter et al., 2009). The research found proves women are shamed by menopause due to social stigma; a new method to deal with hot flushes could vastly improve these social concerns.

#### 2.2.4 Vasomotor Symptoms

Vasomotor symptoms, related to night sweats and hot flushes, are among the most common symptoms of menopause. Vasomotor symptoms are caused by the narrowing of the thermoneutral zone in the brain (Archer et al., 2011). This effect is related to oestrogen withdrawal but to variance in central nervous system neurotransmitters. Oestrogen replacement therapy is currently the most effective method of dealing with the effects of a hot flush, whilst peripheral vascular reactivity in symptomatic women is also altered.

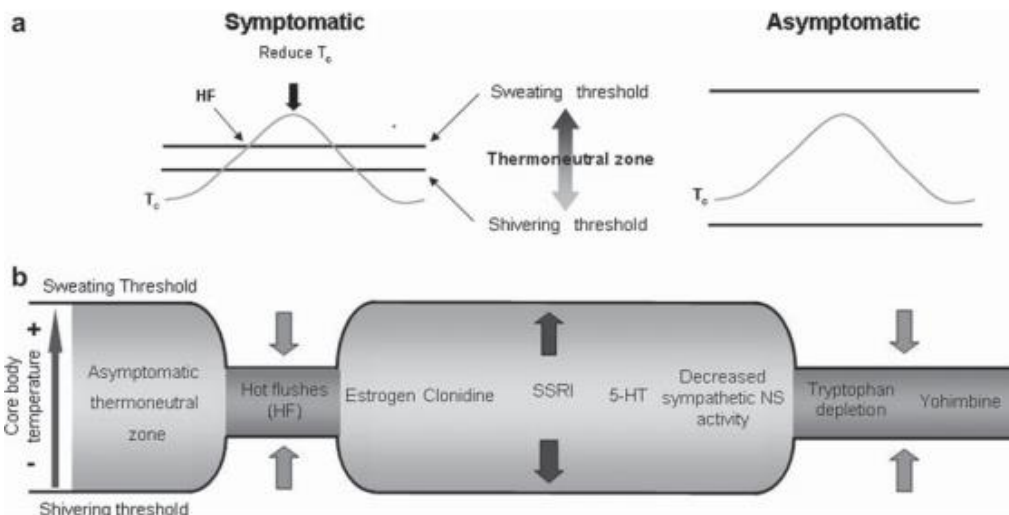
### 2.2.4.1 Hot Flushes

Symptomatic and asymptomatic women induce the same temperature fluctuations during a hot flush. Figure 4 shows that symptomatic and asymptomatic women experience small core temperature elevations of the same scale. Internal temperatures fall after a hot flush, whilst if sweating occurs, skin temperature falls during the flush before rising after (Molnar, 1975). Finger and toe temperature rises sharply at the onset of a flush with a slower fall after a flush. Similarly, a woman's heart accelerates at the onset of a flush. However, there are no premonitory signs of the imminence of a hot flush. There appears to be a build-up of a chemical compound but not heat, with thermal distress evoked by vascular warming in the cheeks. Research has found that dabbing the cheeks with cold water brings prompt relief. Core body temperature is unlikely to trigger a hot flush, with just over '1/2' increasing core temperature (Jones et al., 2019).



*Figure 4 Symptomatic and Asymptomatic Core Temperature Evaluations in Menopausal Women (Molnar, 1975) (a) Core temperature fluctuations at the onset of a hot flush (b) Features that make a thermoneutral zone*

Just prior to a hot flash, heart rate and finger blood flow increase. Two physiological changes happen before the onset of a hot flush; the body has increased cutaneous blood flow by up to 30-fold because of core skin temperature change (Kronenberg, et al., 1984). In addition, the sensation of heat is greater than the difference in skin temperature. As shown in figure 5, only heart rate and finger blood flow alter prior to the onset of a hot flush. With blood flow and heart rate deemed to be the primary indicators of the onset of a hot flush, using biofeedback to monitor these functions through a wearable could be a non-invasive design solution for menopausal women. In addition, it would be fair to surmise that if heart rate and finger blood flow both rises before a hot flush, they directly affect the fingers' skin temperature.



**Figure 5** Heart rate (HR) and Finger Blood Flow (FBF) Rise Prior to a Hot Flush (Kronenberg, et al., 1984)

#### 2.2.4.2 Pulse Points

As heart rate and blood flow increase prior to a hot flush, checking pulse points is necessary as these readings may be vital for later design stages. Firstly, the heart is supposed to beat at a rate between 60 and 100 beats per minute (bpm), where anything below and above are abnormalities (Ismail, 2018). Sorin, Pop & Moldovan (2018) define the pulse points on the human body that readings can use to measure heart rate. The typical pulse points in human bodies are:

- ‘Temporal artery’
- ‘Facial artery’
- ‘Carotide artery’
- ‘Brachial artery’
- ‘Radial artery’
- ‘Femoral artery’
- ‘Popliteal artery’
- ‘Posterior tibial artery’
- ‘Dorsal pedi artery’

The wrists and neck are the most common ways to achieve pulse readings due to ease of access and vein population (NHS, 2021). If considering wearable technology as an output for this research, wristwear seems to be a logical design approach as stigma lowers if an item were worn on the wrist rather than the neck. As pulse is generally not considered when assessing menopausal women during hot flushes, it is essential to acknowledge current methods women can access when seeking relief from vasomotor symptoms.

### 2.2.4.3 Seeking Relief from Hot Flushes

Women currently have limited methods to manage hot flushes. In addition to the methods previously discussed, such as HRT, the NHS (2022d) list some "tips" to manage a hot flush. The list is as follows:

- ‘Limit coffee and tea’
- ‘Limit smoking’
- ‘Stay in a cool environment’
- ‘Apply cooling (spray cool water to the face, or apply a cold gel pack)’
- ‘Wear loose clothes and remove if necessary’
- ‘Have lighter sheets rather than duvets for sleep’
- ‘Limit alcohol’
- ‘Drink colder liquids’
- ‘Have cooler baths and showers’

From the list of tips given by the NHS, it could be said that nearly all solutions must be premeditated. Some women find the symptoms debilitating and difficult to counter as they may not always have the correct apparatus. The unpredictability of vasomotor symptoms makes the solutions above less viable, as some are ineffective depending on the scenario.

Dissecting the NHS's treatments for hot flushes could help identify the effectiveness of information given to women. Firstly, the results of whether hot drinks can affect a hot flush are ambiguous (Ziv-Gal & Flaws, 2010). On the other hand, smoking affects the frequency and severity of hot flushes

depending on the amount smoked currently or in the past (Smith et al., 2015). Research has found that '95.5%' of menopausal women say actions taken to cool are the most helpful, with wearing appropriate clothing nearly as helpful at '93.4%' (Griffiths et al., 2013). In addition, Excessive environmental heat exposure, including limited heat dissipation (such as thick bedding and clothing), can trigger a hypothalamic response (Mold et al., 2012).

Evidence suggests that other daily habits, such as alcohol, can improve and worsen hot flushes (Schilling et al., 2007; Ziv-Gal & Flaws, 2010). Research into the intake of cold drinks found that hot flushes can become more tolerable through consumption (Jones et al., 2012; Casper & Yen, 1985). In addition, bathing and showering are methods to improve symptoms and lessen insomnia (Dhillon et al., 2008; Higano, 2003). The research identified reiterates that the NHS's tips for treating hot flushes are helpful for women as they seek non-medical alternatives to healthcare. Therefore, a holistic approach to improve menopausal well-being could help ideate an alternative. Women can struggle to do daily activities, but if an alternative changed well-being for the better, these activities would be easier to achieve. A biofeedback wearable would offer menopausal women security to do daily activities without limitations as some severe symptoms could be lessened and controlled.

#### 2.2.4.4 Biofeedback

Biofeedback can track a menopausal woman's body to increase well-being. The use of biofeedback can be described as an evidence-based approach to design, where self-awareness is increased to gain further control of the mind and body (Shaffer et al., 2006). Bodily processes that can be managed through biofeedback therapy include heart rate, perception of pain, brainwaves, muscle tone and skin conductance (deCharms et al., 2005) In addition, wearables for biofeedback have proven to offer an increased understanding of emotion whilst increasing well-being (Frey et al.,



2018). Therefore, biofeedback therapy is a viable option to monitor heart rates amongst menopausal women with output to provide cooling before the onset of a hot flush.

### 2.2.5 The Human Senses Effect on Vasomotor Symptoms for Menopausal Women

The relationships between vasomotor symptoms and the human senses could define commonalities where ideation for the design and development of a therapeutic device can begin. This literature review phase will discuss the relationships between the five senses of sight, sound, touch, smell, taste, and vasomotor symptoms. Addressing how a sense can be affected by menopause, then conversely assessing whether menopause could be affected by the senses. Each sense will be assessed separately and then defined if it is a possibility to design for a multisensory concept.

#### 2.2.5.1 The Relationship Between Sight and Vasomotor Symptoms

Sight can be affected by menopause. Nevertheless, sight can also affect menopause. Whilst prior research has found that hot flushes are the most common symptom of menopause, Loss of sight is also a prevalent symptom of menopausal women (Nagar & Dave, 2017). Research has found that current treatments for deteriorating vision are medicinal tablets such as Anthocyanin (Nomi et al., 2019). On the other hand, apart from long-term screening, spectacles and contact lenses are the only physical product a user can buy to improve vision (World Health Organisation, 2019). Therefore, a holistic viewpoint to seek a valid product concept could be ideated.

Vision can also affect the body and menopause. As the temperature fluctuates during a hot flush, vision therapy could decrease vasomotor symptoms' effect on menopausal women. Colours and heat have had a long-term relationship popularised as "hue-heat" (Mogensen & English, 1926). The relationship between thermal stimuli and colour influences the cross-modal relationship between colour and temperature (Ho et al., 2014). For example, there are associations between red and warm and, conversely, blue and cold (Balcer, 2014). For a cooling effect needed to combat a hot flush, research has found that looking at cold objects, such as ice, can be more inclined to extract

temperature responses that respond to visual stimuli (Kanaya et al., 2012). Thus, illustrating the influence of cold colours and objects on a human's perception.

In addition, research has found that colours can be associated with the same warm and cold relationship, where red is the warmest, then yellow, then green and finally blue (Guéguen & Jacob, 2012). As colours can have a thermal perception effect, there would be less need to have direct thermal stimuli to change body temperature (Michael & Rolhion, 2008). Sight can therefore be both affected and can affect vasomotor symptoms. A final design could be ideated to encompass visual stimuli with colours and objects that have been discussed to evoke the alteration of body temperatures amongst menopausal women.

#### 2.2.5.2 The Relationship Between Sound and Vasomotor Symptoms

Hearing, like sight, can be affected by menopause. Menopause is at risk of developing hearing loss, where HRT and old age has attributed to this decline (Curhan et al., 2017). Conversely, research has found that HRT can improve hearing loss and tinnitus (Lai et al., 2017). Hearing aids are a known product that can improve hearing loss (Blamey et al., 2010). Certain foods can improve hearing if they contain magnesium, potassium, folate, zinc or omega 3 (Arakelyan, 2021). Other methods of improving hearing require invasive surgeries such as cochlear implants. Therefore, they are unviable options for menopausal women as they were designed for users with a higher hearing loss category. Sound, although it can be affected by menopause, is not thought to be related to vasomotor symptoms.

Though hearing is not directly affected by vasomotor symptoms, sounds can be used to improve vasomotor symptoms. Like sight, sounds can influence the warm and cold relationship. Research has found that sounds such as a "wind chime, autumn insects and the sound of waves" can have a distinct effect on body temperature (Matsubara et al., 2007). In addition, further studies have shown that human thermal sensation can lower through environmental sounds, such as "Rain", "Stream",

and "Water Bamboo" (Fukagawa et al., 2018). Therefore, displaying the clear link between sight and sound as they both impose a warm and cold relationship on a user. Similarly, a sight like sound can be designed and developed to control body temperatures holistically.

### 2.2.5.3 The Relationship Between Touch and Vasomotor Symptoms

Touch can be one of the most significant triggers for a menopausal hot flush. Room temperature, material and fit of clothing and bedding, and the temperature of baths and showers can all be triggers for the onset of vasomotor symptoms to occur. Conversely, room temperature is cooler, clothing and bedding, if looser and lighter, and cold water can improve vasomotor symptoms (NHS, 2022d). Therefore, causation and solutions can make a direct correlation between vasomotor symptoms and touch.

As Vasomotor symptoms are directly related to touch, many cooling methods have been previously researched to affect body temperature. Previous research has found that ambient room temperatures can influence body temperatures that could trigger hot flushes (Freedman, 1989; Freedman & Woodward, 1992). Alongside ambient temperature, direct application of tepid or cold water to the head and cold water to the stomach can relieve menopausal women during a hot flush (Foxcroft, 2009). Research has found that using a Peltier plate directly applied to the forearm lower skin temperature by 10 degrees in less than one minute (Woods et al., 2009). In addition, Godfrey et al. (2018) review innovative wearable jewellery, stating that 'Grace' wristwear automatically tracks and cools menopausal hot flushes. The first wearable device tested the sides of a user's body, whereas the 'Grace' was designed for wearing on the wrist. The effect of localised cooling of the forearm and dorsal side of the wrist clearly affects menopausal women, where hot flushes can be reduced through touch.

#### 2.2.5.4 The Relationship Between Smell and Vasomotor Symptoms

Vasomotor symptoms can make women sweat. An increased chance of sweating and fluctuations in hormone levels results in a change in body odour for many women ((Bridgewater Community Healthcare NHS, n.d.). Research has quoted women as improving stigma: 'On some days [they] sweat profusely. [They] have a shower in the morning and use anti-perspiration products, but [they] might as well not use them. On certain days [they] feel very uncomfortable around [their] students because [their] sweat smells and it is just unstoppable' (Wales TUC, 2017). In addition, research has stated that 'excessive sweating is not a feminine thing', lowering self-esteem and social interaction (Shayesteh et al., 2021). Men are not as socially embarrassed as women when sweating due to other functions such as flatulence holding higher shame (International Hyperhidrosis Society, n.d.). Women can also have a lower smell acuity from the menopausal transition, which is related to oestrogen levels (Singh et al., 2019). Thus, vasomotor symptoms can harm the user's life and well-being through uncontrollable odours.

Conversely, smells can affect vasomotor symptoms as body temperatures can be affected due to their medicinal properties. Essential oils, such as peppermint oil, have cooling effects due to menthol content, as blood vessels are opened (Sarkic & Stappen, 2018). In addition, inhalation of cold air instigates changes in core temperatures, ventilation, and cerebral blood flow (Tsuji et al., 2015). Therefore, menthol can offer a perceived cooling effect for users. Perceived cooling could be as effective as physical cooling as the user's mind is convinced the body is cooler in both scenarios. If menopausal women perceive their bodies to be cooler than before, their body temperature may not need to change to cool from a hot flush.

#### 2.2.5.5 The Relationship Between Taste and Vasomotor Symptoms

Taste can be affected like other senses by menopause and vasomotor symptoms. Xerostomia, known as dryness of the mouth, can lead to a higher prevalence of root caries, oral discomfort, taste

alterations, oral candidiasis, and periodontal disease in menopausal women (Raina et al, 2012).

Conversely, other research states that taste does not change through menopause (Delilbasi et al., 2003). Therefore, the severity of taste change through menopause is unclear, and it does not appear to be directly related to vasomotor symptoms.

Taste, on the other hand, can directly affect vasomotor symptoms. Evidence shows that hot and cold liquids can alter oral temperature measurements for up to ‘seven to nine’ minutes after consumption (Terndrup et al., 1989). Related studies also acknowledge that liquid consumption can affect oral temperatures (Airoldi et al., 2005). Following sport science studies relating to liquid consumption, crushed ice can also lower core body temperatures (Brearley, 2012). The NHS (2022d) also listed that drinking or sipping cold drinks can help alleviate a hot flush. Even though taste has a common link to vasomotor symptoms, where a viable design for taste would be trickier to develop as the design could borderline an invasive nature where women may not feel comfortable consuming a concept; based upon women having a stronger perception of risks involved with epidemiological research compared to men (Ding, 2007). In addition, if the design was to be ingested, this would be encroaching on a medical solution to the problem women currently face. This thesis on the other hand is assessing viable options of therapeutic design as stated through section 2.1.

## 2.2.6 The Human Senses effect on Sleep for Menopausal Women

### 2.2.6.1 Sleep

Menopause hinders sleep for many women. Vasomotor symptoms can contribute to a decline in sleep due to night sweats. Assessing sensory research as to whether the senses affect sleep and are affected by sleep is necessary. This section aims to refine women's problems with sleep by assessing how the senses of sight, sound, touch, smell & taste can affect and be affected by sleep. Each sense will be assessed separately and then defined if it is a possibility to design for a multisensory concept.

### 2.2.6.1.1 What is Sleep?

All animals need daily sleep throughout their lives. The average human sleeps for a ‘third’ of their lives, which shows health benefits (Zheng & Zhang, 2022). With ‘2/3’ of the UK having sleep problems, the main one being insomnia (Adams, 2011). Sleep disorders can affect men and women in different ways; all levels of a disorder could be different, leading to a more complex diagnosis (Boccabella & Malouf, 2017). Sleep, which is involuntary and essential, is as crucial to the body as eating, drinking, and breathing; whilst also vital to maintaining excellent mental and physical health. Not only does the body get restored, but the brain too (Forster, 2011).

The sleep process is recurring, where the body and mind are in certain states. Consciousness is adjusted, defining sensory activity as repressed, muscle groups are relaxed, and environmental interactions are lowered (Ferri et al., 2008). Unlike in a coma, during sleep, a human can still react to a stimulus (Gosseries et al., 2011). During sleep, a person can go through two reoccurring states. These states are called REM and Non-REM. REM (rapid eye movement) affects many aspects, but the skeletal motor system is most noticeable, as muscles paralyse during this phase (Chokroverty, 2017; Brooks & Peever, 2012). Dreams are also a part of sleep psychology, often described in narrative forms whilst cognisant life is in progress. Dreams are later defined as fantasy (Freud & Brill, 1899).

As sleep is affected by a more significant number than unaffected, a device that could potentially aid sleep for menopausal women could also improve sleep for a larger demographic of users. In addition, the fact that humans can still react to external stimuli during sleep means research could develop ideas that promote sleep wellbeing through stimulus.

### 2.2.6.1.2 How Does Menopause Affect Sleep and Wellbeing?

Hot flushes and night sweats are both vasomotor symptoms. Both directly affect sleep, with many further climacteric symptoms occurring that women generally go through (Stuenkel et al., 2015;

Tom et al., 2010). Night sweats can trigger insomnia due to hormonal fluctuations, which lead to increased arousal (Krystal et al, 1998). thus, when women go through menopause, their well-being is lowered due to disturbances in sleep. Occurring because of side effects such as hot flashes, mood disorders, and obstructive sleep apnoea (OSA), among many, it can be a secondary disorder. However, it can also be a primary disorder (Bruyneel, 2015). Vasomotor symptoms harm sleep for menopausal women. As arousals increase due to vasomotor symptoms, this can lead to increased insomnia and desynchronised circadian rhythms. This further backs the validity of a biofeedback device that could trigger localised cooling for menopausal women during the daytime and at night.

#### 2.2.6.1.3 Seeking Relief from Vasomotor Symptoms During the Night

Sleep can be a terrible experience for many as there are various sleep disorders. Menopause itself can bring on insomnia, depression, sleep-disordered breathing, and fibromyalgia, which can severely affect a woman's circadian rhythm (Eichling & Sahni, 2005). There are two variants of insomnia: dyssomnias (night wakings and difficulty falling to sleep) and parasomnias (somnambulism, somniloquy, sleep terrors, enuresis, bruxism, and rhythmic movements) (Petit et al., 2007). The well-being of menopausal women can be affected due to insomnia, with both physical and mental health deteriorating. Arousals and insomnia are common symptoms for women to experience through the menopausal transition. Present in '40%-60%' of women, disturbed sleep and insomnia has a strong correlation to the menopausal transition (Baker et al., 2015). Attarian et al. (2015) created evaluative literature on treatments for chronic insomnia in menopausal women. They state that common treatments include:

- 'Biomedical and Pharmacological Treatments (HRT, Sedative Hypnotics, Antidepressants & Gabapentin)'
- 'Herbal and Nutritional Supplements (Isoflavones, Valerian Root, Pycnogenol, Phyto-Female Complex & Kampo)'

- ‘Behavioural Interventions (CBT, High-Intensity Exercise, Hypnosis, Yoga, Massage, Acupuncture)’

These three treatments have ambiguous results as women are said to have adequate HRT treatment, but night sweats still trigger insomnia. In addition, insomnia can leave unresolved grief of going through menopause (Krystal et al, 1998). As medication has mixed results and effects on individuals, a non-invasive and un-medicalised design could improve sleep, where women also feel safe using a product that is not changing their bodies.

Cooling before the onset of night sweats and hot flushes could improve insomnia levels in menopausal women. Ebb Therapeutics has developed two forehead cooling devices to be used at night to improve sleep quality. The devices are used to reduce sleep onset latency, wakefulness, and severity of hot flushes in one week. Further improvements were then seen from weeks 2-4 of nightly head cooling. These reductions reduce insomnia severity, alleviating well-being issues for menopausal women (Baker et al., 2020). In addition, the devices are used to treat insomnia in veterans who have trouble with post-traumatic stress disorder. 'Insomnia, anxiety, and depressive symptoms were reduced in veterans over the same trial period of 4 weeks' (Mysliwiec et al., 2020).

When considering the effect senses could have on sleep, forehead cooling appears to be an effective method of cooling. It is possible to hypothesise that a biofeedback wearable that could be worn on the forehead through the night gives feedback to the body to decrease awakenings to develop current research into this area further. With prior assumptions leading towards awakening being linked to hot flushes; a hypothesis could be made that biofeedback to assess hot flushes through the night could be utilised to reduce awakenings further.

#### 2.2.6.2 The Human Senses Effect on Sleep for Menopausal Women

This section will determine if the senses can positively affect sleep. The literature will be discussed to find the relationships between the five senses of sight, sound, touch, smell, taste and sleep. The



senses will be assessed to find the positive and negative effects they may have on sleep. Like when discussing the relationships between the senses and vasomotor symptoms, each sense will be reviewed separately.

#### 2.2.6.2.1 The Effect Sight Can Have on Sleep

Lights can control sleep patterns for humans. The body regulates every 24 hours in a continuous life cycle, where daylight offers timings for animals' sleep patterns (Wurtman, 1975; Blume et al., 2019). Humans can often wake minutes before their alarm goes off as their body acclimates to the routine of getting up at that time (Jermier, 1985). A human's master body clock is located in the suprachiasmatic nucleus and is triggered by light. However, a blind person cannot perceive the light-dark cycle; therefore, the circadian rhythms of blind people tend to "free run" on a longer cycle than 24 hours (Sack & Lewy, 2001). Recent research has outlined that light increases cognitive ability even for those who are fully blind (Vandewalle et al., 2013). Thus, highlighting the importance of light as an environmental synchroniser for internal circadian clocks (Sack et al., 1992).

Artificial light can interfere with a human's natural sleep/wake process and wake the brain during sleep (Puterbaugh, 2011). Though this can be damaging, products like the 'Philips Wake Up Light' can improve arousals by '88%' (Philips, 2022). Light can also be positive for people who suffer from circadian disorders (Gooley, 2008). Research finds that if a human is exposed to 2500 lx of bright light before bed, sleep onset is prolonged (Komada et al., 2000). Sleep onset could be prolonged through blue light and social media viewing (Suganuma et al., 2007). For menopausal women, both morning light and 24-hour exposure to light can be beneficial (Youngstedt et al., 2004). In conclusion, light has a positive and negative impact on sleep; light in the mornings can improve sleep and light prior to sleep can negatively impact sleep. Also, sleep awakenings can

occur through artificial light exposure, which hypothetically could be linked to vasomotor symptoms being triggered.

#### 2.2.6.2.2 The Effect Sound Can Have on Sleep

All stages of sleep still process sound. A human brain can process sound even when sleeping; even though this occurs, the person will not always become consciously aware (Issa, 2008). The second half of the night generally seems to be more disrupted than the first (Institute of Medicine, 2007). These awakenings from noise vary for individuals, where a person may not awaken from their partner's sleep apnoea, but they could awaken from their baby crying (National Sleep Foundation, 2015).

For menopausal women, adjusting noise levels can lead to a relaxing sleep experience (The North American Menopause Society, 2014). Applications such as 'Headspace' offer users the chance to sleep within soundscapes (Rebedew, 2018). Soundscapes give users white noise. Background and peak noise can be reduced through white noise (Salisbury et al., 2002; Stanchina et al., 2005). Research suggests low-frequency noise is a better inhibitor than high-frequency noise on sleep behaviour (Birns et al., 1965). Current research has not explored the possibility of improving menopausal women's well-being through white noise; therefore, a design that accommodates such designs may benefit the user.

#### 2.2.6.2.3 The Effect Touch Can Have on Sleep

External temperatures can affect the body's temperature. Humans have two thermosiological compartments in their bodies. Firstly, the homeothermic core produces heat. The poikilothermic shell regulates heat loss and is dependable on environmental temperature (Kräuchi & Deboer, 2010). The core is homeostatically regulated at around '37 °C', with the shell dependent on environmental conditions (Kräuchi, 2007). With reports suggesting the best room temperature to be '18°C- 19°C', a cool room seems best for sleep (National Sleep Foundation, 2015). During sleep, at

around 03:00-06:00, the core body temperature of a human is at its lowest, compared to approximately 12-14 hours after waking, where body temperature is said to be at its highest (Kelly, 2006). During the night, hot flushes are more substantial and last longer at around 04:00 and 06:00 (de Zambotti et al., 2014). The drop in core body temperature during the period of 03:00-06:00 could therefore be causation for the increased severity of vasomotor symptoms.

Current technology is designed to improve sleep through touch. Recent research defines technology as changing ambient temperatures to aid sleep, with the optimal temperature can depend on the 'age, sex and physical fitness of the subject' (Gupta et al., 2016). Ambient temperatures can be lowered at night and raised in the morning, where a person achieves deeper sleep with higher melatonin secretion, resulting in sensations of being well-rested (Kondo et al., 2007). Immersing menopausal women in a cold environment compared to a warm environment can improve sleep, where hot flushes are less frequent and intense (Kronenberg & Barnard, 1992). Mitsubishi state the importance of air-conditioning to improve menopausal wellbeing through sleep (Oliver, 2020). Devices such as the 'Aircon' start up watch, the 'Grace' wristband and the 'Embr Wave' cooling bracelet could be utilised for localised cooling, though only the 'Embr Wave' is available on the market as the others are still in concept phases. Therefore, in addition to the results found through the 'Ebb' device, localised cooling could offer menopausal women improved sleep as support could be given through all times of the night when vasomotor symptoms occur. This may only be possible through biofeedback as constant cooling and warming through pre-set timings could interrupt sleep.

#### 2.2.6.2.4 The Effect Smell Can Have on Sleep

Products that produce scents are more popular than those without an odour; odours can also improve a user's relationship with the product (Cannard, 1995). Blends of oils have shown benefits to the elderly as an alternative method to medication to battle insomnia. Oils have zero side effects; therefore, aromatherapy could be a non-evasive approach to help people sleep (Ludden &

Schiffstein, 2009). When comparing ‘sleep-with-conditioned-odour; sleep-with-control-odour; or sleep-with-no-odour,’ the odour-conditioned room is shown to be most effective. Odour-conditioned rooms have improved creativity, with sleep creativity improving with odours present (Ritter et al., 2012).

In addition, smells can change our perceptions of objects; users can either like a scent (e.g., food, flowers, potential mates) or dislike a scent (e.g., predators, poisons, gas leaks) (Axel, 1995). Other reports suggest that people’s sense of smell can go unappreciated (Martin, Apena, Chaudry, Mulligan & Nixon, 2001). Conversely, inhaling menthol can induce cooling sensations, although the temperature of the skin and mucous membranes remain unaltered with only respiratory effort deemed to ease (Griffiths et al., 1988; Pereira et al. 2013; Liu & Qin, 2005). Products such as ‘Vicks Vaporub’ are proven to increase sleep quality (Santhi et al., 2017). In addition, essential oils can be combined to enhance sleep and wellbeing in menopausal women (Choi et al., 2018). Aromatherapy can be an innovative alternative design method that could make an olfactory device that could promote sleep through evoking positive scents may improve sleep for menopausal women. This could be an avenue of research that could have an improved outcome for menopausal women, though a comprehensive review of the research of aromatherapy for menopausal women has found limited evidence of benefits of aromatherapy (Lee et al., 2021).

#### 2.2.6.2.5 The Effect Taste Can Have on Sleep

Even though food is necessary for humans, it can negatively impact sleep. Foods that contain an amino acid called L-Tryptophan (a foundation for the chemical serotonin) can make a person feel drowsy, mainly Turkey (Jenkins et al., 2016). Serotonin production necessitates the presence of tryptophan. Recent studies have revealed that the perception of its bitterness is facilitated through the involvement of the bitter taste receptor TAS2R4 (Di Pizio & Nicoli, 2020). Other common foods with similar levels of tryptophan are ‘oats, bananas, dried prunes, milk, tuna fish, cheese,

bread, chicken, peanuts, and chocolate' (Richard et al., 2009). These foods tend to be high in carbohydrates which is good for sleep promotion (Wurtman & Wurtman, 1986). Conversely, fat-induced foods, fried or spicy foods, can upset a person's stomach (National Sleep Foundation, 2015). The taste of food and drink, particularly sweetness and bitterness, has been associated with the prolonged onset of sleep (Alahmary et al., 2019; Rodak et al., 2021). The consumption of dairy, in particular warm milk prior to sleep, has been instilled within humans from an early age as a sleep evoking aid and is considered a nightly routine (NHS Foundation Trust, 2020). The consumption of dairy products is generally considered to promote positive sleep quality and improve physical and mental health (Komada et al., 2020).

People tend to underestimate the amount of caffeine they are intaking daily as they would only calculate coffee consumed. Whereas there is high caffeine content in cold medicines, painkillers, tea, chocolate, hot chocolate, and energy drinks (Sejbuk et al., 2022). In many countries, such as Italy, it is cultural to have a digestive coffee after meals (Morris, 2010). This could be problematic for sleep, as research has found that caffeine can last many hours and is advised not to be consumed within 6 hours prior to the onset of sleep (Drake et al., 2013). As found through this review, vasomotor symptoms are known to be triggered by foods (NHS, 2022d). Therefore, to promote sleep well-being in menopausal women, an improved diet can help reduce the effects of vasomotor symptoms.

Humans have used sleeping aiding products through an oral application. During young adulthood, alcohol and medications are common sleeping aids (Johnson et al. 1998). Studies show sleeping aids have significant impacts on 'cognitive performance, sleepiness and neurophysiologic functioning' (Reynolds & Banks, 2010). Other researchers say sleep deprivation exacerbates the obesity crisis (Spiegel et al., 2004). Research has shown that only medicated outcomes have been provided to menopausal women to improve sleep through taste. The lack of products that embody

taste to improve sleep and decrease vasomotor symptoms could be due to stricter regulations for oral relief.

## 2.2.7 Alternative Design Methods to Reduce Vasomotor Symptoms Through Sensory Design

### 2.2.7.1 Wearable Technologies to Improve Wellbeing

Having assessed how the senses can affect vasomotor symptoms and sleep, critiquing how they can affect the senses in return, the thesis can recommence from section 2.1.3. Wearable technologies are an alternative method of design yet to be fully explored through academic research. Wearable technologies are currently used to improve well-being (El-Gayar et al., 2019). Previous design research has cumulated in a few devices developed; initially, Peter Astbury developed the grace wristband, which is still in development as of 2022. The design uses biofeedback technology to target a hot flush at the onset (Astinno, 2022). In addition, Embr Labs have also developed a wristwear device backed through research (Wang et al., 2018). Research states that Embr's wristwear device can be used to improve menopausal symptoms (Composto et al., 2019).

Other than wristwear, clothing is an area of explored design. Become™ clothing was included in the 'Top 20 Global Innovations for Women's Health and Wellness Apparel' (Become, 2022). In addition, handheld cooling has developed for menopause. The Menopod® used a similar thought process, designed to relieve menopausal symptoms but found no statistical difference was found with the device, but users felt the device brought them relief (Reid et al., 2015). In conclusion, wearable technologies are essential when designing alternative medical-based therapies for menopausal women. Current technologies have limited exploration into biofeedback, which could improve current wearable technologies. In addition, if a product were designed to trigger prior to the onset of a hot flush rather than at the onset of a hot flush, tracking heart rate or finger blood flow could offer improved well-being compared to current designs.

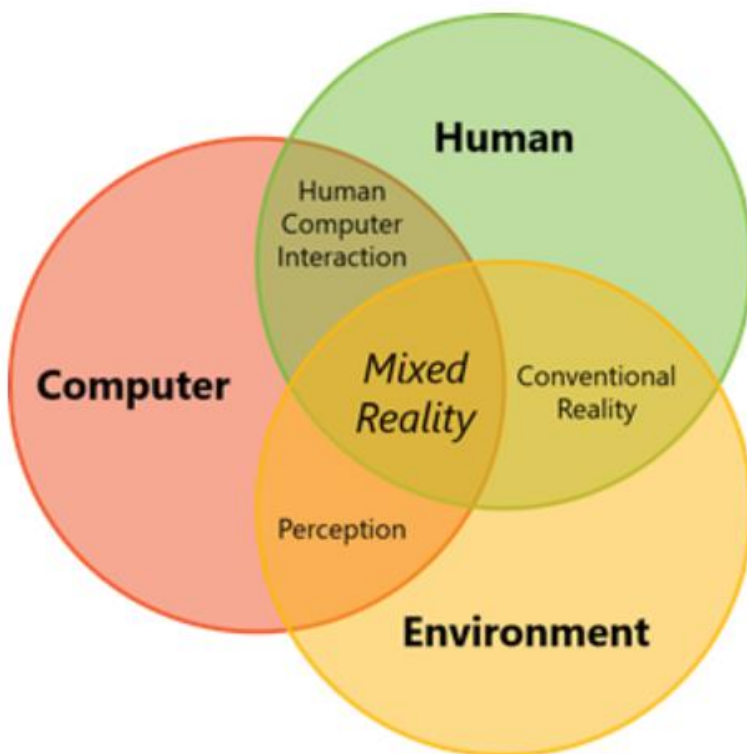
Innovative technologies are being designed to amalgamate products with a human's body movements and shape. Technologies focus on size; compared to many cooling wearables found within the product reviews, the size of upcoming innovative technologies is small enough to be unseen, which is ideal for menopausal women to offer anonymity. An intelligent technology designed by UCLA (University of California, Los Angeles) is a solid-state fridge, using the electrocaloric effect in a 5mm thick pliable device. The electrocaloric effect happens when a material molecule has negative and positively charged ends. The molecules are therefore aligned, increasing order in the material, meaning a rise in temperature and a fall in temperature (Dormehl, 2017).

Furthermore, VTT (Technical Research Centre of Finland) has identified intelligent technologies compatible with innovative fabrics. Their research outlines areas of wound care and user comfort (Pursula et al., 2018; McCaffrey et al., 2019). UC San Diego has also designed intelligent technology, such as a flexible Peltier, battery and circuit board used in their research. This innovative, flexible technology seems to be the upcoming wearable design as technology is bound to be incorporated into clothing (Labios, 2019).

In addition to the San Diego University development, wearable sleep technology has also deemed flexible circuit boards necessary for intelligent wearable technologies. As previously stated, the Reme sleep mask is a wearable sleep technology promoting longer sleep. They also use flexible circuit boards to flex with a user's head without suffering damage. The circuit board weighs less than seven grams, also powered by a small battery. The device also uses pinhead-sized sensors making sure the more diminutive the technology, the higher the comfort level for the user (Reme, 2022). The sising of technologies could apply to any scenario, offering the user flexibility and anonymity. The design of small flexible technologies seems to be the future of intelligent technology.

### 2.2.7.2 Mixed Reality to Improve Wellbeing

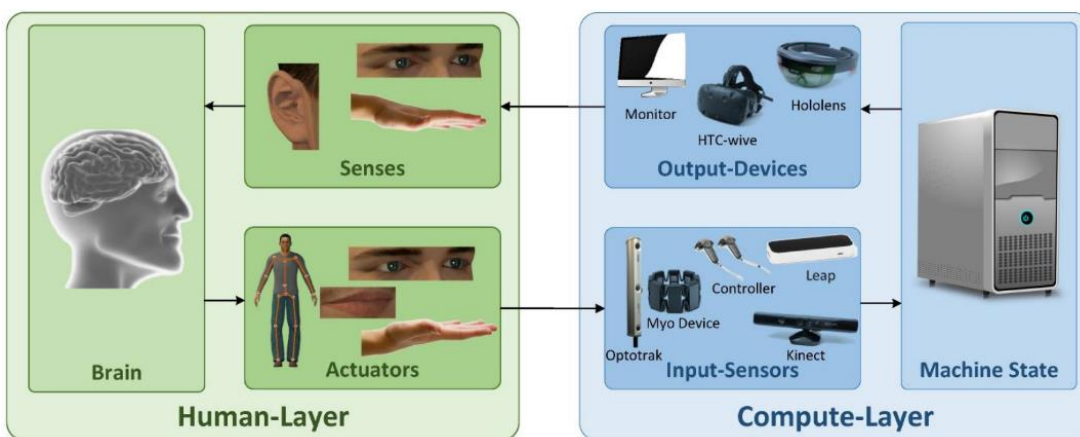
The senses improve menopausal wellbeing and possibly vasomotor symptoms through multisensory design. Therefore, mixed reality could be an alternative design method as a known non-invasive method of treatment amongst patients. Though augmented reality (AR) and virtual reality (VR) has not been considered as design alternative for lessening vasomotor symptoms, it is known to improve wellbeing in older adults (Lee et al., 2019). Research outcomes within this field are vague, where recommendations state that mixed reality could be a positive use design for menopausal women. The research suggests promoting a comfortable environment for the user while promoting social interactions and inducing buoyant feelings. Figure 6 shows the connections between humans, computers, and the environment is mixed reality. Therefore, this research will further assess these areas for menopausal women.



*Figure 6 Connections Between Human, Computer and Environment (Pintea et al., 2018)*



Firstly, mixed reality is linked to human-computer interaction (HCI), as seen in figure 6. In recent years, the use of HCI to improve mixed reality has been apparent. This type of design is currently developed to diminish the barriers between the real and digital worlds. HCI design can coherently affect the senses through mixed reality (Figure 7). The senses are an essential feature of the immersive experience as the user, as heightened senses can provide a realistic experience (Bachmann, Weichert & Rinkenauer, 2018). Research has shown the direct link between the senses and mixed reality due to the links with HCI. The links between the senses and HCI highlight the importance of biofeedback as a design output. As touch, sight and sound are standard sensory controllers and consumption when using mixed reality, an innovative design to offer improved well-being could lower through sensory data utilised to lessen vasomotor symptoms.



*Figure 7 The Interactions Between Humans and Computers (Bachmann, Weichert & Rinkenauer, 2018)*

As stated in chapter 1, menopause is a big problem that affects approximately 13 million women in the UK (NHS England, 2022). With known symptoms of menopause, limited product development to improve the quality of life for menopausal women is a problem. Recently interest has increased in the use of VR for therapy and treatment in the health sector. The National Institute for Health Research has recently approved a £4M project to make VR treatment available in NHS mental health services (NHS Oxford Health, 2018). Virtual reality therapy is already being tested in the NHS to treat fear of heights, Schizophrenia, and mental health (Freeman, 2007; Freeman et al.,

2018; NHS Oxford Health, 2019). With Immersive technology already leading how the NHS offers alternative care, this could be a cost-effective way of improving the well-being of menopausal women. Design for Wellbeing using immersive technology could vastly improve the quality of life for women going through menopause.

## 2.2.8 Design Approaches for the ideation of a Biofeedback Wearable

### 2.2.8.1 Design for Wellbeing

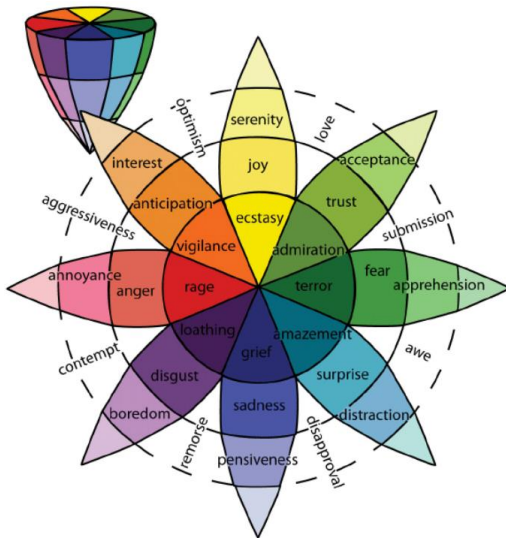
Design for well-being primarily focuses on the impact on a person's living conditions through dynamic support of the design of assistive products in daily use. The top focal point for design for well-being is concentrating on people not in the average demographic. Design for well-being centres around three topics: 'designing innovative products for increased well-being, shaping the future of globally distributed collaboration, and educating the product innovators of tomorrow' (Leifer, 2005). Designers often must uncover uncertainties to improve the final design concept (Leifer, 2005). Conversely, with the use of design for well-being, the complexity of product development is appropriate in the application to generate a solution for both well-being and revenue (Buchanan, 1992). This illustrates Product Design complexity, but if uncertainties are known, the end solution will succeed.

Design for well-being is a prominent part of the healthcare sector, with the co-design of its services coherent with patients, professionals, and the community all inputting to the design development process (Sanders & Stappers, 2008). Co-design and co-creation between menopausal women, designers, and professionals are highly important to increase the design concept's success. UX models have a commonality: they all focus on well-being as the outcome and not the performance of a user's interaction with a product (Hassenzahl, 2008). To Product Designers, this concept of not comprehensively analysing a user's interactions with a product is alien, though well-being testing is still the primary thought for all designers.

Well-being is defined as a state "which allows individuals to realise their abilities, cope with the normal stresses of life, work productively and fruitfully, and make a contribution to their community" (World Health Organisation, 2004). To gain positive aspects of human life, well-being can collaborate with psychology and health care to encourage the cultivation of human strength (World Health Organisation, 2004), with increasing current research into new technologies to support well-being (Cahill et al., 2018). Human-Computer Interaction (HCI) is one current response to well-being. "Responsive Design" is becoming a common term amongst user interface (UI) designers to keep up with continually developing technologies across multiple platforms. Responsive design can be used to adapt to different screen sizes, including contexts. Design changes can still occur when considering virtual due to navigation, content layout and interaction (Mullins, 2015).

A wheel of emotion can be used for both design and assessment of well-being, along with the perception of colour and the feeling colours can evoke. Primarily eight emotions are known: 'joy and sadness; anger and fear; trust and disgust; and surprise and anticipation' (Plutchik, 2001). These are paired into four groups, with one emotion partnered with its contradicting emotion. There are also different intensity levels of the colours chosen, with different intensities meaning a differing emotion. An example of these differing intensity levels is that 'rage' is the primary emotion, with a higher intensity of red, followed by 'anger' and 'annoyance' with lower intensity levels, respectively. Plutchik also mixes emotions between categories. If a person uses 'amazement' and 'grief', they can be combined to get 'disproval'. Similarly, combining 'admiration' and 'terror' and getting 'submission'. Plutchik's 'Wheel of Emotion' (Figure 8) will be used for this testing to see if these colours make participants feel these emotions (Plutchik, 2001). Posner et al. designed a two-dimensional model in which emotions were given coordinates denoting the degree of valence (the positive or negative quality of emotion) and arousal (how responsive or energetic the subject is) (Posner et al., 2005). Similarly, shaver et al. designed a tree of emotions; however, as this is a visual

project where colour is essential, the associations Plutchik has made between emotion and colour are needed for this chapter and thesis (Shaver et al., 1987).



*Figure 8 Plutchik's 'Wheel of Emotion' (Plutchik, 2001)*

### 2.2.8.2 User Experience (UX) Design

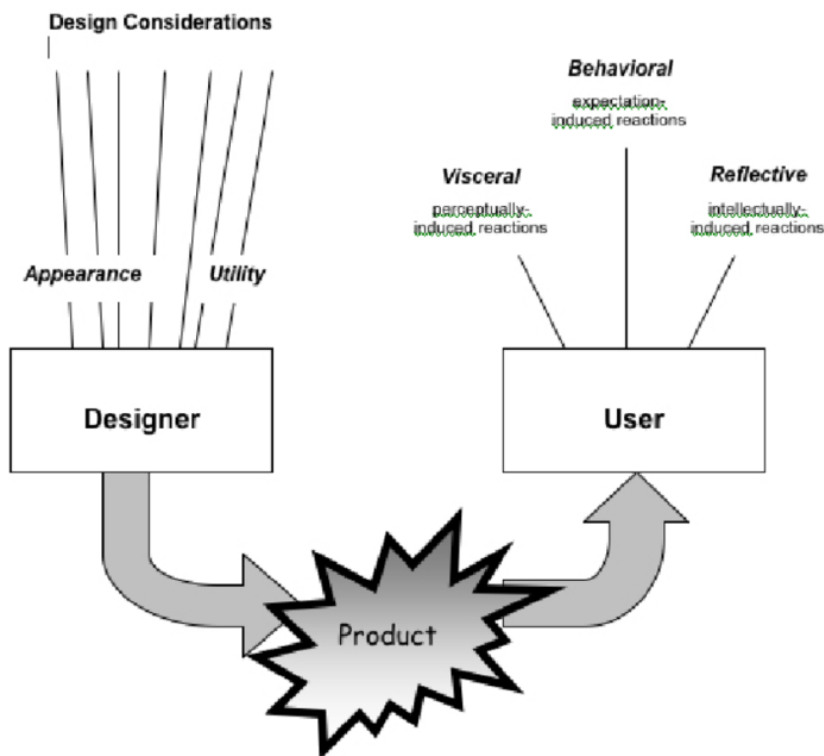
UX Design rose to popularity through Don Norman's self-selected title of "User Experience Architect" at Apple Computer, Inc. in 1993. Since then, UX Design has continued to grow, with the main emphasis still on HCI (Knemeyer & Svoboda, 2018). Hassenzahl often compares UX Design to well-being. He compares the notion of waking in the morning to welcoming light, chirping birds, being well-rested, with the ability to get up and have a coffee, to being awoken abruptly by an alarm clock, in a dark room, with no birds. Stating an alarm clock like "Philips' Wake-Up Light" can improve a person's sleep (See Figure 9). Although the product form is "unremarkable", it improves a person's well-being through its function (Hassenzahl, 2018).



*Figure 9 Philips' Wake-Up Light (Philips, 2022)*

UX itself is a relatively new and broad idea that has varied definitions. In this instance, the term can be defined by a "user's perceptions and responses that result from the use and/or anticipated use of a system, product or service", as stated under ISO 9241-210:2019 (ISO, 2019). Particularly for Product Design, the interactive experience a user would have with a product can be affected by the amount of interaction perceived by the aesthetics and usability of an interface (Borsci et al., 2015). Hence, a UX evaluation test should include both subjective and objective measures. Traditional methods of assessing psychological and practical traits of UX have generally been self-reporting methods, which are generally interviews, questionnaires and contextual inquiry, representing the subjective perception of product use (Ganglbauer et al., 2009). Traditional methods ask users to evaluate their experience with a product through its usability and features (Mele & Federici, 2012). These traditional self-reporting methods are generally used before and after a user's interaction with a product in accordance with the parameters intended to be evaluated.

Norman (2003) himself states the three outcomes of user design that a designer should consider when making a product. Figure 10 shows the thought processes most designers would consider based upon Norman's UX considerations. Firstly, visceral design refers to the perceptible qualities of a product and how they consequently make the user feel. Secondly, Behavioural Design is the pleasure and effectiveness of use. Lastly, thoughtful design considers the rationalisation and intellectualisation of a product where one questions one's identity. This is achieved through how they may view themselves and others, referred to as conspicuous consumption (Taylor & Strutton, 2016). Visceral design is based on affective reactions compared to Behavioural Design and thoughtful design, which are based on cognitive thoughts (Norman, 2003).



*Figure 10 The Designer's View of The Product Differs from the User's View (Norman & Ortony, 2006)*

#### 2.2.8.2.1 Visceral Design

The visceral design focuses on the appearance of a cultural object, intending to make a new product through form, textures, and patterns. It is an integral part of design where appearance matters, as

first impressions are formed (Lin, 2007). Visceral refers to the “gut instinct” and its subconscious levels or reaction. It is triggered by the first sensory scan of the product; it happens immediately and is often uncontrollable (The Interaction Design Foundation, 2015). When testing the designed product with users, the visceral and sensory properties it possesses in terms of touch, sound, sight, smell, and movement are essential for feedback (Gaudion et al., 2009). Therefore, visceral design is imperative for wellbeing as the human senses affect a human’s emotions whilst co-constructing the humans’ perceptions of wellbeing (Humberstone, 2015). Visceral design, therefore, could be a vital consideration when designing and testing in the latter stages of the thesis.

#### 2.2.8.2.2 Behavioural Design

Behavioural Design aims to affect a person's psychological response to a product through cognition and affect (Bloch, 1995). This influences a person's behaviour towards the product (O'Shaughnessy, 1992). When designing for Behavioural Design, the product's use, function, performance, and usability need to be considered. For the product to be considered beneficial, the Behavioural Design of the product is critical (Lin, 2007). To achieve a good level of Behavioural Design, the designer must consider visceral design beforehand (Interaction Design Foundation, 2015). Research provides strong validation that using visceral and Behavioural Design to improve personable interactions with a product is possible as the experience with the product can be meaningful.

#### 2.2.8.2.3 Reflective Design

Reflective design features of a product are the most vulnerable to variability. Due to differences in cultures, experience, and education, individual differences and preferences can be investigated (Lin, 2007). Norman (2003) states that reflective design is the highest level of processing, where people often self-assess their actions and understanding. The two main aspects considered for reflective design are the utilitarian aspect and appearance (Norman, 2003). As stated under visceral design, the senses and wellbeing are the crucial factors that link the three types of design together. Each

section could be considered multisensory as the three types of design (visceral, behavioural and reflective) can be linked to sleep; as research has found the neurobiological, cognitive, and behavioural aspects of sleep that affect emotions.

### 2.2.8.3 Design Processes for Product Ideation and Evaluation

The analysis and review of relevant process models will be gathered; therefore, a research methodology plan can develop. This section defines how design methods achieve the best solutions based on design processes. The design processes reviewed focus on Behavioural Design, UX Design, Information Design, and Software Development.

#### 2.2.8.3.1 Utilising Design to Solve Complex Problems

The design of this biofeedback wearable should be ideated at a postgraduate research level. Gray and Malins (2004) investigate how art and design postgraduate researchers can successfully achieve what they want through implementing design steps throughout the research. They outline the importance of using 'how, what and why' throughout the research to meet the research question. Mixed methods can be used to construct a research design to fit individual research problems. Several dimensions have been previously discussed as to why mixed methodology can benefit a research project (Schoonenboom & Johnson, 2017). Therefore, mixed methods could improve research design output if successful combinations can be developed.

Nickpour (2012) thoroughly examines multiple methodologies, stating important and frequently adopted research methods for design, well-being and behaviour literature are summed below. One primary way to distinguish the difference in research through definition is if the research is qualitative or quantitative (Cresswell, 2009). Although the design is at the forefront of this research, a generic methodology may suit how the research question should be challenged.



### 2.2.8.3.2 Behavioural Design Processes

Understanding the user is becoming increasingly crucial for human-centred design (Hepworth, 2007). Szasz (2016) has researched the paradigm shifts over the past decades, indicating that society and technology influence design through all phases of the innovation process. In addition, Hepworth (2007) states that the paradigm shifts in information behaviour have highlighted the difference between a rising ‘human-centred’ approach and ‘system-centred’ approaches to design and development. Figure 11 shows the four stages of the Behavioural Design Process. Previous research has utilised and endorsed this model for health design (Buttenheim et al., 2019). As Behavioural Design is essential in designing a wearable for menopausal women, the steps outlined by the ‘Behavioural Design Process’ must be considered when designing the methodology for this thesis.



*Figure 11 Stages of the Behavioural Design Process (Datta & Mullainathan, 2014)*

### 2.2.8.3.3 Design Thinking Processes

Information Design is an alternative design method that can improve the research outcome. Prototyping is necessary as user engagement increases, bringing back a higher quality of results (Dam & Siang, 2020). The ‘design information development model’ shows that design space and information are critical to a successful design. A hypothesis can be formed that Shooter et al. (2000)’s model (Figure 12) was sampled by Sanders & Stappers (2008) as their ‘Fuzzy front end of the design process Model’ (Figure 13) also illustrates the design process through the same funnelling process. Successful cooperation studies have been completed using the design information development model (Chen et al., 2015; Nickpour, 2019).

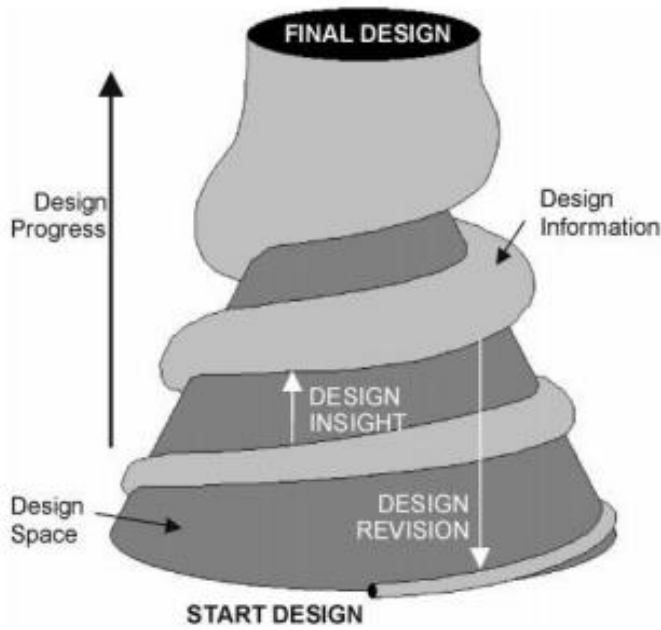


Figure 12 Design Information Development Model (Shooter et al., 2000)

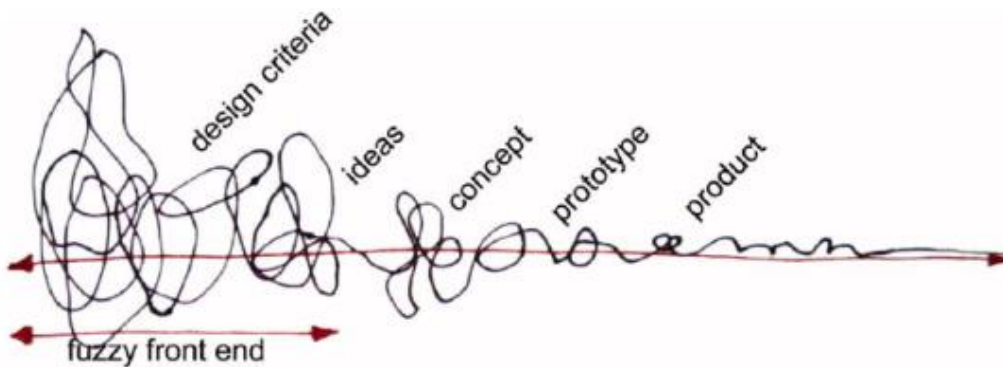


Figure 13 Fuzzy Front End of the Design Process (Sanders & Stappers, 2008)

Furthermore, defined steps are shared across multiple models. Pontis and Babwahsingh (2016) categorised the main steps in the design process by assessing what Information Designers think should be included when designing a product. By analysing students and experienced Information Designers, they concluded that conceptual design has five steps, while prototype design has three steps. Figure 14 illustrates the importance of the conceptual design stages, whereas usual Product Design process models tend only to consider the later design stages in greater detail. This process has started to be successfully implemented within research as findings for exploring the relationship between intercultural communication, visual rhetoric, and Information Design have been achieved (Saurer & Campeau, 2017).

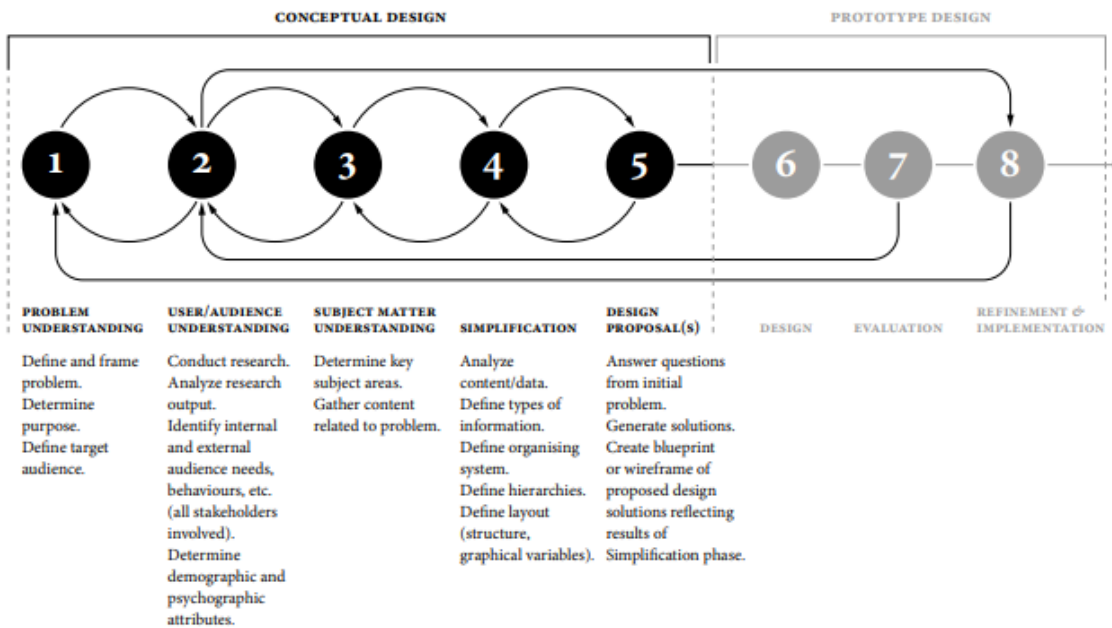
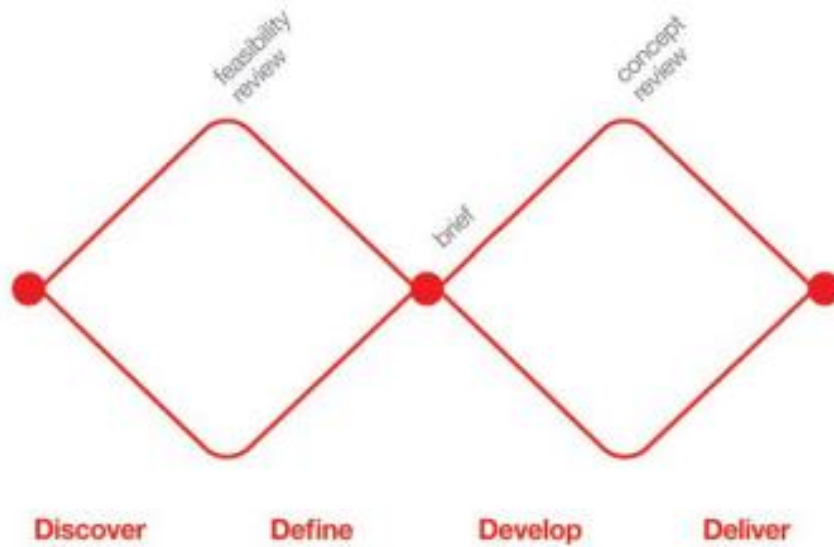


Figure 14 Design Process Overview (Pontis & Babwahsingh, 2016)

In addition, divergent-convergent models are similar in steps followed and produce similar outcomes. The Design Council (2005)'s Double Diamond design process model was defined by a study by eleven leaders in product and service design, offering validity for industry-level design. As the process is generally developed by industry, it nears real-practice design and can describe those scenarios to a better degree. Generally, the Double Diamond design process model, shown in figure 15, has commonly been implemented as a non-academic tool for research. Even though the model has widely been used for industrial, product and service design at an industry level, many academic researchers have adopted the model for their work (Annable and Burns, 2009; McGinley and Dong, 2009). Therefore, design information models can offer research validity to a thesis whilst knowing that a product that meets industry standards could be designed.



*Figure 15 Double Diamond Model of Design Process (Design Council, 2005)*

#### 2.2.8.3.4 Software Development Processes

As the research centres on making a wearable to help women address menopausal symptoms understanding development models related to IT and how they correspond to health design is essential. Knowledge of the context surrounding approaches to the development of software in health design and how it relates to the users can improve the understanding of the overall process. Commonly design information and Behavioural Design processes are iterative, where the designer can recycle through steps until the correct outcome is achieved. When assessing Software Development models' iterations are not as common amongst models.

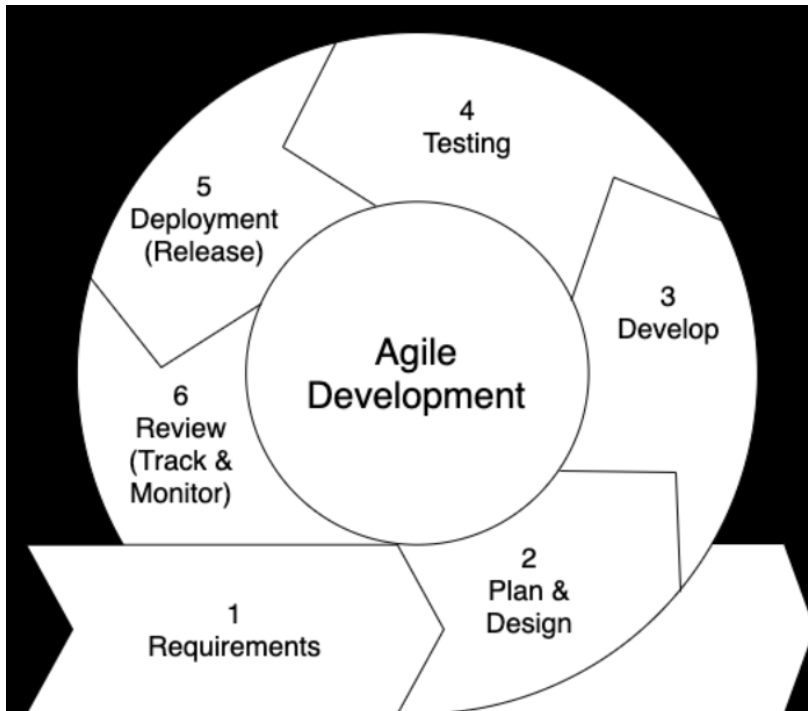
The waterfall model, named due to its shape and design, is one of the most popular models amongst software designers. Benington (1983) ideated the waterfall model, which flows, following a step-by-step plan of development stages. Rigorously detailed, each step must be completed before moving on to the next stage (Munassar & Govardhan, 2010; Ruparelia, 2010). This iterative model is an adaptation of the waterfall model, making it iterative and, therefore, more flexible. A concept can be developed at the end of every iteration, linking it to design as an iterative approach. Feedback can be made in each iteration and implemented in future iterations (Munassar &

Govardhan, 2010; Alshamrani et al., 2015). This model has been used for the design and development of medical devices, and augmented reality (Kinsel, 2012; Buchori et al., 2017).

The spiral model is also iterative, where several prototypes are made throughout the process and tested to prove validity. Research has found this model to be flawed for developers to know exactly when to move on to a subsequent stage of development. Risk management is needed to obtain time management for the events in the spiral (Ruparelia, 2010; Munassar & Govardhan, 2010; Alshamrani et al., 2015). The 2-sided model is symmetrical, with the design and standards verified by the SMART Principle. It avoids the term 'user friendly' as it cannot be verified (Ruparelia, 2010). The spiral model has been used by researchers to design and develop wearable devices within the healthcare industry for many years (Lim, 2015; Brander & von Schewen Sterndal, 2014).

Furthermore, Agile is an iterative model whereby the project manager can see a concept after every cycle and correspond with the user to see if the concept applies to their needs. Agile is a method that requires co-creation in the sense that users are informed at each step of the development

process throughout the project. Starting information is seen as necessary as details may not be known from the start of the project that develops throughout (Leau et al., 2012).



*Figure 16 Agile Development Process (Trivedi, 2021)*

Agile has also been used for the design and development of medical wearable devices (Glazkova et al., 2019; Spreiter et al., 2018). In addition, Agile models have recently been used for combining its methods with Design Thinking methods to create new mix methodologies (Yalcinkaya & Singh, 2019). The Scrum method is one particular method that has been used in combination with Design Thinking models for successful outcomes (Higuchi & Nakano, 2017). Another successful implementation of Design Thinking and Agile methods is the use of the Kanban method (Senapathi & Drury-Grogan, 2020). Figure 16 represents a usual single sprint within the Agile method, more commonly associated with Scrum. Recent research has also highlighted the use of multiple sprints within a sprint to gain more extensive feedback at each stage of a process (Žužek et al., 2020). Therefore, the use of sprints used within Agile methods are known to improve outcomes of projects, with Design Thinking now being used within mixed methods to increase the quality of design outputs and user feedback.

#### 2.2.8.3.5 The Importance of Co-Creation Amongst New Product Development

As stated through design for wellbeing and all relevant design processes, co-creation is a common factor. The use of co-creation shifts the usual rational approach to finding a solution to a problem to a more spontaneous and playful approach which can lead to better solutions (Ind & Coates, 2012). In addition, co-creation as an innovative approach can be easily linked to Design Thinking methods as the steps can be combined (De Koning et al., 2016). As a design researcher, designing for the end user is imperative; the chance to co-create with menopausal women to create a product for them is idealistic.

#### 2.2.8.3.6 Design for Healthcare's Use of Co-Creation

Healthcare is a varied sector where proposing a new concept to a problem requires change management where specific approaches are needed to target a problem (Carroll & Richardson, 2017). The implementation of social sciences for health design is becoming widely accepted. The co-creation between the technology and the people following a structured methodology is found within Software Development (van Gemert-Pijnen et al., 2011). In addition, co-creation, and input from variable participants in the design of a new concept are essential to hit the necessary targets (Van Gemert-Pijnen et al., 2011). A lack of understanding between the designers and the users can be problematic when meeting obligations set at the start (LeRouge et al., 2013). Design Thinking models such as user-centred and human-centred design are approaches that should be considered within software design for healthcare (Altman et al., 2018). Incorporating Design Thinking methods into healthcare is vital to have improved concepts through human-centred approaches (Liebenberg, 2020). The use of Information Design processes that encompass all aspects of UX Design could therefore be easily implemented with Agile research methods to validate the design of a biofeedback wearable whilst also offering validity for the Software Development aspect of the thesis.

## Chapter 3 - Research Methodology



### 3.1 Introduction

This methodology section outlines the process that can be successfully implemented in this thesis to gain improved well-being for menopausal women through a biofeedback wearable. A combination of methods was used to provide a robust framework for the research elements of this project. If steps are successfully laid out through a framework, the disparities in knowledge can be addressed to provide answers to the research questions and aims.

As the research question is evaluating the use of wearables to improve the well-being of menopausal women, a research framework that suits the design of a new innovative product with integrated software and hardware is fundamental as the software is the basis of most wearables. When assessing wearable theses, they commonly use Software Development models as the central methodology structure. The medical wearable design has found the importance of using Software Development models (Glazkova et al., 2019). In addition, mobile health applications have found Software Development models applicable (Banos et al., 2014). As Software Development is of vital importance to the factors within this thesis, it needs consideration regarding the framework of this thesis.

This chapter will therefore use the assessed current Software Development methods in section 2.2.8.3.4. Software Development models that could work coherently with design processes, as discussed in sections 2.2.8.3.2 and 2.2.8.3.3 will be used to combine and develop a new methodology.

### 3.2 Combining Design Thinking Models with Software Development Models

#### 3.2.1 Similarities Between Design Thinking and Agile Methodologies

Design Thinking and Agile methodologies are both iterative approaches, that have gained significant recognition in the field of Product Design. Design Thinking focuses on empathising with

users, defining problems, ideating solutions, prototyping, and testing. On the other hand, Agile methodologies emphasise adaptability, collaboration, and rapid iterations. This section explores the integration of Design Thinking models and Agile models, highlighting their shared principles and how they can be effectively combined to optimise the Product Design process.

Design Thinking is a human-centred approach to problem-solving and innovation. It involves a series of iterative stages, typically consisting of the following or similar stages: Empathise, Define, Ideate, Prototype, and Test. Design Thinking encourages multidisciplinary collaboration, deep empathy for end-users, and a focus on understanding their needs, desires, and pain points. It promotes creativity, iteration, and continuous learning throughout the design process.

Agile methodologies, such as Scrum and Kanban, have gained popularity due to their ability to deliver value quickly and respond effectively to change. Agile methodologies are based on iterative cycles known as sprints, where cross-functional teams collaborate to deliver incremental product changes. Agile methodologies promote flexibility, continuous feedback, and a customer-centric approach.

Design Thinking and Agile methodologies share several core principles, making them highly compatible for integration in Product Design:

- **Iterative Nature:** Both Design Thinking and Agile methodologies embrace iterative cycles, emphasising the importance of learning, adapting, and refining throughout the process. This iterative approach allows for continuous improvement and for product design and development.
- **Customer-Centricity:** Design Thinking places a strong emphasis on understanding user needs and desires, while Agile methodologies prioritise delivering value to the customer. The integration of both approaches ensures that customer perspectives and feedback are incorporated throughout the Product Design journey.

- **Collaboration and Cross-Functional Teams:** Design Thinking encourages multidisciplinary collaboration, bringing together individuals with diverse expertise. Agile methodologies also emphasise cross-functional teams working collaboratively to achieve project goals. The integration of both approaches promotes effective teamwork and knowledge sharing.

### 3.2.2 Integrating Design Thinking and Agile Methodologies

There are several ways in which both Design Thinking methodologies and Agile methodologies can be combined to create a new mixed methodology:

1. **Agile-Driven Design Thinking:** In this approach, Agile methodologies serve as the overarching framework, with Design Thinking principles embedded within each Agile sprint. Teams can start each sprint by empathising with users, defining problems, ideating solutions, and prototyping, followed by testing and iteration. This integration ensures that user insights and needs are continuously incorporated into the Agile development process.
2. **Design Thinking-Infused Agile:** In this approach, Design Thinking stages have agile methods incorporated within them. Certain stages of the Design Thinking process have sprints within them to empathise with users, define and prioritise requirements, and ideate solutions. Agile iterations then focus on prototyping, testing, and implementing the design solutions. This integration allows for a more user-centred approach throughout the Agile development cycles.
3. **Parallel Execution:** Another approach is to run Design Thinking and Agile methodologies in parallel, with Design Thinking feeding into the initial stages of Agile development. Design Thinking activities can inform the product backlog, user stories, and sprint planning, ensuring a strong user-centric foundation for Agile iterations. This approach emphasises a seamless flow of information and feedback between the two methodologies.

There are also key factors in this thesis which need to be considered for the integration of both Design Thinking and Agile methodologies:

1. **Team Collaboration:** Integration requires effective collaboration and communication between the designer and their co-creators. Both parties must align their goals, objectives, and understanding of user needs to ensure a seamless integration process.
2. **Iterative Learning:** Integration should foster a culture of continuous learning and iteration. Teams are encouraged to reflect on user feedback, experiment with new ideas, and refine their approach based on the insights gained throughout the process.
3. **Flexibility and Adaptability:** Both Design Thinking and Agile methodologies thrive in environments that embrace change and adaptability. The designer must be open to adjusting their processes, frameworks, and mindsets to accommodate the integrated approach effectively.
4. **Tools and Techniques:** Consider utilising appropriate tools and techniques that support both Design Thinking and Agile methodologies. These can include user research methods, prototyping tools, Agile project management software, and collaborative platforms.

In conclusion, the integration of Design Thinking models and Agile models presents a powerful framework for Product Design, combining the user-centred focus of Design Thinking with the adaptability and iterative nature of Agile methodologies. By integrating these approaches, designers can foster collaboration, deliver customer-centric products, and drive innovation throughout the design process. Successful integration requires effective communication, cross-functional collaboration, and a shared commitment to iterative learning and improvement.

### 3.3 Introducing ID-Agile: An Integrated Approach to Product Design

The ID-Agile methodology combines the principles of Information Design (ID) models and Agile methodologies to create an integrated approach to Product Design. This new methodology leverages

the systematic analysis and structured approach of ID models with the adaptability and iterative nature of Agile methodologies. The goal is to create a comprehensive framework that enables efficient and user-centred Product Design while maintaining flexibility to respond to changing requirements and market conditions.

#### Key Principles:

- a. **User-Centred Design:** The ID-Agile methodology places a strong emphasis on understanding user needs, preferences, and pain points. User research and empathy-driven techniques from ID models are integrated into the iterative cycles of Agile methodologies to ensure a user-centred approach throughout the design process.
- b. **Structured Analysis and Planning:** The ID-Agile methodology incorporates the structured analysis and planning stages of ID models to establish a solid foundation for design iterations. This involves gathering and analysing requirements, defining design goals, and creating a clear roadmap for development.
- c. **Iterative Development:** Agile principles are integrated into the development phase of ID-Agile. The development process is broken down into short iterations or sprints, allowing for frequent feedback, continuous improvement, and the ability to adapt to changing requirements.
- d. **Collaborative Cross-Functional Teams:** ID-Agile encourages collaboration between involved parties. This collaboration ensures effective communication, knowledge sharing, and alignment throughout the design and development process.

#### Key Considerations:

- a. **Flexibility and Adaptability:** ID-Agile embraces change and encourages teams to adapt their designs and development strategies based on user feedback, market insights, and evolving requirements.

- b. **Effective Communication:** Ensuring seamless communication and collaboration between the designer and their co-creators is crucial for the success of ID-Agile. Regular input, feedback sessions, and clear documentation facilitate effective communication channels.
- c. **Balancing Structure and Agility:** Striking the right balance between the structured analysis and planning stages of ID models and the iterative nature of Agile methodologies is essential. Iterations should be flexible yet guided by a clear understanding of user needs and project goals.
- d. **Continuous Learning and Improvement:** Emphasise a culture of learning, reflection, and continuous improvement within involved parties. Regular retrospectives and co-creation sessions allow for the refinement of the ID-Agile methodology over time.

#### Benefits of ID-Agile:

- a. **User-Centred Solutions:** ID-Agile ensures that the end-user remains at the core of the design process, resulting in products that better meet their needs and expectations.
- b. **Increased Collaboration and Efficiency:** The collaborative nature of ID-Agile promotes effective communication, knowledge sharing, and teamwork, leading to improved efficiency and productivity.
- c. **Adaptability to Change:** By integrating Agile methodologies, ID-Agile enables teams to respond quickly to changing requirements, market dynamics, and user feedback.
- d. **Continuous Improvement:** The iterative nature of ID-Agile allows for continuous learning, testing, and refinement, leading to a higher-quality end product.

#### The ID-Agile Framework:

##### Stage 1: Literary Review

**Problem Empathy:** Develop a deep understanding of the problem by studying existing literature, market research, and user feedback.

User Profiling: Identify and profile the target users to understand their needs, preferences, and pain points.

Subject Empathy: Gain insights into the subject matter related to the problem to comprehend the domain-specific challenges and requirements.

## Stage 2: Conceptual Design

Conceptual Simplification: Create a project space and develop a timeline for the project, focussing on co-creation and visual inspiration for collaboration. Through sprints the designer analyses complex concepts and ideas through preliminary testing. Refine the simplified concepts and ideas from the testing to ensure clarity and effectiveness for future stages.

Design Requirements: Identify and define the key design requirements based on the insights gained from problem empathy, user profiling, subject empathy and conceptual simplification.

## Stage 3: Prototype Design

Existing Product Evaluation: Appraise existing products within your area based upon research findings from previous stages. Reviewing existing products form additional design requirements.

Design and Development: Generate design ideas and develop prototypes based on the defined requirements. Utilise Agile sprints such as iterative development, rapid prototyping, and user feedback loops for quick iterations.

Discussion: Review the research output based on the initial research aims and question. Form key findings through interpretation of the results found. Acknowledge both the

limitations and the contributions this research has made to this research area. And form recommendations for future research.

#### Stage 4: Future Scope

**Improvements:** Analyse the recommendations for future research found during the discussion stage and identify areas for improvement in the design and development process. Make necessary refinements to enhance the product's usability, functionality, and overall user experience.

**Application:** Explore potential future applications and extensions of the product beyond its initial scope. Consider scalability, adaptability, and market demands.

In the ID-Agile model, each step can be restarted and built upon; or the designer can continue to the next step of the process. In addition, restarting the process, current stage, or a previous stage, at the end of every stage, ensures the user has choices for continuous improvement cycles and reinforces the iterative nature of both Information Design (ID) and Agile Development methodologies. By restarting the model at the end of each stage, designers and co-creators could reflect on the outcomes, gather feedback, and apply the lessons learned to enhance subsequent stages. The designer does not have to restart at the endpoints of stages, but the option is available due to this approach's adaptability, agility, and a user-centred focus throughout the entire product design and development process. It allows for the incorporation of new insights, changing requirements, and emerging technologies, ensuring that the final product is continuously refined, optimised, and aligned with user needs. By restarting the ID-Agile model at the end of every stage, organisations foster a culture of continuous learning, innovation, and customer-centricity, ultimately leading to the creation of high-quality products that exceed user expectations. Figure 17 offers a visual guide to the model stating that the next stage of this thesis will be the Conceptual Design Stage, as the Literary Review Stage has been completed.



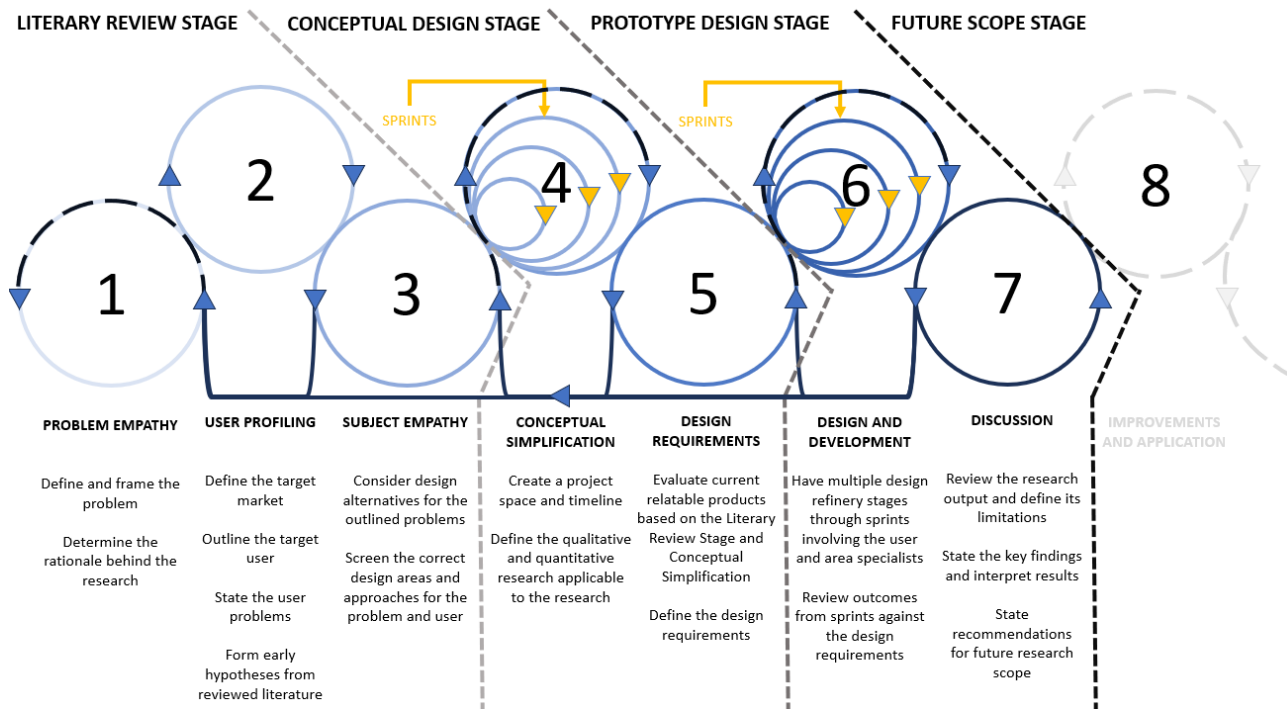


Figure 17 The ID-Agile Method (Authors Own, 2023)

## Conclusion:

The ID-Agile methodology combines the strengths of Information Design models and Agile methodologies, creating a powerful framework for efficient and user-centred Product Design. By integrating structured analysis, user research, iterative development, and cross-functional collaboration, ID-Agile enables teams to deliver high-quality products that meet user needs while adapting to changing requirements. Organisations can adopt and tailor the ID-Agile methodology to suit their specific contexts, fostering innovation, agility, and customer satisfaction throughout the Product Design process.

### 3.4 Defining the Methods Used in the ID-Agile Sprints for the Conceptual Design Stage and the Prototype Design Stage

#### 3.4.1 Conceptual Design Stage Sprints

A user-centred approach to this conceptual design phase is needed to gain the best concepts and find a solution to initial problems. From a Product Design standpoint, these requirements can be made

using the Design Council (2015)'s design method steps relating to their Double Diamond. As this thesis is still during its 'discovery' phase, the design councils' steps on research are a valuable guide for design research.

When considering the methodology, discovering identifiable problems is necessary to find a solution (Jonas, 1993). The Design Council's Double Diamond process, which offers steps in which a designer can follow when developing a new product. Incorporating the Design Council's Double Diamond approach, the following methods can be applied during the Conceptual Design Stage within the Adapted ID-Agile Development framework:

Project Space and Timeline:

- Define the project space and establish a clear timeline for the conceptual design stage.
- Allocate resources, set project goals, and identify key milestones.
- Ensure that the project space and timeline accommodate both iterative development and user-centred design practices.

Brainstorming Session:

- Conduct collaborative brainstorming sessions to generate a wide range of ideas and concepts.
- Encourage open and creative thinking amongst co-creators.
- Emphasise the inclusion of diverse perspectives to foster innovation.

Quantitative Surveys:

- Utilise quantitative surveys to gather data from a larger user base.
- Use surveys to gain insights into user preferences, behaviours, and pain points.

- Analyse survey data to identify trends and patterns that can inform the conceptual design process.

#### Focus Group:

- Organise focus group sessions to gather in-depth qualitative feedback from a targeted user group.
- Facilitate group discussions to explore user perceptions, preferences, and expectations.
- Use insights from focus groups to validate and refine design concepts.

#### Pilot Testing:

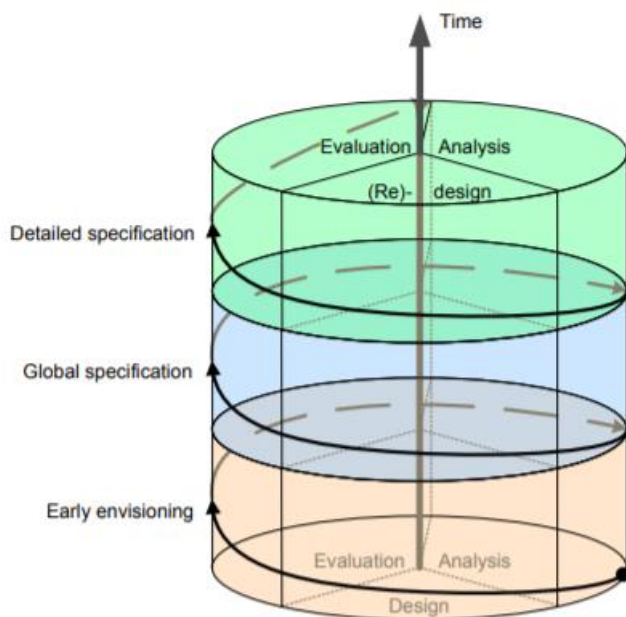
- Conduct pilot testing to evaluate the usability and effectiveness of design concepts in a real-world setting.
- Invite users to interact with prototypes or early versions of the product.
- Collect feedback and observations to identify areas for improvement and validate design decisions.

The integration of these methods from the Design Council's Double Diamond approach into the Adapted ID-Agile Development framework allows for a holistic exploration of design possibilities and iterative refinement. By combining collaborative brainstorming, quantitative surveys, focus groups, and pilot testing, designers can gather valuable insights, iterate on design concepts, and ensure the alignment of their solutions with user needs.

It is important to note that the application of these methods should be adaptable to the specific project context and goals. These methods are specifically tailored to this thesis. The iterative nature of Agile Development allows for flexibility in incorporating these methods at different stages of the conceptual design process, ensuring a user-centred approach while embracing agility and innovation.

### 3.4.2 Prototype Design Stage Sprints

As the methodology used throughout this thesis is based upon iteration that focuses on user requirements, the visualisation of the design can be defined by a three-step sprint process. Wassink et al., (2019) define the three stages as the early envisioning phase, the global specification phase and the detailed specification phase. The early envisioning phase is usually when the user is analysed and assessed in their daily lives. As user analysis has previously been assessed within the conceptual design phase, fast visualisation can occur from the information gathered and implemented in concept designs. In the latter global specification phase and detailed specification phase, final solutions are proposed and presented to the users. As Wassink et al., (2019) shows in figure 17 many iterations can be developed within each stage of the visualisation process.



*Figure 18 User Centred Visualisation Process (Wassink et al., 2019)*

Each section of this design process involves three individual phases. Firstly, the analysis looks at the user, their scenarios, and their daily lives. The further along the design and development in the process of user-centred visualisation, the changes identified from previous phases can be reimplemented into this analysis section. Next, the design of that section should allow for innovative ideation from the outcomes of the analysis. Prototyping and design work will increase in

finalisation as each stage becomes completed. These designs can then finally be evaluated by visual appeal and user interaction. Ideally, the research would have analysed body language and personality traits through this chapter. This was impossible for most testing as most were done via online meetings, where observations that can usually be seen, are not seen through a computer monitor.

The prototype design is a stage typical in both Software Development models and Design Thinking models alike. Both are user-centred, with this stage focusing on ideology and complexity to solve problems. UX Design outlines the importance of having the user at the centre of the research focusing on empathic solutions. This mixture of methodologies defined in the ID-Agile method promotes solution-based approaches to solve initial problems. Prototyping is a proven method in all methods discussed. Prototyping is based on the information gathered so far.

Multiple variables can be introduced at the prototype design stage of a project to identify relevant progress. Sketching, prototyping, and material billing are deliverables that can be inputted to identify and implement a final solution to gain and analyse a set of data and results from the final testing. At this project stage, the design and development of an outcome are considered. The evolution of the iterative process continues through prototype design. The information gathered through the thesis influences all decisions made within this section; also, decisions made throughout this section can be developed from the outcomes of individual stages. Each prototype developed, whether it be sketching, storyboarding or physical modelling is the superior knowledge gained about the final concept. Therefore, the deliverables discussed not only communicate the ideas to others but also hold the information about the product, outlining the importance of information during this process.

By incorporating the early envisioning phase, global specification phase, and detailed specification phase into prototype design sprints, the designer can effectively leverage both ID and Agile

development methodologies. This integrated approach ensures that prototypes are user-centred, functional, and aligned with project goals. Throughout the prototype design sprints, maintain a continuous feedback loop with co-creators and users, embracing agile principles of iteration, collaboration, and responsiveness to deliver impactful prototypes that meet user needs and drive successful product development.

### 3.5 Summary

This chapter has emphasised the similarities that can be found between Design Thinking models and Agile models. The research gathered throughout this section has found correlations between Agile development and Information Design methods. Due to similarities, the project can use a mixed methodology where both are backed by research-led projects within this field. This chapter has found that using Information Design with sprints found within Agile development models can improve outcomes drastically.

Combining design process methods within Agile development is not a new thought process. Research looking into the combination of Design Thinking and Agile has been assessed previously, outlining what the contribution of Design Thinking can do within engineering. If so, Agile and Design Thinking are thought to be successfully implemented (Lindberg et al., 2010; Darrin & Devereux, 2017). Many other researchers have thought of implementing Design Thinking with Agile for Software Development projects (Adikari, McDonald & Campbell, 2013). Nevertheless, when combining the methods for this project, which is deemed to be Product Design based, the use of Design Thinking with Agile is a novel process that has been developed and implemented. As this is a new theory, the implementation of Agile and Design Thinking for Product Design could be an area that could be vastly improved if the use of Agile development sprints were successful in an Information Design based model.

Chapter 4 - Adapted ID-Agile Development for Product Design: Conceptual Design Stage

## 4.1 Introduction

In the realm of product design, the conceptual design stage is a critical phase where ideas take shape, possibilities are explored, and the foundation for the final product is laid. This chapter delves into the integration of Adapted ID principles with Agile Development methodologies during the conceptual design stage, creating a harmonious synergy between these two approaches.

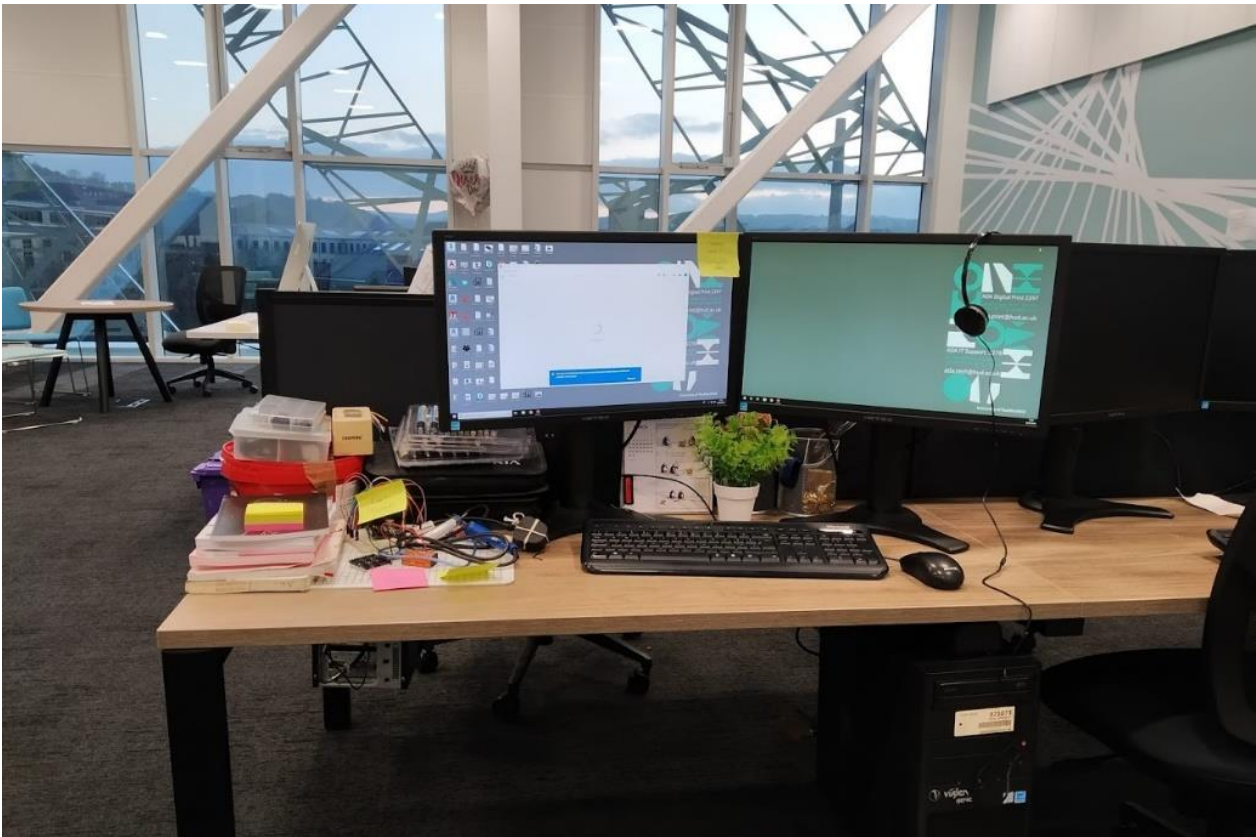
Within the conceptual design stage, the primary objective is to transform user needs and requirements into tangible concepts and design directions. This involves understanding the problem domain, empathising with users, and simplifying complex concepts to create intuitive and meaningful experiences. By employing Adapted ID-Agile Development practices during this stage, the designer can maintain a user-centred focus while embracing the agility required for iterative design and development.

This integration of co-creation empowers the designer to create innovative and meaningful product designs that truly address user needs while adapting to evolving project requirements. Through the exploration of user research, ideation, iterative development, and collaboration, this chapter will equip the designer and the co-creators with valuable insights and practical strategies to navigate the conceptual design stage successfully.

## 4.2 Project Space and Timeline

Creating a project space and having a plan are vital to the ID-Agile development model. The ID-Agile methodology is a plan and method that should be followed to get the best out of a thesis. The project space was initially set out in a university postgraduate environment. The final stages of the process were undertaken in a home study setting due to government lockdowns from the COVID-19 outbreak. The change of research space lowered the level of creativity available for research as the space provided in a home setting is not optimal for research and design. A creative space is required to organise materials, workload, and meeting availability, see figure 19.





*Figure 19 Project Space (Authors Own, 2022)*

Research states conditions for informal-mutual learning is where a researcher can be involved within co-creation, this requires the creation of boundary of spaces (Calvo & Sclater, 2021). This space cannot be intentionally designed as it evolves over time (Klooker & Hölzle, 2023).

Furthermore, recent research frameworks have shown the need for collaborative spatial design, structures, and practices to then have a phase of reflection, which can then be implemented into a collaborative-participatory design approach which involves co-creation (Klooker & Hölzle, 2023).

Further research states the need for visual stimuli to promote and evoke creativity for collaborations (Sanders, 2005). A university setting is ideal for this creative space, as a designated zone is made for the postgraduate student to set out their workload and plan accordingly.

Conversely, home study settings are different in many ways. Software used to design and develop is not readily available, with less space to organise and set a workload. A positive of home studying can be meeting people. Meeting others through online discussions and meetings can be considered

more accessible as everybody can meet remotely in the same virtual space. Even though online meetings can be viewed as simple, the connections and feedback through a computer screen cannot be judged the same as in real life. This later became a problem for testing as observations in specific testing could not be deciphered the same through a computer screen. Ample creative space helps organise a large amount of information gathered through research. The organisation required can improve the visibility of the project and help communication with others when understanding a project's concepts.

In either a university or home setting, a dedicated project zone is needed to use walls and floor space to thrive in this setting. Research can therefore be viewed spatially, meaning when working on the project or holding creative sessions, the surrounding stimuli can influence new notions and the project's development. The space is vital to develop a story about the thesis that can be shared with others, whether for user feedback or co-creation interactions. This idea of constructing a space that can offer a story through research and images can often promote the contribution of input from others to the project. As the project develops into differing stages, the space used can offer insight into the completed parts and rekindle interactions that may be lost from past parts of the research. The central part of any workspace, though, is the comfort offered. As both researcher and designer, the space required to complete all methods has to offer comfort, as most of the time is spent in this pace throughout the project cycle.

A timeline plan is also required to identify each step in the process and the time frame allowed for the project length. A detailed timeline was generated at the start of the project and modified throughout due to unforeseen circumstances. The timeline was developed from the start of the research, though the research plan had constant alterations and developments due to the uncertainty and prolonged nature of COVID-19.

## 4.3 Brainstorming Session

### 4.3.1 Introduction

Brainstorming ideation sessions are a method of research commonly used within design. It enables ideation for a fast turnaround as ideas can be generated quickly with effectiveness. At this stage of research design, problems can still be identified. This specific brainstorming session was developed to identify menopausal user problems, how they can be assessed and what solutions could work for them. Challenging problems mean many researchers rely on idea generation sessions, such as brainstorming. Brainstorming should look to offer up as many different solutions as possible and be diverse in its early stages. There are points within an idea generation session where convergent thinking takes over. Multiple techniques can be used and adapted to prolong idea generation if convergent thinking is not wanted to avoid any exhaustion to the ideation.

Ritter & Mostert (2018) state that techniques to accommodate ideation are: silence, evolution, random connections, and scamper. Silence is a technique in which ideas are allowed to flow freely, and no rules are established at the start of the session. Only goals are stated at the beginning of the session, and each participant chooses what they want to undertake within that time range. It is stated that evolution is an excellent way to start brainstorming sessions. This technique assesses evolution; therefore, a change in the state of an object from solid to liquid and then to gas could be an example. Real-world innovations and their evolutions, such as smartphones with several revisions throughout time, are used in design evolution.

Evolution is an idea generation method that focuses on the participants' feelings about an idea's present state and how they believe the concept can be transformed into the next generation's idea. In addition to silence and evolution, a suggested method is random connections. This strategy attempts to link unconnected subject matters by establishing links between them. Connections between the initial issue and an unrelated object can occasionally provide a creative if unexpected, idea. Even

though this strategy is unconventional, it does generate ideas that would not otherwise be considered.

Finally, the scamper approach assumes that emerging ideas are generated when participants are asked to consider prospective adjustments. Scamper stands for: substitute, combine, adapt, modify, purpose, eliminate and reverse. Though scamper is an excellent method for achieving design outcomes, a product review has already been undertaken. A scamper review would be re-assessing the same products that have already been thoroughly assessed using the Pugh matrix. Therefore, the scamper method will not be used within this research as it is seen as unnecessary. However, the evaluation of existing technology will be considered in the latter design phase instead.

#### 4.3.2 Method

##### 4.3.2.1 Participants

In this experiment, a total of 11 (9 females, 2 males) UK residents aged 24-54 years of age ( $M=44.27$ ,  $SD=11.77$ ) participated in the consented study. Typically for these grouped sessions, a group size would be 5-8 people, although the ideal group size can be anything up to 12 (Krueger & Casey, 2015). Therefore, 11 participants are small enough to offer insight and large enough to have diversity. This study followed ethical requirements stated and approved by the University of Huddersfield. Participants were recruited via online methods to partake in voluntary research. The participants consisted of the facilitator (and designer), a Product Designer, a psychology graduate, and 8 women who were experiencing menopause at the time of the research. Participants took part in the brainstorming session for free and were all willing to offer opinions and insight. The data was conducted and collected on 8th July 2019, in a creative space at Lancaster University.

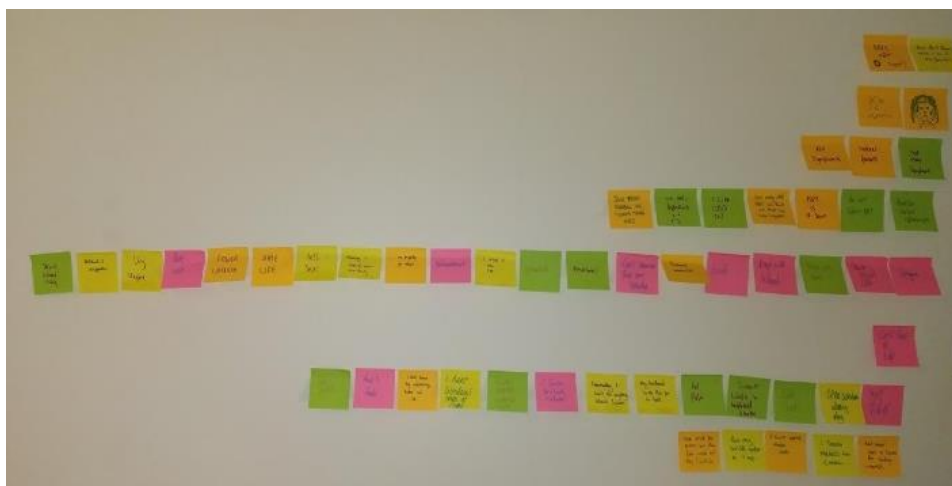
#### 4.3.2.2 Procedure

As described during the introduction, the four methods of silence, evolution, random connections and scamper are used to widen the research outcome. Silence is the initial method to be used throughout this session. All participants are made to work alone and ideate concepts on (1) User-Centred Problems and (2) how wearables can improve a menopausal women's life. After the group shares an idea created during the silence phase, evolution is used to change a concept iteratively. The next phase is random connections, whereby random objects are chosen to collaborate with the original concept of a wearable.

Moreover, the final stage of scamper is used to finalise a thought-provoking concept. Participants were welcomed into the space where the study was taking place. Once all participants were in the space together, the facilitator introduced themselves to the group. The facilitator then proceeded to outline the tasks the session would entail and the time scale for each part of the session. The time scale for each phase was 30 minutes, including feedback and categorisation when required, for a total of a maximum 2-hour period.



The method of categorising was through finding similarities in the words or drawings. Eight categories were found within the research (Figure 21). Discussions were made as to whether some categories could be made smaller and more precise, but the group decided the eight categories found were correct as a collective. The first group derived from two suggestions claiming menopausal women are unaware of the stage at which they currently are in their menopausal journey. This relates to the next suggestion in the first category states that no help is offered from supporting bodies such as the NHS. To some degree, this is understandable as the NHS can only offer a certain amount of help, although the fact that women are not sure of the stages in which they may be is concerning. Women should know a rough estimate of where they are in the menopausal cycle; this could be due to a lack of technology, technical information, or unwillingness to help menopausal women.



*Figure 21 Categories Found (Authors Own, 2022)*

The second group was found to have two drawings inside it. One drawing showed a simple face that had crosses for eyes, typically denoting death. Through discussion, this was thought to be tired, and the participant had reached a stage of menopause where they could no longer take the symptoms they were receiving. The other drawing portrayed a woman profusely sweating. This was a general feeling that women do not just feel sweating or hot; they also show it leading to stigma and embarrassment. Conversely, the following category found three commonalities around women having no or few symptoms and the fact that women must go through menopause as a natural

process. When this was brought up in the debate, most women agreed that menopause is a natural process, but they also brought up the fact that just because they go through the process does not mean they should be helped through it.

The fourth set of suggestions categorised regarded previous and current treatment methods to aid and relieve symptoms. Most stated they had used HRT, with one suggesting they could not take HRT. A few participants had stated herbal alternatives as a method they had tried, along with CBD oils. One participant wrote down anti-depressants; at this point, the psychology graduate stated the commonalities within a few areas that could be well-being. The facilitator agreed but stated that the commonality of well-being could be evident due to menopause controlling a life for roughly ten years. The menopausal women fully agreed, stating that well-being is common throughout the menopausal period.

In addition to the current categories, a fifth category was found where social effects of menopause were assessed. This fifth category had just under '1/2' of the whole number of suggestions. Therefore, social effects on menopausal women considerably affect menopausal women. The suggestions from the silence session were as follows: Stigma and embarrassment, effects on sex life and relationships, a hateful life, and emotions. Other suggestions suggested lower social lives amongst menopausal women; when discussed, women collectively linked social lives to embarrassment and stigma, surrounding mainly vasomotor symptoms. In addition, one participant brought up memory loss, whilst another suggested menopause affected their work and social life.

The following singular category of sleep was linked to vasomotor symptoms. The links were made between sleep as a category and the following category of vasomotor symptoms. Many women experienced vasomotor symptoms during the day and at night; therefore, the groups were differentiated. When the group discussed sleep, the consensus was that sleep was a problem, with insomnia tendencies found across the women. When the facilitator asked why the group felt they



could not sleep, multiple suggestions ranged from overthinking to waking. The waking mentioned was not always due to vasomotor symptoms. Nevertheless, the group concluded that vasomotor symptoms did affect sleep.

Lastly, the eighth category was categorised as how menopausal women try to cool down when suffering from vasomotor symptoms. One method was using ice packs; the participant also stated that ice packs do not last. This was generally seen as a method trialled by a few of the group, all stating flaws with icepacks. Some said the initial contact was too cold, and they would have to self-modify the icepacks to encounter the skin. This was done by wrapping the icepack with any material that still lets the cold through but not too much, stating the opposite effect compared to a hot water bottle but trapping the temperature in the same way. A participant also noted that they could touch metals to cool down; when the topic was expanded through discussion, the group noted they would seek anything cold but agreed that metals tend to be a good source. Others added that they had never looked at/for wearables to help with vasomotor symptoms or well-being. All but one of the group participants stated that they were unaware of wearables overall as they are not commonly discussed. The group then discussed the final post-it from this category, stating the expense of wearables. As the group had generally not seen wearables advertised, they were unaware of what they were. One participant brought up the expense of wearables which did not shock others in the group. The majority were willing to pay a fair price for a wearable that offered effective treatment against menopausal symptoms.

#### 4.3.3.1.2 Results

Table 1 summarises the information gathered from the silence methodology. The silence method found eight categories with similarities in the table. Firstly, the left shows ideated categories merged by the group, whereas the left illustrates the variables stated by the menopausal women contributing to each category.

Category Found	Variables Found Within the Category
No support through the menopausal journey	<ul style="list-style-type: none"> <li>• NHS offer no support</li> <li>• Uncertain of where they are in the menopausal journey</li> </ul>
Facial expressions	<ul style="list-style-type: none"> <li>• Dead/tired/worried</li> <li>• Sweating</li> </ul>
Natural process	<ul style="list-style-type: none"> <li>• No/limited symptoms</li> <li>• Natural process</li> </ul>
Hormone therapy	<ul style="list-style-type: none"> <li>• Cannot have HRT</li> <li>• HRT does not work</li> <li>• HRT is a scam</li> <li>• Do not want HRT</li> <li>• Anti-depressants</li> <li>• CBD oil</li> <li>• Not offered many other alternatives</li> </ul>
Social effects	<ul style="list-style-type: none"> <li>• Stigma and embarrassment</li> <li>• Sex life</li> <li>• Relationships</li> <li>• Hateful life</li> <li>• Emotions</li> <li>• Lower social life</li> <li>• Effects work life</li> </ul>

	<ul style="list-style-type: none"> <li>• Memory loss</li> </ul>
Sleep	<ul style="list-style-type: none"> <li>• Lower sleep quality</li> </ul>
Vasomotor symptoms with cooling methods and wearables	<ul style="list-style-type: none"> <li>• Hot flushes</li> <li>• Sweats</li> <li>• Partner dislikes cooling methods associated with vasomotor symptoms</li> <li>• Swim, so sweating looks natural</li> <li>• Open windows</li> <li>• Undress</li> <li>• Water and icepacks</li> <li>• Touch metals to cool</li> <li>• Wearables not offered/ too expensive</li> </ul>

*Table 1 Silence Results*

*4.3.3.2.1 Evolution*

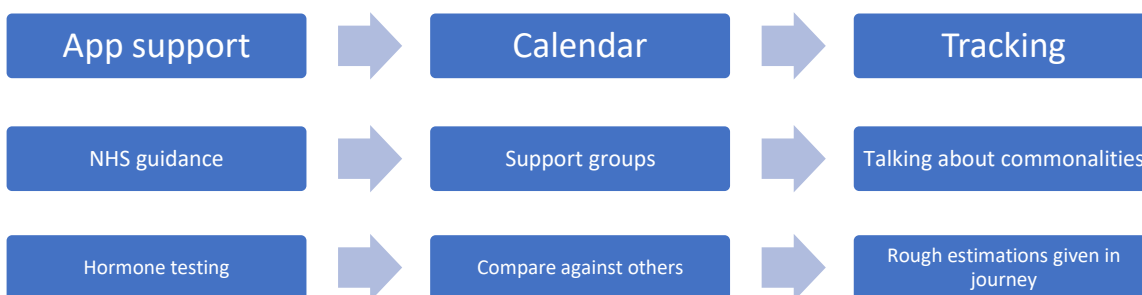
Participants were given the categories found from the first round of silence. In this method, all participants collaborated and offered suggestions on how the original problems and areas within could evolve into differing solutions to battle the original research question of “how design for wellbeing can affect vasomotor symptoms of menopausal women through the use of biofeedback technology”. Evolutions were found within each category, with the facilitator starting the discussions by revealing the categories and their variations. The group first stated what could potentially be offered to them to provide a solution to the problems found within the main categories defined through the silence method. The next step of evolution then ideated how the

solution could support the user as a specific area within the solution. The final step could be created from these suggestions, which offers a different solution to the specific area within the original solution. This method, therefore, narrows down potential errors and vague solutions, where ideas are put through a three-step concentration process. The end solution will give the researcher a specific area in which designs could potentially be created.

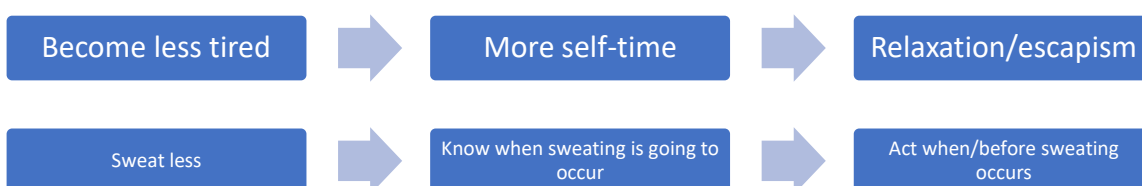
#### 4.3.3.2.2 Results

The following evolutions were found from the group discussion.

#### No support through the menopausal Journey



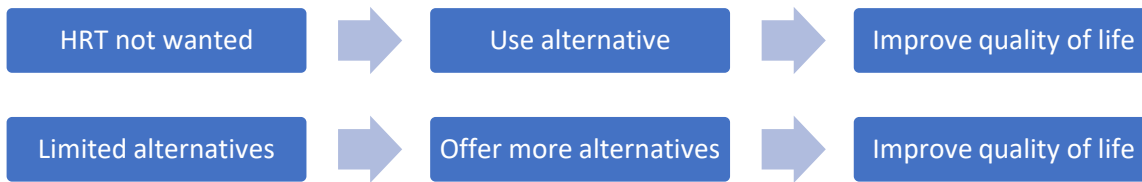
#### Facial Expressions



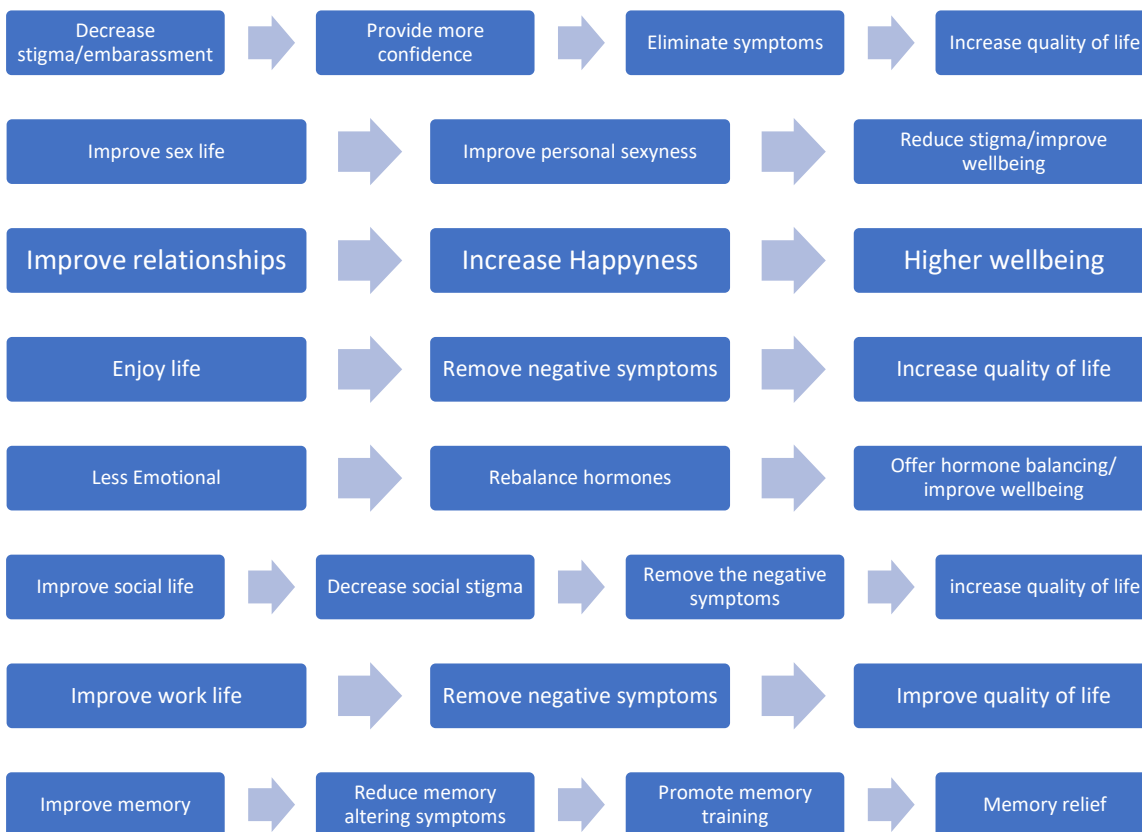
#### Natural Process



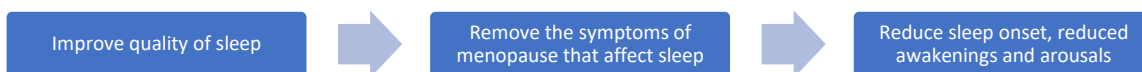
## Hormone Therapy



## Social Effects



## Sleep



## Vasomotor symptoms with cooling methods and wearables



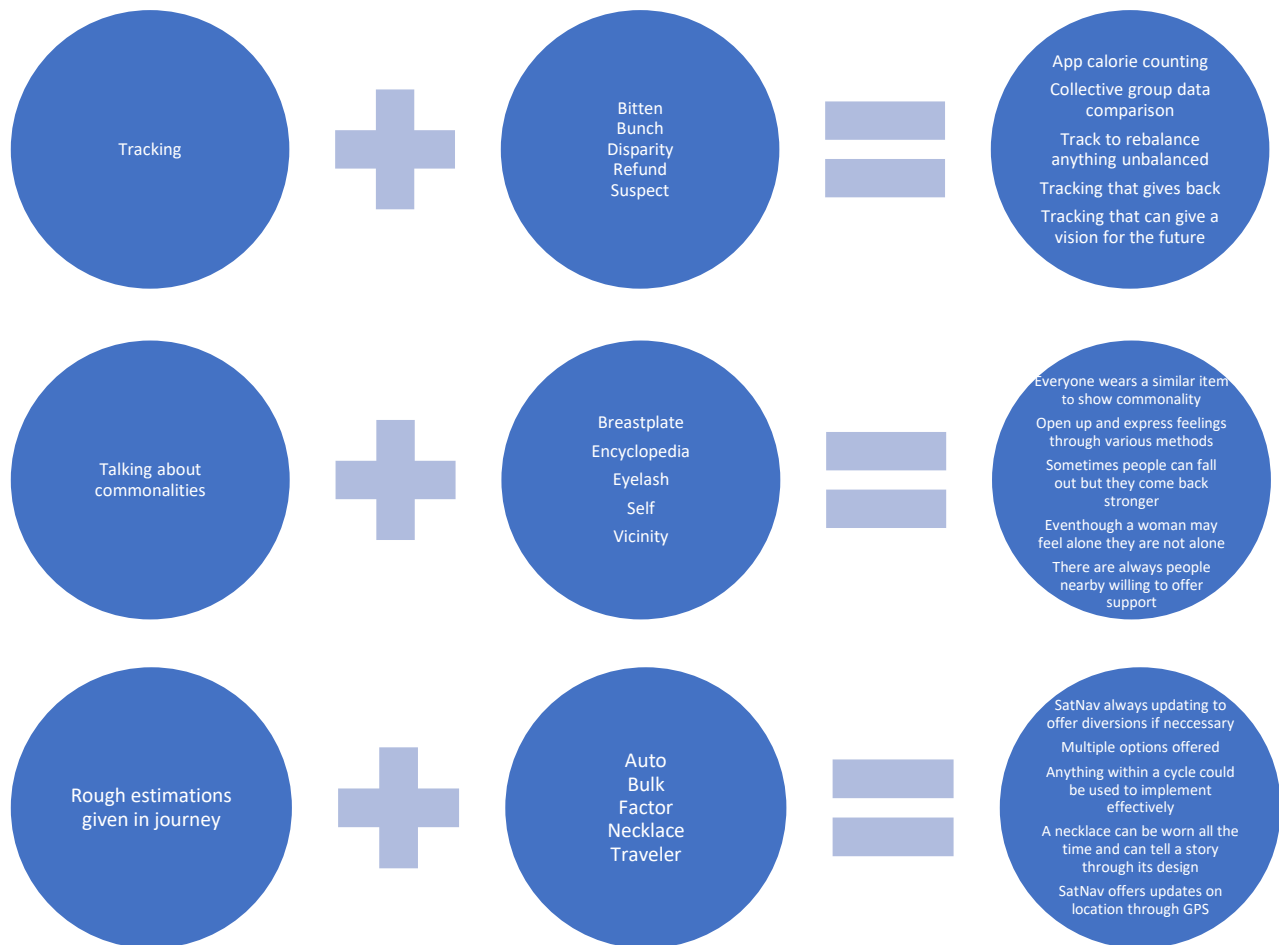
### 4.3.3.3.1 Random Connections

The outcomes found from the evolution method of brainstorming were then implemented into the random connections' session. The random connections session involved participants connecting random words with outcomes from the evaluation method. The facilitator used a random word generator, accumulating nouns that could be used to ideate new ideas. The generator would potentially accumulate five words with the outcomes listed to be included in new product development. The best suggestion for each word was taken forward to be used to ideate potentially. Usually, random words are not auto generated, but this unique process offered increased creativity as no member of the brainstorming session knew the direction of the study. The outcomes,

therefore, were unknown prior to the session, but the researcher thought creativity for this final method of random connections would be necessary for idea generation.

#### 4.3.3.3.2 Results

### No support through the menopausal Journey



### Facial Expressions





**Natural Process**



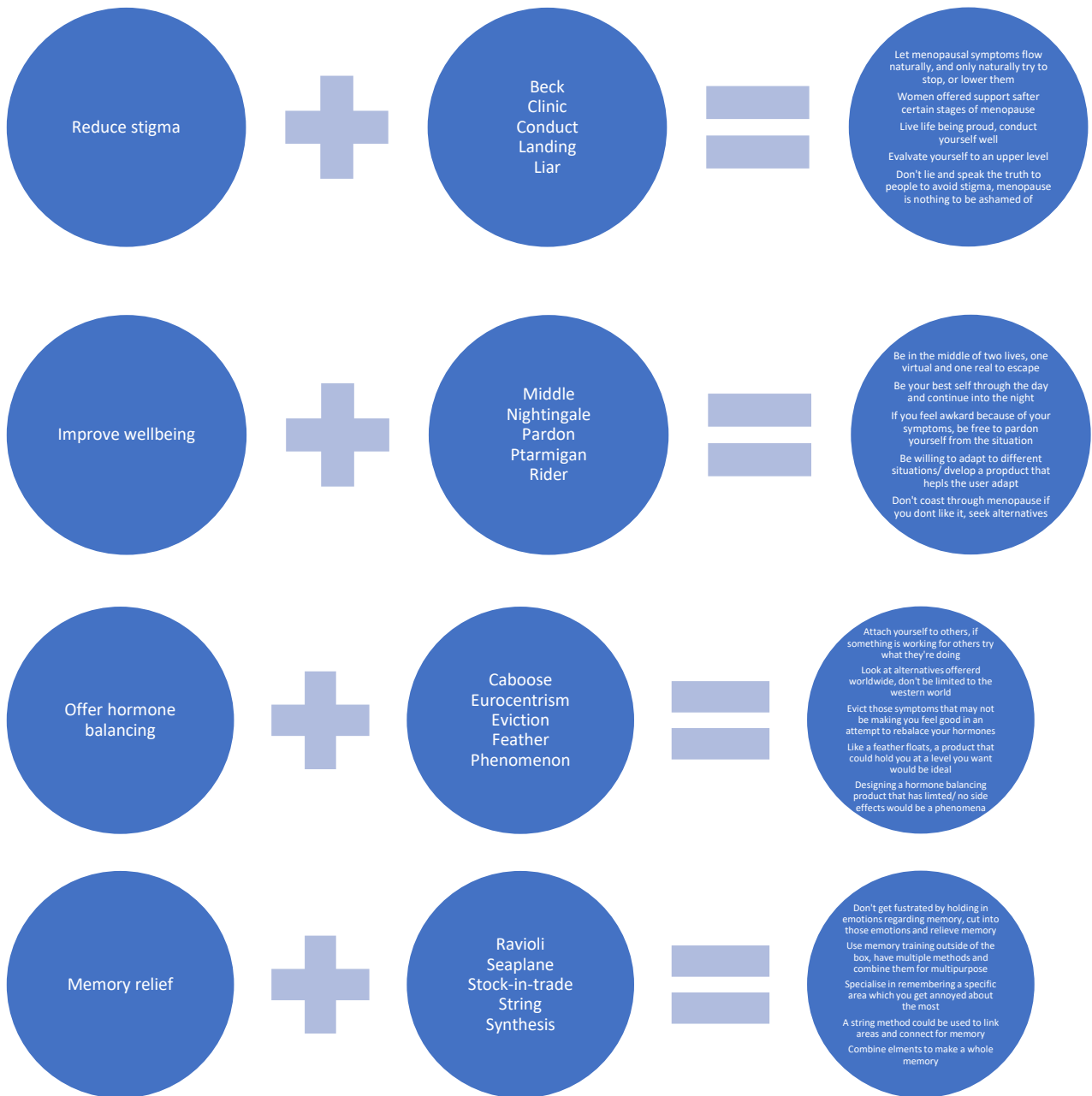
**Hormone Therapy**



**Social Effect**



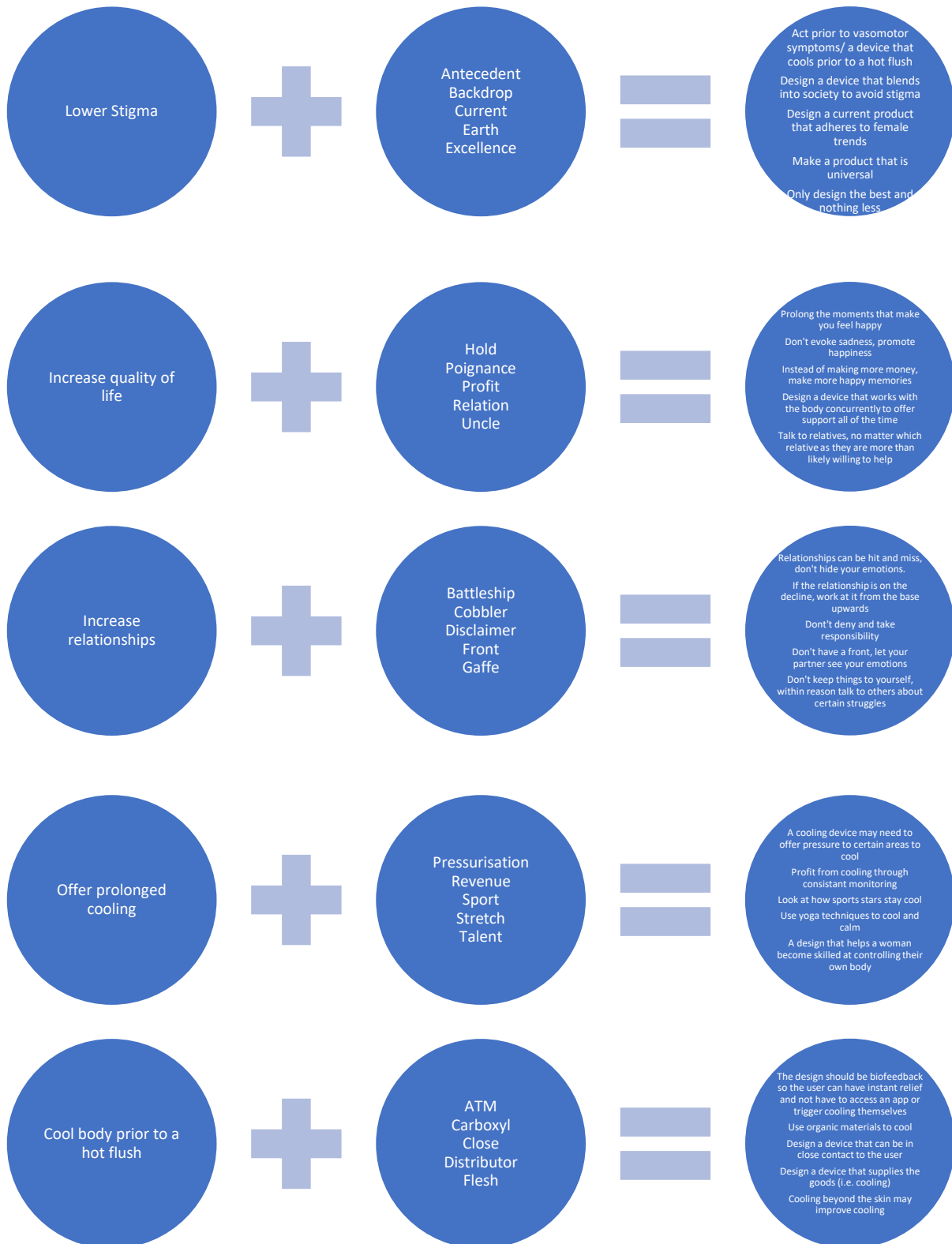


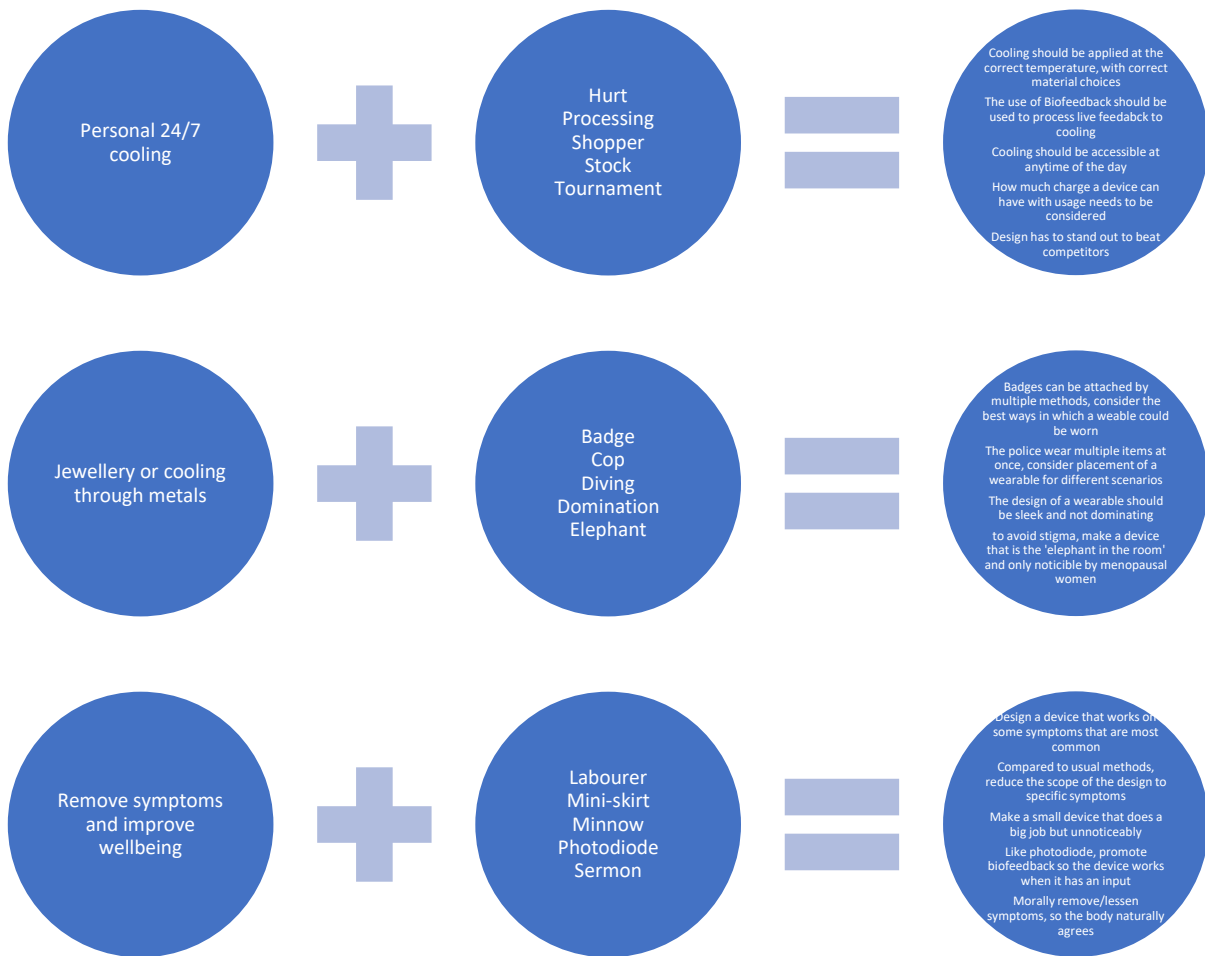


## Sleep



## Vasomotor symptoms with cooling methods and wearables





#### 4.3.4 Brainstorming Session Conclusions and Recommendations

The outcomes of this brainstorming session can be developed into design proposals and included in the subsequent design phases. Conclusions can now be found as commonalities across this final phase of random connections can be surmised. The random connections method of research was surprising to not only the researcher but the whole group as thinking “out of the box” was necessary to provide a link to random words that would previously not have been linked to keywords within this thesis.

The researcher gathered all information from the final random connections phase and made connections between the outcomes to define solutions that can be inputted into a finalised design.

Table 2 illustrates the grouped commonalities found from this brainstorming session.

Conclusions	Recommendations
<p>Vasomotor symptoms should be reduced</p>	<ul style="list-style-type: none"> <li>• Design a device that lessens hot flushes</li> <li>• Design a device that reduces night sweats</li> <li>• Use biofeedback for constant assessment of the body</li> <li>• Morally lessen symptoms, so the body naturally agrees</li> <li>• Design a modular device that can be worn in multiple places</li> <li>• Improve current methods used to lessen the effects of vasomotor symptoms</li> <li>• Design a device that cools prior to the onset of a hot flush</li> <li>• Offer localised cooling</li> </ul>
<p>Social life and quality of life should be improved through the outcomes of this research</p>	<ul style="list-style-type: none"> <li>• Offer a space for women to talk with each other</li> <li>• Offer a platform where women can grow themselves to be the best versions of themselves</li> <li>• Remove social burdens</li> <li>• Improve relationships with family members and friends</li> </ul>
<p>Wellbeing should be considered through design and improved for menopausal women</p>	<ul style="list-style-type: none"> <li>• Affect menopausal symptoms without modifying the body's physiological state</li> <li>• As 24/7 support is required, create a device with interchangeable batteries</li> <li>• As 24/7 support is required offer multiple modules</li> <li>• Increase women's knowledge of their journeys</li> </ul>

	<ul style="list-style-type: none"> <li>• Reduce some symptoms of menopause</li> </ul>
Stigma should be avoided	<ul style="list-style-type: none"> <li>• Design for multiple users</li> <li>• Design for inclusivity</li> <li>• Ideate subtle designs that can be hidden if worn</li> <li>• Design fashionable items that women would be proud to wear</li> <li>• Remove social burdens</li> </ul>
Menopausal women should be supported through their journeys	<ul style="list-style-type: none"> <li>• Create a device that tracks the user's wellbeing</li> <li>• Create a device that offers biofeedback</li> <li>• Give women the chance to monitor their journeys</li> <li>• Women could project their menopause paths by viewing their current path</li> <li>• Design an incognito device that menopausal women can feel at one</li> <li>• Create a space where women can feel together</li> <li>• Offer women access to support groups and friendships</li> <li>• Offer users various methods of controlling their bodies</li> <li>• Neck cooling could be introduced through pulse points</li> </ul>
Women need to escape from their daily lives	<ul style="list-style-type: none"> <li>• Offer women an alternate experience where they can relax within their homes</li> <li>• Immerse women in a virtual world to provide a cooling experience</li> </ul>

	<ul style="list-style-type: none"> <li>• Women require a time where they can have their personal experiences</li> <li>• Combine reality and non-reality where women can have an immersive experience within their homes</li> </ul>
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*Table 2 Brainstorming Session Conclusions and Recommendations*

#### 4.3.5 Summary of the Brainstorming Session

The brainstorming session evoked thoughts that could not have previously been conceivable via other research methods. Firstly, the validation that can be offered when a session is put through various stages of critiquing has improved the research output from this session. Notable, the introduction of the random word generator has provided unique design solution ideas that could not have been ideated via any other method. The initial ideas from the group on common problems and groups found offered a platform in which the group felt comfortable to share experiences as similarities were found within the groups. The silence stage, therefore, brought the group together, offering insight into individual experiences and opening debates surrounding these topics. The unique outputs from the silence method were then put through the 3-step evolution process. The process narrowed down the problem areas and increased the targeted solution output from the final phase of random connections.

Using a random word generator is a new concept that provided a positive research outcome for this design process. Improved ideation has been developed as the scope has been greater than previous methods. The filtering of problem-solving offered by this tiered version of brainstorming, with the three methods used, has provided a set of conclusions. The designer could then provide recommendations on how the conclusions could be taken forward to the latter design process.

#### 4.4 Quantitative surveys

This quantitative survey allowed participants to share their experiences and how their life and well-being have been affected during their transitional period. Further knowledge about menopausal women will assist in their health care and quality of life during menopause. Keeping Menopausal women healthy and engaged in life benefits them, their families, their communities, and the supporting medical system. The studies addressed what issues menopausal women are encountering daily and how design can be used to improve issues. The study addressed the primary aims and objectives outlined in chapter 1. The primary questions were:

- To understand how the well-being of women is affected by menopause.
- To understand how individual menopausal symptoms can affect women differently.

The feedback on what menopausal women experience daily will structure the foundation for designing an alternative method of dealing with menopause. Public health practitioners and services may also benefit from this new knowledge as newly designed public health programs could be trialled. This section, therefore, provides a basis of knowledge for further market assessment and feedback from a broader range of women that could not be assessed individually. 4.4.1 Recruitment

Recruitment of study participants occurred all over the UK for the questionnaire through certain media avenues, whilst the questionnaire was reciprocated between both parties using ‘Online Surveys’ (a University of Huddersfield approved surveying website). All participants were informed of the study and its use prior to answering any questions. All participants were given contact details of the researcher and the researcher’s primary supervisor. Due to the inquiry of this research on menopausal women, it was deemed socially moral to use mutual environments for participants of these studies. This homogenous sample used for assisting the recruitment of participants with knowledge and experience needed to address the objectives and research question.

#### 4.4.2 Demographic Questionnaire

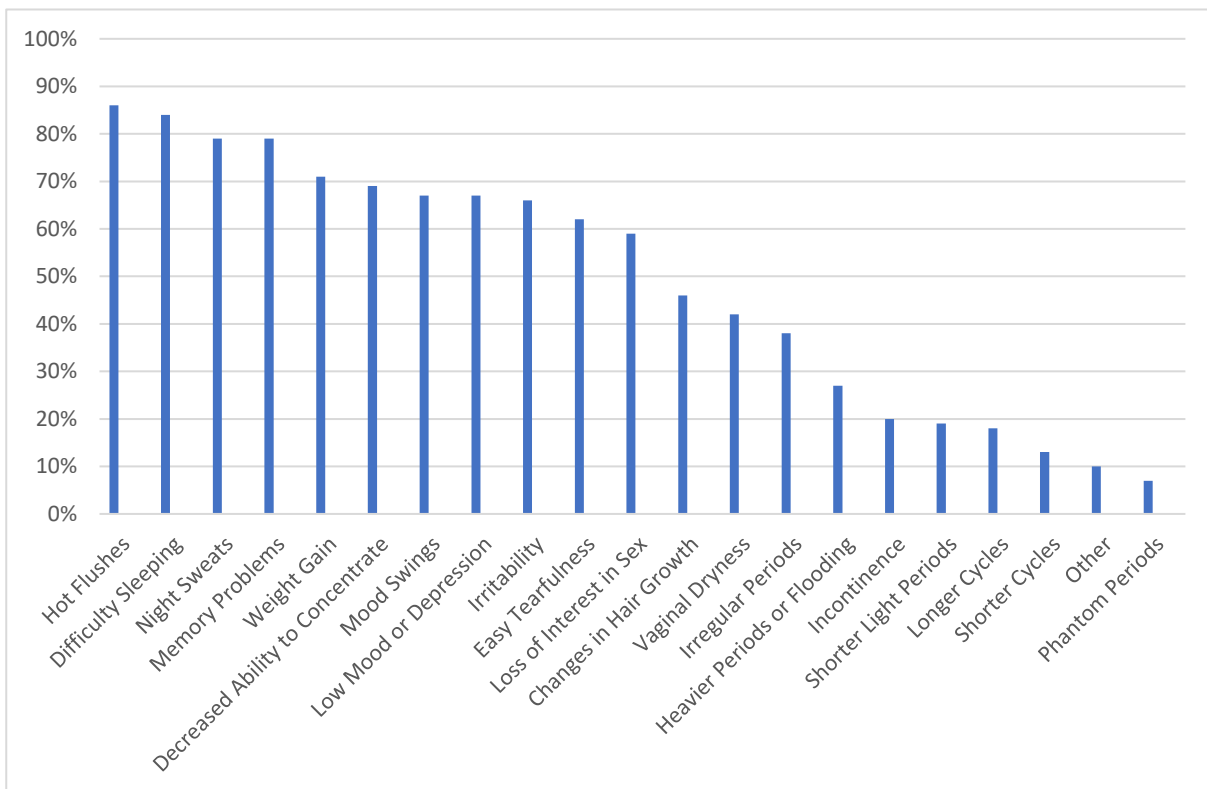
This demographic questionnaire delivered further information about the study group of women participating in this research. The survey gave women a choice to answer twenty-five questions in four different areas: daily living with menopause, sleeping with menopause, lifestyle and vasomotor symptoms. The questionnaire looked to get primary data from menopausal women, with questions based on well-being. The information gathered can describe the group of women going through menopause and be used as a sample for the whole UK. Each participant received a unique code that can be referenced for individual answers to specific questions. The answers found in the questionnaire were used in the in-depth interviews for background knowledge; however, in the in-depth interviews, participants were left to tell their own stories regarding menopause. No consent was needed for this demographic questionnaire as participants were anonymous. The demographic questionnaire is shown in Appendix.

#### 4.4.3 Results of the Questionnaire

'40%' of the group stated being at the menopause stage, '32%' being peri-menopausal, '14%' either post-menopausal or have been through menopause and '14%' unsure of their stage of menopause. '38%' of the women surveyed know what stage of menopause they are at as a doctor has informed them. A further '26%' state they know their stage of menopause due to looking at online sources. Like knowing what stage of menopause women are at, '14%' were unsure of which stage of menopause they were at. In addition, an astounding '61%' of the women surveyed thought they had gone through menopause on time. Women who answered the open-ended question by selecting others majorly stated they knew what stage of menopause they were at due to having either surgery or a medical condition that affected their onset of menopause. It was found that '14%' of the women had a medical condition that encouraged menopause, which is likely to have contributed to the high percentage of women that go through menopause early at '28%'.

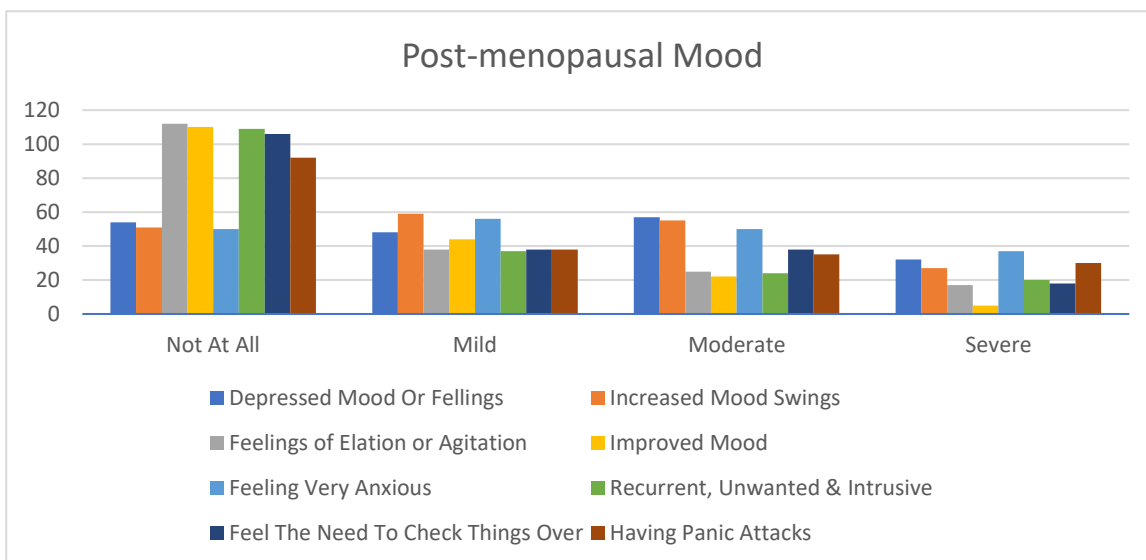
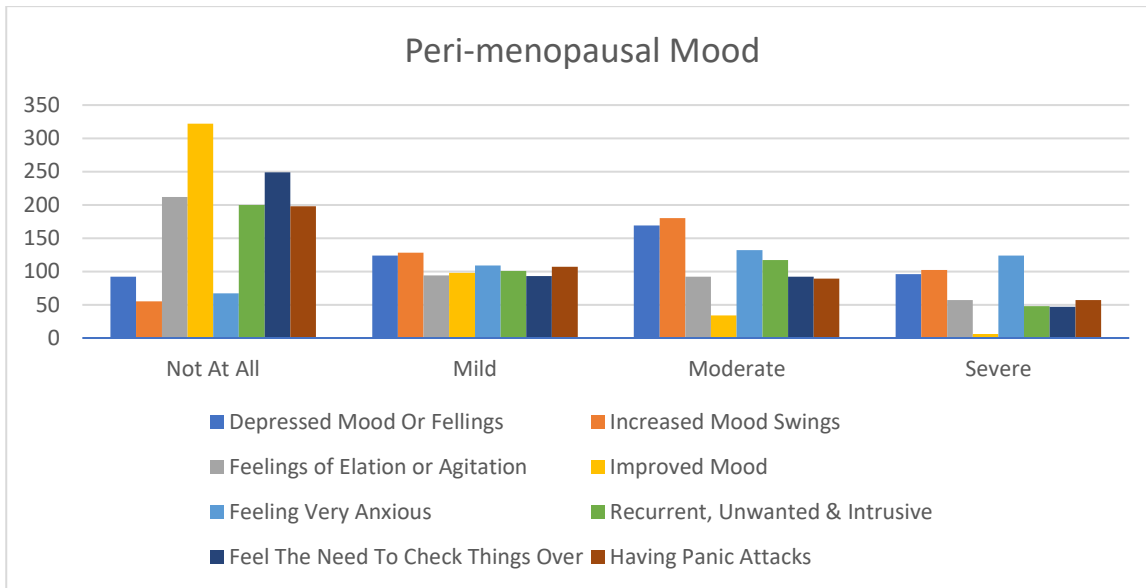


The next multiple-choice question asked about symptoms that menopausal women face when transitioning. Vasomotor symptoms are prevalent in these women. ‘86%’ and ‘80%’ had hot flashes and night sweats, respectively. Sleeping problems are also severe amongst menopausal women, with ‘84%’ having difficulties. Both physical and emotional effects of menopause can have a prolonged effect on the body; figure 22 shows the most common symptoms for menopausal women. The open-ended option answer was mainly answered with the women having aching joints and pains due to menopause.



**Figure 22** Main Symptoms of Menopause (Authors Own, 2022)

HRT was previously thought to be the primary way of dealing with menopausal symptoms, although ‘40%’ of the women stated they have never taken any form of it. The rest of the participants had either taken HRT, were still taking HRT, or chose to take other supplements. With only ‘62%’ say using it would alleviate any mood symptoms associated with menopause. The next set of results followed the use of NRS-11/MRS scales.



*Figure 23 Moods Pre and Post Menopause (Authors Own, 2022)*

Figure 23 illustrates the difference between menopausal mood symptoms of peri-menopausal women compared to post-menopausal women. Clearly, the women who answered these questions had felt no real difference as both show strong correlations between both charts. This shows that moods are not relieved, where a woman’s wellbeing should be considered. The transition has also hindered the participants’ quality of life. ‘72%’ of the participants said their social lives had decreased, and ‘70%’ stated their relationships with family members had been affected. In addition, large sections of the participants thought their work-life and home life had been massively affected by menopause.

The next open-ended question received a total of 336 responses and asked the women, “Is there anything about your experience with menopause on a whole that you wish you could change? If so, what?”. The answers are varied as every woman goes through different experiences with menopause. The overwhelming feeling from looking at the answers is that women do not enjoy the experience. HRT is the most common way to deal with the symptoms of menopause.

Although what has become apparent is that not all women can take HRT, and they feel there is no other method to deal with the symptoms. Women's well-being seems to be the primary reason they feel they have no support during this transitional period.

In addition to the '84%' of women with sleeping difficulties, '81%' state they have insomnia. The literature review found that OSA was common amongst menopausal women. This survey found that both women who had OSA and did not have it were at '40%' each, with the other participants unsure whether they had it. Sleep appears difficult for menopausal women as '85%' say sleep is affected by hot flashes and night sweats.

The diet that menopausal women choose is said to affect their experience through this transition. '80%' of the women had tried nutritional products and medications, with a further '36%' purchasing sleep-aiding drugs. Whilst only '28%' of the women had tried phytoestrogen supplements to help reduce the effects of menopause. Contrary to belief, '82%' of the women think they eat healthily, with '87%' stating they do not eat before bedtime. '64%' have not been put off eating spicy or acidic food, and '79%' still consume nicotine, caffeine and alcohol, with '26%' admitting to doing this just before bedtime.

During sleep, '99%' of the women say they either wear light clothing or none. A further '66%' of the women stated they use a lighter (less tog) bedding. In addition, the participants were asked if they tried to improve circulation throughout the night. Over half of the respondents sleep with the window open at night. Other ways of dealing with circulation are leaving the doors open and using

fans or air conditioning; also relating to family relationships breaking down, menopausal women choose to sleep separately from their partners. The women also responded to many other ways they feel they can keep cool at night through the open-ended question. This was the first real sign that 'under half' of the women had attempted to buy products designed to help them through this transition with cooling pillows, special clothing and lamps.

The analysis of well-being was heavily considered in the next stage. A goliath, '74%' of the women stated they often feel stressed, with many respondents stating that work is the most significant factor. As found out in a previous question, menopause affects women's work life and, therefore, could increase stress values amongst these women. The consensus is that all parts of life can contribute to stress and can be an amalgamation of many parts of daily life. In addition to the sleeping section of the questionnaire, participants were asked what they would like to change about sleeping at night. Overwhelming responses stated that night sweats and hot flashes are the main reason they struggle to sleep. It points to a strong argument that menopausal women have insomnia due to vasomotor symptoms and, in return, have an out-of-synchronised circadian clock.

Half of the study group state they experience roughly 1-5 hot flashes during the day, with just under a quarter stating they receive 6-10 daily. '10%' are fortunate enough not to have any hot flushes, but this may be due to them already having been through menopause. In an open-ended question, the women were asked, "How do you currently try to relieve the effects of a hot flash? (How do you attempt to cool down)". The responses were varied as women sought any way to try and relieve these symptoms. Answers included: taking items of clothing off, using fans, either drinking water or applying it to the skin, breathing and relaxation techniques and some wait it out and putting up with the effects. In addition, the women were then asked, "How do you currently try to relieve the effects of a night sweats? (How do you attempt to cool down)". The answers were varied, but all were general ways to cool the body. The responses stated that removing clothes or bedding, opening

windows and doors, whilst using fans, or cold/wet items could be used to help them through the night.

#### 4.4.4 Conclusions of the Questionnaire

This chapter entailed relevant outcomes from this enquiry into menopausal women's well-being whilst considering the rationale of this research approach. The questionnaire had varied answers but was generally restricted due to the questioning. The most common symptoms amongst menopausal women were:

- Hot Flashes
- Sleep problems and insomnia
- Night Sweats
- Memory problems

This was hypothesised initially due to exploring vasomotor symptoms as a vital issue. Vasomotor symptoms are likely the cause of menopausal women not being able to sleep correctly, mainly due to hot flushes at night and night sweats. It has also become apparent that mood swings are likely to affect a menopausal woman's life. Not only is personal life affected, but social and professional lives are also affected. The lowering of well-being is typical in all menopausal women, with their quality of life decreasing during this transitional period. For many adult women, time restraints mean there is no time for them to escape their own lives for a short period to recover mentally.

Therefore, the outcomes of this questionnaire provide a foundation that supports the use of biofeedback technology through either wearable technology or VR. Research now provides virtual reality with a case to improve the well-being of menopausal women whilst giving them escapism in

the comfort of their homes. On the other hand, a wearable may seem a preferred option as it can be worn constantly to assess a user's body, compared to VR, which is unlikely to be worn all the time.

An empirical focus group will further define the critical issues within this research area to add to these notions from this chapter. The common symptoms within the qualitative survey and recommendations within the brainstorming session will be used to assess the effect that VR has on menopausal women and if well-being can be improved to provide validity at the current stage of this thesis.

## 4.5 Focus Group

### 4.5.1 Introduction

The focus group is used to develop in-depth knowledge of what affects menopausal women's well-being. Information found through the literature review, brainstorming sessions, and quantitative surveys will influence the structure of the focus group to get the best outcomes possible. The aims and objectives of this session are to conceive the possibility of immersive technology as a viable design option for this research. These focus groups follow a tight schedule in an hour's workshop to complete all tasks within the focus group. The input from the menopausal women in the focus group will help provide foundations to design a concept surrounding problems found, and solutions raised through this focus group. Participants were asked to evaluate their levels of well-being throughout this section whilst being visually immersed.

### 4.5.2 Aims of this Focus Group

This focus group aims to develop a foundation on which to design further tests and input into the final concept. Understanding if immersive technology could be a viable option for new product development is essential as multisensory technology has been highlighted as a possible avenue for design. As a designer, it is important to get user feedback throughout the design process; in this

case, the well-being of menopausal women should be vastly improved when working alongside them. To ensure that attendees fully understood the context of this research, they were given a briefing before the workshop, where they had the chance to ask their questions if needed. As the user requirements were for themselves, there was not much further information the participants required. Participants were encouraged to focus on their well-being throughout the focus group, as personalisation was vital as each woman experiencing menopause has a different story. Through their input, design principles for the concept development could address or prevent current design issues.

In addition, the design principles made from this initial focus group are directly related to improving the well-being of menopausal women. Based on the feedback from this focus group, design ideas can be initially developed if successful. The women in the focus group were happy to openly talk about their problems, which was an initial concern, as it was thought that women might be hesitant to talk about personal issues in a group and with a male. To support further studies and concept development, principles found from this first focus group will be used to facilitate these following stages.

#### 4.5.3 Design of the Focus Group

This focus group had four activities to follow concurrently (see Appendix 2). The table illustrates the reasoning behind each activity. A detailed design of how this activity was planned and the resources and instruments used to gather feedback. Participant descriptions and experience with menopause and visual immersion are shown in Appendix 2. This Focus Group was conducted at Lancaster University on the 16th of July 2019.

#### 4.5.4 Results and Outcomes of the Focus Group

The personal experience task got the group to start being creative by drawing a self-portrait of themselves. Therefore, five portraits and stories were gathered (see appendix 2) from the discussion of needs and requirements, along with critical issues for women experiencing menopause.

Participants were encouraged by the facilitator to concentrate on well-being but were free to venture off in their directions. The Participants experienced many of the same symptoms and issues raised in the personal experience task. Appendix 2 outlines the agreed outcomes from the personal experience task, with all similarities between the women deemed prevalent symptoms.

The personal experience task outlines the personal stories of each candidate. This activity shows that all women have different experiences when going through menopause. Like what was found in the previous chapter, the most common symptoms were also prominent amongst these ladies. It seemed the ladies were already looking for non-invasive methods to deal with menopause by not using HRT but trying oils and natural products. Some comments moved towards the emotional side of menopause, as this is also prominent amongst menopausal women. All the women seemed to have a part of their social lives affected by menopause.

In the collecting the visual immersion and improvement feedback activity, participants were asked to watch ten videos each whilst stating at the end of each grouping what could have made the experience better for their well-being. Three of the videos portrayed "cooling" conditions, a further 3 portrayed "warming" conditions, with the final four videos portraying "relaxing". This All videos were royalty-free and depicted items typically found within the conditions portrayed. A combination of both live-action videos and animated videos were shown to the group. Live action can be defined as "action involving real people or animals, not models, or images that are drawn, or produced by computer" (Cambridge Dictionary, 2023b). Conversely, animation can be defined as "moving images created from drawings, models, etc. that are photographed or created by a



computer” (Cambridge Dictionary, 2023a). Participants filled out forms to say whether the videos had the desired effect on them. The feedback between participants had similar outcomes; the results are shown in Appendix 2.

This task was insightful for the researcher. The group were given videos to watch whilst being visually immersed. All the videos shown correlated; the more real videos, therefore not ones that have been computer-animated, had a more significant effect on the menopausal women. The women also feel that additional items could help with either cooling, warming or relaxation. Many additional products may have to be designed to help the overall well-being of menopausal women.

In addition, in collecting well-being information from the participants regarding how mixed reality could improve their well-being, the participants were asked to express how certain words, chosen from Plutchik's 'Wheel of Emotion', made them feel and what they associated with those words.

The outcomes of this activity are in Appendix 8.

This task allowed the women to share what words they associated with specific emotions. What became apparent across the participants is that: Anger was seen as a human factor and was generally seen as hatred of humans or animals. Joy surrounded happiness, with the women stating what makes them happy, including family, pets, and holidays. Disgust, for some, brought out similar factors to anger but was generally personal opinions about what is disgusting to individuals. Sadness was across all participants linked to death, loss, and grief, as expected. Fear was seen literally as what actual fears the women have; therefore, is individual for each participant. Surprise shows how the women could be surprised in real life due to unexpectedness. What became clear during this task was that certain words make people think of specific things, which are likely to be the same as others, as those words are strongly linked to those emotions. Therefore anger, joy, sadness, and surprise appear to be easier to evoke in people.

In the focus group synopsis task, participants could give feedback on how they thought the focus group went. The demographics and comments were collected using all participants' questionnaires (see appendix 2).

Participants thought Virtual Reality could be tested to treat hot flushes as they thought it could be a viable, non-invasive option. They thought the workshop was suitable, but more time could have been allowed for specific tasks, but overall, the participants thought more focus groups could be applicable. Also, a few more organisations could have improved the group with an in-depth introduction to each task. Women loved that they could talk openly about the same and even different experiences with other women. Even though the facilitator was a young man, participants still felt at ease. In summary, the main points taken from this focus group that will help design an alternative are:

- All women are different and experience different symptoms.
- Women tend to seek non-invasive approaches to deal with menopause, but minimal solutions exist.
- Immersive videos can be a viable method, but menopausal women prefer live action videos in all aspects over animated videos.

The concept could either:

- Design for a set of symptoms
- Try and make and make a menopausal woman's general well-being improved

Extra items should be added to the experience to improve their overall well-being. For example:

- Music and sounds
- Physical objects

#### 4.5.5 Summary of the Focus Group

The focus group proved that VR has the potential to work as a design alternative for a wearable device, due to how visual immersion was received. Women agreed that immersive videography does have the capabilities to cool the body through perceived cooling. Therefore, VR will be reviewed through pilot testing to assess the level of relief it can provide. In addition, research will closely assess wellbeing testing for menopausal women and VR testing through pilot studies, as these biofeedback measures are necessary for the final stages of design and development within this thesis.

#### 4.6 Pilot Testing

##### 4.6.1 Mixed Reality Temperature Testing for Vasomotor Symptoms

###### 4.6.1.1 Introduction

Recent research has proposed the benefits of using VR for medical applications, such as phobia research (Botella et al., 2004). This type of research can be thought to manipulate human physiological responses, with the outcome of research leading towards the future of VR to be used for testing not typically done in laboratories. This study will look to assess both the psychological and physiological effects being immersed in virtual reality has on the objective skin temperature of participants, as well as their subjective perception of temperature. The study addresses the primary aims and objectives outlined in chapter 1. The aims of this study were:

- To design an alternative in a co-creation workshop to improve the well-being of menopausal women.
- To design and test a prototype to improve the well-being of menopausal women.

- To analyse the results from the testing to see if the design has improved the well-being of menopausal women.

#### 4.6.1.2 Using Biofeedback for Menopause

The researcher felt that menopause could be significantly improved if virtual reality therapy could be used to relieve specific symptoms that women face when going through this biological change. This method of therapy could be seen as biofeedback. This is a method of monitoring involuntary processes such as a person's blood pressure or heart rate. Biofeedback also influences bodily functions; an example could be a polygraph test. In a polygraph, it is the physiological responses measured. Biofeedback is used to make people aware of the physiological functions of the human body. Therefore, a person can manipulate their bodies to a desired physiological state, such as calming after a panic attack. There are frequently used machines that can be used to monitor biofeedback, for example, a thermometer for body temperature.

As the well-being of menopausal women is also an area that would be needed from this immersive experience, biofeedback can be combined with relaxation training. This has already been trialled and used within clinics to treat conditions such as irritable bowel syndrome and even Raynaud's disease (Leahy & Epstein, 2001; Karavidas et al., 2006). Raynaud's is a prime example of why this type of feedback is the best to research, as people experience cold body extremities and stress with the disease.

#### 4.6.1.3 Using Biofeedback to Measure Temperature

As previously discussed, biofeedback can offer feedback regarding the blood flow to extremities. Menopausal women are known to have vasomotor symptoms. Biofeedback has been shown to relieve vasomotor symptoms in menopausal women to lower luteinising hormone pulses (Albrecht et al., 1981). It may be possible to link this biofeedback amongst menopausal women to relaxation therapy. Relaxation training is combined with temperature biofeedback to allow individuals to gain

self-control over certain blood flow extremities and combat Raynaud's disease (Karavidas et al., 2006). Virtual reality could make these biofeedback therapies more interactive when considering this approach, increasing effectiveness. With this knowledge, virtual reality could be implemented to combat vasomotor symptoms to improve a woman's well-being.

#### 4.6.1.4 Method

##### 4.6.1.4.1 Participants

Initially, thirty people were asked to participate in pre-screen testing, which was completed. Thirteen of the participants were male, with seventeen being female. Due to health reasons, six participants were excluded from the research due to self-reporting a higher chance of epilepsy or motion sickness. Five of the remaining participants did not meet the inclusion criteria for the research due to the size of the test equipment. The remaining 19 participants were invited to the test room to complete the experiment. Sixteen participants contributed to the experimental trials, with three unable to make the test period due to other commitments. Of the sixteen participants, two had incomplete data and were removed from the final analysis due to misreading's from devices. The fourteen participants who completed the testing were all menopausal, as the male participants had previously been unable to partake in the testing. The group had an average age of 52. The testing took place in a private room on the 12th august 2019.

##### 4.6.1.4.3 Experimental Design

This experiment investigated how temperature cues affect subjective and objective body temperatures when immersed in a virtual world. The first independent variable used for testing was the virtual environment temperature (Cold against warm).

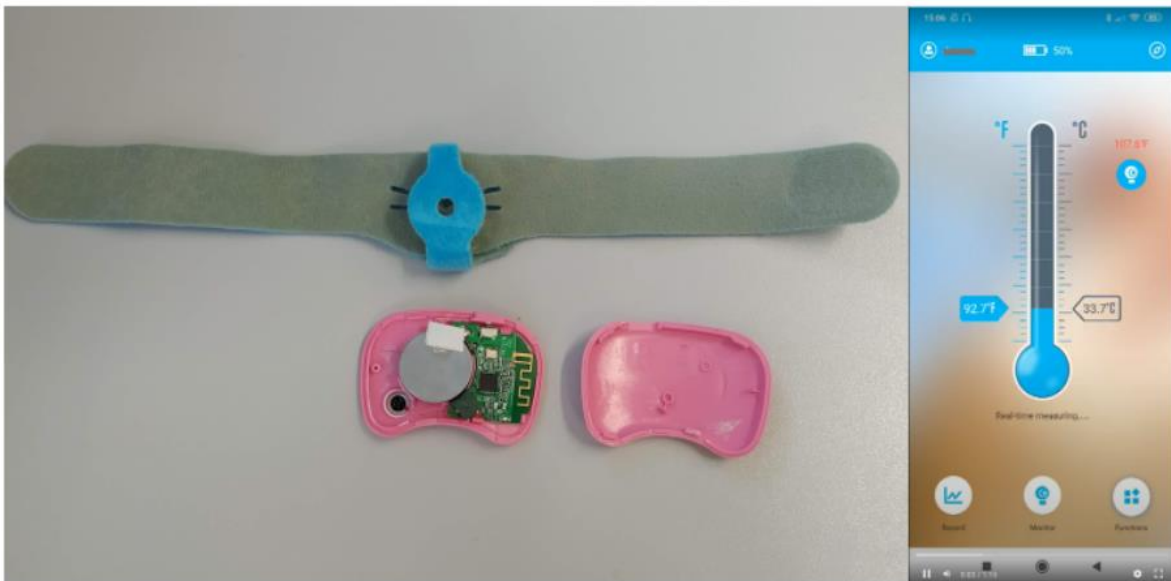
#### 4.6.1.4.4 Materials

Google Cardboard VR headsets simulated a virtual environment for the participants. The phone used was a Xiaomi Redmi 7. The room temperature was kept at a constant of 21°C, defined as the ideal temperature for main spaces in households, defined as normal (Shipworth et al., 2009).

Humidity was attempted to be made constant as a result throughout the testing. The chosen test room had multiple air vents and allowed for circulation whilst the test was occurring. To reduce the thermal effect of surrounding objects, direct contact with other furniture, such as tables, was prohibited, along with contact with walls. The device was worn on the test subjects' left wrist. A constant recording of the temperature of the radial artery region was taken. The measurements were sent to an accompanying application that shows and records real-time temperature measurements. Each subject wore trousers and a short-sleeved shirt (0.57 clo). A short questionnaire regarding the temperature changes they felt they experienced throughout the test to conclude if the perceived heat temperature change was the same as the actual temperature change was given at the end of the experiment. Participants were placed in a static chair that had no movement or armrests. Participants were placed as far away as others surfaced to avoid temperature transfers.



*Figure 24 Google Cardboard VR and Temperature Tracker in Situ (Authors Own, 2022)*



*Figure 25 Temperature Tracker and Screen Capture of Accompanying Application (Authors Own, 2022)*

#### 4.6.1.4.5 Measures

The perceived temperature was measured on a Likert scale that ranges from one to seven, where participants were asked to assess their subjective perception of temperature (Likert, 1932). The

objective temperature was measured using a skin thermometer placed on the wrist's radial artery region. In addition, a thermal imaging camera was used to assess where body temperature changes were occurring.

#### 4.6.1.4.6 Procedure

Participants were given instructions on how to conduct themselves during the test before the testing. Participants were immersed in two different virtual environments (Hot and Cool). Each condition took ten minutes, with a ten-minute neutralisation period, to recover from the previous condition, eliminating the residual effects. Participants were exposed to fiery conditions for the first assessment of the experimental condition. This is classed as an extreme temperature condition. In the second assessment, participants were exposed to icy conditions. These icy conditions were also classed as extreme temperature conditions. The objective surface temperature was measured using a skin thermometer on the radial artery part of the wrist. The temperature was measured before and after testing. Subjective body temperature was assessed using the accompanying questionnaire.

#### 4.6.2 Results

The main analysis of objective temperature measurements of the dorsal side of the wrist from the start and the end of the experiments. This was done for fiery and icy conditions to gain objective and subjective temperature measurements. A thermal imaging camera was also used to see where the most body heat was in the body for these tests.

##### 4.6.2.1 Skin temperature before and after

Given the smaller sample size, these exploratory paired sample sizes were calculated against dependent measures for each condition. Results showed that for both conditions, there was a significant temperature difference. For the fiery conditions, there was a significant difference at  $p < .01$ , results indicated that the participant's body temperatures increased from the start of the test



( $M = 33.70$ ,  $SD = 0.34$ ) to the end ( $M = 34.34$ ,  $SD = 0.39$ ). There was also a significant difference in the icy conditions at  $p < .10$ , results indicated that the participant's body temperatures decreased from the start of the test ( $M = 33.56$ ,  $SD = 0.35$ ) to the end ( $M = 33.31$ ,  $SD = 0.29$ ). This shows that both conditions had significant results from the start to the end of the tests.

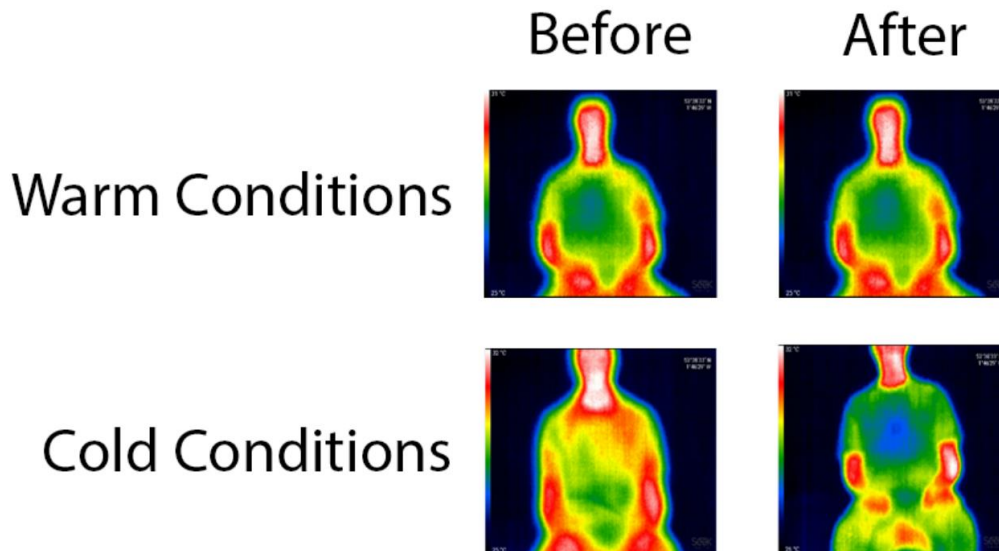
#### 4.6.2.2 Subjective Measure of Temperature

Participants provided their ratings on a Likert scale to measure perceived body temperature before and after the VR conditions. This can have limitations as the feedback can be subjective, though it offers personal user feedback for well-being which can then be used in line with physical feedback testing. The scale tested ranged from 1 (very uncomfortably cold) to 7 (very uncomfortably warm). These exploratory paired sample sizes were calculated against dependent measures also for each condition. Results showed that for both conditions, there was a significant difference in the perceived temperature. For the fiery conditions, the results indicated that the participant's perceived body temperatures increased from the start of the test ( $M = 3.86$ ,  $SD = 0.74$ ) to the end ( $M = 5.50$ ,  $SD = 0.98$ ). There was also a significant difference in the icy conditions. Results indicated that the participant's perceived body temperatures decreased from the start of the test ( $M = 4.36$ ,  $SD = 0.72$ ) to the end ( $M = 2.86$ ,  $SD = 1.06$ ). This shows that both conditions had significant results from the start to the end of the tests.

#### 4.6.2.3 Thermal imaging measure and placement of temperature

The analysis of thermal heat using thermal imaging showed that the hottest places were where the bare skin was showing on the participants, as expected, due to being immersed in both fiery and icy conditions. The study showed that the neck and forearms were marginally hotter than other areas of the body where bare skin was showing. Interestingly, this study was that for both experiments, the participants generally experienced the same chest effects where the fiery conditions saw an increase in chest temperature through the participant's clothing. In contrast, the icy conditions showed that

chest temperatures visually decreased over the ten minutes. Figure 26 shows a difference between warm and cold body temperatures when a user is immersed in a virtual environment.



*Figure 26 Temperature Differences Between Participants in Warm and Cold Conditions Before and After Being Immersed in Virtual Reality. (Authors Own, 2022)*

#### 4.6.3 Conclusion

This study aimed to determine if virtual reality could manipulate the human body into thinking it was cooler or warmer without physically changing the participant's body temperature. Both objective and subjective temperatures were measured, and both had the desired effects, with the critical areas of the body that were cooled effectively also identified. It was previously hypothesised that both conditions would have the desired effects of either raising or lowering body temperatures. The fiery conditions seemed to offer a more significant desired difference in body temperature than the icy conditions, although both still worked as expected.

Not many studies have previously investigated the physiological effects of being immersed in virtual reality. Research has been compiled in a similar area defining that virtual reality can also be used to affect temperature cues (Lauderdale, 2017). Past research only focused on the clinical effects of therapy for medical application, basing research on manipulating perception (Botella et

al., 2004). The placebo effect is a prime example that a person's physiological effects can be manipulated with a person's perception (Price et al., 2008). In addition, research has found that perceiving temperature can strongly affect visual perceptions (Hashiguchi et al., 2016). The present study has shown that those temperatures can be affected by visual cues and where these temperature changes occur. Menopausal women's well-being could be significantly improved with the ability to manipulate the biological perceptions of temperature.

The results of the objective measurement study showed significant results during both tests. The fiery conditions showed greater skin temperature differences than the icy conditions since participants were immersed in the icy conditions before the fiery conditions. Though this could have made a difference, the participants were allowed enough time between tests to adjust to an average body temperature. Participants' body temperatures were also measured before both tests to see if they were not ordinary. Therefore, this would be an unlikely reason why the fiery conditions showed a greater significance in results. Both showed significant results in skin temperatures, making it possible to make a reasonable assertion that body temperature can be affected by immersive technologies.

In addition, subjective body temperatures also showed that the participants thought their body temperatures were rising or lowering in the fiery and icy conditions, respectively. Both conditions showed similar results in a difference in perceived body temperatures. This aids the previous knowledge that the skin temperature changes when immersed in these environments. Also, proving that a person's body temperature can be influenced through virtual reality with non-invasive measures. In addition to just looking at body temperatures, it is critical to note that the well-being of menopausal women could also be improved through the use of relaxing environments in virtual reality.

Biofeedback was used to analyse this present study. Biofeedback could be applied to further research and products to analyse and effectively manage menopausal symptoms. More personalised and realistic applications for temperature biofeedback therapy could drastically improve well-being as these are seen as the worst symptoms of menopause for menopausal women, as discovered in previous chapters. The notion that participants could be immersed within a particular environment to improve their well-being is interesting whilst providing scope for potential design alternatives. Virtual reality is available to the public, meaning therapy for menopausal women can be done in their homes rather than at clinics.

The fiery conditions, overall, showed more significant results. This could be because the room was tried to be kept at a constant temperature. Testing was challenging due to all the equipment in the room making heat and the room itself having lower air dispersion. The room was made more soundproof, with gaps around the door sealed during the experiment; this was mainly to improve immersivity. Consequently, this soundproofing could have retained the heat in the room as most air could not be as ventilated as hoped. The participant was asked to remain as still as possible throughout the experiment, but they could place their hands wherever they wanted. Most chose to rest their arms on their legs; this could have added to the heat dispersion during the test. In addition, the virtual reality headset can give off much heat while trapping air between the headset and the user's face, resulting in increased perspiration, and likely affecting body temperature.

Another limitation could be seen as the sample size was relatively small (fourteen); though the sample size is small, it is like previous research's sample sizes (Lauderdale, 2017). The smaller sample size for this research was due to a few factors. Firstly, the inclusion criteria were strict, eliminating five people. Secondly, six participants were excluded due to health reasons (Including motion sickness). A further two had incomplete data and were therefore removed from this study. Of the initial thirty people who offered to participate in this study, fourteen completed the study.

This study aimed to determine if body temperature could be affected within specific virtual reality environments. Both objective and subjective temperatures were measured during this experiment, offering significant results. This study proves that virtual reality and subjective temperatures can change objective body temperatures. This study provides an analysis that proves body temperatures can be affected through virtual reality therapy.

#### 4.6.4 Summary of Mixed Reality Temperature Testing

Though VR has been found to lower body temperature for subjects, it cannot be seen as a viable option for menopausal women. VR is not viable for menopausal women as it cannot offer constant and consistent relief. Women require a device to be designed that can react to vasomotor symptoms prior to the onset of hot flushes and night sweats. It would be possible if a woman wanted to cool down using virtual reality. However, the time and process of setting up VR would prolong the experience of vasomotor symptoms, which are currently negatively affecting menopausal women.

Therefore, it is proposed that a biofeedback wearable with localised cooling is the design focus as biofeedback from VR is unlikely to offer instant relief for women. Conversely, VR is a proper alternative design method for women to escape their busy schedules for a short period. During this time, their wellbeing can improve through cooling and escapism, as found within the brainstorming session, the qualitative survey, and the focus group.

Future research stages, therefore, may integrate the use of a localised cooling biofeedback wearable to be integrated within a virtual environment to increase the immersive experience. This thesis, however, will now assess the design and development of a biofeedback wearable to decipher whether the design for wellbeing affects vasomotor symptoms of menopausal women through biofeedback technology.

## 4.7 Evaluation of Current Products to Evoke Design Thoughts

### 4.7.1 Introduction

This section of the thesis will decipher the positives and negatives of current products across variables. The designer feels that the areas of the head, neck and wrist cooling wearables should be considered prior to develop design specifications. Designers utilise an existing product review to compare and define what is already in the market to outline any gaps. The review can be defined using a Pugh Matrix system (Pugh, 1990). The review will score the products against these factors by giving a plus if the product achieves the criteria.

Conversely, if the product does not achieve the criteria, a minus score has been given to the product. There could be an argument for both cases where the product may have equally positives and negatives in the same criteria. In this instance, a zero has been given to the product. In addition, a product may not be able to define whether it could affect a specific category. For example, if the product has not been designed to improve sleep and there has been no research-backed data to define whether the product can meet that criterion, a score of zero has also been applied. If the product scores positively, it can be considered consumer appropriate as the overall design has a positive outcome.

Burge (2009) states how the system can be utilised for product development. The system allows several products to be compared against a baseline to see if differing criteria can be achieved. This method authorises some qualitative development of design alternatives. In addition, the system is straightforward that has a prominent advantage over Decision Matrix with the ability to handle multiple decision criteria effectively. The method offers the researcher multiple factors to consider when reaching decisions. Thus, ensuring the research has vigour when achieving a design decision.

Essentially Pugh's matrix system is ideal for a design researcher to utilise if comparing multiple alternatives against one another. Initially designed by Pugh to sieve potential alternatives, Burge

(2009) states it is now developing into a general-purpose decision-making aid. The research will delve into the product's cooling capabilities, its weight if considering the user carrying the device with them, the cost, its effect on sleep, its durability and longevity, how comfortable it can be for the user and the ergonomic aspects of the design.

In addition, aesthetics were considered to be assessed through this section. Aesthetics is a concept that is undeniably relative, hinged upon individual judgment or preference, or even influenced by societal factors. What one person may perceive as attractive can differ greatly from another's perspective. Individual judgment plays a significant role in shaping our perceptions of beauty. Each person has their own unique set of experiences, values, and cultural background, which colour their interpretation of aesthetics. What may be visually appealing to one person may not resonate with another due to personal taste and preferences. Moreover, the notion of beauty is also socially relative, meaning it can be influenced by societal norms, trends, and cultural expectations. Society's collective beliefs and standards of beauty can shape our understanding of what is deemed attractive or desirable. Ultimately, the relativity of beauty lies in the eye of the beholder, influenced by personal and societal factors that shape our perceptions and judgments. Therefore, aesthetics could be reviewed by the researcher as an individual view, and the researcher will comment on aesthetics periodically where necessary, but it cannot be defined within the Pugh Matrix, as user viewpoints are necessary.

The Pugh Matrix itself has been identified as a usable tool for small teams and individual designers. Current research has found that Pugh Matrix based product development has increased efficiency for individual designers and small teams (Guler & Petrisor, 2021). The researcher considers themselves to be an individual designer and only incorporates others in co-design and development of a biofeedback wearable. As this assessment can be self-assessed at this stage users will not be involved with this product review.

The selection for cooling wearables to be evaluated within this section is based upon where they are designed to be placed on the user's body. Cooling wearables designed for the head, neck, and wrist, targeting pulse points, offer a valuable solution for temperature regulation and comfort. Forehead cooling was found to improve vasomotor symptoms through the night, as found within section 2.2.6.1.3. In addition, under section 2.2.4.2, it was found that the wrist and neck are the best pulse points for readings, which is vital if heart rate is to be monitored by a biofeedback wearable, alongside users currently targeting these areas with cooling to lower the effects of vasomotor symptoms. These wearables leverage the body's natural pulse points, where blood vessels are closer to the surface, allowing for efficient heat exchange. By applying cooling technologies or materials to these specific areas, these wearables effectively dissipate heat, providing a refreshing sensation. Cooling the head, neck, and wrist pulse points can help regulate body temperature, relieve heat-induced discomfort, and promote a sense of overall well-being, particularly in hot and humid environments or during physically demanding activities. The localised application of cooling wearables on pulse points enables targeted cooling and enhances the body's natural thermoregulatory mechanisms, contributing to a more comfortable and enjoyable experience. Furthermore, it is important to state that only devices that could be considered therapeutic and not medical have been chosen to be assessed, this is due to the researcher stating infringement on medical device design would not occur in section 2.1.2.



#### 4.7.2 Head Cooling Wearables

	<p>1. Vanderbilt University Medical Centre's baby asphyxiation cooling cap (Vanderbilt University Medical Center, 2022)</p>
	<p>2. Paxman cooling cap (Paxman, 2022)</p>
	<p>3. Ebb Therapeutics sleep system (Ebbsleep, 2022)</p>
	<p>4. Aliexpress cooling headband (Aliexpress, 2022)</p>
	<p>5. Amazon cooling sleep mask (Amazon, 2022)</p>
	<p>6. Aurox Texh cooling headband (Auroxtech, 2022)</p>
	<p>7. Head and neck cooling device (All-star Goods, 2022)</p>

Table 3 Head Cooling Wearables

Product Criteria	Baseline	1	2	3	4	5	6	7
Cooling Effect	0	+	+	+	+	+	+	+
Weight	0	-	-	-	+	+	0	+
Cost	0	-	-	-	+	+	-	-
Effect on Sleep	0	0	0	+	0	0	0	0
Durability/ Longevity	0	+	+	+	-	-	0	+
Comfort	0	0	0	+	0	0	0	-
Ergonomics	0	+	+	+	0	0	+	-
$\Sigma+$	0	3	3	5	3	3	2	3
$\Sigma-$	0	2	2	2	1	1	1	3
$\Sigma$	0	1	1	3	0	0	2	0

*Table 4 Head Cooling Wearables Pugh Matrix*

#### 4.7.3 Head Cooling Wearables Conclusion

In conclusion, there are many head wearables available that offer head cooling. All products reviewed are deemed effective enough for cooling, as they are supposed to do. Even though all products offer head cooling, some problems have been found. For example, products that require freezing water do not last for a long time and can only be initially one temperature set to in the freezer. For many people freezing objects in contact with the skin would be uncomfortable. Many designs have accessories that are not necessarily needed and could potentially be dangerous during sleep. The Ebb device, for example, and the Paxman cooling cap both require water to be pumped into the system. This could potentially be dangerous during sleep, where asphyxiation may occur. Both the Ebb device, along with the Paxman cooling cap, are backed through research (Baker et al., 2020; Mysliwiec et al., 2020; Unver et al., 2019). The Ebb device has explicitly been designed to improve sleep, including insomnia, which is seen as a common symptom amongst menopausal women. The Ebb device is a preferred design due to its research aiming to lessen the effects of insomnia is a preferred design. The Ebb device could be improved, though, as the additional water

pump and tubes that connect the tank to the headband could potentially be dangerous during sleep if people are likely to toss and turn. In addition, if the tubes were removed, the product would have to be a standalone and be a singular product offering cooling through a biofeedback system.

#### 4.7.4 Neck Cooling Wearables








	<p>1. CoolWare personal cooling system (Shaper Image, 2022)</p>
	<p>2. DHport cooling neck fan (DHport, 2022)</p>
	<p>3. Black Ice Cooling (Black Ice Cooling, 2022)</p>
	<p>4. Ucool neck cooling device (eBay, 2022a)</p>
	<p>5. Neck cooler created for Hammacher Schlemmer (Hammacher, 2022)</p>
	<p>6. Revit fluid cooling collar (Bobs Bmw, 2022)</p>
	<p>7. Ebay icepack neck cooling scarf (eBay, 2022b)</p>

Table 5 Neck Cooling Wearables

Product Criteria	Baseline	1	2	3	4	5	6	7
Cooling Effect	0	+	+	+	0	0	+	+
Weight	0	0	0	-	+	-	+	0
Cost	0	+	+	-	-	0	-	0
Effect on Sleep	0	0	0	0	0	0	0	0
Durability/ Longevity	0	-	0	+	-	-	-	-
Comfort	0	-	0	-	0	0	0	-
Ergonomics	0	0	0	0	-	-	0	-
$\Sigma+$	0	2	2	2	1	0	2	1
$\Sigma-$	0	2	0	3	3	3	2	3
$\Sigma$	0	0	2	-1	-2	-3	0	-2

*Table 6 Neck Cooling Wearables Pugh Matrix*

#### 4.7.5 Neck Cooling Wearables Conclusion

Products designed specifically for neck cooling are limited and costly. The product found through this product review was found to be less ineffective for cooling than head cooling devices. The products listed above were categorised as negative overall through the Pugh matrix equation. The poor scoring from neck cooling wearables is mainly due to the longevity of the products reviewed. The product reviews state they are all generally aesthetically unpleasing, with the cheapest, DHport cooling neck fan, arguably being the most aesthetically pleasing due to its sleekness and not overly bulky. Black Ice's neck cooling product is designed for sports injuries but is also supposed to improve menopausal symptoms such as hot flushes. The product is rechargeable and is said to offer 24/7 cooling. However, one charge only lasts 1.5 hours, whereas a biofeedback device would look to be lasting a longer duration due to the constant feedback the user would be receiving. Due to only one of the neck cooling wearables being made for menopause, Black Ice's neckwear could no doubt be effective. The issue outlined is its longevity. Even though, theoretically, it can offer all-day cooling, it cannot. An improved device for this market would be an increased aesthetically pleasing

design with longevity to offer women comfort throughout the day. The fact that these products do not offer longevity is down to the fact that they are on full power until they die, which is battery draining. A new concept should consider biofeedback to save battery consumption and only offer cooling when necessary.

#### 4.7.6 Wrist Cooling Wearables



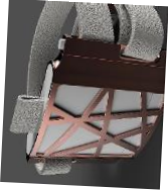



<p>1. Aircon start up watch (Kickstarter, 2017)</p>	
<p>2. San Diego University flexible wrist cooling (Labios, 2019)</p>	
<p>3. Grace biofeedback wristband (Astinno, 2022)</p>	
<p>4. Sports wrist cooling from Pune specialists (Krishnan et al., 2018)</p>	
<p>5. Frozen water wrist wraps (Polar Products Inc, 2022)</p>	
<p>6. Embr Wave cooling bracelet (Embr Labs, 2022)</p>	

Table 7 Wrist Cooling Wearables

Product Criteria	Baseline	1	2	3	4	5	6
Cooling Effect	0	+	+	+	+	+	+
Weight	0	0	+	+	+	+	+
Cost	0	+	0	0	0	+	-
Effect on Sleep	0	+	0	+	0	0	0
Durability/ Longevity	0	+	+	+	+	-	+
Comfort	0	+	+	+	+	+	+
Ergonomics	0	+	+	+	+	+	+
$\Sigma+$	0	6	5	6	5	5	5
$\Sigma-$	0	0	0	0	0	1	1
$\Sigma$	0	6	5	6	5	4	4

*Table 8 Wrist Cooling Wearables Pugh Matrix*

#### 4.7.7 Wrist Cooling Wearables Conclusion

Through the Pugh matrix, the ability to assess the wrist cooling wearables was achieved through the same scoring system as above. Firstly, the Air-con start-up watch. The watch still has not been released or tested and is an anomaly in this section. It scores well throughout the assessment due to what the design promises. Like the "Grace" wristband, both scored highly, the main difference being that "Grace" works on biofeedback technology. "Grace" through their website does not state what biofeedback technology is used, although assumptions can be made due to the page suggesting that the device is triggered at the onset of a hot flush. As found in the menopause section of this literature review, heart rate and finger blood flow increase before the onset of a hot flush. If the "Grace" wristband used either of those methods to track a hot flush, the cooling should occur prior to the hot flush and, therefore, not at the onset. The San Diego University wrist cooling band is a fascinating design that uses flexible technologies. Flexible batteries and Peltier plates are not yet readily available to the mainstream manufacturing sector. Again, as the design is a prototype, it is not easy to assess actual products. The San Diego University's band, the Embr Wave and the sports



wrist cooling band from Pune are all backed through research. This validation gives hope that the wrist is an excellent place for biofeedback because it is a pulse point close to veins. The Embr Wave itself is the only intelligent technology watch found that is readily available on the market currently. The watch does not offer biofeedback, although it can offer the user to set their preferred temperature throughout the day. Like the other body areas that have been reviewed with existing products, the wrist also has many cheap products that use frozen water to cool. These are an excellent idea for initial relief, but they have lower longevity, along with comfortability due to the initial coldness from being straight from the freezer. From a design standpoint, the aesthetics of the "Grace" wristband and the Embr Wave are both pleasing. The colours chosen could be said to be more female-orientated. The use of rose golds and silvers has long been associated with women's accessories and is still fashionable today.

#### 4.7.8 Differing Cooling Wearables Considered

The market offers many other variables to cool the body. Clothing is a critical method that existing products have explored. Table 9 shows the variable cooling wearables for other body parts.

1. Sony Reon Pocket (Engadget, 2022)	2. Tajima Seiryō Jacket Cooling System (Ponce, 2022)	3. Refrigerated T-Shirt (Crunch Wear, 2022)
		

Table 9 Differing Cooling Wearables

##### 4.7.8.1 Differing cooling wearables conclusion

The products found within the differing cooling wearables found a large sum of products. Products found were generally other clip-on fans, such as the Tajima Seiryō Jacket Cooling System. The Tajima Seiryō Jacket Cooling System is aesthetically unpleasant due to its protruding nature. Devices designed as wearables should be sleek and trim so, therefore, unnoticed to avoid stigmas. Stigma is essential when considering menopausal women; women often feel ashamed of their conditions, so subtle design is often needed. The Sony Reon Pocket is a small air conditioning device designed in Japan for the 2020 Olympic games. The technology differs from many other items because it uses a fan for cooling, whereas other ideas have used Peltier plates or water flow. The third design in this list uses water flow and is the same as refrigerators. The design is personally aesthetically displeasing, which could lead to a lower target audience. The design is similar to those found within the head cooling wearable review where water flow is needed for cooling. When considering wearables, this has less viability for menopausal women. This is largely down to that fact that women need to wear light clothing and accessories during this period to adjust to their environmental temperatures (Baram et al., 2005). In addition, the design does not avoid

stigmatisation for menopausal women as the design clearly shows the tubing that allows water flow. The fluid tubes also usually protrude and therefore are unpleasant to look at and hazardous as they could catch on items in the external environment. The design could be made viable if stigmatisation was removed, where the tubing was hidden. Also, if an alternative method was ideated, which used a lighter cooling method instead of water, may create a valid concept.

All wearables need to consider material choices for the user. A WGSN (Worth Global Style Network) report found that design against the challenges of plus-size, modest wear, pregnancy, menopause, and older age can be enhanced with fibre innovated garments (WGSN, 2021). They state that designs such as ‘Thigh Society’, ‘Adidas Terrex’ and ‘Elastique Athletics’ using moisture-wicking, soft and light fabrics such as ‘MicroPerle’ would make women more comfortable through their life experiences. Therefore, materials are essential to the user as they can improve experiences with a product. In this instance, a remarkable moisture-wicking material for menopausal women should be considered for the design and development phases.

#### 4.8 Design Requirements

A series of design criteria have evolved into the design phases of this prototype design chapter for a wearable biofeedback device, to which the designer returned multiple times due to the iterative nature of the design process. A list of needs based on several variables can be created.

Partheniadis & Stavrakis (2018) define a set of requirements that can be used to assess the user, activities, context, and system/technologies. These requirements allow all individuals within the research to input separately and evaluate which needs are more important from the final concept. As a result, the researcher concluded that it is critical to comprehend the viewpoints of involved parties for the device's design and use, including both the designer and the user.

Throughout this thesis, it has become apparent that the designer can develop a new and improved design alternative. Co-creation can be implemented in all design stages. The designer interacts with

the user to improve the overall outcome of the research. Thus, table 10 a compiled listing of the factors and features considered when designing and later evaluating the design. This research method is valuable to the designer as it allows the user to state which factors are most valuable to them. The items listed in table 10 are gathered from previous findings within this thesis.

Wearability was seen as a key factor, as this research is designing a wearable. The placement of the wearable therefore is an important factor when assessing how to measure biofeedback, found within section 2.2.4. Comfort has been referred to throughout this thesis in many areas, from sexual comfort, heat comfort, oral comfort, and environmental comfort. Comfort is a crucial factor in the design and development of a biofeedback wearable, previously used in sections 4.6.2.2 and 5.2 as scale factors to assess both temperature and current marketed products.

All wearables should consider anthropometrics of the user group as the device is going to be worn by that whole group. Design commonly states the use of anthropometric characteristics for ergonomic design (Wang et al., 2019; Fajobi et al., 2016). The space requirements that certain placements on the body require would mean this would be a key factor for this research as designing for biofeedback using pulse points can limit the design of this wearable.

This thesis has defined perspiration as a common sign of menopausal hot flushes and night sweats.

The designed device therefore should consider hygiene and cleanliness of high importance.

Previous research states the importance of, not only hygiene and cleanliness as important factors, but also user safety (Stein et al., 1998). Safety should also offer the user security as a key factor as a design requirement; this was summarised in sections 2.2.3 and 2.2.4.3.

Section 2.2.8.2 stated the importance of aesthetics and usability for user interactions. In section 2.2.3 the magnitude of stigmatisation due to menopause was found, and therefore is a key factor within the design and development of a wearable. This is directly linked to social acceptance as the design of a wearable would have to blend into society to avoid stigmatisation. Therefore,

personalisation and customisation of a wearable are design factors that are implemented at this stage. Women can also personalise and customise their own journeys as this was seen as a crucial part of a woman's experience that was currently lacking, when collaborating in the brainstorming session in section 4.3.

The wearable should consider factors such as physical exertion intervention, as found in section 2.2.3 exercise is a factor that could increase the likelihood of menopausal symptoms occurring but is also necessary alongside a healthy diet. Therefore, a wearable that was capable of functioning under these extremities is a key factor.

The most important factor to be considered for this thesis is the wellbeing of menopausal women. Section 2.2.3 specifically correlates the menopausal journey to having a lower wellbeing. Wellness persuasion falls under the umbrella of wellbeing, as a key design factor is to promote wellness, which would in turn improve wellbeing. From section 1.6, wellbeing was defined, and wellness was categorised under the emotional side of wellbeing.

Learnability has been referred to throughout the thesis in many ways. Chapter 1 states women are finding out about their own bodies and journeys. In turn learning and developing techniques. This can then be given to a younger generation, so they are informed about menopause from an early age. In addition, from chapter 3, Design Thinking, Information Design and Agile methods have found to be user experience focused where learnability of new designs is of high importance.

Throughout section 2.2 the research validates the necessity for a new wearable to work through both the day and night as vasomotor symptoms can occur through any time within this period. In addition, section 2.2.8.2.2 stated the necessity of function and performance, making these key factors for design and development of a product for improved UX. For the performance to be unaffected potential faults and shortcomings should be defined as a key factor within the design and development of a biofeedback wearable when concluding testing.

Performance also questions the lifetime of a wearable device. As found within the product evaluation, not only the life expectancy of the product should be considered but how it is powered and how long each charge would last between power inputs, where a vast selection of current designs have not considered this aspect. Women are therefore reliant on a wearable to provide biofeedback though both the day and night as these are not only issues found with current products from section 5.2, but also the main symptoms of menopause from section 2.2.2 are known to be common through both the day and night, lasting throughout this experience and can even be chronic for the rest of a woman's life.

The cost of the device and the cost of maintenance can be compared directly to that of medicinal treatments and existing products. This is a key factor as a design requirement to keep costs to a minimum. Medicated treatments such as HRT are known to be costly, only this year the government have decided to reduce costs to roughly £20 a year for around 400,000 women in the UK (Department of Health and Social Care et al., 2023). Even though HRT is becoming more financially viable, women are seeking therapeutic alternatives at a reasonable price, as found from the results and outcomes of the focus group.

As it became apparent through section 2.1.2, the scalability of the product became a prominent design factor. The MHRA was defined as a key aspect to defining whether the product designed would be either medical or therapeutic. The section outlined what can be set as constraints to ensure the design is categorised as therapeutic rather than medical. In addition, the users would need to see monitoring data for biofeedback to work in a full cycle. The data should be able to be analysed by the device and the user through visual graphics. This in turn should make the user more knowledgeable about their own journeys and give women a greater understanding about what their bodies are doing during this period as found throughout chapter 4.

As discussed in section 4.6.1.4.5, a Likert weighing scale was used to assess these requirements from '1 being least important and '5 being most important. The average of the designer and the user can then be used to input these features into the final design and development stages.

#### 4.8.1 Design decisions

A design can be improved when considering a structured set of features essential to the user. Functionality and aesthetics gain increased interest when based upon twenty-two user requirements, where biosensors that add to people's quality of life ought to be slight, ergonomic, robust, and aesthetically pleasing to use (Rantakari et al., 2016). These factors make the design criteria for the developed wearable's physical product must include unobtrusive design and interactions, gracefulness, minimalist visuals, robustness, and water resistance (Motti & Caine, 2014). Intuitive physical interactions highlighted the tactile and embodied interactions merging with the mobile application's graphical user interfaces (UIs). The system should provide interactive design, UX, and continuous and non-intrusive tailoring to the user's regular lives. This technology must be content-appropriate and capable of keeping users up to date with their journeys through this colossal stage of their lives. Biofeedback designs should be minimally invasive for therapeutic technologies, used by users for sociable interactions that offer comfortability for the user's body and well-being.

Feature	Constraint	Designer	User	mean	Description
F1	Wearability	5	5	5	Both think wearability is vital as the device will be a worn by the user.
F2	Placement on body	4	2	3	The user felt less inclined to be specific about where on the body would be the best placement for this device. The designer thinks this is crucial as particular points on the

					body are better for cooling than others.
F3	Comfortability	4	5	4.5	Both think that comfortability is a priority as the device will be constantly worn.
F4	Anthropometry	5	4	4.5	The designer needs size data as the design must fit a large percentile.  The user also wants a well-fitted wearable.
F5	Hygiene	5	4	4.5	Both feel hygiene is crucial as the device will be worn all the time.
F6	Safety	5	5	5	Safety is critical as a therapeutic device should offer this as a minimum.
F7	Aesthetics	4	4	4	Both are intrigued by the device's design but feel function takes priority as they want a device that works for them.
F8	Stigmatisation	5	4	4.5	The designer strongly desires not to give the user a stigma with the design. Therefore design is considered vital as it must look like a standard wearable to blend in with society.



F9	Social acceptance	5	4	4.5	Like social acceptance, the user did not have a strong affiliation with this as the designer.
F10	Physical exertion intervention	5	4	4.5	The designer wanted to tackle this problem as the body is likely to achieve high temperatures and excessive blood flow during this period and hopes the design with also cater for physical exertion.
F11	Wellbeing	5	5	5	Both want the woman's well-being to improve through design.
F12	Usability	5	5	5	Both feel usability is essential due to the ease at which a user can interact with the device.
F13	Learnability	4	5	4.5	Current menopausal women are at an age where some use technology and others are technophobes. Both the designer and the users felt that learnability is essential, though as a designer, it is felt that only a certain amount of learnability can be offered.
F14	Application during sleep	5	5	5	The device must work during sleep and must be worn day and night.

F15	Application during the day	5	5	5	Like above, the device had to work 24/7 to offer relief to menopausal women who seek it.
F16	Customisation	3	3	3	Customisation is possible but could be a future development if the project is taken further with investment.
F17	Personalisation	3	3	3	Like above, personalisation could be offered at a later stage; the women could choose to personalise the device themselves if the integrity of the design remains intact.
F18	Wellness persuasion	5	4	4.5	As the designer, it would be ideal if the device improved well-being as specific symptoms of menopause can be alleviated.
F19	Security	5	4	4.5	The women need to feel safe whilst using the product. The product should not harm or injure any users.
F20	Performance	5	5	5	The product needs to do what it is designed to do. The performance needs to be constantly high for the duration of its life.
F21	Life expectancy	5	5	5	The product's life expectancy should be longer than the 1-year warranty

					usually offered for wearable technologies.
F22	Space requirements	5	5	5	The device is wearable and, therefore, should not be too bulky for the user to wear.
F23	Reliability	5	5	5	The product must be reliable as the user needs to have the device work for their well-being.
F24	Fault tolerability	4	5	4.5	Faults should not be tolerated. However, it is difficult to envisage faults at the concept stage.
F25	Cost	3	4	3.5	The cost of the device should be competitive with other devices of a similar nature.
F26	Cost of maintenance	3	4	3.5	Maintenance should be low in price, with the user mainly controlling the maintenance.
F27	Scalability	4	3	3.5	The project has a large scale currently but has the potential to be massive with the correct investment.
F28	Monitoring	5	4	4.5	The developed application (web designer co-creation) will allow the user to monitor the use of the device.
F29	Data analysis	4	4	4	Analysis should allow users to see their own bodies biofeedback data.

F30	Data visuals	4	4	4	The visuals should be aesthetically pleasing, allowing the user to analyse the data themselves to identify what their bodies are doing.
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*Table 10 Design Requirements for Co-creation*

#### 4.8.2 Technical Requirements

Biofeedback devices generally need small components that can acquire data and respond quickly to give the device an output request, thus providing feedback for the user. Data analysis provides a chance for the user to self-assess their level of wellbeing as the biofeedback device would let them know what their own body is doing.

Other factors, such as the longevity of batteries and charging capabilities, can be assessed, but most importantly is the communication between the designed device and the application. The aiding application should therefore offer constant feedback along with the biofeedback wearable so that the user can track and monitor their journey. The severity and frequency of hot flushes will be monitored, and the user can assess when the biofeedback device is enabled.

Industrial technical requirements mean usability and ergonomic should aim to seamlessly evolve into a part of a woman's everyday life without affecting their current lives negatively, meaning a higher UX value can be attained. In addition to technical requirements for industry standards, the biofeedback device and application design should look to improve a woman's life on a social level. The application would need to offer women the chance to meet others in a similar scenario to themselves. Furthermore, finally, but most importantly, the design must improve a woman's wellbeing to promote an improved quality of life.

#### 4.8.3 Industrial Design, Electronic Components and Sensors

The industrial design phase of this project is essential since it focuses on satisfying a set of design needs regarding the physical device's form, appearance, usability, technological standards, and limits. Stigma can be avoided if the user-centred inclusive design is adopted (Bichard et al., 2007). Medical and therapeutic devices worn daily usually involve stigma as the user can be socially discriminated against (Farrington, 2016; Vaes et al., 2016). The design should therefore improve the user's confidence while lowering the stigma surrounding their lives as the user would feel improved self-worth.

The physical model's design should be synonymous with other wearables that a menopausal woman may wear. The device must be large enough to fit a heart rate sensor, a Lithium Ion (Li-ion) battery, RGB LED and a Peltier plate. Table 11 shows how these components are used within the wearable and what job they have within the device's design.

Input/output	Part type	Identification	Job
Input	Heart Rate Sensor	HRS	Monitors the user's heart rate temperature to assess atypical results
Input	Docking Station	DOC	To charge one device while the other is in use, for constant feedback
Input and Output	Lithium Ion (Li-ion) battery	BAT	Approximately two days of battery life, depending on the severity of vasomotor symptoms
Output	RGB LED	LED	Users can see the device monitoring their heart rate
Output	Peltier Plate	PEL	To trigger at the onset of a hot flush or when heart rate is deemed atypical

*Table 11 Components*

#### 4.8.4 Mobile Application and UX Design

The design of the accompanying mobile application should be implemented for ease of use, eliminating current user-interface problems facing menopausal women. The application's scope can be deemed limited as outputs are generally already known through primary research. Due to the project's scope, the design process can be streamlined by focusing on specific user-interface issues

that can be addressed using ideation methods surrounding storyboarding (Holtzblatt, 2005).

Therefore, storyboarding should be introduced to design a fully functioning application.

In addition, research states the positives of co-creation for increased UX Design. She writes that designing with the user is always for the user (Kohler et al., 2011). When considering research that does not involve co-creation, it can be considered less valuable (Grönroos et al, 2011). With these considerations, it is imperative that storyboarding is considered for the mobile application design.

UX Design needs to be considered an asset to the research due to the co-creation aspect, where a design should be developed that is designed with the user and for the user.

## Chapter 5 - Adapted ID-Agile Development for Product Design: Prototype Design Stage



## 5.1 The Early Envisioning Phase

### 5.1.1 The Early Envisioning Phase – Initial Concept Development

#### 5.1.1.1 The Early Envisioning Phase Analysis – Initial Concept Development

The initial design phase identifies solutions to critical problems within the user research in previous chapters. The menopausal symptoms in which users were found to have the highest commonality were hot flushes, sleep problems and insomnia, night sweats & memory problems. The initial concept development, therefore, involves initial sketch concept ideation.

Designers know there is a difference between drawing and designing an object through drawing. Many art features will draw objects, and designers will often create the objects drawn, hence the differentiation. Therefore, the designer seeks to develop an idea that will have only previously been thought of or partially imagined (Tovey et al., 2003). Design has always had a strong relationship drawing, with comprehensive summaries of previous research regarding the importance of drawing for design collated (Purcell & Gero, 1998). For new product development, previous research has found that not having a basic understanding of visual design representations can affect collaboration for designers (Pei et al., 2011). Therefore, a designer needs sketching to innovate for concept creation.

Sketching can depend on the stage of the design process. Usually, in the early stages of a design process, sketch-work would tend to have fewer limits with creativity provoked. Sketches throughout a design process are thought to be what designers focus on due to the innovative nature of this design work (Purcell & Gero, 1998). Therefore, this initial design and development stage needs sketching to promote free-flowing creativity as the designer would already have many ideas at this stage, gathered from research collected to this stage.

### 5.1.1.2 The Early Envisioning Phase Design – Initial Concept Development

When designing solutions for these areas, many solutions have already been ideated through brainstorming, with some components assessed within the pilot testing. As found within the literature review, it is known that heart rate and finger blood flow are triggered and rise prior to a hot flush. Therefore, it is vital to design a wearable that can be worn on pulse points, to monitor blood flow (BF) and heart rate (HR). Several pulse points on the human body could be used to monitor BF and HR. Even though there are many pulses points, the main pulse points for monitoring BF and HR are the carotid, brachial, radial, femoral, posterior tibial and dorsal pedal (Lowry & Ashelford, 2015). Ergonomic design can be helpful in this situation as designs can be modular and flexible to work on many pulse points. Cooling on these pulse points has also been found to lower body temperature and the BF and HR faster, as shown in the literature review. Therefore, forehead cooling is also necessary for this design as it has definitive research finding that sleep-onset is helped whilst awakenings are lowered. A total of five initial concepts were created from the information gathered. The concepts are designed to solve certain aspects of many aspects and be flexible to wear across many different pulse points. The design influences are based on the research from WGSN, a leading trend forecasting company, as the design will be current and hopefully long-lasting.



Figure 27 Initial Concept Designs (Authors Own, 2022)

The concepts were then cross-examined with menopausal women to gain valuable feedback on which parts of the designs are best for a solution to the problems they face; this was achieved in a session that was combined with the latter form of the development phase. Figure 27 illustrates the concepts created by the designer. Concept one was designed to have a replaceable battery for daily use. The idea from a design standpoint means the device can only be wrist or ankle due to the anthropometric style and shape. The battery is worn on the top of the wrist as a style point as it can be seen clearly, like usual wrist wear. The design is therefore flawed somewhat in the sense that the

design cannot be modular and can only be worn as a wrist wearable. This design style limits the possibilities for much further scope as the cooling needs to be on the radial pulse.

Concept two is like concept one in many ways. The module is worn on the radial side of the wrist with both BF and HR monitored, providing biofeedback within the same module to output cooling to a Peltier plate. The design uses a geometric pattern on the front surface, allowing air to escape, and eliminating any overheating; geometric patterns are a future trend (Watkins et al., 2021).

Concept three is again like the other concepts, this time in the sense of how it functions. The design uses the same mechanics; BF and HR are monitored, and biofeedback is taking place like concept two. The main difference with this concept is the flexibility of where the user could wear the product. The design is modular, this not only makes the product easier to charge and interchange for all-day use, but it also means the device can be worn in differing places for the discretion of the user. Modular design is an upcoming trend which could lead to the aesthetical personalisation of the device (Baidoo, 2022). This design has been designed to work with a wrist wearable and a combined necktie and bandana. The necktie and bandana are an ideal clothing choice with this design due to the ergonomic and anthropometric advantages and flexibility around size changeability.

Concept four differs from the previous concept ideations, as the design has two separate components. The device has a flexible wraparound wrist strap for ergonomic differentiality. The accompanying ring is worn as the literature review found hard evidence for finger blood flow to rise prior to the onset of a hot flush. The two components are Bluetooth connected, and when BF and HR increase triggers the ring, the wrist device will begin cooling in the same methods as previous concepts. The concept also thinks about potential branding, as the vertical lines on the device have a function and a purpose. One is used as a power button; the other flashes with the user's heartbeat, so they are aware of the heartbeat without looking at an accompanying application. In addition, the branding could lead to using 'Meno' as the name of the device, which means less in Italian, and then

the two vertical lines 'II' meaning pause but also having a purpose. The final concept created, number five, is not dissimilar from concept four. The design is more rigid than the previous one, based on a snap band. Designed to curve around any woman's arm, wrist, or ankle, it can also fit around any size ergonomically due to its flexibility. This time the indicator is designed to pulse when cooling occurs, so the woman is aware of when the device is working to be reassured.

### 5.1.1.3 The Early Envisioning Phase Evaluation – Initial Concept Development

#### 5.1.1.3.1 Method

This phase was conducted and co-created with menopausal women to use the think-aloud protocol (TAP) inspection method. The TAP method is used within usability feedback for concepts when users are immersed in a task. The method introduced by Lewis (1982) reveals aspects of the design that might be unsuitable to the target user due to constraints such as confusion and frustration. The feedback from users is gathered and evaluated against the design decision constraints that scored an average of 4.5 and, out of the five available, were chosen as essential features related to the product whilst covering two-thirds of the overall feature points. These outcomes are then implemented into the form development phase, designing through an iterative development process.

It is known that for research using TAP, a group of 5 participants is the perfect amount for feedback (Nielsen & Landauer, 1993). The same participants were selected from the focus group. Therefore, participants were familiar with the research and had already inputted the research up to this stage. The research was conducted via Zoom, where participants used their phones and laptops in their homes due to Covid-19.

### 5.1.1.3.2 Results

Feature	Constraint	Design 1 outcome	Design 2 outcome	Design 3 outcome	Design 4 outcome	Design 5 outcome
F1	Wearability	A simple design that appeals to all as it is not offensive. An adjustable strap could improve comfort to improve wearability.	The design is simple, and a particular device looks neat.	With a replaceable module, the device can be placed into multiple straps making it even more wearable as it could be worn in different places.	Participants felt the design would be nice to wear as it would look like an intelligent device for fitness.	Like design 4, the design would be nice to wear as it would look like an intelligent device for fitness.
F3	Comfortability	Lightweight module, the strap is a breathable material.	The breathable stretch fabric would be comfortable	The straps would be comfortable due to soft, stretch, and	The design could be too tight and can hinder circulation.	The rigid design could be too stiff and cause the user pain,

			and increase wearability.	breathable fabric.		hindering circulation.
F4	Anthropometry	The adjustable strap allows for users of all sizes; only the pulse point and battery would also need to be adjustable for placement.	The design fits like most adjustable watches, with all parts in one module.	With the device being modular, the device is ideal for wearing all over the body as accompanying adjustable straps would also be provided with the device.	With magnets keeping the device closed, it can be adjusted. The accompanying ring would have to be available in multiple sizes. Participants also stated they would be less likely to wear a ring.	The strap could fit around most users' wrists.

F5	Hygiene	All parts can be cleaned, with the material of the strap breathable; this allows for more ventilation.	The device would be more brutal to keep clean as the device is all in one.	The device is very hygienic as straps could be washed separately as they have no electrics.	The device can always be cleaned with a metal finish and is more likely to stay clean. The ring could also be hard to take on and off.	The metal finish would make cleaning easy.
F6	Safety	Wristwear could be taken off quickly; also, due to the simple design, other civilians would not know what the designs	Velcro is easy to attach and detach. Participants thought the device would also blend into society.	The device could be easier to lose due to multiple ways to wear the device, but if the user cannot wear a device in a particular area, this	The device is easy to take off if needed as it would only be clasped together by magnetisati on.	The wristband could be easily removed, although it could be hard for some users due to its rigidity.



		intended to use.		could improve safety.		
F8	Stigmatisation	Due to the simple design, it looks like casual wristwear.	The design looks like most wearables, though it could look sleeker to blend in.	A small modular unit could be placed on the body, hidden, or shown.	The ring would more likely be a talking point and, therefore, less likely to wear.	The stylish device would not look out of place on the participant's wrists.
F9	Social acceptance	It is blending into society with its plain design and colourway.	The design could be shaped differently to not be as significant depending on the space for the technology.	The device looks small and natural; the device blending into wear makes it more acceptable.	The ring is less acceptable as it must be worn because it would always be on show.	The design would not look on most societal members' wrists.

F10	Physical exertion intervention	The device would aid through exercise as it would cool when the heart rate increases.	The device would aid through exercise as it would cool when the heart rate increases.	The device would aid through exercise as it would cool when the heart rate increases.	The device would aid through exercise as it would cool when the heart rate increases.	The device would aid through exercise as it would cool when the heart rate increases.
F11	Well-being	To cool at the onset of a hot flush, the device would be thought to improve aspects of well-being.	Well-being could be improved due to hot flush onset cooling.	With the device being modular, it can be worn in any situation, offering full-time support.	The device is set to cool at the onset of a hot flush, which is thought to improve well-being.	Alleviation of a hot flush could improve well-being.
F12	Usability	No user interface means the user is less able to see	Power levels could be seen on the user interface.	Interchangeable modules mean the device can	The device relies on having both the ring and the wrist	The device relies on having both the ring and the wrist

		what the device is doing than being worn.	However, it cannot be worn all the time due to the device being one part.	be worn all day and on different body parts at different times.	wearable; the number of components makes this device less usable.	wearable; the number of components makes this device less usable.
F13	Learnability	The battery charging system is easy to use but needs an accompanying application to monitor battery levels and data feedback.	The device does not require too much learning as the device is one piece and offers biofeedback.	The device could be learnt quickly through diagrams and a user manual. The user could also modify the wearability to be worn in other places at the user's discretion.	The Bluetooth connection between the ring and the wrist wearable could have issues, and the generation of menopausal women could be technologically lacking.	The device attaches to the user's wrist and instantly offers to cool. Limited learning would be needed.

F14	Application during sleep	The device, due to battery charging and offering two batteries, means the participants could wear the item 24/7.	The device may not be able to be used during sleep as the whole device would need to charge. It could be charged whilst being worn, but that could be dangerous.	The device can be worn all over the body, including the forehead, to improve sleep; the device has multiple modules to charge one at night whilst the other is in use.	The device can be worn at night, though it would need charging at some point.	The device can be worn at night, though it would need charging at some point.
F15	Application during the day	The device, due to battery charging and offering two batteries, means the	The device may not be able to be used during the day as the whole device would need	One device can charge during the day whilst the other can be working.	The device can be worn during the day, though it would need	The device can be worn during the day, though it would need

		participants could wear the item 24/7.	to charge. It could be charged whilst being worn, but that could be dangerous.		charging at some point.	charging at some point.
F18	Wellness persuasion	Participants thought the device would promote wellness due to the alleviation of vasomotor symptoms.	The device offers constant cooling for hot flushes, which could improve wellness.	With improved sleep, this device could offer further support than other concepts.	Participants thought the device would be less likely to promote wellness due to decreased willingness to wear a ring.	The device should promote wellness due to the alleviation of vasomotor symptoms.
F19	Security	The device offers a constant cycle of	The device is secure as the device is all one and	The module could be easily lost as it is	The device is more likely to be lost because	Participants thought the device could

		cooling when the user requires it. The battery could be easier to use as it comes from the other parts.	can be tightly fastened.	modular and not as secure as other designs.	the security relies on magnets.	escape the user easier than other secure methods.
F20	Performance	The device always offers power cooling at the onset of a hot flush would improve well-being.	The device might not be able to be worn all day and night due to charging. It could be worn and charged simultaneously, but that could be unsafe.	The device has a higher performance quality due to its adaptable modular system can be placed in multiple locations.	The performance could be hindered due to Bluetooth issues between the wristband, ruing and then supporting the application.	The device should perform well, as it is all one part.

F21	Life expectancy	The product's life expectancy would be higher due to an external battery that can replace the battery when needed.	The life expectancy should be higher, though if there are any issues, they could be harder to fix due to the product's configuration. It also may not be able to be worn all day and night due to charging issues.	Parts could be replaceable, but as all parts are electrical, this could offer performance issues. Also, the devices require a Bluetooth connection, which could fail.	Parts could be replaceable, but as all parts are electrical this could offer performance issues. Also, the devices require a Bluetooth connection between themselves, which could fail.	The design would have a high life expectancy depending on if internal components could be malleable to go around the user's wrist, as constant use could strain the metal.
F22	Space requirements	The device is slimline and sleek but is more	The device could be smaller to be less	Participants thought space is optimally	The design is small as the ring takes half of	The design could have problems bending

		shapely and smaller.	intrusive. All parts included in one part offer space saving as only one side of the wrist would be covered at one time.	used through this design as the module can be moved to accommodate other items and make space.	the software away from the cooling wrist wearable, but overall, it uses more space due to the design being in multiple places.	around the user's wrist as the design would have some rigid parts.
F23	Reliability	Interchangeable batteries could improve reliability; if one failed, it could be replaced. The reliability would be	The device would be reliable like other designs, but it might not be able to offer reliability all the time due to	The device is as reliable as other designs, as they all use the same technology, but if this module faults, the module alone could be replaced,	The Bluetooth connection could be unreliable for the user, as during a hot flush, the connection could be lost, and therefore no	The device is more likely to break through stress in the metal. However, the reliability of the technology would be



		like the other concepts as they all have the same technology.	charging issues.	or if another part breaks, it could also be easily replaced.	support would be offered.	good, like the other designs.
F24	Fault tolerability	Tolerance is limited, but if batteries fail, they can be removed and swapped.	The device could be opened easily to repair parts, but if it needed to be replaced, the whole wearable would need to be replaced.	If there is a fault, the part could be changed or repaired. Other parts that have not failed can remain where costs to replace a single part would be lower.	A fault could be harder to detect due to multiple electronic parts, but those distinct parts could be replaced. Due to the design, the parts would be less likely to be	The design would make the device hard to repair. The device would be redundant if there were a stress fracture in the metal through use.

					repaired, however.	
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*Table 12 Initial Concept Development Critical Review*

### 5.1.1.3.3 Conclusion

This test concluded that certain features are necessary to ideate a final concept development. Firstly, it was deemed necessary for stigma and social acceptance to be appropriately designed. This was made possible with a modular design of the third initial concept. Due to the design being able to be worn in multiple places, and through discussion, it occurred that if two modules are provided, it could offer twice as much effect as other methods. In addition, participants felt a modular device would be suitable for more of the user demographic as the user could then choose where they feel the device works best for themselves. Secondly, designs 1 and 3 were highlighted as exceptional for performance, night and day usage, reliability, and fault tolerability. This occurred as both either a removable battery or modular units. Therefore, whilst the battery or one of the devices is charging, the other can be in use. Other designs seemed dangerous in comparison as the participants felt wires could be a hindrance and even dangerous whilst sleeping.

In addition, the user interface was an important factor for participants. It was concluded that users would have a higher chance of understanding usability if crucial features such as cooling, and power usage were shown on the wearable interface. Therefore, designs 4 and 5 had ideal user interfaces for users. Also, designs 4 and 5 offered the user a sleeker design that would improve wearability. The designs that more closely resembled either jewellery or other smart wearables were thought to be more appropriately designed for inclusivity for all users. The user interface needs further consideration, as the participants thought the design needed to show power usage and cooling levels as a minimum. The primary thought process behind these features to be involved

within the user interface is that if a user is less technologically advanced, they may struggle to use and access an application to monitor what the device may be doing at certain times.

In addition, participants felt security was related to anthropometry as the user would require an adaptable strap as users can be of all sizes. Specific designs that would not be applicable for further development, such as magnetic fasteners and snap bands, would be more likely to get lost than other designs surrounding a user's wrist and other body parts. The device's performance was essential to participants as they wanted constant relief from symptoms, as vasomotor symptoms can be triggered at any time during the day or night. As all initial concepts would involve the same components but in differing configurations, the actual performance would be high in all concepts. However, it would be higher in designs with fewer separate electrical components. Life expectancy is of priority to the users, not only long-term life but short-term life also. The device needs to work consistently throughout its life. Participants thought designs where individual components could be replaced, if necessary, for example, design 1 and 3, would be easier to replace or repair and be cost-effective to the manufacturer and user. In addition, if the design had defined parts, faults could be detected better than if the design was one whole item.

#### 5.1.1.4 Recommendations for Future Design Phases

The final concept needs to include certain features within this testing phase. Firstly, wearability needs to consider current wearables. Social acceptance is less likely to become an issue if designed to blend in with society. Keeping the design simple with a current colour trend that can stand the test of time, the final concept should be socially relevant. In addition, if the design were minimalist, there would be lower stigmatisation around the wearable. The device needs to be comfortable, so the user wants to wear the device. This includes all the wearable parts, where a breathable material is necessary for a strap, as the user is still likely to sweat due to vasomotor symptoms. This would also be advantageous for hygiene; due to the user's skin being able to breathe, the device would become less unclean due to excess sweat. The device also needs to be easy to clean, as hygiene is important for participants. Alongside breathable materials, if the device were modular, it would be easier to clean all the applicable parts as the 'accessories' could be washed thoroughly compared to if the device were one.

Participants also found that physical exertion intervention would be helped through a wearable design as the device activates due to an increase in heart rate. This, in turn, could improve the well-being of users, targeting the most common symptom amongst menopausal women. In addition, the device must work through the daytime and at night. A twenty-four-hour cycle is needed from a device; this was found only to be possible safely if the battery was removable or if two or more modules were available to the user. Alongside improved performance, if there were a fault found with the device, fixing a modular system, whether that be the battery or the whole device, would be easier to repair or replace whilst being cost-effective.

## 5.1.2 The Early Envisioning Phase – Form Development

### 5.1.2.1 The Early Envisioning Phase Analysis - Form Development

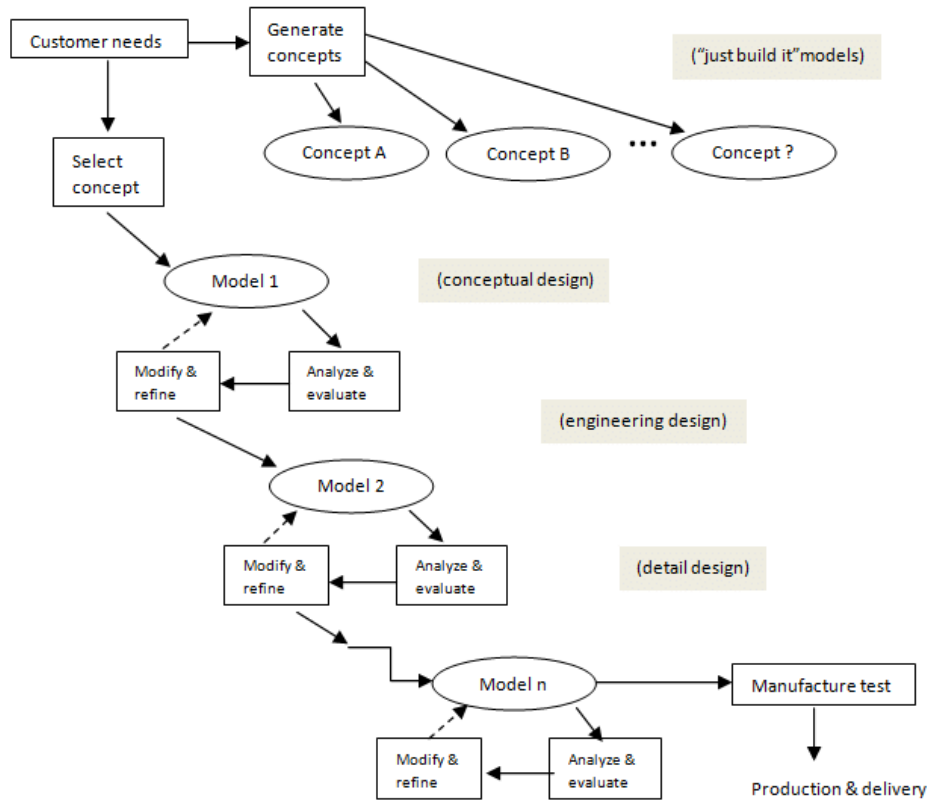
The constraints measured are usually incomparable during the evaluation process of most wearable health technology concepts (Keogh et al., 2021; Vijayan et al., 2021). The factors on which evaluations can be based are usually user, activity and context related. The differing stages of prototype development discussed throughout this chapter often add to the complexity of evaluation. Due to this complexity, a tiered evaluation assessment methodology has been utilised in line with the system design lifecycle (Ling-Chin et al., 2016). The reasons behind this methodology usage are to be co-creative with users whilst finding a solution that works for them. The research experimentally evaluates the benefits of biofeedback technology for menopausal women. The research aims to use biofeedback to cool the body before the onset of a hot flush. To evaluate the software's development to assess the prototype's overall design to achieve the research aims.

Multiple evaluation sessions have been conducted during the design and development of the final prototype. The iterative nature of the methodology used throughout is also used to design the final concept. In addition to identifying and addressing issues found within the design and development of a concept, the overall user experience is evaluated simultaneously. Differing prototypes for the final concept have been ideated and cross-examined during the following stages.

### 5.1.2.2 The Early Envisioning Phase Design – Form Development

Form development often occurs at the start of the design and development of a product. Design iterations can be used for modelling and sketching. It is different from other types of development as the designer can continue redesigning the same problem. The designer is in a loop compared to the straightforward nature of other processes (Gevers, 2000;). The iterative development process is useful when working with an Agile based NPD process (Bergs et al., 2021). The number of cycles at the start of the design process is unknown due to the uncertainties of Product Design. A designer

should realise how to use iterations to get the best out of their work (Interaction Design Foundation, 2018).



*Figure 28 Model Iteration Stages for Prototype Development (Chermahini et al., 2014)*

Prototyping is a valuable stage for Product Design and Software Development. During this design phase, physical modelling from sketch ideation is created to evolve the form of the model to gain feedback on the form from the users. As stated through the methodology, an iterative process is required at all stages to gain the best outcomes for this research. Stoll (1999) outline the importance of model making for design. In addition, research has now used the iterative prototyping methods for Product Design development (Chermahini et al., 2014) with the new product development of Product Design. Figure 28 shows the stages of form development to achieve a successful outcome from an iterative process. The following section shows the form development modelling stages to decide of size and shape of a final concept. The customer needs are already known in section 5.1.3. In addition, concepts have already been devised through the pilot testing found within the chapter 4 where virtual reality and temperature testing were assessed. The chosen concept to be taken into

final development is a wearable to measure blood flow and react to a hot flush before the onset of these symptoms. As this concept has been chosen for further development, the second part of the prototype modelling model can be used to aid development. This process has made several models to gain knowledge of form and wearability.

### 5.1.2.3 The Early Envisioning Phase Evaluation – Form Development

#### 5.1.2.3.1 Method

This phase was conducted and co-created with menopausal women to use the inspection method, think-aloud protocol (TAP), for foam modelling, as mentioned in section 5.4.1.3.1. The same women were involved in this phase, which took place directly after the previous initial concept phase. The TAP method is used within usability feedback for concepts when users are immersed in a task. In this case, the participants are shown images on a screen/ or watching a live video of the researcher. The feedback from users is gathered and evaluated against the design decision constraints. Only features that their form can assess can be used in this phase. Therefore, it was decided by the group that only seven feature points would be of use when testing from development as most features cannot be tested through foam modelling. Meaning testing focuses on the user interface, size, design placement, comfort, and social acceptance. Through the modelling stages, conclusions will be made from the outcomes of participant feedback. Recommendations will then be made to find a solution to the conclusions made. If a recommendation is a correct solution to the conclusion, the next iteration will not assess that feature point in the next phase.

### 5.1.2.3.2 Results

#### Model 1



*Figure 29 Model 1 (Authors Own, 2022)*

Feature	Constraint	Conclusions	Recommendations
F1	Wearability	<ul style="list-style-type: none"> <li>• The design has a large depth.</li> <li>• Edges are overly sharp.</li> </ul>	<ul style="list-style-type: none"> <li>• Lessen the depth by having a wider surface area to depth ratio.</li> <li>• Round edges to assure the user has safety.</li> </ul>
F2	Placement on body	<ul style="list-style-type: none"> <li>• The design overly protrudes.</li> </ul>	<ul style="list-style-type: none"> <li>• Lessen the depth by having a wider surface area to depth ratio.</li> </ul>
F3	Comfortability	<ul style="list-style-type: none"> <li>• Edges are overly sharp.</li> <li>• Wrist movement could be problematic.</li> </ul>	<ul style="list-style-type: none"> <li>• Round edges to assure the user has safety.</li> <li>• Move device slightly lower down the wrist.</li> </ul>



			<ul style="list-style-type: none"> <li>• Design to accommodate wrist movement.</li> </ul>
F4	Anthropometry	<ul style="list-style-type: none"> <li>• Users with larger wrists may not benefit from the small surface area provided by model.</li> </ul>	<ul style="list-style-type: none"> <li>• Widen design to cover more surface area across the wrist.</li> </ul>
F7	Aesthetics/style	<ul style="list-style-type: none"> <li>• Design too angular.</li> <li>• Depth of design too bulky.</li> </ul>	<ul style="list-style-type: none"> <li>• Soften edges by filleting.</li> <li>• Lessen the depth by having a wider surface area to depth ratio.</li> </ul>
F8	Stigmatisation	<ul style="list-style-type: none"> <li>• The design is too large, making women uncomfortable to wear it.</li> </ul>	<ul style="list-style-type: none"> <li>• Re-design model to be more slimline by altering surface area.</li> </ul>
F9	Social acceptance	<ul style="list-style-type: none"> <li>• The design is too large, making women uncomfortable to wear it.</li> </ul>	<ul style="list-style-type: none"> <li>• Re-design model to be more slimline by altering surface area.</li> </ul>

*Table 13 Model 1 Conclusions and Recommendations*

## Model 2



*Figure 30 Model 2 (Authors Own, 2022)*

Feature	Constraint	Conclusions	Recommendations
F1	Wearability	<ul style="list-style-type: none"> <li>Edges have been overly sharpened.</li> </ul>	<ul style="list-style-type: none"> <li>Lessen the radius added to filleted edges.</li> </ul>
F2	Placement on body	<ul style="list-style-type: none"> <li>The design is slimmer meaning it could be placed on differing parts of the body.</li> <li>The design is slightly too tall meaning wrist movements could be hindered.</li> </ul>	<ul style="list-style-type: none"> <li>Reduce the overall height of the design.</li> <li>Move the device further down the wrist.</li> </ul>
F3	Comfortability	<ul style="list-style-type: none"> <li>Wrist movement could be problematic.</li> </ul>	<ul style="list-style-type: none"> <li>Move device slightly lower down the wrist.</li> <li>Design to accommodate wrist movement.</li> </ul>

F4	Anthropometry	<ul style="list-style-type: none"> <li>• Users with larger wrists may not benefit from the small surface area provided by model.</li> </ul>	<ul style="list-style-type: none"> <li>• Widen design to cover more surface area across the wrist.</li> </ul>
F7	Aesthetics/style	<ul style="list-style-type: none"> <li>• Vent for air flow needs configuration.</li> </ul>	<ul style="list-style-type: none"> <li>• Add vent holes for aesthetic purposes.</li> </ul>
F8	Stigmatisation	<ul style="list-style-type: none"> <li>• Participants felt the design was small enough to offer protection against stigmatisation.</li> </ul>	
F9	Social acceptance	<ul style="list-style-type: none"> <li>• Due to having stigmatisation lowered through design, the model is socially accepted.</li> </ul>	

*Table 14 Model 2 Conclusions and Recommendations*

### Model 3



*Figure 31 Model 3 (Authors Own, 2022)*

Feature	Constraint	Conclusions	Recommendations
F1	Wearability	<ul style="list-style-type: none"> <li>• Edges should be less rounded.</li> <li>• Design should still have less depth.</li> </ul>	<ul style="list-style-type: none"> <li>• Lessen the radius added to filleted edges.</li> <li>• Widen the surface area and decrease depth.</li> </ul>
F2	Placement on body	<ul style="list-style-type: none"> <li>• The design is slightly too tall meaning wrist movements could be hindered.</li> </ul>	<ul style="list-style-type: none"> <li>• Reduce the overall height of the design.</li> <li>• Move the device further down the wrist.</li> </ul>
F3	Comfortability	<ul style="list-style-type: none"> <li>• Wrist movement could be problematic.</li> </ul>	<ul style="list-style-type: none"> <li>• Move device slightly lower down the wrist.</li> <li>• Design to accommodate wrist movement.</li> </ul>

F4	Anthropometry	<ul style="list-style-type: none"> <li>• Users with larger wrists may not benefit from the small surface area provided by model.</li> </ul>	<ul style="list-style-type: none"> <li>• Widen design to cover more surface area across the wrist.</li> </ul>
F7	Aesthetics/style	<ul style="list-style-type: none"> <li>• Air flow ventilation would need a larger surface area to be successful.</li> <li>• User interface points should be developed.</li> </ul>	<ul style="list-style-type: none"> <li>• Widen top surface are to accommodate more ventilation points.</li> <li>• Add bars to show power levels and cooling times.</li> </ul>
F8	Stigmatisation		
F9	Social acceptance		

*Table 15 Model 3 Conclusions and Recommendations*

## Model 4



*Figure 32 Model 4 (Authors Own, 2022)*

Feature	Constraint	Conclusions	Recommendations
F1	Wearability	<ul style="list-style-type: none"> <li>• The edges have a good radius.</li> <li>• Less edges may make more space within the design.</li> <li>• The design is of good depth to move with the user's wrist.</li> </ul>	<ul style="list-style-type: none"> <li>• Make more space by reducing sides of design.</li> </ul>
F2	Placement on body	<ul style="list-style-type: none"> <li>• The design is a good size for the wrist and other parts of the body.</li> </ul>	
F3	Comfortability	<ul style="list-style-type: none"> <li>• The design is of good depth to move with the users wrist.</li> </ul>	

F4	Anthropometry	<ul style="list-style-type: none"> <li>• Users with larger wrists may not benefit from the small surface area provided by model.</li> </ul>	<ul style="list-style-type: none"> <li>• Widen design to cover more surface area across the wrist.</li> <li>• Change shape to widen the surface area.</li> </ul>
F7	Aesthetics/style	<ul style="list-style-type: none"> <li>• User interface shows necessary power levels and cooling times.</li> </ul>	
F8	Stigmatisation		
F9	Social acceptance		

*Table 16 Model 4 Conclusions and Recommendations*

#### 5.1.2.3.3 Conclusion

Firstly, the participants as a group thought the user interface could have two bars. One for power and another not only to show that the device is active but also to represent menopause. The designer introduced the thought that the device could be called ‘Meno’, which was found to mean less than the Italian introduction of the word. This prompted the group to develop the power bars to look like a pause icon. This was a welcoming interjection for product branding whilst also making sense of the design as the interface required power levels and an activity status to be shown for usability issues.

Secondly, the modelling process has shown that an overly filleted module would be less stylistic to participants and users. The participants preferred smaller radius fillets added to edges and corners, as defined edges were preferred. In addition, the final model from this new product development

phase concluded that a smaller-sided shape would offer more surface area to store components quickly and ensure a larger demographic of users can use the device.

Compared to university facilities, modelling in a home environment made this design section more challenging than it would have been pre-COVID-19. Access to machinery and materials was not possible; therefore, limited design work could be achieved to the possible potential needed for this research. In addition, facilitating an online workshop for modelmaking was not ideal, as participants could not see what the designer was constantly modelling. In addition, connection issues were lacking, where user expressions that could be judged in person cannot be assessed the same through an online meeting. Therefore, this section had a limited output due to the outbreak of the COVID-19 pandemic.

### 5.1.3 Recommendations for the Final Design

The final design requires the researcher to consider using a pause icon style to show vital information on the user interface and for branding purposes. The design should consider altering the model's shape to either a hexagon or a rectangle instead of an octagon. A heptagon and pentagon are not thought to be necessary for consideration as they are both odd-sided, which would not only be challenging to design for user comfort, but from a design standpoint, the straps would be challenging to place on an uneven module. In addition, the design of the final module needs to be filleted for comfort and aesthetic purposes. However, participants through this testing phase did not like the module to be overly filleted as the design could quickly lose its shape.

## 5.2 The Global Specification Phase – Application Development

### 5.2.1 The Global Specification Phase Analysis – Application Development

The application development phase follows the form development and initial concept phases. This phase will configure steps for how the application design would be used through a storyboarding



process. Storyboarding has long been an effective method of creating user experience designs at the best potential they can be. Storyboarding is thought to have first been ideated in the Walt Disney design department in the 1930s to implement thoughts into a film. This has since been adapted in many industries: user experience and Software Development. In this instance, it is essential to identify how storyboarding helps with health Software Development. Harte et al. (2017) state that the product must meet the user's needs centred around the end user. For health design, the structured nature of the human-centred design is thought to be challenging to design around, although storyboarding can be used to improve final concepts. In addition, a storyboard design should use flow diagrams, screenshots, interface design, paper prototypes, and user profiles. Therefore, this section will involve a software developer to ideate a user interface for the front-end application that would accompany the wearable device.

## 5.2.2 The Global Specification Phase Design – Application Development

### 5.2.2.1 Storyboarding

Early contact was made with an experienced software developer (S. Sutton, Personal Communication, November 26, 2019). Communication was made at an early stage to initially state the project's intentions, where an initial layout could be made. The software developer helped co-create the app interface through the early stages and user experience design alongside the designer. This ensures a higher quality outcome than if the design was developed alone. Figure 33 illustrates the outcome of storyboarding session where screenshots of a phone application were ideated. The screenshots added to this phase have since added final design images to the user interface. At the time of testing, participants were shown a simple dark grey background.

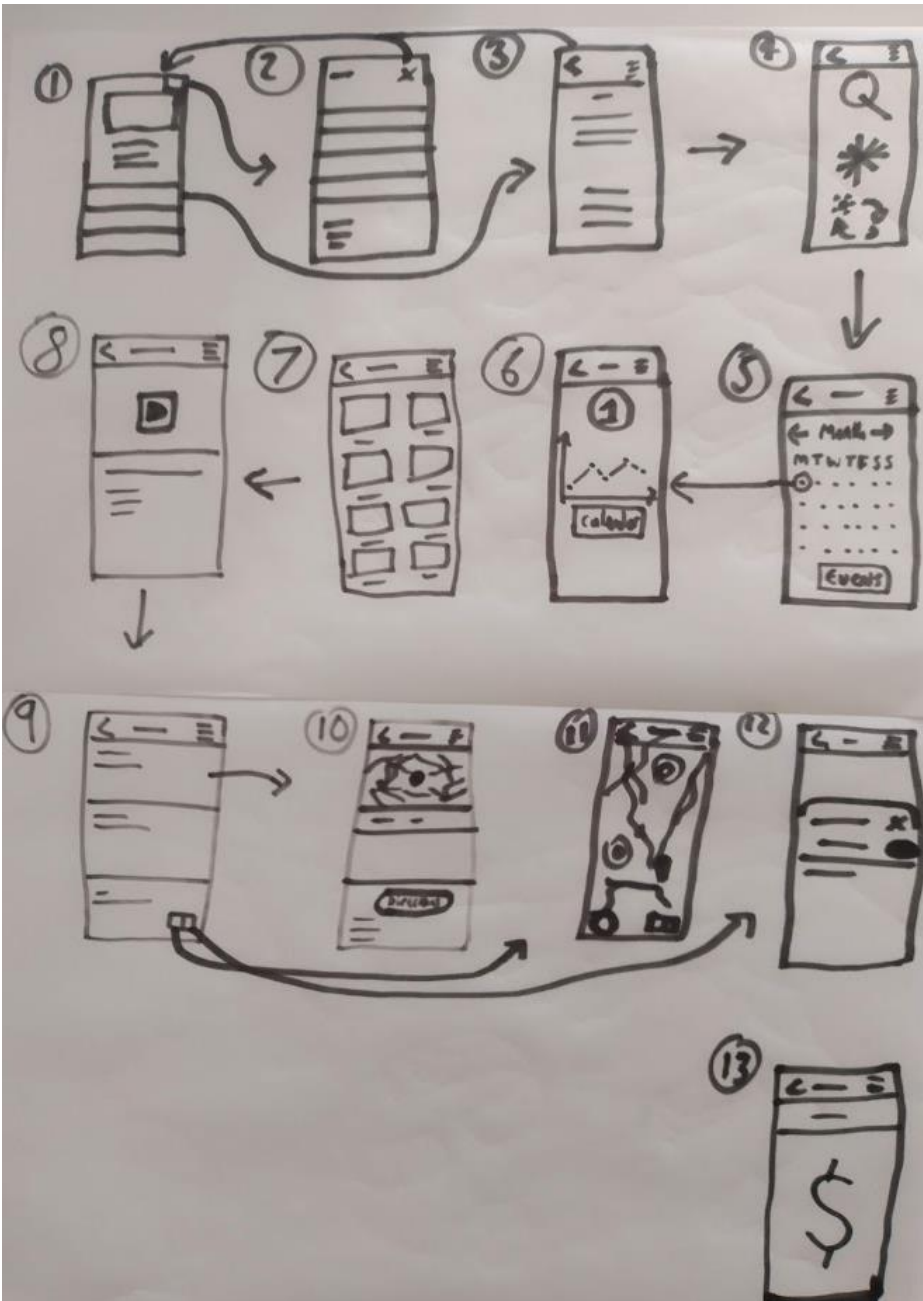


Figure 33 Storyboarding (Authors Own, 2022)

### 5.2.2.2 Storyboarding Translation to the Final Application Design

#### Step 1

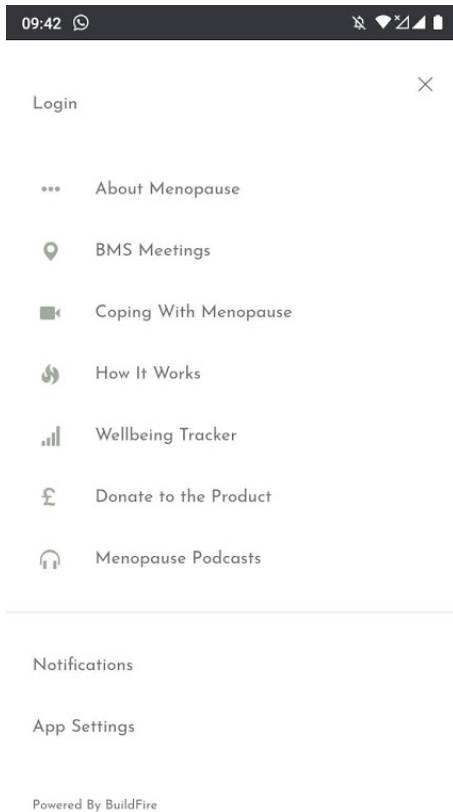
The home screen interface was designed to include an image of the product's logo and product in a box in the top section. Underneath the main image would include a short description of menopause and its main symptoms. The user could then scroll down the page to select the following topics: about menopause, how it works, wellbeing tracker, menopause podcasts, BMS meetings, and donate to the product. These are all accessible through touch on the individual boxes. In addition, if pressed, the top right corner brings up an additional menu where all these topics can be accessed.



*Figure 34 Home Screen of 'Meno' Application (Authors Own, 2022)*

## Step 2

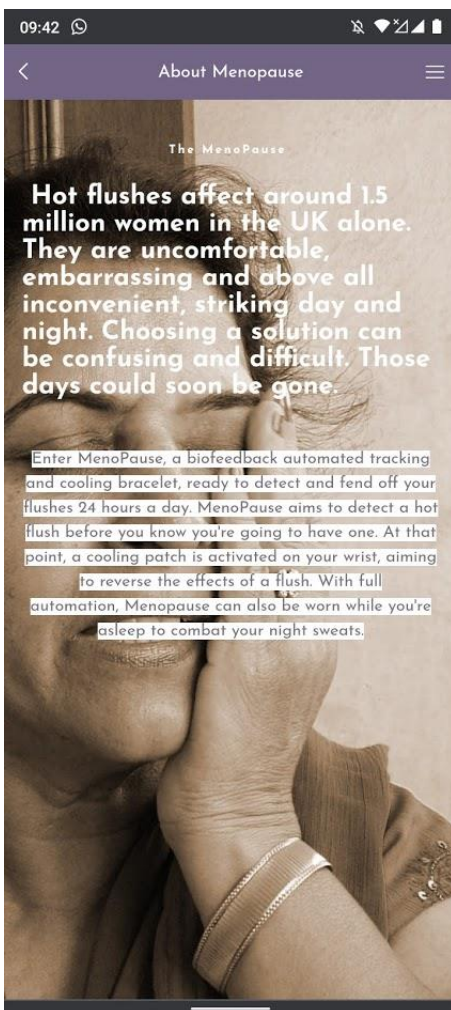
After clicking the button in the top right corner of the home screen, the user is taken to an always-accessible screen. The screen has a close icon in the top right. The list of accessible topics from the home screen is available on this screen also. Alongside the topics, the user can log in to their account whilst managing notifications and app settings.



*Figure 35 Always-accessible Screen of 'Meno' Application (Authors Own, 2022)*

### Step 3

About menopause can be selected from either the home page or the side dropdown discussed in step 2. About menopause briefly discusses what menopause is and who may be affected. This section is designed to comfort women and help them feel in control of their own bodies through knowledge.



*Figure 36 About Menopause Screen of 'Meno' Application (Authors Own, 2022)*

#### Step 4

The next topic to be accessed is the how it works page. A synopsis of how the product is designed to help a menopausal woman is stated. A woman can either look at this section for information about the product or look through the accompanying manual that would come with the designed packaging. This page can be scrolled through to access the relevant information.

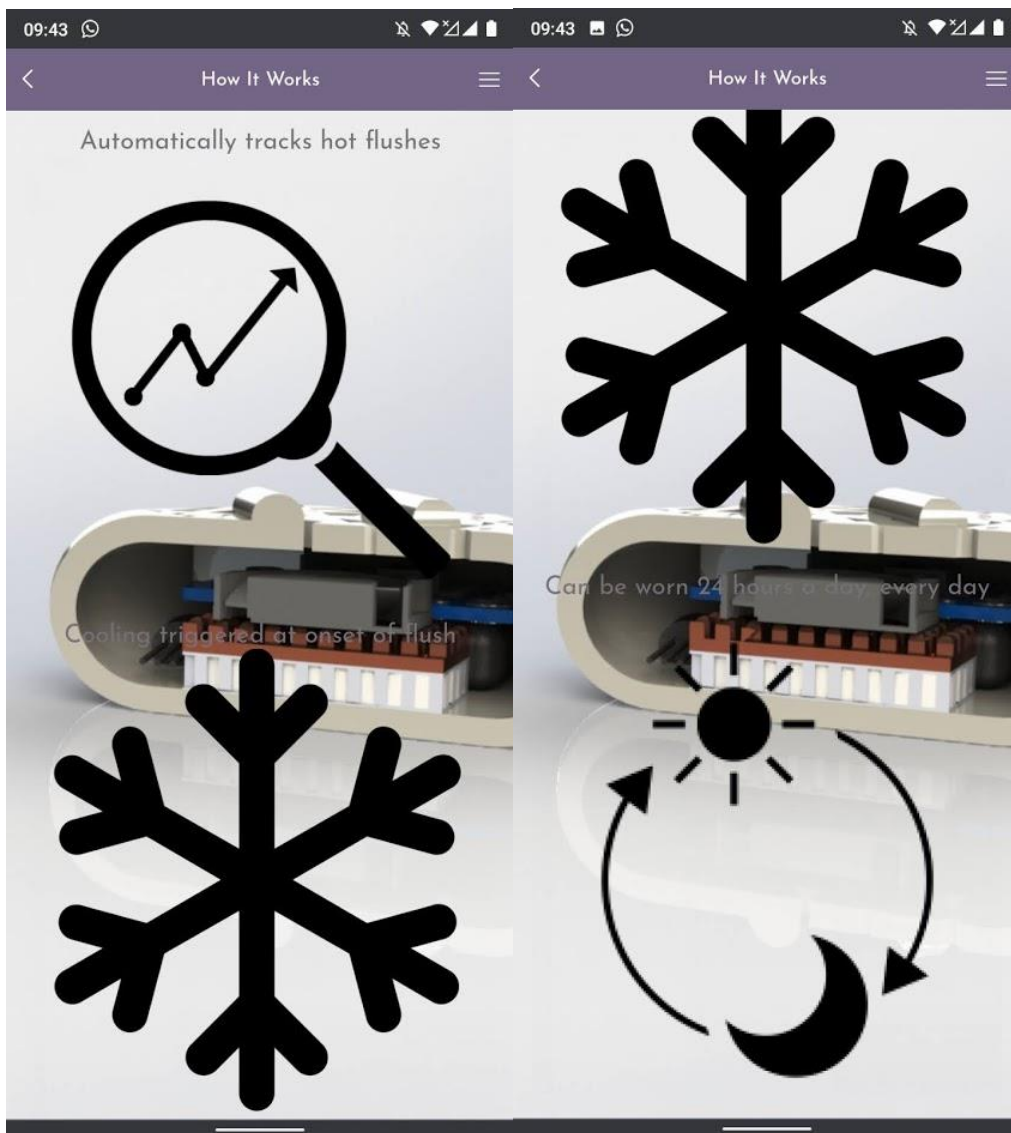
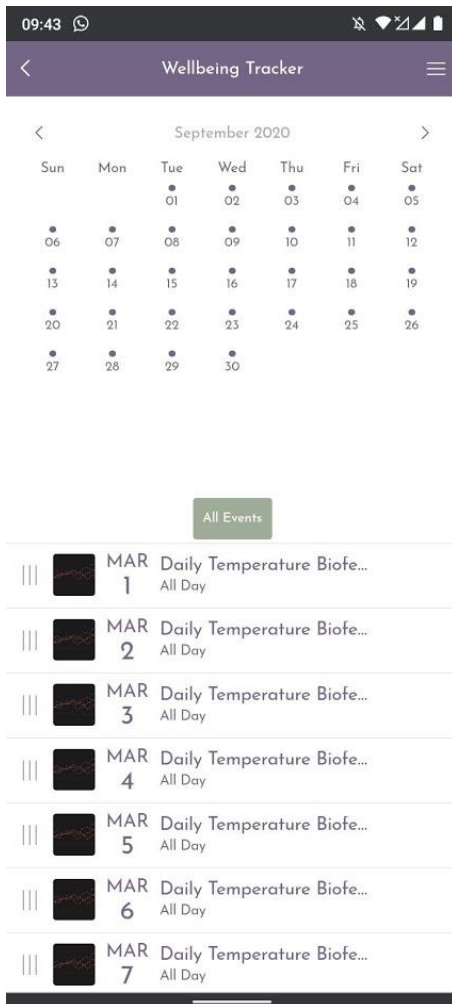


Figure 37 How It Works Screen of 'Meno' Application (Authors Own, 2022)

## Step 5

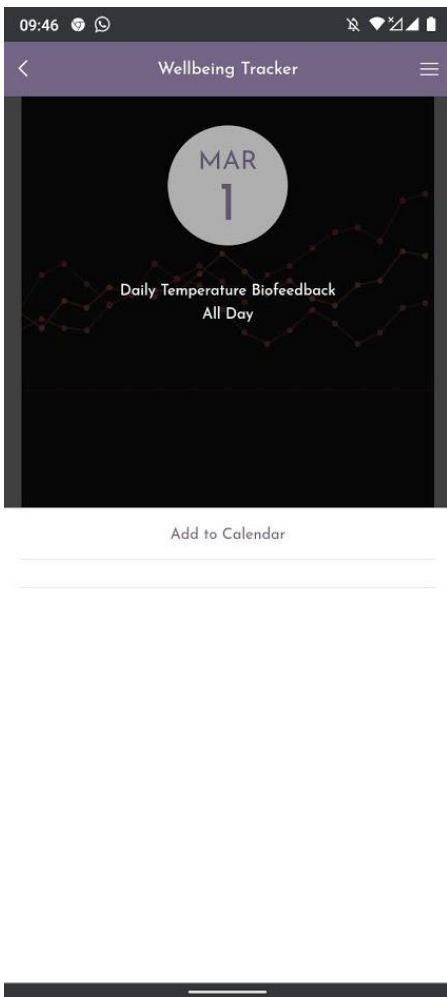
The next selectable topic is then chosen. The wellbeing tracker brings up a calendar for women to be able to track not only their well-being, but they can also see feedback from the biofeedback device to see what their beats per minute are along with when the device had to be used.



*Figure 38 Wellbeing Tracker Screen of 'Meno' Application (Authors Own, 2022)*

## Step 6

The user can then press a date button on the screen. Once the date has been selected, this next page will appear with the graph of feedback from the wearable, and a button is available at the bottom of the page top add personal wellbeing feedback to the calendar.

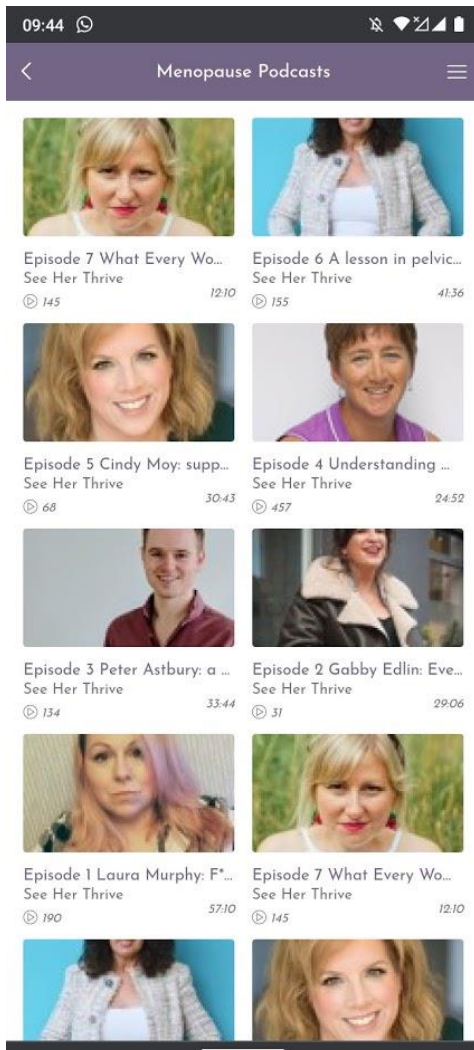


*Figure 39 Wellbeing Tracker Information Screen of 'Meno' Application (Authors Own, 2022)*



## Step 7

The next page takes the user to the widely available podcasts. The podcasts allow women to understand the transitional period in their lives and listen to what other women are experiencing and how they can cope with menopause.



*Figure 40 Menopause Podcasts Screen of 'Meno' Application (Authors Own, 2022)*

## Step 8

The next selectable topic that women can choose is podcasts. However, this time offers YouTube videos from the NHS on what women are expected to experience through menopause and how symptoms can be improved. Additional help from a health service like the NHS is necessary for any health care design as they often hold increased information and have developed experience with most diagnoses.



Coping with the menopause | NHS

Two women describe their experience of the menopause and a GP explains how it can affect women's bodies, common symptoms and treatments. Also read: <https://www.nhs.uk/conditions/menopause/>

**Figure 41** Coping with Menopause Screen of 'Meno' Application (Authors Own, 2022)

## Step 9

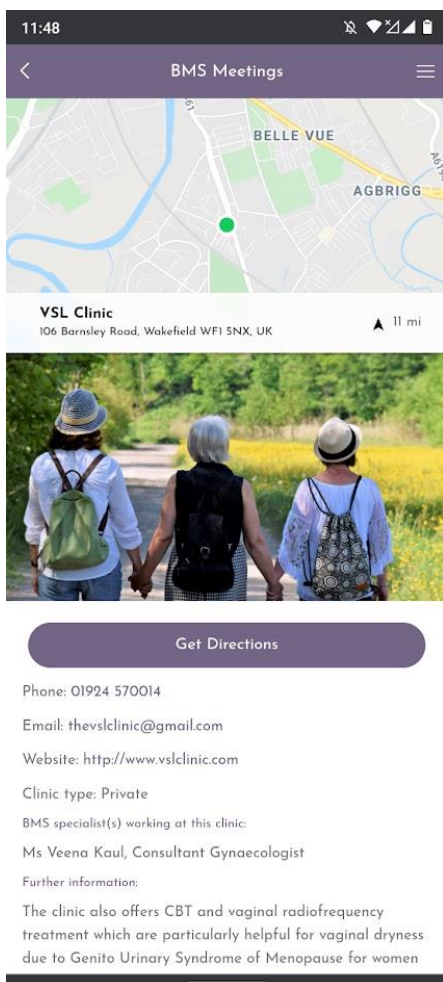
The following page then offers users to be able to access local British Menopause Society (BMS) meetings. The updated schedule allows women to see what meetings are nearby and when they are coming up in the calendar. On this page the user can either click on a specific meeting from the scrollable list, or they can press one of two buttons in the bottom right.



*Figure 42 BMS Meetings Screen of 'Meno' Application (Authors Own, 2022)*

## Step 10

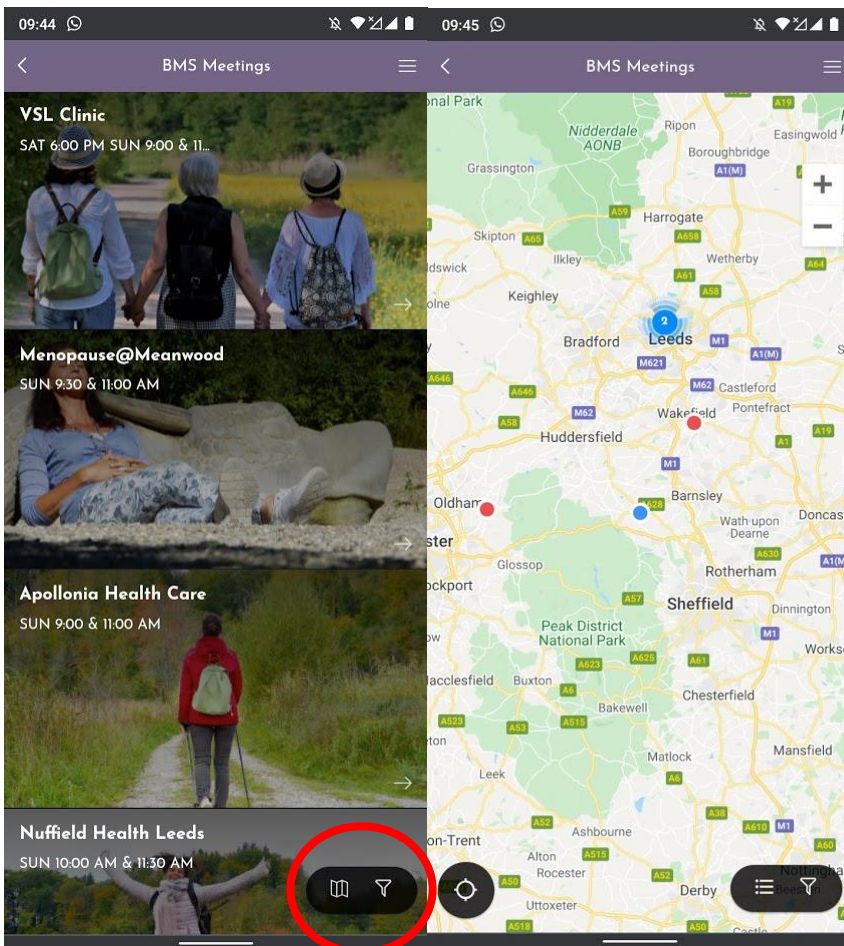
If the user selects the BMS meeting they would like to attend, they are then taken to an additional page offering information about that specific meeting. The top section of the page offers a map to identify the location of the meeting. Below is then the date and location of the meeting. The user then has an option to get directions to the meeting, which takes the user externally to google maps. Below is all relevant information about the meeting, such as who the organiser and facilitators are.



**Figure 43** BMS Meetings Further Information Screen of 'Meno' Application (Authors Own, 2022)

## Step 11

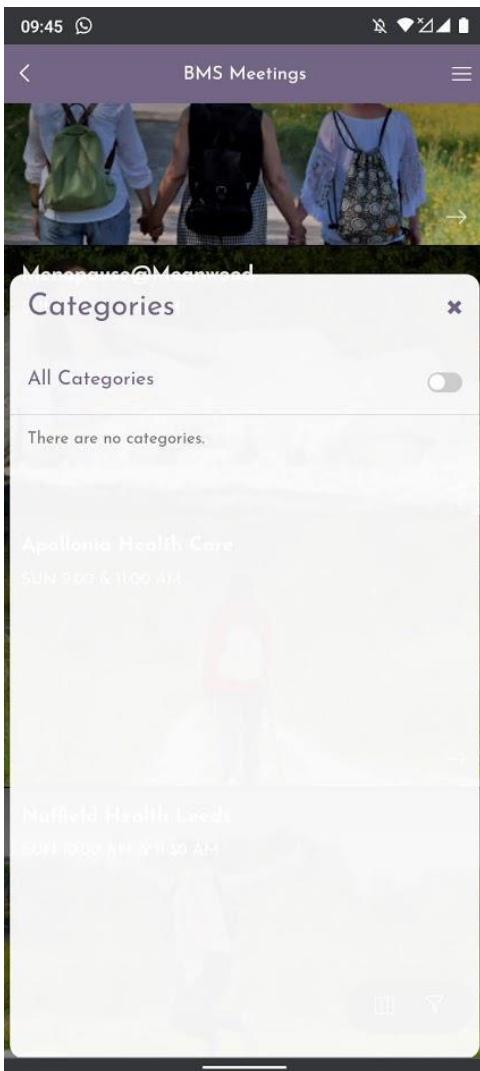
From step 9, the user can choose one of two icons in the bottom right corner. If the left of the two icons is chosen, a page opens a map identifying all the available meeting and their locations concerning the user's current GPS location.



*Figure 44 BMS Meetings Map Screen of 'Meno' Application (Authors Own, 2022)*

## Step 12

If the user were to select the right of the two options from step 9, the user would see a pop-up on the screen from the bottom of the page, overlapping the current page. This pop-up allows the meetings to be filtered to choose the most relevant sessions available to menopausal women.

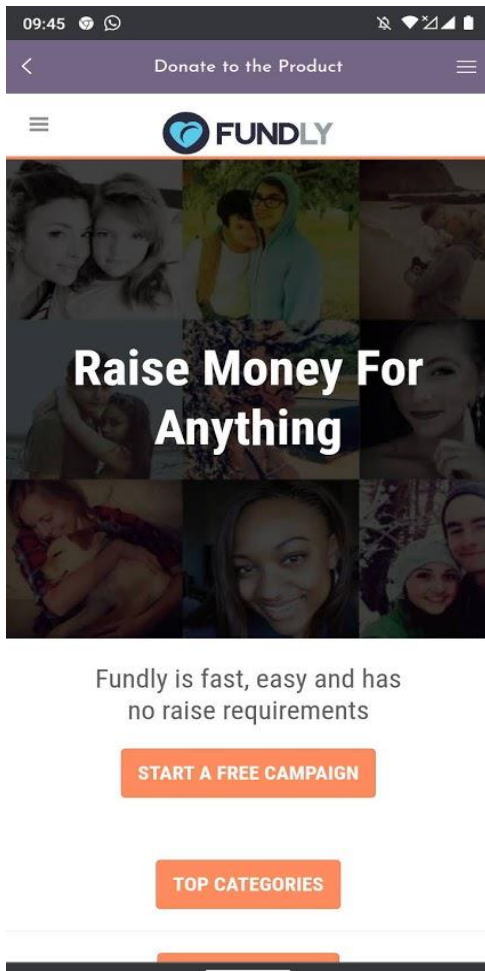


*Figure 45 Categories Screen of 'Meno' Application (Authors Own, 2022)*

### Step 13

The final selectable page is a donation page. As this product is a self-funded creation, users are offered to contribute to the development process to make increasingly improved ideas in the future.

Women could also use this page to provide donations to charities researching menopausal support.



*Figure 46* Donation Screen of 'Meno' Application (Authors Own, 2022)

## 5.2.3 The Global Specification Phase Evaluation – Application Development

### 5.2.3.1 Method

Co-creation is often essential in storyboarding development to achieve the best outcome for an idea. Again, this section will be reviewed and assessed by the participants involved in the design process up to this stage. The user group will again use inspection via the think-aloud protocol (TAP) for application development. The same women were involved with this phase as this phase took place later after the application was developed via a Microsoft Teams meeting. The TAP method is used within usability feedback for concepts when users are immersed in a task; in this case, the participants are shown images on a screen/ or watching a live video of the researcher. The feedback from users is gathered and evaluated against the design decision constraints. In this phase, features that are related to application usage are assessed. Therefore, it was decided by the group that only six feature points would be of use when testing the application interface. The testing will focus on the application's usability, the biofeedback user knowledge and how wellness could improve. The participants are given a link to the open-source web-based application. The researcher then takes the participant group through the application, which would not be dissimilar to a user manual provided with the devices as a package. The group will then discuss the application covering the notable six feature points defined by the group. A conclusion will then be made as to the outcome of the results from this analysis phase.



### 5.2.3.2 Results

Feature	Constraint	Conclusions
F12	Usability	<ul style="list-style-type: none"> <li>• The application was, overall, was easy to navigate.</li> <li>• The home screen and top right button menu were considered excellent additions, where the menu could be accessed from any page due to this feature.</li> <li>• The calendar to monitor the biofeedback assessment was a key feature for users; it allowed them to see not only what the device was doing and when but also what their body was doing.</li> <li>• The podcasts and videos were easy to access. However, the videos can go externally through to YouTube, where some participants expressed a challenge in re-entering the application, having to restart the Application.</li> <li>• Participants also enjoyed the meeting and mapped feature, stating it would have previously been challenging to share with others what their menopause experiences are, where a meeting awareness may help menopausal women.</li> <li>• Text size was seen as an issue for some.</li> </ul>
F13	Learnability	<ul style="list-style-type: none"> <li>• Participants felt an about menopause section on the home page was unnecessary. Still, they also thought that it was</li> </ul>

		<p>confusing what the application was designed for without that present.</p> <ul style="list-style-type: none"> <li>• Due to the same icons appearing throughout the application, participants thought this would make users familiar with the application faster.</li> <li>• The heading bar at the top of each page always features a back button and a menu button. Participants felt these constants throughout the application would make the user comfortable delving further into pages and know they could always return or get to another section quickly.</li> <li>• Text size was seen as an issue for some.</li> </ul>
F18	Wellness persuasion	<ul style="list-style-type: none"> <li>• The wellbeing tracker is a feature not seen by the participants before. The majority thought this was a vital feature if wellbeing was to be improved. The women also thought that if their progress could be tracked, it would be easier to talk to others about their menopausal status.</li> </ul>
F28	Monitoring	<ul style="list-style-type: none"> <li>• The wellbeing tracker showing the biofeedback from the wearable offers an excellent opportunity for menopausal women to track their hot flushes, heart rate and overall wellbeing. Users can also use the wellbeing tracker as a calendar to monitor and note life events and use the</li> </ul>

		application as a life application, not only a menopausal application.
F29	Data analysis	<ul style="list-style-type: none"> <li>• Data can be seen on a visual graph. A graph can be seen for daily fluctuations in heart rate and where the device has been activated.</li> <li>• Participants thought that the ability to add to a calendar means users could analyse their data further through special notes.</li> </ul>
F30	Data visuals	<ul style="list-style-type: none"> <li>• The visual representation of both the user's heart rate and then the biofeedback device's activation on the same graph means users can envisage both simultaneously and compare when the biofeedback device has been helpful to their journey.</li> <li>• Other visuals throughout the application were thought to be appropriate by the participants.</li> <li>• Text size was seen as an issue for some.</li> </ul>

*Table 17 Mobile Application Feedback*

### 5.2.3.3 Conclusion

The participants felt the final application design was easy for all users. Navigation was easy, with users stating icon and text sizes were good enough across the group. Future development could look like this, becoming an option for users to alter icon and text sizes. The older a person gets, the weaker their sensory functioning and personality can become (Stephan et al., 2017). Prior research

has defined how font sizes and icons can be tailored toward younger adults (Zhou et al., 2013).

Therefore, future designs should consider text and icon size for older generations. And this application should have a feature that allows the user to change the text size to their preference.

The wellness tracking calendar was successful; users stated they had not seen supporting material like that before. This was due to the biofeedback feature that the user can access. In contrast, other applications to track menopause only offer manual data inputs for women to assess their journeys. The users thought the podcasts and videos were a good idea for users as they could feel adjoined to others in the same phase of their lives. This feedback was like the meetings section. Participants thought the collaboration between women could be a powerful tool to target menopause together rather than alone. The women stated that talking to other women about their issues usually led to increased knowledge of the subject whilst offering essential tips and tricks on living with menopause. Participants then thought this might be an excellent feature to add to the application in the future. A blog-style system could be implemented where women could ask questions and join conversations with topics they would like to know about.

Participants added that the wellness tracker could improve certain aspects of well-being as previously a fear amongst menopausal women was an acceptance that they could not see or know where they were in their journeys. Participants felt that if they could follow what their bodies were doing, they would, in turn, be more in control, where previously there were no control options for users. The visual options of graphical data analysis were essential to the participant user group. It was necessary to see what their bodies were doing every minute of every day and when the biofeedback device was aiding them. This feature found higher importance to the user group as they stated visually seeing lower vasomotor symptoms over time could help indicate a near end to this phase.

### 5.3 The Detail Specification Phase – Final Concept

#### 5.3.1 The Detail Specification Phase Analysis – Final Concept

In this final phase of the new product development process, the concept images from the early envisioning stage and the global specification phases are brought into the final concept design phase. The design of a biofeedback wearable will be finalised in this section. It has been found that wrist cooling before the onset of a hot flush can influence the body to be cooler once initiated to lessen the effect of vasomotor symptoms. Compared to the pilot testing, this final concept will test the well-being of menopausal women to conclude whether reducing the effects of vasomotor symptoms through biofeedback would improve well-being. This phase will assess users through a questionnaire, a cultural probe and observation testing.

Firstly, a questionnaire will be used as a self-simulation exercise, where menopausal women will use ice and cold water as a direct replacement for the biofeedback wearable. This simulation experience is achieved as an alternative online method of research where women are asked to observe their journeys and state the feelings, they thought about the cooling powers to battle vasomotor symptoms. Secondly, the researcher sent the users a cultural probe package. The package consisted of several self-assessment materials where women could answer the questionnaire in their own time. The cultural probe testing involved the same women in the focus group's previous testing phases, the early envisioning phase, and the global specification phase. Lastly, a study to test actual concepts on three sample groups. This study will involve two sample groups from the UK (8 menopausal women and 8 control group participants).

#### 5.3.2 Final Concept Design

The final designed concept has been developed to this point with menopausal women. Via differing co-creation sessions, idea generation has led to a final stage of design where the designer can implement findings from the previous testing and improve previous designs to complete the new

product development of a biofeedback wearable for vasomotor symptoms. Firstly, through primary research, it was found that heart rate and finger blood flow increase before a hot flush. This led the researcher to see where the best placement for a wearable device would be. Research has found that the wrist and finger can detect heart rate like other pulse points, but when using a wearable, these two places seem to be the less intrusive methods of monitoring heart rate.

In addition to the biofeedback wearable being used as a wrist wearable, it became apparent that menopausal women liked the modular designs where they could wear the device in multiple places through the concept design phase. This worked well in the previous concept design phase as research had found forehead cooling before and during sleep can improve sleep. Sleep troubles affect a large majority of menopausal women. Women had improved confidence in a design concept that could work anywhere on the body where a biofeedback wearable could monitor heart rate. Therefore, the wearable would also benefit if the part of the device that housed the Peltier plate was made from a material with a higher thermal conductivity to adjust to temperature differences quicker than other materials. This meant that either aluminium or copper would be best for conductivity. In addition, looking at trend forecasts via WGSN, which foresee fashion trends for years and seasons to come, it was found that copper is a future trend forecast for 2023 and 2024 (Palmer, 2021). Copper is also popular due to its long-term integrity, as copper is the chosen primary material. A colourway surrounding copper's natural finish needed to be implemented to blend and merge colours. A forecast for the same period of 2023 and 2024 found pastels to be on trend. The report states the harnessing of nature as a base of therapy with neutral tones (Kostiak, 2021). As menopause is seen as a natural process for women to experience, using a colourway that promotes the enhanced use of biological therapy offers the design a more substantial design validity.

The design's shape from the form development phase found a sleek design that looked like existing wearables would be preferred to a bold and outlandish design. Geometrics have always been a

mainstay for women's fashion accessories. The year-over-year (YoY) data rose '10%' for geometric designs. Geometric designs have always been popular in fashion; but linking geometrics with checkerboard/repetitive designs with a YoY of '128%' would make the wearable fashionable for the ages (Watkins et al., 2021). Along with an aesthetic design focus, a modular design can be backed by WGSN, where 'modular' is a common word across many reports for future trends of 2023 for women (Baidoo, 2022). The design has been modular due to feedback from numerous co-creation sessions. As the invention will be modular, the final design will require housing. For the prior three years, caging has been at the forefront of accessory design, where a robust outer material secures the contents, it holds (WGSN, n.d.a; WGSN, n.d.b; WGSN, n.d.c). WGSN is a trusted trend forecasting service that has over a '90%' accuracy, which increases trust in the service for brands (WGSN, 2023a). They have a methodology to achieve this accuracy, where they follow a 5-step plan from observation, to synthesising, to forecasting, to focusing, before a re-evaluation (WGSN, 2023b). Previous theses have investigated and validated the use of WGSN as a trend forecasting service for research (Frohm & Tucholke, 2020).

As the module will be modular, other body areas must be considered for placement. Other areas in which women may feel benefits from using the wearable are the neck due to heart rate measurability. In addition, the module would be worn at night on the forehead. A design that could incorporate both areas into one and the wrist wearable. A consideration for this design could be backed through a timeless trend, where a necktie design could be implemented (Kaufmann, 2021). A necktie would also be excellent for anthropometric data coverage as a tie could be placed anywhere on the body where women would feel comfortable wearing it. In addition, both the wrist strap and the necktie/ headband would benefit from improved wearable well-being. The overall experience of this design needs to evoke positive well-being for women. A WGSN report found that design against the challenges of plus-size, modest wear, pregnancy, menopause, and older age can be enhanced with fibre innovated garments (WGSN, 2021). They state designs such as 'Thigh

Society', 'Adidas Terrex' and 'Elastique Athletics' using moisture-wicking, soft, and light fabrics such as 'MicroPerle' would make women more comfortable through their life experiences.

In a paper published by the Imperial College London, the future of wearable technologies has been defined. It states the divide between therapeutic devices and medical devices will become more blurred, where users should have a 'small chemical lab on their wrist' where biofeedback is available (Brophy et al., 2021). The article further states the future benefits of wearable devices for low and middle incomes, as devices can make accurate diagnosis', reducing the need for people to see a medical professional, which would reduce the overcrowding of hospitals, lowering healthcare costs at the same time (Brophy et al., 2021).

Further research looks into the future scope of material choices for wearable devices, stating the importance in the development of "breathable, flexible, and stretchable materials is still an important challenge to satisfy the rigorous requirements of wearable applications (such as adaptation to electronic skins, smart patches, or textiles). Furthermore, transient and recyclable (even compostable) substrate materials are desired for the sustainable and low-cost mass production of wearable sensors" (Ates et al., 2022). In addition, the paper outlines the future of wearable electronics in further areas, such as self-powered wearables, continuous measurement, linking wearables into internet of things, and developing beyond current diagnosis monitoring into the third generation of wearables which offers biofeedback such as, smart bandages and the administer of drugs or glucose monitoring and the in-built dispenser of insulin in a closed loop manner (Ates et al., 2022).

Future trends for wearable technology are promoting the use of smart point of care textile platforms for everyday use in combination with clothing. With an extra care taken on the comfort of a device where the weights, feeling, breathability and biocompatibility is considered (Chen et al., 2021). In addition, the same research paper states future trends should consider the fundamental textile



features, such as tailoring, washability and its aesthetic properties, which are all based upon user demand (Chen et al., 2021).

The UK government also have assessed the ‘generation-after-next’ wearable technologies, stating the use of ‘functional and biocompatible’ materials whilst having novel measurement methods (Defence and Security Accelerator, 2022). In addition, according to ‘The National Security and Investment Act 2021 (Notifiable Acquisition) (Specification of Qualifying Entities) Regulations 2021’ it is stated that “textile-based wearable electronics with potential to enable subtle integration of electronics with the human body for human-machine interfacing; and the integration technologies to enable functionalities such as energy harvesting, data storage and communication, camouflage, structural and personnel health monitoring and protection” are future trends as this is being invested into by the government (legislation.gov.uk, 2021).

Furthermore, Underwriters Laboratories (UL) who are most widely known for standards in electrical products, state connected wearable technologies close to the skin incorporate miniaturised Internet of Things sensors to capture and transmit data, where the future would incorporate further sophisticated features (UL Solutions, 2023). UL further add, a product should consider the following:

- “Product safety and performance”
- “Battery safety”
- “Data security”
- “Toxicology”
- “Interoperability”
- “Human factors”
- “Usability”

The design to be passable for UL inspection also must meet set safety and compliance testing for health-related technologies:

- “Electrical safety testing and certification (UL/C-UL Mark, CB Scheme, Europe, INMETRO)”
- “Battery safety testing and certification”
- “Specific Absorption Rate (SAR) testing”
- “Biocompatibility”
- “Cybersecurity”
- “Electromagnetic compatibility (EMC)”
- “Wireless device testing and certification solutions”
- “Interoperability”
- “Usability”
- “Smart clothing and footwear quality and performance testing and claims verification”
- “Custom testing and execution of verification and validation protocols”

The report also states the relevant worldwide standards for wearable technology for a design to be acceptable in the market:

- “Wellness or nonmedical wearable — IEC/UL 62368-1, the Standard for Audio/Visual, Information and Communication Technology Equipment – Part 1: Safety Requirements, UL 1431, the Standard for Personal Hygiene and Health Care Appliances”
- “Medical device safety — IEC 60601-1, IEC 60601-1-11 — and all related standards”
- “EMC — IEC 60601-1-2 (or equivalent for nonmedical applications)”
- “Usability — IEC 60601-1-6 (or equivalent for nonmedical applications)”
- “Biocompatibility — ISO 10993”

- “Software cybersecurity — ANSI/CAN/UL 2900, the Standard for Software Cybersecurity for Network-Connectable Products, Part 1: General Requirements”
- “Software Lifecycle Process — ISO 62304”
- “SAR for wireless communication devices in EU — EN 50566, EN 50360, EN 62209-1, EN 62209-2, EN 62311, EN 62479”
- “AR/VR/MR equipment — ANSI/CAN/UL 8400, the Standard for Safety for Virtual Reality, Augmented Reality and Mixed Reality Technology Equipment – Part 1: Safety (in development, world’s first dedicated equipment safety standard for AR/VR/MR)”

Therefore, WGSN has been stated as to how it will be used to form the design of the biofeedback wearable due to its prolonged and accurate use not only within fashion but also within research. In addition, due to research outcomes and new technologies, the method in which the module will work should use the assessed research to form the concepts. And finally, even though the design is for therapeutic purposes, it must consider the worldwide standards for wearable technologies and meet them where possible. This thesis will produce a concept that could then be taken into further development beyond this thesis with further funding, at that stage the design would fully have to meet standards and regulations for testing.

#### 5.3.2.1 Biofeedback Module Design

The Final module design uses trend forecasting for aesthetic pleasure for menopausal women. Firstly, the overall shape of the modular unit is based on geometric shapes. It uses a hexagonal outer shell. This was also an ideal number of sides from the form development phase. The design housed components better than the previous octagonal shape as a lesser-sided shape, in this instance, has a larger surface area. In addition, the device now has a lower depth than that designed through form development. These features were defined as necessary by menopausal women to improve the wearability of this device. The device uses neutral pastel colours to promote nature in menopausal

women. The chosen colours and materials are natural copper, alongside cream plastic. Copper is preferred due to its thermal conductivity.

Similarly, plastic is chosen for the same reason only a particular part of the device wants to cool. If the whole device cooled, the targeted cooling could have less effect. In addition, the geometric triangular cut-out prints on the topside of the device acts as an air vent to allow heat to escape, as the top side of the Peltier plate can increase in temperature as the bottom side lowers. Like the overall module shape, geometric designs are known to be on trend and future trends with an increase in YoY percentage. This vent design is also based upon a checkerboard style design, which saw a significant rise in YoY in the previous year. Air vents are needed in this design to allow air to ventilate and escape, as this could also become a trend with the design. It is not instantly apparent that this is an air vent, meaning a subtle design can be achieved.

The module also has a charger where charger ports are placed on the top or bottom. In addition, this is dependent on which wrist the user would wear the device. The device's branding is also on the user interface as the design incorporates the feedback from the initial concept design phase. The menopausal women thought the device could incorporate the classic pause icon into the design as the device could then be called 'Meno'. The device, therefore, uses one of the rectangular protrusions as an on/off button so the user can power the device. This button will also show power levels to the user. In addition, the other rectangular button shows when the device is activated to cool. This will give menopausal women faith that the device is acting; some comfort can be provided with this knowledge. The overall design is sleek and obscure whilst offering a stylistic and trendy output where women will not feel ashamed and stigmatised to wear such a device as it now blends in with other wearable devices.



**Figure 47** Biofeedback Module Design (Authors Own, 2022)

### 5.3.2.2 Wristwear and Caging Design

The design of the wrist strap is plain to be obscure as the device will be worn on the dorsal side of the wrist. The strap will be the part that all other members of society are likely to see. Again, like the modular device, the colour of the design was based upon pastel colours that blend naturally into the design. The design, therefore, uses a cool grey. Cool grey is also used to factor in the cooling nature of the design, where women will feel security from the design if cooling is offered. Offering cooling as a visual representation through the strap could improve the overall experience for menopausal women. The strap is also made from a stretchy, soft, sweat-wicking fabric, like the 'Thigh Society' design. In addition, it was found via WGSN that over the past three years, accessories and footwear have used caging designs. This design style was needed for this project as the primary modular device needs to be taken in and out of the caging housing. Taking the device in and out is necessary as the device needs to be replaced for 24/7 protection against vasomotor symptoms, where one device can charge as the other is in use. Also, the device must be removed from the wrist wearable to be placed in other areas of the body. The cage design is based on surrounding the modular device, securely holding it in place whilst using.

The number of structures that hold the module in place is kept to a minimum. This is because air vents cannot be covered as ventilation still needs to occur, and the user would also need to see the user interface to see what the main module is doing. Therefore, this caging design is not only on trend but has also improved the final design's use as it does not hinder the performance of the intended use. The colour scheme of the caging is there to mimic that of the copper underside of the device. This copper structure will remain cool to the touch and is strong compared to plastic, which has a more significant chance of fracturing with the thin caging design structure of the wrist wear.



**Figure 48** Wristwear and Caging Design (Authors Own, 2022)

### 5.3.2.3 Necktie and Bandana Design

Using the same caging design used for the wrist wearable strap and cage, this concept is based upon the mainstay in women's fashion, a necktie. This design can be worn all over the body, including the legs, arms, and wrist. Though the main design is to be used on the neck as this is a secondary pulse point compared to the wrist, the Temple is used for night-time sleep. The design of a necktie would be great for wearability as anthropometric data extremities can use the necktie design, allowing more women to wear the device of all shapes and sizes. Again, like the wrist wearable, the design uses a cool grey for the strap, also made from a stretchy, soft, and sweat-wicking fabric. The same cage design using copper is used for the necktie design also.



**Figure 49** Necktie and Bandana Design (Authors Own, 2022)

#### 5.3.2.4 Packaging

The user would receive the device in a packaged cardboard box. The branding of Meno would be placed on the top side of the box. Once the user opens the box, the package includes two modular devices, a wrist strap, a necktie, a charger, and an instruction manual, including a QR code to download the accompanying biofeedback wellbeing application.



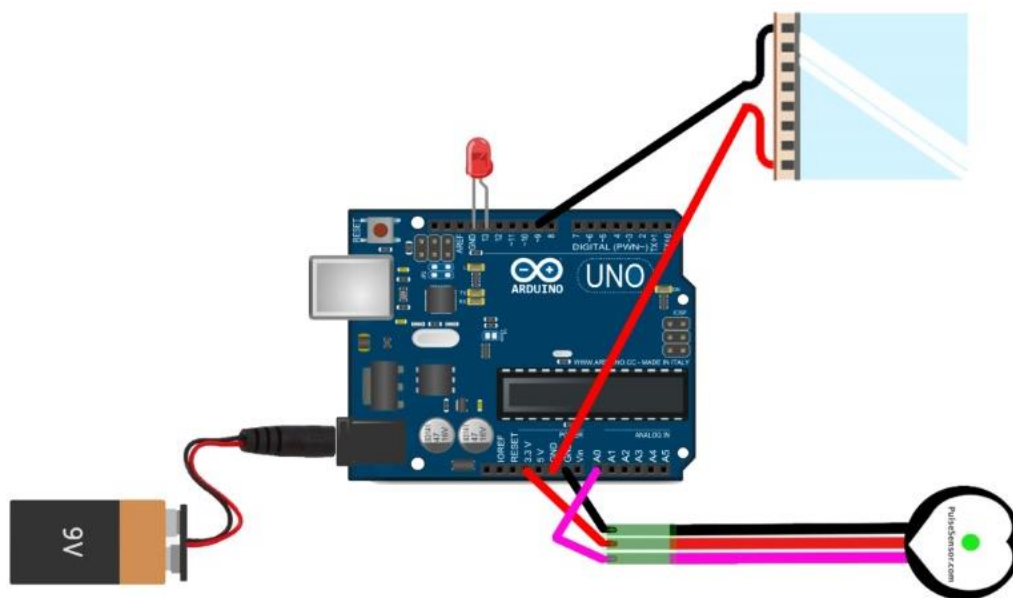
**Figure 50** Packaging Design (Authors Own, 2022)

### 5.3.2.5 The Coding and Programming of the Final Design

The final designed concept is used to monitor a user's heart rate, and once the heart rate measures over 100bpm, the Peltier plate becomes active. Arduino programming boards and coding software were used for this design concept to develop the idea. The researcher undertook courses on how to



programme through the University of Huddersfield's extracurricular activities and online tutorials. The basis of the design is like that of a lie-detector machine. By combining and further improving previous codes, the researcher developed a unique code where the heart rate sensor registers changes in heart rate levels; the Peltier plate is not activated until the heart rate pulse sensor records a measurement above 100 bpm. This is due to over 100 bpm being atypical. The LED was designed to flash once a heartbeat was sensed; in this case, the user could see if the device could monitor heart rate.



**Figure 51** Schematic of Final Prototype (Authors Own, 2022)

The Arduino Uno board (shown in figure 51) displays the layout of the design in a schematic view. Firstly, the design uses a 9v power supply for the testing phase. The LED is plugged into ports GND and 13. GND is the ground, and 13 is the pin that activates the LED to blink when a heartbeat is found.

CODE	<code>int blinkPin = 13; // pin to blink led at each beat</code>
------	--

*Table 18 Coding Section 1*

The heartbeat is found through a pulse sensor. The pulse sensor is connected to 3.3V, GND and A0. 3.3V is the necessary power to use the pulse sensor. GND, once again being the ground pin, and A0 were used to receive readings from the sensor, hence why the pin is based on the analogue in the section of the Arduino Uno board. Along with the LED, another output was the actual Peltier plate. The circuit powered the Peltier plate and used some 9V battery power. The Peltier plate also went into a GND pin for the ground connection, slotting into pin 9 to activate the Peltier plate. When setting up a volatile variable for the Arduino device, the researcher stated that reading would be taken constantly at a rate of 2 milliseconds (ms) if the reading was true; where a heartbeat was found, the researcher wanted to be acknowledged of this through the Arduino interface. If reading were not found, the Arduino board would continue searching for a pulse.

The Arduino set up requires a set of integers that provide thresholds for how the pulse sensor readings are taken and therefore displayed. The next phase of the coding process requires the researcher to implement a void setup. The 'void setup' states 'pinMode's' for the LED, sensor and Peltier plate. The 'pinMode' then requires the researcher to state whether the plug-in is an input or an output. In this case, the LED and Peltier plate were outputs, and the sensor was classed as an input. A 'Serial.begin' value was selected, which meant readings could be visible on the Arduino user interface. In addition, an 'interruptSetup' was created based upon the 'volatile int BPM', as discussed previously, which was set to gather information every 2ms.

The following coding phase used a 'void loop', which instigated what the output of the Arduino Uno board would do in certain situations. For this final design, the researcher wanted the Arduino to know when a heartbeat is found; if it is not, it will continue looking for a heartbeat. The device knows to power the Peltier plate; to full when that heartbeat is over 100bpm. If the heartbeat is below 100bpm, the Peltier plate will not be active, or if it has come from an on phase of being over 100bpm to under 100bpm, the Peltier plate will switch off at this state. Arduino used 'digitalWrite' to trigger the Peltier plate on and off whilst synonymously using 'Serial.println' to showcase if the

Peltier plate is on or off whilst the researcher and user are interacting with the Arduino interface. In addition, the reading timings stated as 2ms can be set via coding 'delay'.

CODE	<pre>void loop()  {  serialOutput();  if (QS == true) // heartbeat recorded  {  serialOutputWhenBeatHappens();  QS = false; // resets for next recording  }  if (BPM &gt;= 100) // if BPM goes above 100 peltier on  {  digitalWrite(peltierPin, HIGH); // peltier powered  Serial.println("Peltier ON"); // prints on serial monitor  }  else  {  digitalWrite(peltierPin, LOW); // peltier has no power</pre>
------	---

```
Serial.println("Peltier OFF"); // prints on serial monitor

}

delay(20); // 2ms between readings

}
```

Table 19 Coding Section 2

Finally, the integers created by the researcher were then implemented into the final coding phase, ‘void interruptSetup’. An interrupt was needed every 2ms for the timer of the readings. This time the user interface would benefit from the researcher implementing into the coding that if a heartbeat were found a heart emoji would appear on the Arduino user interface, alongside numerical values for a heart rate found by the sensor, using ‘Serial.print’. Furthermore, the integers were used to activate the Peltier and LED from the readings taken from the sensor. Figure 52 illustrates the user interface on the Arduino test page, where the device can be seen to activate when the users heart rate exceeds 100bpm.

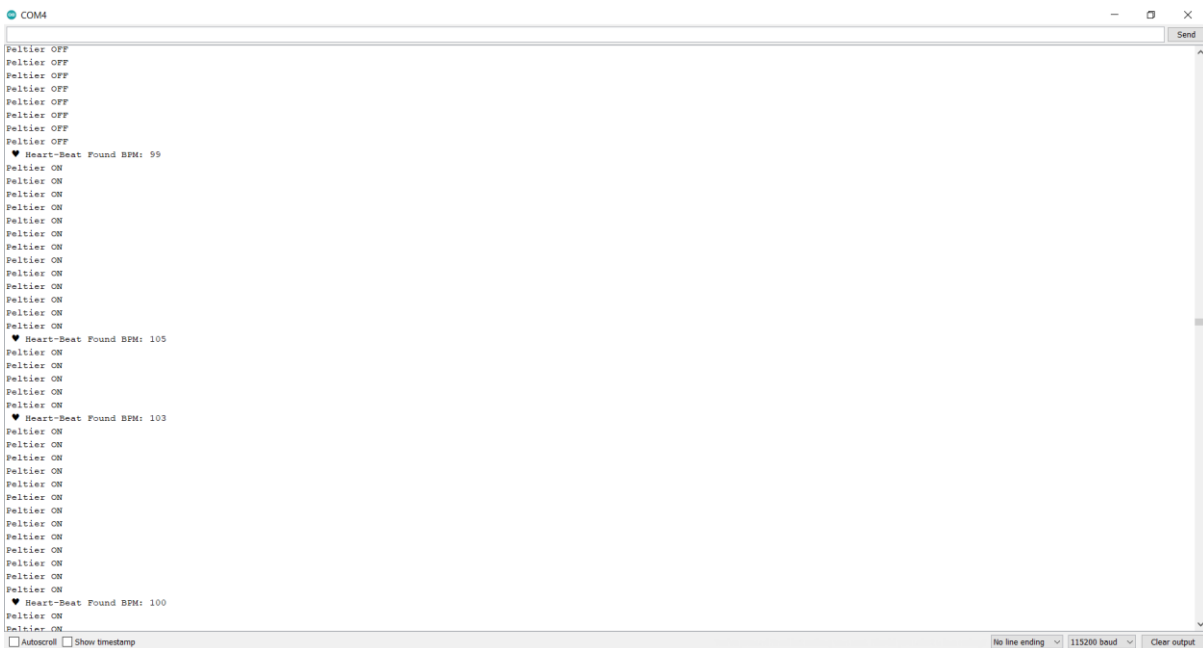


Figure 52 Screen Capture of Heart Rate Monitoring (Authors Own, 2022)

### 5.4.3 Final Testing Questionnaire

The final testing stage aimed to define whether wrist cooling prior to the onset of a hot flush would offer relief to menopausal women. The first testing stage was for women who could participate in their own homes during COVID-19. The initial test used a set of questions to gain further information about cooling at the onset of a hot flush. The survey had ten questions related to cooling with a wearable. The participants were asked to provide their ice or cold water due to the research being undertaken throughout lockdowns during COVID-19 and therefore was the only initial viable option to test the designed concept. Ice and cold water were asked to be placed on the wrist for this test when a menopausal woman felt they were experiencing a hot flush. As participants used their items to participate in this testing phase, the risk of transmission of COVID was eliminated. A positive of this testing phase is that the women participating were already at home due to the lockdown, were constantly near water, and ice was advantageous. The information gathered would therefore indicate whether the final concept from this thesis has validity within the environment it had been designed for. Each participant received a unique code that can be referenced for individual answers to specific questions. Due to the anonymity of online submissions, the users read an initial statement that stated individual identities were not in danger as all answers submitted were anonymous.

#### 5.4.3.1 Final Testing Questionnaire Questions

A total of 109 participants answered the questionnaire. The questionnaire first started the research intentions, and all answers to the questionnaire were anonymous. This initial statement was necessary and can assure participants that questions can be answered to their highest capability. The results from the designed questionnaire were collated and compared after a week of feedback. The questions asked were deemed private to individual users. Therefore, an anonymity statement meant women could openly answer questions. The initial questions were used to determine where women

thought they were within their menopausal experiences. The women were asked what age group they were within and then what group they would categorise themselves as from peri-menopausal, menopausal, post-menopausal or none of these. To round out the initial demographic questions, the women were asked to state whether they experienced hot flushes or not. The questionnaire then asked women to use ice or freezing water to emulate the same feelings that the biofeedback wearable would offer women. The women were then asked if this feeling were applied prior to the onset of a hot flush; they would feel cooler, be less embarrassed, have improved wellbeing, or none of these. Like hot flushes, the women were then asked if they had any symptoms during sleep, including night sweats and insomnia. The follow-up question then stated whether cooling the forehead at night would help alleviate these symptoms from menopause. The questionnaire then asked whether the participants would feel comfortable wearing a biofeedback wearable that would cool at the onset of a hot flush. They were then shown the accompanying application. The participants were asked if their whole experienced would be improved if they had access to an application that offered support and feedback. Finally, the participants were shown the final package offered through the conceptual design solutions. The participants were then asked whether they would be interested if the package were available to purchase.

#### 5.4.3.2 Final Testing Questionnaire Results

The initial question asking the women to specify what age group they were within meant a hypothesis could later be made to state what age groups are most common within menopause. Unsurprisingly, 45–49-year-olds and 50–54-year-olds were the most common participant groups sharing over '61%' of the feedback. Interestingly, leading onto the second question, nearly '59%' of participants stated they were menopausal. When comparing these figures between the first two questions, it is apparent that prior research leading the NHS to give an age range of 45-55 for menopause is very accurate. In addition, five participants stated they were not menopausal; this could be because they have been through menopause and do not consider themselves post-

menopausal or are yet to be peri menopausal. When asked if hot flushes were an occurrence, either menopausal or not, the women answered unanimously yes. With only six women stating they never experience hot flushes; it could be assumed that most could be participants that do not class themselves as menopausal.

Following the demographic questions, the participants were asked to use ice or cold water and apply those for a minute. The feedback showed that over '95%' of the women felt cooler, whilst only '75%' thought they were lower in temperature. Over half of the women subsequently felt improved well-being, and nearly half felt more peaceful after application. Only four women felt no changes through this test. More than '9 in 10' participants stated in the follow-up question that they would feel cooler if the same cooling was applied at the onset of a hot flush. In addition, around '70%' of women felt they would have improved well-being and feel less embarrassment. These results from questions four and five argue that even if actual cooling could occur, the perceived feeling of cooling is excellent enough to alter a woman's perceptions of a hot flush.

The following questions then investigated sleep for menopausal women. With '80' women stating they have awakenings during the night and '77' women having night sweats, a positive correlation could be made that night sweats directly affect awakenings during the night. In addition, '60%' of the women felt they had insomnia through their menopausal journey; even though this statistic is lower many of the participant's insomnia could solely be from night sweats and awakenings. When the women questioned whether cooling throughout the night would improve their sleep, '80%' of women thought biofeedback cooling would help. Conversely, fewer women were confident that a biofeedback device would help improve night sweats and awakenings.

When the women were presented with images of the designed biofeedback wrist wearable, over '90%' of the participants stated they would feel comfortable wearing the device. On the other hand, fewer women were more inclined to use an application with the device, with just over '½' the

women interested in the application and a further '15%' open to using the application. In addition, participants were then shown the final package that would be available to purchase. '80%' of the women said they would buy the whole package, with '12%' stating they would be open to the idea of buying a package.

The feedback from this questionnaire has backed the idea significantly. Firstly, it was pleasing to see that a correlation between the age groups from 45-54 was a similar percentage to those participants that said they were menopausal. In addition, the fact that many women were currently menopausal gives this research more substantial validity. The designed device's primary attribute is to control hot flushes; with '103' women stating they experience hot flushes; the research could hold a higher value.

The initial demographic questions backing initial predictions proved that women felt cooler from applying ice and cold water to their wrists. Even though results show that biofeedback cooling may only offer perceived cooling, relief for menopausal women is given due to the feeling of being cooler. In addition, well-being is seen to improve for many, along with peacefulness. Also, over '3/4' of the participants felt lower in temperature, which means they did not only perceive colder but also stated they had cooled. Women were, therefore, open to this sense of cooling being used at the onset of a hot flush, with over '9 in 10' women stating they would feel cooler. This demonstrates that perceived cooling has meant women not only think they are cooler but would also assume they would be cooler if cooling were applied during a hot flush. In turn, it could be assumed that self-perception of well-being is lower due to lower embarrassment through cooling.

Similarly, for cooling during sleep, it has been found that sleep would be thought to improve if cooling were applied at the onset of night sweats. This could be due to night sweats themselves, in addition to reduced awakenings. It had previously been hypothesised that these would be linked because of one affecting another, like well-being improving when cooling is applied for a hot flush.



Finally, it was pleasant to see women feeling comfortable wearing a biofeedback device that had been designed but also willing to try an application and were open to purchasing the whole package. It could be assumed that lower participants were open to using an application as current menopausal women are less technologically aware than younger generations, which would benefit from application help in the future.

#### 5.5.4 Cultural Probe

In this phase, the researcher wanted information on whether cooling impacted well-being. As stated within section 2.2.8.2, psychological and practical traits of UX have generally been self-reporting methods. Cultural probes are a method of self-analysis that has been used since the turn of the century (Gaver & Dunne, 1999). This method of gathering information, through co-creation, usually takes place at the start of the front end of the design process (Sanders & Stappers, 2014). This stage of the process is unusual to introduce a cultural probe. However, the researcher felt it was essential to introduce a cultural probe at this stage of the research due to restrictions enforced through a global pandemic. Cultural probes offer the researcher a chance to gain valuable insight into a participant's quality of life, where no input from the researcher is possible due to the research being self-assessing. Therefore, cultural probes are known to gather information about user groups gathering empathic data through this research.

Due to the COVID-19 pandemic, a cultural probe was derived from being a viable option for gaining user research feedback. This method was valuable to the research as an alternative method of gaining research from a user group, where no human contact was made between the researcher and the participants. The restrictions brought upon the United Kingdom for this period limited research outputs and quality. An alternative research method that produced valuable outputs was necessary for a researcher. Cultural probes allow users to answer research questions and tasks

truthfully; this method could be seen as improved as users can provide honest feedback due to the removed pressures of a laboratory set-up.

The number of items given to users was less than what would have been without COVID-19, as fewer restrictions would have been made about what items could be sent to participants. The number of items sent to participants was also lowered due to the size of the package needing to be lower for postal fees and ease of delivery. The Royal Mail postal service delivered these items to the participants where covid regulations were followed. During the pandemic, user interactions were impossible as contact with another household was not allowed. Therefore, a cultural probe was ideated where the user could fill an online form to showcase their results compared to previous methods of cultural probe testing where the package would be sent back to the user to see the results. Previously, the new method of applying a cultural probe to final testing had not been developed. The new online approach to assessing women's well-being through a virtual cultural probe was created to show future researchers if a virtual research method can achieve as much success as the previous versions of a cultural probe.

#### 5.5.4.1 Methods

The participant group for this testing phase was chosen to include the co-creation participants that had previously been involved in the focus group, the early envisioning phase, and the global specification phase. The researcher thought it would be imperative to keep the same user group from the start of the research to the end, as they had aided the design process. The participants were sent a package (see figure 53) which included plastic ice cubes, a biro and a set of 5 coloured pens, and a 3D print of the final design. This package was sent to users via Royal Mail. Participants had two weeks to fill out the online form in which a link was provided. The participants were given ten questions that could be accessed via a link to the women. Cultural probes allow for small user group

testing as usually under 10 participants is an acceptable group for this type of research as the information gathered can often be higher in value (Cho et al., 2021; Tuli et al., 2022).



**Figure 53** Cultural Probe Package (Authors Own, 2022)

#### 5.5.4.2 Cultural Probe Questions

The form first stated who the researcher was and what the research was trying to discover. The form stated that the contents of the form submitted would therefore be implemented in this thesis to correlate results. The questions asked are private; therefore, an acknowledgement of this in the introduction was needed. As a result, it was hoped the women would answer as openly as possible. Initially, general information was gathered about the participants, such as age, the severity of hot flushes, and general well-being before testing. Furthermore, the following questions asked the women to measure their temperature before testing. Using Plutchik's emotion wheel, the participants were asked to note what emotions they felt before and after the test. This section aims to unearth the emotions a woman experiences without any aiding technology during hot flushes, comparatively to the assistance of biofeedback wearable technology. It is predicted that emotions will likely change for the better through this experience.

Participants were then asked to make a sentence including one/some of the emotions to describe their feelings. Participants were then asked how wrist cooling has affected their experience with hot flushes. Penultimately, participants were then asked to sketch their experiences with hot flushes prior to aiding technology. They were then comparatively asked to sketch their experience with cooling technology. Finally, the women were invited to share their journeys through their developed timeline of how a hot flush affects them, defining the best and worst parts of the experience. Additionally, they were asked if they would like to add other thoughts about the experience at the end of the online booklet.

#### 5.5.4.3 Cultural Probe Testing Results

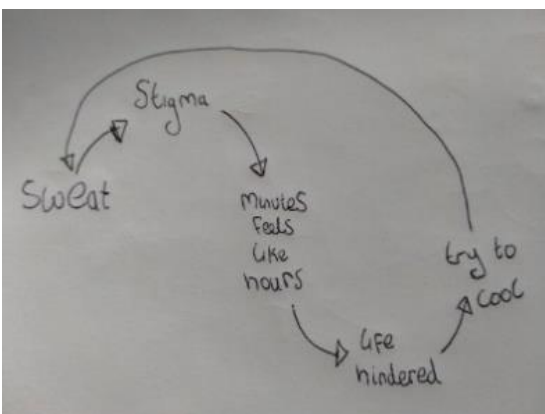
The cultural probe was designed to evoke thoughts and feelings that would be true to the participant, as the users assess themselves whilst completing the research in their own time. Firstly, the users were asked about their ages. The participants' ages ranged from 47-57 years old, with 2 participants under 50 years old and 3 participants above 50 years old. The participants' average severity of hot flushes was found to be high ( $M=5.6$ ,  $SD=1.14$ ). On the other hand, well-being was considered lower than average for this test group at the start of the research ( $M=3.4$ ,  $SD=0.89$ ).

Using Plutchik's colour wheel, participants were asked to state how they felt at the start of the testing. The research found that 80% of the participants felt sadness. Other emotions found in the research group were 'anger, fear, disgust and anticipation'. Users were then asked to draw their feelings when a hot flush occurred. All users appeared to draw themselves or a part of their bodies. The text was added to three images, stating the phases 'sweaty mess', 'hot' and 'I want to hide'. In addition, what appears to be sweat was seen on 3 of the portraits. Participant 5 also appeared to add colour to places where the temperature was higher than other places as the body of the portrait is red apart from the face, where only the cheeks are seen to be of higher temperature (figure 54).



*Figure 54 Participant 5 Sketch of Themselves During a Hot Flush (Authors Own, 2022)*

The menopausal women were then asked to ideate their timeline of a hot flush through sketching. 4 of the 5 participants added a defined timeline where a start and an end could be visible. Participant 1, on the other hand, sketched a cycle of how a hot flush works (figure 55). Similarities can be found within users' journeys, as 60% of the participants stated sweating as a standard part of their journeys. A differing 60% of the users stated that heart rate fluctuations occurred through this period. Over half of the participants stated wellbeing to be affected as the foremost step within their journeys. Sadly, only participant 3 stated that at the end of their hot flush experience, they became normal again, as prior to the experience.



*Figure 55 Participant 1 Sketch of a Timeline of Their Hot Flush Journey (Authors Own, 2022)*

Users were then asked to apply ice when they experienced a hot flush to the dorsal side of the wrist. Participants were found to have a lower severity of hot flushes after testing ( $M=3.6$ ,  $SD=1.14$ ). In addition, well-being had been seen to increase significantly ( $M=4.8$ ,  $SD=0.84$ ). All the women then stated, from Plutchik's wheel, that they felt 'surprise' after applying ice to the dorsal side of the wrist. Other emotions then included 'trust' and 'joy'.

Similarly, to prior questions, users were asked to draw their feelings after applying ice at the onset of a hot flush. 80% of the participants were shown to portray that their bodies were cooler; as emoticons, such as snowflakes, were used alongside the colour blue. Participant 5 changed the areas where cooling had been felt compared to the start of testing (Figure 56). The image shows the arm in which the ice was seemingly applied to be cooler up to the neck. Participant 5 also seems to have felt head and face cooling.



*Figure 56 Participant 5 Sketch of Themselves After Application of Ice (Authors Own, 2022)*

On the other hand, participant 3 was shown to have still a higher temperature in the head and face (Figure 57). Under half of the women still stated that sweating was a commonality through their sketching. This was noted through written communication also due to Participant 2 stating, ‘feel cooler, still sweaty’.



*Figure 57 Participant 3 Sketch of Themselves After Application of Ice (Authors Own, 2022)*

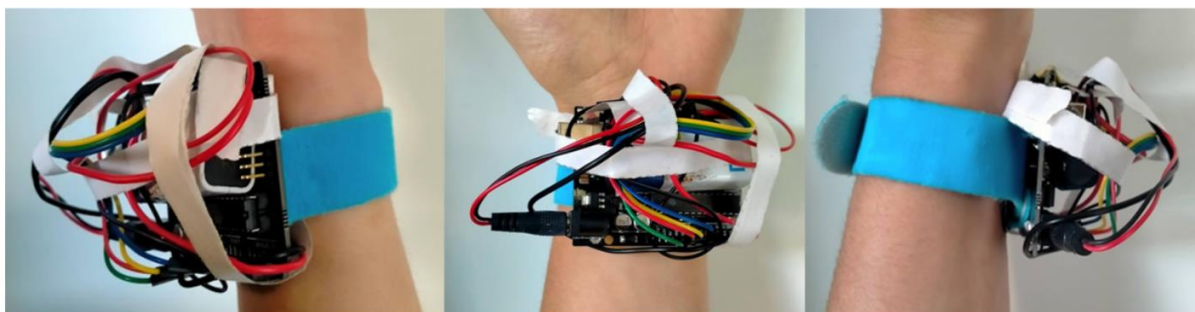
The following question asked the user group to redraw their hot flush experience through a timeline. Interestingly all users had been seen to use the same templates that had been used prior. The feedback shows users still had a hindered well-being, but well-being had improved as words such as 'less' and 'little' were used to describe the exact scenarios. In addition, if arrows had been used to sketch severity in the initial timeline, the arrows within this timeline would have been reduced.

The cultural probe has therefore validated the knowledge that cooling at the onset of a hot flush to the dorsal side of the wrist can improve well-being. Firstly, users stated well-being had increased by a mean of 1.4, where well-being was seen to be below half at the start and above half after cooling. This can be directly linked to cooling at the onset of a hot flush as the mean of hot flush severity had lowered by 2. This showcases the link between both lessening vasomotor symptoms and well-being improvement. In addition, words to describe well-being were negative at the start of the cultural probe, changing to positive feelings at the end. This was correlated to a participant's use of colours and cooling, which is helpful as Plutchik's colour wheel also states that the colours chosen meant that feelings felt were rightly analysed. These improvements in well-being have led to an

improved experience of hot flushes for menopausal women. The journeys of a woman's experience of a hot flush were still affected by poor well-being. However, imagery showcased how well-being had increased with the addition of localised cooling.

#### 5.5.5 Designed Biofeedback Prototype Observation Testing

In connection with the cultural probe testing, it was paramount that the prototype device was tested on a group of menopausal women and a test group to define whether the prototype offers support and if it can indeed promote improved well-being. Firstly, a small selection of menopausal women with high hot flush rates was chosen to partake in the test. Higher hot flush rates were necessary as the device needed to be tested on higher heart rates during a hot flush to attempt to cool at the onset of a hot flush. A control group is also needed to assess whether they cool when their heart rate exceeds a certain threshold. The feedback gained is based on the design requirements at the start of this chapter.



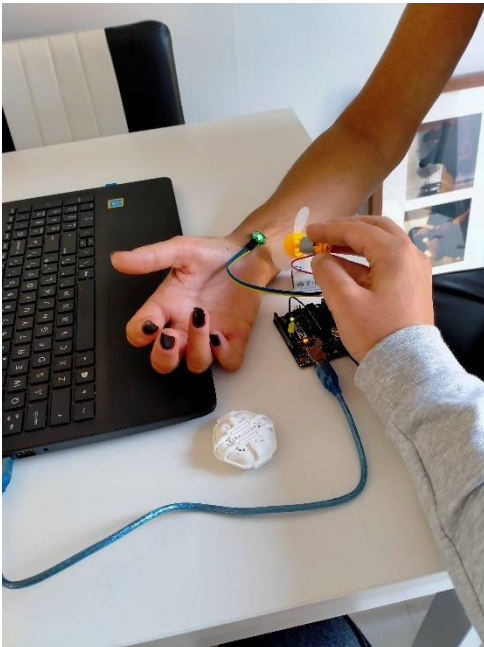
*Figure 58 Working Biofeedback Prototype (Authors Own, 2022)*

##### 5.5.5.1 Methods

The participants selected were as follows: (1) women themselves stated they were menopausal, and (2) the women that took part stated they had regular hot flushes. The age range of the study group was 45–57 years old. All participants stated they had been experiencing hot flushes for over one year. In addition, a control group was defined with the same number of participants to compare



results. It was expressed that participants should not be on medications up to one week prior to testing. The experiment was conducted in a COVID-safe environment where the facilitator wore a mask. The menopausal group were allowed to choose a time slot which suited them whilst also being their most active hot flush periods, tending to be afternoon. All participants had a 10-minute rest before testing to reach an equilibrium. If the menopausal group experienced a hot flush during this period, a further 10-minute period would be made to allow for equilibrium once again. Each participant of the menopausal group participated in mild activities to emulate real-life; as follows, sitting, walking, and resting for 80 minutes. All experiments were conducted inside with an acknowledgement that all environments for testing had natural thermal conditions. Throughout the test, the subject was required to wear the designed biofeedback wearable on their wrist. The device measured the participants' heart rate concurrently through testing. The data was collected via the facilitator's laptop. Arduino is always taking the data and providing graphs from the inputted data from the biofeedback device.



*Figure 59 Testing Biofeedback Prototype on a Menopausal Woman (Authors Own, 2022)*



*Figure 60 Testing Biofeedback Prototype on a Control Group Participant (Authors Own, 2022)*

#### 5.5.5.2 Designed Biofeedback Prototype Observation Testing Results

Data collected during testing from the eight menopausal women and the eight control group participants were wrist measurements of heart rate and when cooling was applied. Graphs of the observations are shown for comparisons between participants. Figure 61 shows the results of the menopausal women's heart rate whilst wearing the biofeedback device and raising their heart rates above 100bpm. The women were told to increase their heart rate through an exercise from minutes 10 to 20 and then again from 60 to 70. The women took, on average, 7 minutes to reach and then maintain 100bpm. Outside of these heart raises that participants were meant to experience, Participant 3 (P3) and Participant 6 (P6) have raised bpm's. These heart rate raises are hot flushes the participants had between exercise periods. The women at the start of the research were told not to do anything whilst they experienced a hot flush. In these cases, heart rates decreased to under 10% within 2 minutes and went from above 100bpm to under 100bpm within this timescale.

In comparison, Participants 2 (P2), 4 (P4), 7 (P7), and 8 (P8) had hot flushes that were deemed to be less intense. For these hot flushes, the biofeedback wearable did not trigger as the bpm of the participants was still deemed to be within the 'normal' heart rate range. In the same 2-minute period that the biofeedback wearable affected body temperature, the participants that did not achieve 100bpm with their hot flushes had a maximum temperature decrease of just under 9% with the average. Even though there is only a 1% difference between the maximum temperature differences

between these statistics, the average temperature differences in 2 minutes between participants that had hot flushes over 100bpm compared to participants that had hot flushes under were 6.7% and 5.3%, respectively. This shows that cooling appears to lower temperature faster than no cooling, with an average difference of 1.4%.

The women took up to 10 minutes to reduce their heart rates to near their resting heart rates. So, during this exercise period, the women's usual heart rate decreases. This may have been increased through biofeedback cooling as it did appear to influence heart rate. The women struggled to get to and then maintain 100bpm for the whole 10-minute duration. At the end of the 10-minute exercise, the women had heart rates above 100bpm, meaning cooling would still have been effective at the end. Throughout the test, the subject was required to wear the designed biofeedback wearable on their wrist. The device measured the participants' heart rate concurrently through testing. The data was collected via the facilitator's laptop. Arduino is always taking the data and providing graphs from the inputted data from the biofeedback device.

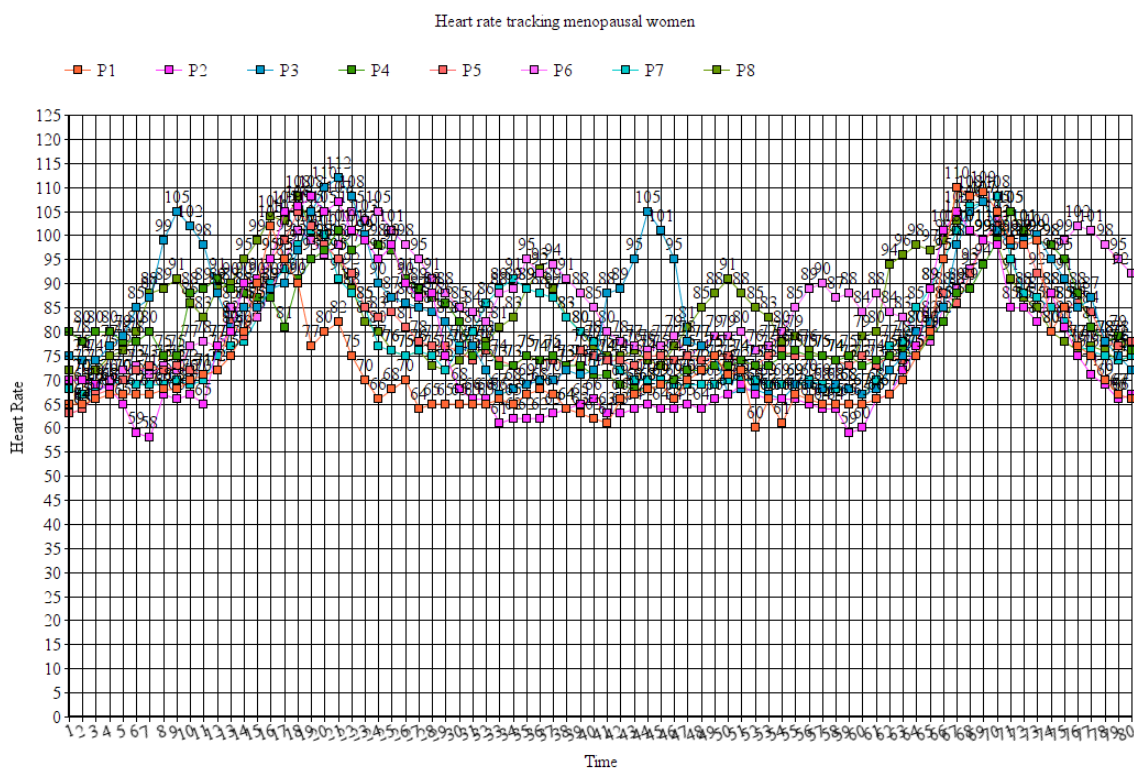


Figure 61 Biofeedback Heart Rate Tracking Results for Menopausal Women (Authors Own, 2022)

Comparatively, the control group only saw one irregularity outside the 10-minute exercise periods (Figure 62). Participant 4 (P4) rose by 5 bpm as the first exercise period ended. Aside from this irregularity, all other data appear regular. The control group's heart rates took an average of 2 minutes less to get to their resting heart rates than the menopausal women. This could be due to the average age differences between the two groups. When assessing the difference between both the groups, the menopausal women struggled to maintain a resting heart rate compared to the control group. Menopausal women were thought to be constantly battling hot flush fluctuations compared to the control group, who had no such bodily functions to deal with. This shows that without menopause, not only would a resting heart rate be able to stay in a closer range, but it would also be able to regain a regular resting heart rate faster than that with vasomotor symptom fluctuations.

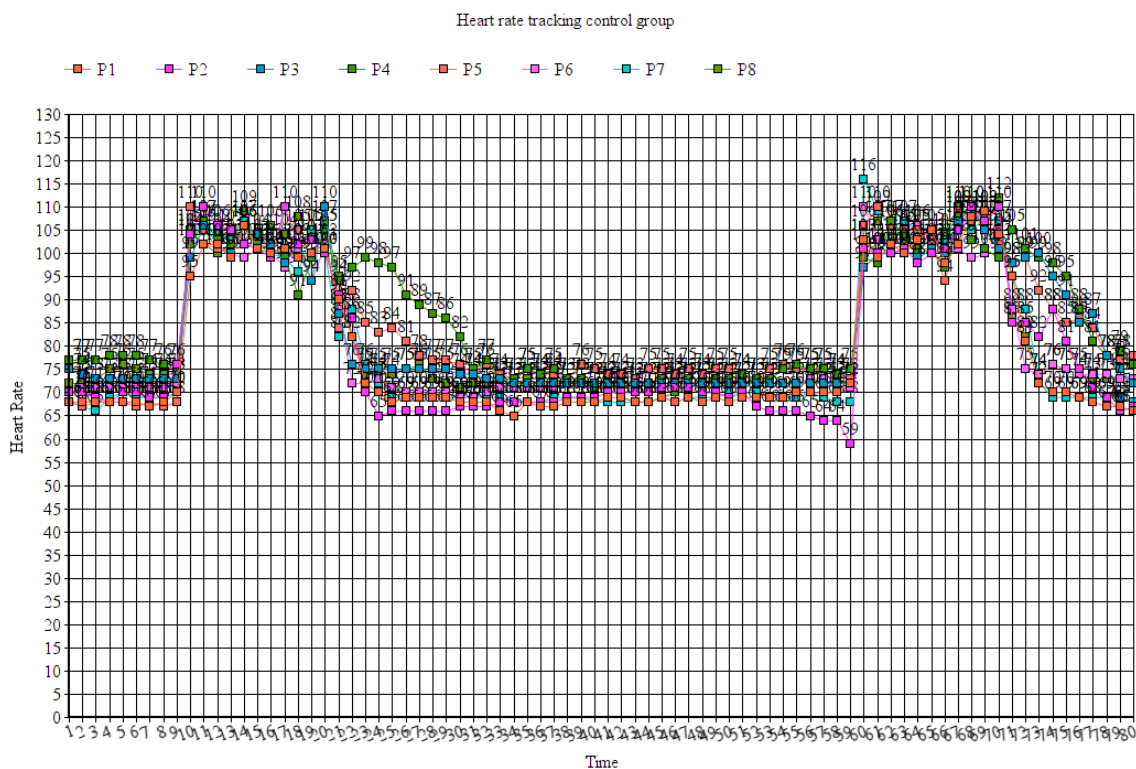
The testing aimed to simulate a menopausal hot flush as exercise was known to increase heart rate for participants like a hot flush would. Menopausal women who achieved a bpm over 100 found their heart rate decreased faster when cooling was applied than when a hot flush occurred. This was because hot flushes in-between exercise periods did not rise above the 100bpm threshold, which is considered atypical. Some hot flushes can occur within the normal resting heart rate range.

Therefore, if the device's design were to assess individual increases in heart rate compared to the baseline heart rate, the device would trigger at the onset of every hot flush and not just hot flushes that reach over 100bpm.

In comparison, Participants 2 (P2), 4 (P4), 7 (P7), and 8 (P8) had hot flushes that were deemed to be less intense. For these hot flushes, the biofeedback wearable did not trigger as the bpm of the participants was still deemed to be within the 'normal' heart rate range. In the same 2-minute period that the biofeedback wearable affected body temperature, the participants that did not achieve 100bpm with their hot flushes had a maximum temperature decrease of just under 9% with the average. Even though there is only a 1% difference between the maximum temperature differences between these statistics, the average temperature differences in 2 minutes between participants that

had hot flushes over 100bpm compared to participants that had hot flushes under were 6.7% and 5.3%, respectively. This shows that cooling appears to lower temperature faster than no cooling, with an average difference of 1.4%.

The women took up to 10 minutes to reduce their heart rates to near their resting heart rates. So, during this exercise period, the women's usual heart rate decreases. This may have been increased through biofeedback cooling as it did appear to influence heart rate. The women struggled to get to and then maintain 100bpm for the whole 10-minute duration. At the end of the 10-minute exercise, the women had heart rates above 100bpm, meaning cooling would still have been effective at the end. Throughout the test, the subject was required to wear the designed biofeedback wearable on their wrist. The device measured the participants' heart rate concurrently through testing. The data was collected via the facilitator's laptop. Arduino is always taking the data and providing graphs from the inputted data from the biofeedback device.



*Figure 62 Biofeedback Heart Rate Tracking Results for the Control Group (Authors Own, 2022)*

## Chapter 6 - Discussion

## 6.1 Review of the Research Output

At the beginning of this journey, the research made several aims and objectives for the outcomes of the research, with a vision to improve menopausal well-being through biofeedback technology. The hope of answering the initial research question was intended to further understand the subject through a literature review and targeted research studies. The design of a biofeedback wearable was thought to improve the well-being of menopausal women by lessening the effects of vasomotor symptoms. The researcher feels that through answering the accompanying objectives made at the start of the research, these objectives have been answered, leading to a conclusion to the research question. The initial objectives:

- To investigate whether biofeedback technology can alter body temperature.
- To define a design framework to improve the well-being of menopausal women.
- To design an alternative in a co-creation workshop to improve the well-being of menopausal women.
- To design and test a prototype to improve the well-being of menopausal women.
- To analyse the results from the previous test to see if design has improved the well-being of menopausal women.
- To understand the implications of the test and results for the well-being of menopausal women.

Firstly, it was questioned whether biofeedback technology could alter body temperature. The outcome of this question can be looked at in multiple ways. The designed device has been seen to have an increased effect on body temperature, where body temperature is lower, and women perceive their temperature to be lower.

The developed testing was to identify if a biofeedback device could affect actual body temperature. The device may have been effective if designed to have more power to increase the cooling capacity

from the Peltier plate. Though results showed subtle differences between body temperatures, the surprising factor for this research was the findings that perceived temperature could make a person feel cooler, even if actual body temperatures hardly change. This research found that perceived body temperature for menopausal women could outbalance the hormone imbalance leading to menopausal hot flashes. Therefore, the device designed can offer women relief from vasomotor symptoms through perceived cooling.

Secondly, the designed framework for this study used the 'Adapted Hybrid ID-Agile Design Model'. When considering the different areas this thesis covers, a mixed research methodology was an appropriate choice as the most valuable parts from several previous methodologies had been used to create a hybrid methodology and plan that could be used to complete this research.

The main reason it is thought this research has been effective is the fact that menopausal women were constantly involved in the design and development phases of the research project. As a designer, the knowledge and input from users experiencing the problem can be valuable to find a solution, which is the most valuable tool for a research study. The iterative nature of interaction design and an Agile development plan meant users could constantly be involved in the process through each iteration. Therefore, the success of the final design is contributed to by menopausal women. It can be stated that co-creation is the single most valuable asset of this type of research.

As expressed in the previous paragraph, the following question is heavily linked to the research methodology cycle. The researcher wanted to 'design an alternative in a co-creation workshop to improve the well-being of menopausal women. This was again a success, as all workshop events found helpful information from users about their lives. The findings from these workshops led the research and evaluated that all users are different and experience menopause differently. This, at first, could be a confusing thought, but through primary research into well-being and the individual user's lives, it became apparent that a designed device had to be inclusive to all women. The



outcome of this question led to many gatherings between the designer and users, where their valuable input created a successful biofeedback device.

The biofeedback device was designed and tested to see if improvements could be made to well-being. Firstly, through a review of the literature and later questionnaires, it was known that well-being is a varied subject, and a single designed item is unlikely to solve all problems the user may have in their lives that cause lower well-being. Nevertheless, it was thought that if some of those problems were alleviated, well-being could be significantly improved. Through the initial questionnaire, users stated the most common symptoms they have from menopause. With users stating that vasomotor symptoms and sleep are the most common symptoms of menopause, the researcher understood these areas in much more detail than others. The developed biofeedback device does alleviate these areas and therefore has an impact on overall well-being. This research has found that menopausal women's well-being can be improved through targeted symptoms being alleviated, in this case, vasomotor symptoms and night sweats.

In addition, many differing prototypes have been ideated to gain user feedback on multiple areas:

1. Ideation sketching allows co-creation with users to create ideas based on the research up to that point. These ideas could then be collated in a way that combines features to have a design that can achieve the most user satisfaction.
2. Once a design has been developed, the size and shape can be successfully developed with users. Forming a shape for modelling using foam was helpful to both the designer and the user as the design became more realistic when this 3-dimensional element was introduced. This modelling phase defined the shape and sizes acceptable for the design of the focus group user's anthropometric and ergonomic needs.
3. The users could test the fully functional prototype and corresponding application.

The results found from the final testing found that there was indeed improved well-being overall from the feedback of menopausal women. In the testing period, the research found monitoring the timings of hot flushes challenging. As discussed, hot flushes can occur at any time point. In this research, it was important that the user could simulate this to the best of their abilities even if hot flushes did not occur through testing. The device was designed to be triggered when a user's heart rate surpasses the 'normal' range. Therefore, users were asked to elevate their heart rate through exercise to trigger the cooling element of the device. This not only allowed the user to experience the effects of cooling when the heart rate is simulated like a hot flush but then to achieve further knowledge as to whether their well-being is thought to have improved because of the designed device. The testing aimed to simulate a menopausal hot flush as exercise was known to increase heart rate for participants like a hot flush would. Menopausal women who achieved a bpm over 100 found their heart rate decreased faster when cooling was applied than when a hot flush occurred. This was because hot flushes in-between exercise periods did not rise above the 100 bpm threshold, which is considered atypical. Some hot flushes can occur within the normal resting heart rate range. Therefore, if the device's design were to assess individual increases in heart rate compared to the baseline heart rate, the device would trigger at the onset of every hot flush and not just hot flushes that reach over 100 bpm.

## 6.2 Key Findings

The researcher has argued throughout this thesis the point that reductions in vasomotor symptoms can improve the well-being of menopausal women. Firstly, the research intended to assess the physiological effects of being immersed in a virtual world. The results of the objective and subjective measurement studies showed significant results. When users are immersed in a virtual world that evokes cooling or warming, skin and perceived body temperature can lower or rise accordingly. In addition, using thermal imagery, subjects showed temperature differences when immersed in both cooling and warming conditions. Therefore, VR has proven effective in cooling

or warming the body when a user is immersed in a virtual environment promoting heating or cooling. In addition, VR can improve a user's well-being as it can be a place of escapism that had not previously been considered for menopausal well-being and could now be a valuable tool to improve quality of life.

In addition, over 95% of menopausal women were found to have perceived cooling when applying ice or water to the wrist. Of those users, over 93% thought cooling from the wrist prior to the onset of a hot flush could cool the body. In addition, the research found to agree with previous research outcomes, such as 'Ebb's' therapy sleep cooling device, where over 2/3 users feel they would have fewer night sweats with forehead cooling, they would also have fewer awakenings, which leads to over 80% of participants expecting to have a better sleep from cooling. This validated the idea of a modular device for multiple body parts with pulse points to instigate biofeedback technology to monitor heart rate values where extremities are acted upon with cooling. These extremities are seen during hot flushes, where localised cooling has been found to offer relief to menopausal women.

In addition, the cultural probe validated that cooling at the onset of a hot flush via ice to the dorsal side of the wrist can improve well-being. Well-being had increased by a mean of 1.4 from before applying ice to after the application of ice. This correlated to the severity of hot flushes that had lowered by a mean of 2 for a Likert scale of 7. This proved the link between well-being and hot flushes, where both can affect each. This correlated with the final testing phase, where menopausal women found that cooling appears to lower temperature faster than no cooling, as there is an average difference of 1.4% between applied cooling and non-cooling.

### 6.3 Interpretation of Results

The research found strongly validates that using biofeedback to cool before the onset of a hot flush can indeed improve menopausal wellbeing by lessening the effects of vasomotor symptoms. Even though some results for cooling showed minimal changes in rates of cooling through heart rate,

perceived cooling was found to be of more considerable importance to the user. As perceived cooling occurs through stages of actual cooling, it is thought that the cognitive rebalance of applied cooling has tricked the user into thinking their body is cooler than it was. This outcome is essential for future research as options for a design where subjective temperature can impact a menopausal woman more than objective temperature.

As proved through the pilot VR testing, subjective cooling made the participants feel cool without any cooling applied to the user. Thus, proving that manipulating a menopausal woman's senses through therapeutic design can indeed offer validated results that are non-invasive to the user. Before this research, the therapeutic design had not been considered in the sense of modular wearables. The modular functionality of the wearable has been a popular outcome where women feel they can avoid stigma when necessary. In addition, the device can be used during the daytime and night, where constant cooling can be offered at an ant pulse point on the body. Though it has been found that women are open to using the device on the temple and forehead as prior research has backed this concept (Schoggl, 2019; Baker et al., 2020; Mysliwiec et al., 2020).

#### 6.4 Limitations of the Research

Limitations found within this research were that all women could experience menopause differently. This means that designing for all menopausal women was a tough challenge. Through research, it was found that vasomotor symptoms are the most common and worst symptoms for menopausal women. Therefore, designing a group of menopausal women with negative experiences with vasomotor symptoms was efficacious. In addition, co-creation was vital for this design research. The researcher would have liked to have consistently kept the same group of women involved throughout the research, but this became impossible for some. As the research developed through years of input, the ages of the women involved at the start increased to a point where many would, therefore, no longer consider themselves menopausal. This was disheartening for the

researcher as the research involved new participants. This has both positive and negative connotations. The research could have been positively affected by new user groups as they have differing opinions from those prior. Conversely, the previous user group were part of the whole journey of this research and inputted into the final design.

The main limitation of this research was the worldwide pandemic of COVID-19. The research was difficult to validate due to the pandemic starting at a critical point for this thesis, where the country was forced into lockdowns, at the point when final primary research was to be gathered. The government stated within these lockdowns' certain restrictions. The restrictions introduced social distancing for a few years. This social distancing meant the researcher could not conduct in-person research due to these restrictions (Institute for Government, 2022).

The use of university facilities during this period was an issue that had to be overcome. Prototyping had to be done at home, where tooling and materials were of lower quality and self-funded. This took far longer than it would have taken if the facilities at the university were open. In addition, without precision machinery and tooling, the modelling quality was lower than desired. The laptop used at home is not a similar specification to personal computers at the University of Huddersfield. Without high-quality computers at the university, specific computer programs and software (such as Solidworks, Arduino, 3DS Max, and Adobe packages) were harder to run on a low-end laptop. Fortunately, a remote desktop feature was available for university students during this period. Although this was available, there were daily connection issues, where work would be lost. In addition, the software mentioned before was tough to use as the connection was slow. This meant 3D modelling, and the research process took far longer than hoped with limited techniques.

In addition, whilst at home, WI-FI was problematic as it was shared between several students, all studying on the same WI-FI synonymously. For research, WI-FI is essential; when it does not work correctly, the research and design process is prolonged. In addition, a slower WI-FI connection

when using online meeting rooms, such as Microsoft Teams, can make interactions with participants and supervisors challenging. Lagging screen shares, desynchronised audio and video, and other connection issues lead to miscommunications for vital research input. In addition, when speaking to participants through online meeting rooms, the observations that could be made in person cannot be seen through a computer screen. Critical body language assessments and personality traits could not be fully gauged during the research process.

During Covid-19, the research had to change course multiple times to accommodate new restrictions and rules limiting the prescheduled methodology. This took longer than usual as research has not previously been assessed under the same restrictions placed upon the entire world; therefore, researching a strategy from previous studies had not previously covered researching through a pandemic. The research had to be self-ideated to overcome this problem using current design research techniques, such as a cultural probe, then adapting them to become an online self-reporting research style. Unfortunately, this process also took far longer than hoped. Due to the researcher and the participants being unable to meet in person, research materials had to be sent through postal services to participants and then sent back through postal services. This costly and time-consuming method relies on external parties to conduct the research, as they would take the materials to the participant.

## 6.5 Contribution to Knowledge

This thesis makes a significant contribution to knowledge by introducing a new mixed methodology called the ID-Agile method, which combines the principles and practices of Information Design with Agile methods for Product Design. This innovative approach bridges the gap between two distinct domains and brings together their strengths to enhance the overall Product Design process.

Information Design encompasses a set of principles and practices focused on organising, presenting, and communicating information in a user-friendly and visually appealing manner. Agile methods,

on the other hand, are iterative and flexible approaches to Software Development that emphasise collaboration, adaptability, and responsiveness to change. While both disciplines have demonstrated their value in their respective fields, their combination has the potential to provide unique benefits for Product Design. By integrating Information Design principles with agile sprints for the ID-Agile method, the thesis deepens the understanding of how Information Design can positively impact the overall user experience and product success within an Agile development environment.

Agile methods are widely recognised for their iterative, adaptive, and collaborative nature, allowing for quick iterations and continuous feedback. However, there can be challenges in ensuring that user-centred design principles are effectively integrated into the Agile process. The ID-Agile method addresses this gap by proposing strategies and techniques to seamlessly incorporate Information Design into Agile development, resulting in improved usability, accessibility, and overall user satisfaction.

The thesis also contributes to the practical realm by providing a tangible methodology that can be applied in real-world Product Design scenarios. By validating the ID-Agile method through case studies, experiments, and user evaluations, this thesis demonstrates its effectiveness and practicality in diverse contexts. This empirical validation contributes to the body of knowledge by offering evidence-based insights and best practices for professionals and practitioners seeking to adopt the ID-Agile method in their own design processes.

The ID-Agile method builds upon the existing knowledge of Information Design and Agile methods and creates a cohesive framework that seamlessly integrates their strengths. This methodology introduces innovative techniques, processes, and communication strategies that address the challenges faced in Product Design, such as ensuring user-centred design within an iterative and fast-paced development cycle.

By combining the principles of Information Design, which emphasise clarity, usability, and aesthetics, with the adaptive and collaborative nature of Agile methods, the ID-Agile method enables designers and development teams to create products that are not only visually appealing but also highly functional, user-friendly, and responsive to user needs.

The development of the ID-Agile method involved a research process, including a thorough literature review that examined the foundational concepts and best practices of Information Design and Agile methods. This review identified the areas of overlap and compatibility between the two fields, laying the groundwork for the integration of their principles.

Based on this research, a comprehensive methodology was formulated, outlining the key components, activities, roles, and responsibilities within the ID-Agile method. This conceptual framework provides a roadmap for Product Design teams to follow, ensuring the effective integration of Information Design and Agile methods throughout the design and development process.

To validate the effectiveness of the ID-Agile method, a series of case studies were conducted in diverse settings. These case studies involved applying the ID-Agile method to a real-world Product Design project, documenting the outcomes, and evaluating its impact on the final product. The results of these studies provided empirical evidence of the benefits and practical implications of the ID-Agile method.

The contribution of the ID-Agile method extends beyond academia, as it offers tangible value to industry professionals and practitioners involved in Product Design and development. By merging the principles of Information Design with Agile methods, the ID-Agile method enables teams to streamline their processes, enhance collaboration, and ultimately deliver superior products that meet user expectations.



Furthermore, this thesis demonstrates the effectiveness of the ID-Agile method in the context of a pandemic, such as COVID-19, where restrictions are constantly changing. The ID-Agile method offers a unique and valuable approach to Product Design by integrating the principles and practices of Information Design with the adaptability and collaboration inherent in Agile methods. The methodology enables design teams to create user-centred, visually appealing, and functional products while maintaining flexibility and responsiveness to evolving constraints, such as those imposed by a pandemic.

During a pandemic, when restrictions and guidelines are subject to frequent changes, the ID-Agile method becomes particularly relevant and beneficial. The following key points are necessary:

- **Iterative and Agile Approach:** The ID-Agile method embraces an iterative and incremental approach to Product Design, allowing teams to work in short, focused sprints. This iterative nature facilitates adaptability to changing circumstances, enabling design teams to quickly adjust their strategies and deliverables in response to new restrictions or requirements imposed by the pandemic.
- **Remote Collaboration:** The ID-Agile method emphasises effective collaboration and communication among team members, even when physically dispersed. This becomes crucial during a pandemic when remote work and virtual collaboration are essential. Through digital tools and Agile practices, teams can collaborate in real-time, share progress, provide feedback, and adapt the design process seamlessly despite physical restrictions.
- **User-centred Design:** Information Design principles integrated into the ID-Agile method ensure a user-centred approach to Product Design. This emphasis on understanding and meeting user needs is particularly important during a pandemic when user behaviours and preferences may change rapidly due to evolving circumstances. The ID-Agile method enables design teams to gather user feedback, iterate quickly, and adapt Product Designs to align with changing user requirements.

- **Flexibility and Adaptability:** Agile methods, inherent in the ID-Agile method, emphasise adaptability to change. This flexibility allows design teams to respond swiftly and effectively to the dynamic nature of a pandemic. With constant changes in restrictions, the ID-Agile method empowers teams to adjust project timelines, re-prioritise tasks, and allocate resources efficiently to ensure continued progress and successful product outcomes.
- **Rapid Prototyping and Feedback Loops:** The ID-Agile method promotes early and frequent prototyping, testing, and gathering feedback from users. This iterative feedback loop allows design teams to validate their assumptions and make necessary adjustments promptly. During a pandemic, where circumstances evolve quickly, the ability to obtain user feedback and refine designs in short cycles becomes invaluable.
- **Application and Validation:** The ID-Agile method during a pandemic, such as COVID-19, demonstrates its effectiveness in navigating the challenges posed by uncertain and changing restrictions. Through case studies and empirical data, this thesis showcases how the ID-Agile method enables design teams to deliver high-quality products that align with user needs and remain adaptable in the face of unforeseen circumstances.

Overall, the creation of the ID-Agile method represents a significant contribution to knowledge. It advances the fields of Information Design and Agile methods by introducing a new mixed methodology specifically tailored for Product Design. The integration of Information Design principles into the Agile development process not only enhances the overall user experience but also provides a comprehensive framework that combines the strengths of both domains. This contribution has the potential to shape future research, theory, and practice in the field of Product Design and further advance the understanding and application of mixed methodologies. Moreover, its applicability during a pandemic highlights its effectiveness in addressing the challenges posed by constantly changing restrictions. The ID-Agile method empowers design teams to navigate through

uncertain times, maintain productivity, and create user-centred products while adapting to evolving circumstances.

## 6.6 Recommendations for Future Research

The findings from this thesis have contributed to the research fields of menopause, well-being, and design. Firstly, menopausal research has been improved as perceived well-being was thought to have improved with the designed device. This means the device could be viably used by women daily as a wearable to improve well-being through cooling. As this device is generically designed to cool when a heart rate surpasses the range categorised as atypical, it could be implemented in other areas of medical and therapeutic research. Since the start of this research thesis, the 'Grace' cooling wearable was introduced and won many awards. This proves the validity of this research, as a successful design for a therapeutic outcome has improved menopausal women's well-being.

This research has improved its importance as recent news showed mass shortages in available HRT supplies (Briggs, 2022). As discussed throughout the literature review, it was clear that HRT had a higher negative to a positive ratio, and many women who take HRT would have been interested in alternatives. The recent shortages in HRT supplies are very worrying for menopausal women, where the cost-of-living crisis is making HRT a more challenging commodity to access. Therefore, a device like the one designed in this research could improve menopausal women's lives as an alternative to HRT, with no added side effects linked with medicalised outputs. This device would be therapeutic and non-invasive, unlike most current methods to change a woman's hormone balance. This device does not want to affect a woman's hormone imbalance but supports their imbalance, embracing it as a natural part of life rather than a hindrance.

Although the results were ambiguous in terms of if the device effectively cooled users, it was clear that perceived cooling affected users. In addition, perceived cooling correlated to improved well-being, meaning the designed device, overall, was successful. Even though the thesis was successful,

the researcher would redesign the device to trigger cooling by assessing heart rate value fluctuations. Rather than when 100 bpm was reached if the device were programmed to monitor thresholds based on a percentage rather than a target, the device would have improved user feedback.

Found to be the value in which a higher value was medically deemed unnatural. Through the final testing, it appeared that some women experienced hot flushes, or certainly extremities in heart rate rises, that the cooling device did not react to due to these values not reaching 100bpm. Therefore, future research developments should aim to design a device that can monitor heart rate rises as an individual variable. For example, a certain percentage could be added as a threshold for the device to activate from a constant heart rate the user would usually experience. The researcher feels that if this adaptation were made to the device design, the project would have had an increased successful outcome.

The device itself is only a concept design. Users can see the design through a 3D printed scale model, but the user testing involved more oversized items with circuit boards and wires uncontained. Future research would benefit from a higher money input where a device could be designed to size and tested as the designed concept and not just a working prototype. The researcher felt that the research output might have been hindered because the testing was not exact to the designed concept. This was mainly due to cost and access to resources. Through the final stages of this thesis, where design and development stages were undertaken, access to university equipment was unavailable due to COVID-19. As COVID-19 kept the researcher at home and only able to use home equipment to manufacture a working prototype, it ultimately reduced the overall output of the research. Though the research has had limitations, this thesis offers researchers who may find themselves in a similar predicament in the future a new research methodology and adaptation to research strategies to generate successful outcomes from home research projects, which delivered a successful thesis outcome through a worldwide pandemic with everchanging restrictions.

Therapeutic and medical devices generally have a sizeable monetary input and backing that allows for in-depth research. Therefore, it is suggested that future research would investigate backing to design and develop a successful solution based upon the findings found within this research. In addition, a higher monetary input would generate a prototype that works and looks like the exactly designed concept. The research in this thesis has not allowed for realistic prototyping due to funding. Increased funding for future research would also increase part output, where expensive parts could be purchased. Flexible technology could be implemented for comfort and reduced stigma, as found in the market research and existing product sections.

The results found within this research have had a positive outcome for menopausal women's well-being. It is suggested that future research analyses the effects of heart rate fluctuations to monitor hot flushes, as all hot flushes can be monitored correctly. In addition, the VR testing found that immersive environments can offer a place of escapism for participants, where cooling and warming can be achieved through VR. These findings should be taken into other research areas where these functions may be helpful, such as escapism for patients and cooling and warming for certain diseases.

## Chapter 7 - Conclusion

This thesis has concluded to find answers on how design for well-being affects vasomotor symptoms of menopausal women using biofeedback technology. Through finding that heart rate and finger blood flow both rises prior to the onset of a hot flush, it was then known that this would be a guaranteed avenue to attempt to lessen the effect of vasomotor symptoms. To attempt to monitor heart rate or finger blood flow, the researcher thought it was of importance to investigate biofeedback technology. Biofeedback technology was one of the design alternatives ideated alongside virtual reality. Virtual reality was pilot tested, where a significant result was found to cool the body through immersive content. It was decided that VR would not be viable for further development as it cannot be worn constantly to offer users support when needed. Therefore, Biofeedback technology was implemented into wearable technology. Subsequently, biofeedback technology was found to lower body temperature at a faster rate than where no cooling was offered. In addition, the perceived temperature was thought to be lower in participants. Though biofeedback proved cooling could reduce heart rate faster, the perceived lower body temperature participants experienced through this thesis proved that even if cooling is not found in research, perceived cooling is possible. This was deemed as necessary as actual body temperature losses due to hot flushes being a cognitive experience also, where treating such experienced with perceived effects can offer.

This thesis brought a new combined framework from information and software design strategies. Using common structures within Information Design, Behavioural Design and Software Development processes ideated a new method known as the 'ID-Agile' methodology. This iterative model brought massive success to the thesis as all parts across the areas of the design and development of a biofeedback wearable had a planned structure to follow. The method ideated worked due to the introduction of co-creation, where users were involved with this research process from the start through to the end. The alternative ideation results from various co-creation

workshops, such as brainstorming, focus groups, questionnaires, and design workshops. The constant and consistent user feedback and input during this thesis resulted in improved output. Implications from testing and the results found have been positive. Where outcomes have been seen to correlate with the early hypothesis, this research has found and validated that biofeedback technology can improve the well-being of menopausal women by lessening the effects of vasomotor symptoms.

Lastly, it is important to note the importance of this research at the current moment. The past year has been filled with news reports on the topic of menopause. Unfortunately, menopausal women are not being taken seriously by as the HRT shortage crisis worsened (BBCa, 2022). Due to the undue stress placed upon menopausal women, some are taking their own lives (BBCb, 2022). Though now an upturn has begun for menopause as firstly the house of commons has become ‘menopause friendly’ (BBCc, 2022). And secondly, the NHS are offering improved support (BBCd, 2022). This is a prime opportunity for therapeutic design to improve the quality of life for menopausal women through biofeedback technology.

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## Chapter 9 - Appendix



## Page 1: Living with Menopause

This survey is aiming to research how design for wellbeing can affect vasomotor symptoms of menopausal women through the use of immersive technology. I am a PhD student that specialises in product design. The data gathered from this survey will be used to design a new solution that will help women overcome vasomotor symptoms. The data gathered will comply with the University of Huddersfield Data Storage Policy and the data protection act. Nobody other than myself James Allen will have access to the data obtained. As submissions are anonymous by completing this survey; you are acknowledging that you have read this statement and agree to be a part of this research.

- [Next](#)

## Page 2: Daily Life Living with Menopause

1. What stage of menopause are you at?

- Perimenopause
- Menopause
- Post-Menopause
- Been through it
- Unsure of which stage I am currently at

2. How do you know what stage of menopause you are currently at (or when you were going through menopause how did you know what stages you were at)?

- My doctor has informed me of the current stage
- When I talk to other women, they have said which stage I am at
- Through online sources
- Through books
- I am unsure/ do not know
- Other

3. What symptoms do you/ have you had due to menopause?

- Hot flashes
- Night sweats
- Weight gain
- Vaginal dryness

- Irregular periods
- Phantom periods
- Shorter, lighter periods
- Heavier periods or flooding
- Shorter cycles
- Longer cycles
- Loss of interest in sex
- Changes in hair growth
- Difficulty Sleeping
- Mood swings
- Low mood or depression
- Easy tearfulness
- Decreased ability to concentration
- Memory problems
- Irritability
- Incontinence
- Other

4. Women usually go through menopause from the ages of 45-55, and hit menopause at the age of 51. Would you say you are going through/ went through menopause:

- Early
- Late
- On time

5. Have you received any medical treatment, such as a hysterectomy or chemotherapy that caused or precipitated menopause?

- Yes
- No

a. If yes, what treatment did you receive?

6. Did you or do you currently take hormone replacement therapy (HRT)?

- YES, I am currently on HRT
- YES, I have taken HRT but do not currently
- NO, I do not and have never taken HRT
- NO, but I have taken other supplements to cope with the symptoms

a. If yes, has it alleviated any mood symptoms?

- Yes
- No

This part of the survey uses a table of questions, view as separate questions instead?

7. Please fill out the following chart. It lists some mood descriptions. Please indicate the extent to which you felt these mood descriptions during the peri-menopause time period.

Please don't select more than 1 answer(s) per row.

	Not at all	Mild	Moderate	Severe
Depressed mood or feelings of hopelessness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Increased mood swings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Feelings of elation or agitation associated with symptoms like an exaggerated self-confidence; decreased need for sleep without a loss of energy; a sense that thoughts are racing; or increased activities or plans.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Improved mood (specifically an improvement in the symptoms of your mood disorder)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Feeling very anxious, more so than what you would consider normal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recurrent, unwanted, intrusive ideas,	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

images, or impulses that seem silly or horrible				
Feeling the need to check things over and over, or repeat actions over and over, in order to prevent bad things from happening	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Having panic attacks. (Panic attacks are sudden unexpected episodes of anxiety often associated with physical symptoms such as rapid heartbeat, feeling faint, lightheaded, trembling, chest tightness, or shortness of <u>breath</u> ; lasting approximately 10 minutes)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

This part of the survey uses a table of questions, view as separate questions instead?

**a.** and, if applicable, after you became post-menopausal.

Please don't select more than 1 answer(s) per row.

	Not at all	Mild	Moderate	Severe
Depressed mood or feelings of hopelessness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Increased mood swings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Feelings of elation or agitation associated with symptoms like an exaggerated self-confidence; decreased need for sleep without a loss of energy; a sense that thoughts are racing; or increased activities or plans.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Improved mood (specifically an	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

improvement in the symptoms of your mood disorder)				
Feeling very anxious, more so than what you would consider normal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recurrent, unwanted, intrusive ideas, images, or impulses that seem silly or horrible	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Feeling the need to check things over and over, or repeat actions over and over, in order to prevent bad things from happening	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Having panic attacks. (Panic attacks are sudden unexpected episodes of anxiety often associated with physical symptoms such as rapid heartbeat, feeling faint, lightheaded, trembling, chest tightness, or shortness of <u>breath</u> ; lasting approximately 10 minutes)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7 Have or did your symptoms, as listed above, interfere with any of the following:

- Your work efficiency
- Your relationships with coworkers
- Your relationships with your family
- Your social life activities
- Your home responsibilities
- Other

8 Is there anything about your experience with menopause on a whole that you wish you could change? If so what?



• Next

### Page 3: Sleeping with menopause

As the research I am conducting is centred around circadian rhythms and sleep, the next section is solely based on sleeping with menopause.

**9.** Generally, post-menopausal women are less satisfied with their sleep and as many as 61% report insomnia symptoms. Do you feel you have insomnia symptoms (struggle with sleep)?

- Yes
- No
- Unsure

**10.** Snoring has also been found to be more common and severe in post-menopausal women. Snoring, along with pauses or gasps in breathing are signs of a more serious sleep disorder, obstructive sleep apnoea (OSA). Do you have any of these symptoms?

- Yes
- No
- Unsure

**11.** Changing and decreasing levels of oestrogen cause many menopausal symptoms including hot flashes, which are unexpected feelings of heat all over the body accompanied by sweating. They usually begin around the face and spread to the chest affecting 75-85% of women around menopause. Prior to the hot flash, body temperature rises accompanied by an awakening. Hot flashes last on average three minutes leading to less sleep efficiency. Most women experience these for one year, but about 25% have hot flashes for five years. While total sleep time may not suffer, sleep quality does. Hot flashes may interrupt sleep and frequent awakenings cause next-day fatigue. Do you feel your sleep is affected by hot flashes and night sweats?

- Yes
- No

**12.** There are a number of alternative methods for dealing with menopause to aid sleep, without the use of HRT. Do you or have you used any of the following?

- Nutritional products and medications such as calcium supplements, vitamin D, and Bisphosphonates for the prevention or treatment of osteoporosis (thinning and weakening of the bones)
- Estrogen creams

Rings for vaginal dryness

Sleep-promoting drugs for insomnia

a. In addition to the previous question, alternative treatment for menopausal symptoms may come from soy products (tofu, soybeans, and soymilk). They contain phytoestrogen, a plant hormone similar to estrogen. Phytoestrogens are also available in over-the-counter nutritional supplements (ginseng, extract of red clover, black cohosh). Have you tried any phytoestrogen supplements to help?

Yes

No

• Next

#### Page 4: Lifestyle

13. Would you say you eat healthily?

Yes

No

14. Do you usually eat just before bedtime?

Yes

No

15. Do you find it easy to maintain weight?

Yes

No

16. Do you eat spicy or acidic foods?

Yes

No

17. Do you consume nicotine, caffeine and/or alcohol?

Yes

No

a. If so do you consume just before bedtime?

Yes

No

18. What type of night wear do you use?

- Light
- Heavy
- I don't

19. What type of bedding do you use?

- Light
- Standard
- Heavy

20. Do you use any of the following to help circulation through a night?

- A fan
- Air conditioning
- Leave the window open
- Leave the doors open
- Sleep separate from partner
- Other

21. Do you often feel stressed?

- Yes
- No

a. If yes, what makes you stressed?

22. And finally, what parts of sleeping with menopause would you most like to change (or wish you didn't have to live with)?

• Next



23. How many times do you experience the effects of vasomotor symptoms (hot flashes, night sweats, etc.) during an average day?

- 0
- 1-5
- 6-10
- 11-15
- 16+

24. How do you currently try to relieve the effects of a hot flash? (How do you attempt to cool down)


25. How do you currently try to relieve the effects of a night sweats? (How do you attempt to cool down)

• **Finish**


## Appendix 2- Focus Group

	Task	Intent	Notes	materials
1	Personal experience.	Gather personal stories from the participants about their menopausal stories.	Facilitator explains the focus group and gives out relevant resources.	Presentation slides on portrait.
				Presentation slides of stories.
				Paper.
2	Collecting VR immersion and improvement feedback.	To see if menopausal women are affected when immersed within certain 3D environments, and how the experiences could be improved.	Facilitator introduces VR technology.	Example videos.
				Form.
				Collect forms.
3	Collecting Wellbeing information from the participants regarding how mixed reality could improve their wellbeing.	To find out what images or thoughts menopausal women have that could improve wellbeing.	Facilitator issues the relevant areas in which they would like sketching to be done for certain words.	Paper.
				Key words.
				Collect forms.
4	Focus group synopsis.	Comments on the focus group and gathering extra participant data.	Facilitator brings the workshop to a close.	Semi-structured Questionnaire.

Participant	Description	Experience with menopause	What experience have you had with Virtual Reality before? (on a scale of 1 (none)-10 (Lots))
1	<ul style="list-style-type: none"> <li>• 60 years old</li> <li>• Post-menopausal</li> <li>• Administrator</li> </ul>	10+ years	6
2	<ul style="list-style-type: none"> <li>• 54 years old</li> <li>• Post-menopausal</li> <li>• Project co-coordinator</li> </ul>	6-10 years	1
3	<ul style="list-style-type: none"> <li>• 47 years old</li> <li>• Menopausal</li> <li>• Cohort development manager</li> </ul>	3-5 years	1
4	<ul style="list-style-type: none"> <li>• 51</li> <li>• Menopausal</li> <li>• Design Manager</li> </ul>	3-5 years	7
5	<ul style="list-style-type: none"> <li>• 36 years old</li> <li>• Just starting peri-menopause</li> <li>• Imagination coordinator</li> </ul>	None	5

Tish - 60  
 Mother of 2   
~~Alone~~  
 1 daughter special needs.


Post menopause.  
 Onset at 42 following  
 sudden unexpected death of partner.  
 Then stopped / started for  
 ten years.  
 Hot sweats, headaches,  
 emotional - didn't realise  
 it at the time.  
 Tiredness  
 Loss of memory.  
 Insomnia.

Sharon 52 (almost)  
 2 children - both adults, one still @ home  
 Divorced   
 History of depression  
 Experiencing hot flashes 2+ yrs  
 Around 6 months off post-menopause  
 Occasional heart palpitations  
 forgetfulness  
 often experience insomnia  
 Don't feel too negatively affected by  
 symptoms  
 The flushing of the face can be  
 embarrassing.  
 (always seems to happen at the  
 worst moments)  
 Was on implant until 2yrs ago.  
 Tried CBD oil for awhile.

Pam  
 54  
 1 child  
 Divorced  
 Post menopause  
 Symptoms of menopause for me =  
 - Tiredness  
 - Hot Sweats  
 - Memory loss  
 - Mood swings  
 Went through menopause (Peri menopause)  
 in my early / mid 40s.



feel so much better now that I'm on post  
 menopause, although still have flashes in the night.

Jane - 36   
 perimenopausal  
 Mum of feral toddler

Claire  
 47  
 Kids x 2 (18 + 22)  
 Husband  
 Menopausal - NIGHT SWEATS!!  
 anti-depressant / Gabapentin  
 Fibromyalgia - Pain, fatigue,  
 Brain fog  
 over educated  
 - Dog owner  
 - bike rider  
 - Loves sewing  
 - FEMINIST  
 Hot flashes  
 Itchy skin  
 NIGHT BAIN !!  
 HRT ☹️



Participant	Issues raised
1	<ul style="list-style-type: none"> <li>• Post-menopausal</li> <li>• Single</li> <li>• Social life (Mother of 2, one has special needs)</li> <li>• Menopause started early due to stress and grieving at loss of husband at 42</li> <li>• Felt like menopause was stop and start for 10 years</li> <li>• Hot flushes, night sweats, tiredness, loss of memory &amp; headaches</li> <li>• Emotional, but only realised how emotional after menopause</li> </ul>
2	<ul style="list-style-type: none"> <li>• Just post-menopausal</li> <li>• Social life ( Mother of 1)</li> <li>• Divorced</li> <li>• Menopause- Tiredness, memory loss, hot flushes, night sweats &amp; mood swings</li> <li>• Peri-menopause in early/mid 40's</li> <li>• Feels better now post-menopause, although still has night sweats</li> </ul>
3	<ul style="list-style-type: none"> <li>• Menopausal</li> <li>• Social life (2 children)</li> <li>• Married</li> <li>• Activities within social life hampered</li> <li>• Menopausal- Hot flashes, night sweats, itchy skin, anti-depressants/ gabapentin, fibromyalgia, pain, fatigue &amp; brain fog</li> <li>• HRT hasn't worked</li> <li>• Work life made harder</li> </ul>
4	<ul style="list-style-type: none"> <li>• Menopausal</li> <li>• Social life (2 children, both adults but one still lives at home)</li> <li>• Menopause- has a prior history of depression, experiencing hot flashes for 2+ years, feels around 6 months from post-menopause, heart palpitations &amp; insomnia</li> <li>• Still feels positive even though they experience these symptoms</li> <li>• Can be embarrassing to get a hot flush in front of people, seems to be more prominent in the worst situations</li> <li>• Was on implant until 2 years ago</li> <li>• Has used CBD oil, but no HRT</li> </ul>
5	<ul style="list-style-type: none"> <li>• Peri-menopausal</li> <li>• Social life (Mother to a toddler)</li> <li>• As journey has only just started, no major symptoms</li> </ul>

	Participant 1	Participant 2	Participant 3	Participant 4	Participant 5
Cooling video 1	NO	YES	YES	YES	YES
Cooling video 2	NO	YES	YES	NO	YES
Cooling video 3	NO	NO	YES	SLIGHTLY	YES
What could be added to the cooling experience?	Use of Ice more in imagery, And something physical to hold that is cold	N/A	Could be a realistic video (Lake Coniston)	Fans & sounds	N/A
Warming video 1	YES	YES	YES	YES	YES
Warming video 2	NO	YES	YES	NO	YES
Warming video 3	NO	NO	NO	NO	NO
What could be added to warming the experience?	Feel of heat, realistic video in an actual warm climate	Use of a fan to cool	Real life cosy living room, Tea, sleeping cat, book	Limited recording movements, smells & sounds	Less motion, cosy fire, candle lights
Relaxation video 1	NO	NO	NO	NO	NO
Relaxation video 2	YES	NO	SLIGHTLY	NO	NO
Relaxation video 3	NO	YES	NO	YES	NO
Relaxation video 4	NO	YES	YES	YES	YES
What could be added to relaxation the experience?	Add music, and more realistic than 3D animation	Beach, sunbathing, make more realistic	Sounds and smells	More realistic, less like a video game, music, soothing voices	Real life videos are preferred, addition of music would be good

	Participant 1	Participant 2	Participant 3	Participant 4	Participant 5
Anger	<ul style="list-style-type: none"> <li>• Cruelty (kids, animals)</li> <li>• Idiotic drivers</li> </ul>	<ul style="list-style-type: none"> <li>• Certain people</li> </ul>	<ul style="list-style-type: none"> <li>• Pollution</li> <li>• Racism</li> <li>• Violence</li> <li>• Mistreatment of people &amp; animals</li> </ul>	<ul style="list-style-type: none"> <li>• Politicians</li> </ul>	<ul style="list-style-type: none"> <li>• Injustices</li> <li>• People hurting one another</li> </ul>
Joy	<ul style="list-style-type: none"> <li>• Happiness</li> <li>• Children</li> <li>• Grandchild</li> </ul>	<ul style="list-style-type: none"> <li>• Holidays</li> </ul>	<ul style="list-style-type: none"> <li>• Family</li> <li>• Dogs</li> <li>• Ponies</li> </ul>	<ul style="list-style-type: none"> <li>• Cuddles</li> </ul>	<ul style="list-style-type: none"> <li>• Fish in sea</li> <li>• Wildlife</li> <li>• Open spaces</li> </ul>
Disgust	<ul style="list-style-type: none"> <li>• Cruelty</li> </ul>	<ul style="list-style-type: none"> <li>• People spitting</li> </ul>	<ul style="list-style-type: none"> <li>• Egg sandwiches</li> <li>• Donald Trump</li> </ul>	<ul style="list-style-type: none"> <li>• Mushrooms</li> </ul>	<ul style="list-style-type: none"> <li>• Bodily Fluid</li> </ul>
Sadness	<ul style="list-style-type: none"> <li>• Death</li> <li>• Illness</li> <li>• Sad films</li> </ul>	<ul style="list-style-type: none"> <li>• Close personal deaths</li> </ul>	<ul style="list-style-type: none"> <li>• Grief</li> <li>• Loss</li> </ul>	<ul style="list-style-type: none"> <li>• Depression</li> <li>• Loss</li> <li>• Loneliness</li> </ul>	<ul style="list-style-type: none"> <li>• Death</li> <li>• Loss</li> </ul>
Fear	<ul style="list-style-type: none"> <li>• Fast fairground rides</li> <li>• Violence</li> </ul>	<ul style="list-style-type: none"> <li>• Lifts</li> </ul>		<ul style="list-style-type: none"> <li>• Spiders</li> </ul>	<ul style="list-style-type: none"> <li>• Danger</li> </ul>
Surprise	<ul style="list-style-type: none"> <li>• Parties</li> </ul>	<ul style="list-style-type: none"> <li>• Unexpected visits from children</li> </ul>		<ul style="list-style-type: none"> <li>• Gift</li> <li>• Unkindness</li> </ul>	

End questionnaire

1	What is your current job role? Cohort Development Manager
2	What experience do you have with menopause? a) None b) 1-2 years <b>c) 3-5 years</b> d) 6-10 years e) 10+ years
3	What experience have you had with Virtual Reality before? (on a scale of 1 (none)-10 (Lots)) 1 2 3 4 5 6 7 8 9 10 <b>5</b>
4	Have you any comments about today's focus group? felt odd discussing my health with a young man but he was very cool about it!
5	What was the best thing about the workshop? Good discussion
6	How could the workshop be improved? <del>More</del> But more organised → where tasks more clearly → Why are we doing them - introduce Tell everyone what tasks are at the beginning → articulate purpose Bit more time needed → felt rushed

End questionnaire

1	What is your current job role? Administrator
2	What experience do you have with menopause? a) None b) 1-2 years c) 3-5 years d) 6-10 years <b>e) 10+ years</b>
3	What experience have you had with Virtual Reality before? (on a scale of 1 (none)-10 (Lots)) 1 2 3 4 5 <b>6</b> 7 8 9 10 At a friends house
4	Have you any comments about today's focus group? Interesting information, good to have an insight into others experiences.
5	What was the best thing about the workshop? Gave an insight into colleagues experiences & how it may affect them.
6	How could the workshop be improved? Videos on a <del>screen</del> large screen with sound. Final element on a printed sheet with fuller instructions. Worked well though - very useful.

End questionnaire

1	What is your current job role? Design Manager
2	What experience do you have with menopause? a) None b) 1-2 years <b>c) 3-5 years</b> d) 6-10 years e) 10+ years
3	What experience have you had with Virtual Reality before? (on a scale of 1 (none)-10 (Lots)) 1 2 3 4 5 6 <b>7</b> 8 9 10
4	Have you any comments about today's focus group?
5	What was the best thing about the workshop?
6	How could the workshop be improved?

End questionnaire

1	What is your current job role? Imagination Co-ordinator
2	What experience do you have with menopause? <b>a) None</b> b) 1-2 years c) 3-5 years d) 6-10 years e) 10+ years
3	What experience have you had with Virtual Reality before? (on a scale of 1 (none)-10 (Lots)) 1 2 3 4 <b>5</b> 6 7 8 9 10
4	Have you any comments about today's focus group? Very interesting topic, lots to try could VE be used during hot flash?
5	What was the best thing about the workshop? Came in friendly manner
6	How could the workshop be improved? Longer to discuss

End Questionnaire:

1	What is your current job role? Project coordinator
2	What experience do you have with menopause? a) None b) 1-2 years c) 3-5 years <b>d) 6-10 years</b> e) 10+ years
3	What experience have you had with Virtual Reality before? (on a scale of 1 (none)-10 (Lots)) <b>1</b> 2 3 4 5 6 7 8 9 10
4	Have you any comments about today's focus group? Today's focus group was a great way to meet with other women to see what symptoms they go through with the menopause?
5	What was the best thing about the workshop? As above. Meeting Sinder woman to discuss problems of the menopause and knowing you are not on your own.
6	How could the workshop be improved? Workshop was brilliant. Maybe more focus groups in the future.



## Appendix 3- Coding

[code]

```
int pulsePin = A0;          // Pulse Sensor purple wire connected to analog pin A0
int blinkPin = 13;         // pin to blink led at each beat
int peltierPin = 9;        //pin to have peltier trigger cooling

// Volatile Variables, used in the interrupt service routine!
volatile int BPM;          // every 2ms the raw int updates from A0
volatile int Signal;       // stores the raw data
volatile int IBI = 600;    // seeded time interval between beats
volatile boolean Pulse = false; // if true a beat is detected, if false no beat is detected
volatile boolean QS = false; // qs becomes true when a beat is found

static boolean serialVisual = true; // set to false

volatile int rate[10];     // holds 10 ibi values
volatile unsigned long sampleCounter = 0; // determines the pulse timing
volatile unsigned long lastBeatTime = 0; // finds ibi
volatile int P = 512;     // finds the seeded peak
volatile int T = 512;     // finds the seeded trough
volatile int thresh = 525; // finds heartbeat
volatile int amp = 100;   // holds amplitude
volatile boolean firstBeat = true; // seeds the array rate
volatile boolean secondBeat = false; // seeds the array rate
volatile int lowThreshold = 450; //determines a low threshold of 55bpm

void setup()
{
  pinMode(blinkPin, OUTPUT); // blinks on pulse
  Serial.begin(115200);      //
  interruptSetup();         // pulse reading every 2ms
  pinMode(peltierPin, OUTPUT); // peltier is output
```

```

pinMode(pulsePin, INPUT);    // pulse sensor input
}

void loop()
{
  serialOutput();

  if (QS == true) // heartbeat recorded
  {
    serialOutputWhenBeatHappens();
    QS = false; // resets for next recording
  }
  if (BPM >= 100) // if BPM goes above 100 peltier on
  {
    digitalWrite(peltierPin, HIGH); // peltier powered
    Serial.println("Peltier ON"); // prints on serial monitor
  }
  else
  {
    digitalWrite(peltierPin, LOW); // peltier has no power
    Serial.println("Peltier OFF"); // prints on serial monitor
  }
  delay(20); // 2ms between readings
}

void interruptSetup()
{
  // interrupt needed every 2ms for timer
  TCCR2A = 0x02; // CTC enabled when PMW 3 & 11 disabled
  TCCR2B = 0x06; // 256 prescaler
  OCR2A = 0x7C; // the top count is 124 for the 500Hz sample rate
}

```

```
TIMSK2 = 0x02; // anything between TIMER2 & OCR2A enables interrupt
sei(); // global interrupt enabled
}
```

```
void serialOutput()
{
  if (serialVisual == true)
  {
    arduinoSerialMonitorVisual('-', Signal); // visualises the serial monitor
  }
  else
  {
    sendDataToSerial('S', Signal); // sends data
  }
}
```

```
void serialOutputWhenBeatHappens()
{
  if (serialVisual == true)
  {
    Serial.print(" ❤️ Heart-Beat Found "); //displays heartbeat
    Serial.print("BPM: ");
    Serial.println(BPM);
    delay(1000);
  }
  else
  {
    sendDataToSerial('B', BPM);
    sendDataToSerial('Q', IBI);
  }
}
```

```

void arduinoSerialMonitorVisual(char symbol, int data )
{
  const int sensorMin = 0;    // minimum of sensor
  const int sensorMax = 1024; // maximum of sensor
  int sensorReading = data; // maps the sensor range
  int range = map(sensorReading, sensorMin, sensorMax, 0, 11);
}

void sendDataToSerial(char symbol, int data )
{
  Serial.print(symbol);
  Serial.println(data);
}

ISR(TIMER2_COMPA_vect) //triggered at 124
{
  cli();
  Signal = analogRead(pulsePin);    // takes data from pulse sensor
  sampleCounter += 2;                // variable in ms
  int N = sampleCounter - lastBeatTime; // time between beats
  if (Signal < thresh && N > (IBI / 5) * 3)
  {
    if (Signal < T) // T = trough
    {
      T = Signal;
    }
  }
  if (Signal > thresh && Signal > P)
  {
    P = Signal;          // P = peak
  }
  if (N > 250)
  {

```

```

if ( (Signal > thresh) && (Pulse == false) && (N > (IBI / 5) * 3) )
{
    Pulse = true;
    digitalWrite(blinkPin, HIGH);      // pin 13 on
    IBI = sampleCounter - lastBeatTime;
    lastBeatTime = sampleCounter;
    if (secondBeat)
    {
        secondBeat = false;
        for (int i = 0; i <= 9; i++)
        {
            rate[i] = IBI;
        }
    }
    if (firstBeat)
    {
        firstBeat = false;
        secondBeat = true;
        sei();
        return;
    }
    word runningTotal = 0;
    for (int i = 0; i <= 8; i++)
    {
        rate[i] = rate[i + 1];
        runningTotal += rate[i];
    }
    rate[9] = IBI;
    runningTotal += rate[9];
    runningTotal /= 10;
    BPM = 60000 / runningTotal;
}

```

```
    QS = true;
  }
}
if (Signal < thresh && Pulse == true)
{
  digitalWrite(blinkPin, LOW); // turn off pin 13
  Pulse = false;
  amp = P - T;
  thresh = amp / 2 + T;
  P = thresh;
  T = thresh;
}
if (N > 2500)
{
  thresh = 512;
  P = 512;
  T = 512;
  lastBeatTime = sampleCounter;
  firstBeat = true;
  secondBeat = false;
  sei();
}
}
[/code]
```

## Appendix 4- Data Sheet

### Heart Rate Sensor Datasheet

Maximum Ratings	VCC	3.0 – 5.5V
	IMax (Maximum Current Draw)	< 4mA
	VOut (Output Voltage Range)	0.3V to Vcc
Wavelength	LED Output	565nm
	Sensor Input	525nm
Dimensions	L x W (PCB)	15.8mm (0.625")
	Lead Length	20cm (7.8")

## Appendix 5- Final Testing Questionnaire



### Cooling Wearable Questionnaire

All data recorded will be confidential and the rights of confidentiality will be respected. The data recorded will comply with the University of Huddersfield data storage policy and the data protection act. Nobody other than myself James Allen will have access to the data obtained. Names of the participants will be disclosed, along with the premises and organisations. Participants will be aware that their contributions may be used for publications and my final PhD thesis.

All answers are anonymous, and no names will be attached to the participants.

This requires participation with regards to cooling, therefore ice and water are necessary for feedback.

1. What age range are you within?



Multiple choice

- under 40 X
- 40-44 X
- 45-49 X
- 50-54 X
- 55-59 X
- 60 and over X
- Add option or [add "Other"](#)



2. Which of the following would you describe yourself as? \*

- Peri-menopausal
- Menopausal
- Post-Menopausal
- None of the above

3. Whether menopausal or not, do you experience hot flushes? \*

- Yes
- No

4. This next stage requires ice (or cold water). If you could apply ice or cold water to the wrist \*  
for a minute. After this experience, did you:

- Feel cooler
- Actually lower in temperature
- Feel improved wellbeing
- Feel more peaceful
- Feel no change
- Other...

5. Following on from the last test, do you feel that if cooling was applied to the wrist prior to the onset of a hot flush, you would feel: \*

- Cooler
- Less embarrassment
- Improved wellbeing
- None of the above
- Other...

6. Do you suffer from any of the following during sleep: \*

- Night sweats
- Awakenings through the night
- Insomnia
- None of the above

7. Applying cooling to the forehead prior to sleep has helped menopausal women have improved sleep. But if a device reacted to your body throughout the night to cool when necessary, do you feel: \*

- Night sweats would be improved
- Less awakenings would occur
- General sleep would improve
- None of the above

8. I have designed a device, with menopausal women, that can be worn anywhere on the body\* (specifically for the wrist and forehead). Would you feel comfortable wearing a wearable to monitor hot flashes and night sweats?



- Yes
- No

9. Do you feel your menopausal experience would be improved through an app that is connected to the wearable device? (The app offers information about menopause, how the wearable works, a wellbeing tracker, podcasts and local groups)



- Yes
- No
- Maybe

10. Would you be interested if this low-cost wearable to improve menopausal wellbeing through a reduction in hot flushes and night sweats, was available to purchase? \*



Yes

No

Maybe

## Likert Scale Hot Flush Questionnaire

All data recorded will be confidential and the rights of confidentiality will be respected. The data recorded will comply with the University of Huddersfield data storage policy and the data protection act. Nobody other than myself James Allen will have access to the data obtained. Names of the participants will be disclosed, along with the premises and organisations. Participants will be aware that their contributions may be used for publications and my final PhD thesis.

All answers are anonymous, and no names will be attached to the participants.

What is your age?



Short answer

Short answer text



Required



On a scale of 1-7, What is the severity of your hot flushes? \*

	1	2	3	4	5	6	7	
Not Severe	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Severe


On a scale of 1-7, how would you rate your wellbeing prior to testing? \*

	1	2	3	4	5	6	7	
Low Wellbeing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	High Wellbeing

Using Plutchik's colour wheel, what emotions do you feel prior to testing? \*

- Anger
- Fear
- Sadness
- Disgust
- Surprise
- Anticipation
- Trust
- Joy

Upload a sketch of how you currently feel when having a hot flush.

 Add file

 [View folder](#)

I would now like you to upload a timeline of your current experience with a hot flush.

 Add file

 [View folder](#)

This section requires you to use ice at all the times when you feel you have a hot flush.

Use ice as quickly as possible, and only answer following questions once ice has been used after at least 5 hot flushes.

On a scale of 1-7, what was the severity of your hot flushes after testing? \*

	1	2	3	4	5	6	7	
Not Severe	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Severe

On a scale of 1-7, how would you rate your wellbeing after to testing? \*

	1	2	3	4	5	6	7	
Low Wellbeing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	High Wellbeing

Using Plutchik's colour wheel, what emotions do you feel after to testing? \*

- Anger
- Fear
- Sadness
- Disgust
- Surprise
- Anticipation
- Trust
- Joy

Upload a sketch of how you feel after testing when having a hot flush.

 Add file

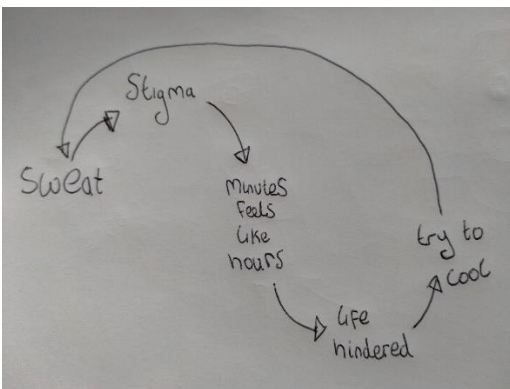
 [View folder](#)

I would now like you to upload a timeline of your experience after testing with a hot flush.

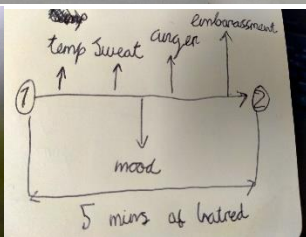
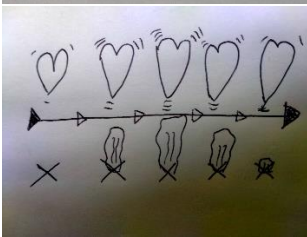
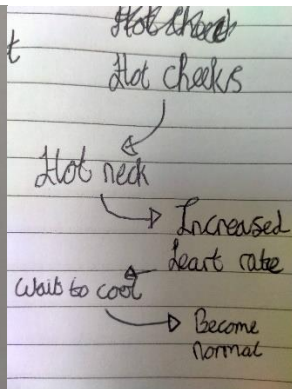
 Add file

 [View folder](#)



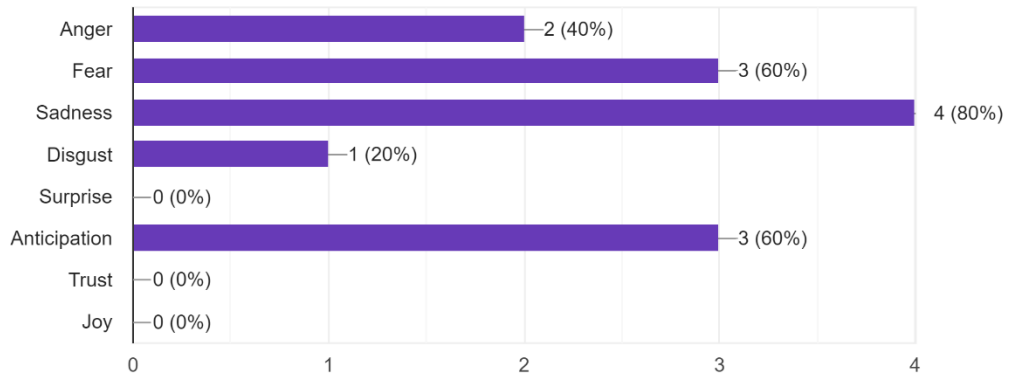


Start  
 Panic  
 Sweat  
 feel bad  
 Shy away  
 heart rate rises  
 temp rises  
End



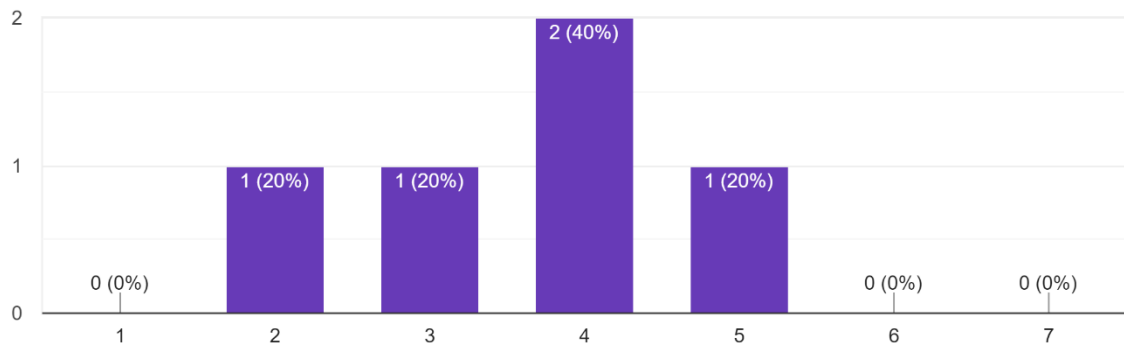
Using Plutchik's colour wheel, what emotions do you feel prior to testing?

5 responses



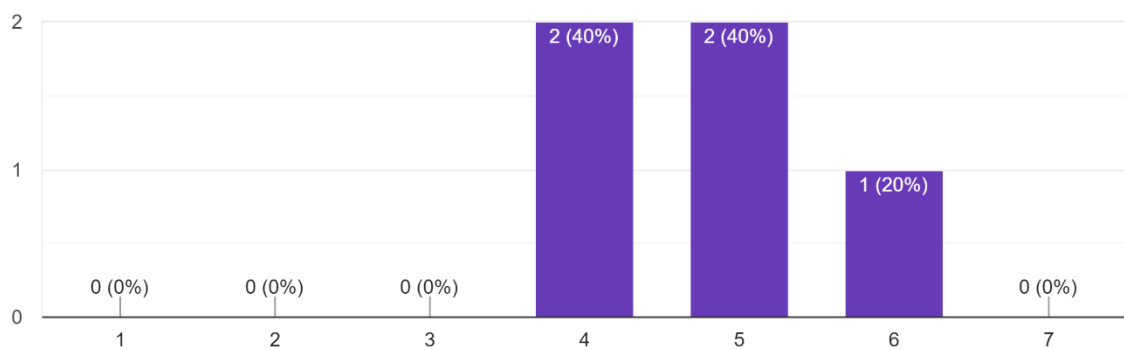
On a scale of 1-7, what was the severity of your hot flushes after testing?

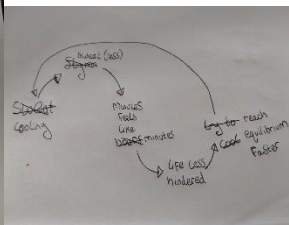
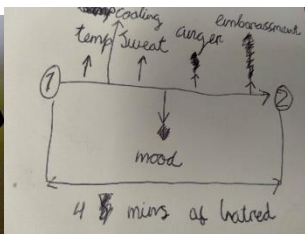
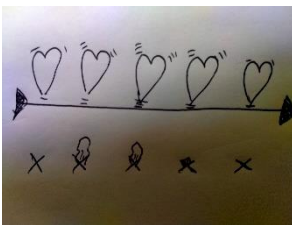
5 responses



On a scale of 1-7, how would you rate your wellbeing after to testing?

5 responses





Start  
Cooling  
Less panic  
Feel more normal  
Carry on with life  
heart rate rises  
temp rises a little  
Shorter time  
End

Feel cooling  
works way through body → Still get hot head + cheeks  
wants to cool → Get to normality quicker

**THE UNIVERSITY OF HUDDERSFIELD**  
**School of Art, Design and Architecture**

**ETHICAL REVIEW**  
**(Limited or Significant Risk)**

APPLICABLE TO ALL STUDENTS and STAFF

Undergraduates and taught postgraduates, please complete and return via email to your Project / Dissertation Supervisor along with the required documents (shown below)

**Staff and research students, please complete and return via email to the school research office (sadapgradmin@hud.ac.uk) along with the required documents (shown below).**

SECTION A: TO BE COMPLETED BY THE APPLICANT

Before completing this section please refer to the School Research Ethics web pages which can be found using [this link](#). Applicants should consult the appropriate ethical guidelines.

Please ensure that the statements in Section C are completed by the applicant (and supervisor for PGR students) prior to submission.

SECTION A: TO BE COMPLETED BY THE STUDENT/ Pi

---

Before completing this section please refer to the School Research Ethics web pages which can be found using [this link](#).

Students should consult the appropriate ethical guidelines. The student's supervisor is responsible for advising the student on appropriate professional judgement in this review.

Please ensure that the statements in Section C are completed by the student and supervisor prior to submission.

**Please type your answers, hand written forms will not be considered by the ethics panel.**

Project Title:	How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?
Name:	James Dennis Allen
Student number:	U1456287
Course:	PhD
Supervisor:	Omar Ivan Huerta Cardoso
Project start date	20/09/2017
Risk level: (limited or significant)	Limited <input checked="" type="checkbox"/> Significant <input type="checkbox"/>

SECTION B: PROJECT OUTLINE (TO BE COMPLETED IN FULL BY THE STUDENT)

---

Issue	Please provide sufficient detail for your supervisor to assess strategies used to address ethical issues in the research proposal
-------	---

<p><b>Aim / objectives of the study</b> These need to be clearly stated and in accord with the title of the study. (Sensitive subject areas which might involve distress to the participants will be referred to the Course Approval Panel).</p>	<p>The aim of the study is to design a new solution to improve the effects of vasomotor symptoms for menopausal women through design. By developing a further knowledge and understanding from the literature review and Research studies; an answer to the main research question can be achieved, which is:</p> <ul style="list-style-type: none"> <li>• How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?</li> </ul> <p>To answer the research question, some objectives have been established. Meeting these objectives will set the foundations on which to design a new product to improve the circadian rhythms of menopausal women. The objectives are as follows:</p> <ul style="list-style-type: none"> <li>• To investigate whether immersive technology can alter body temperature.</li> <li>• To define a design framework to improve the wellbeing of menopausal women.</li> <li>• To design an alternative in a co-creation workshop to improve the wellbeing of menopausal women.</li> <li>• To design and test a prototype to improve the wellbeing of menopausal women.</li> <li>• To analyse the results from the previous test to see if design has improved the wellbeing of menopausal women.</li> <li>• To understand the implications of the test and results for the wellbeing of menopausal women.</li> </ul>
<p><b>Brief overview of research methodology</b> The methodology only needs to be explained in sufficient detail to show the approach used (e.g. survey) and explain the research methods to be used during the study.</p>	<ol style="list-style-type: none"> <li>1. Initial Questionnaire and Interviews</li> <li>2. Mixed Reality Testing</li> <li>3. Brainstorming and Co-creation</li> <li>4. Concept Testing</li> <li>5. Cultural Probe</li> <li>6. Final Questionnaire and Interviews</li> </ol>
<p><b>Does your study require any third party permissions for study?</b> If so, please give details i.e. company permission</p>	<p>No</p>
<p><b>Participants</b> Please outline who will participate in your research. If your research involves vulnerable groups (e.g. children, adults with learning disabilities), it must be referred to the Course Assessment Panel.</p>	<ol style="list-style-type: none"> <li>1. Initial Questionnaire and Interviews- Women who experience/ have experienced menopause</li> <li>2. Mixed Reality Testing- University students</li> <li>3. Brainstorming and Co-creation- Specialists in the field, Menopausal women, Designers.</li> <li>4. Concept Testing- Menopausal women</li> <li>5. Cultural Probe- Menopausal women</li> <li>6. Final Questionnaire and Interviews- Menopausal women</li> </ol> <p>No research will involve vulnerable groups and the research will not make the participants vulnerable.</p>
<p><b>Access to participants</b> Please give details about how participants will be identified and contacted.</p>	<p>Participants will either be asked directly (Face to face), through email, phone calls, letters etc. All participants will be gathered from existing connections to this area.</p>
<p><b>How will your data be recorded and stored?</b> Please confirm that as a minimum this will comply with the university data storage policy and the Data</p>	<p>I confirm that all sensitive/ confidential data will be stored on a secure university system (i.e. K drive) Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> (provide further details if No)</p>

Protection Act. Please indicate also any further specific details.	
<b>Informed consent.</b> Please outline how you will obtain informed consent.	All participants will have to sign participant consent forms to acknowledge they are willing to take part in the research.
<b>Confidentiality</b> Please outline the level of confidentiality you will offer respondents and how this will be respected. You should also outline about who will have access to the data and how it will be stored. (This should be included on information sheet.)	All data recorded will be confidential and the rights of confidentiality will be respected. The data recorded will comply with the University of Huddersfield data storage policy and the data protection act. Nobody other than myself James Allen will have access to the data obtained. Names of the participants will be disclosed, along with the premises and organisations. Participants will be aware that their contributions may be used for publications and my final PhD thesis.
<b>Anonymity</b> Do you intend to offer anonymity? If so, please indicate how this will be achieved.  NB for most projects anonymity should be offered as standard unless there are compelling grounds not to.	Yes, anonymity will be offered to all of the participants. Names of the participants will be disclosed, along with the premises and organisations. A code description (i.e. P-1) of the participants, and the space/ environment used for research will be described as an alternative. All data recorded will be confidential and the rights of confidentiality will be respected. The data recorded will comply with the University of Huddersfield data storage policy and the data protection act. Nobody other than myself James Allen will have access to the data obtained. Names of the participants will be disclosed, along with the premises and organisations. Participants will be aware that their contributions may be used for publications and my final PhD thesis.
<b>Harm</b> Please outline your assessment of the extent to which your research might induce psychological stress, anxiety, cause harm or negative consequences for the <b>participants</b> or the <b>researcher</b> (beyond the risks encountered in normal life). If more than minimal risk, you should outline what support there will be for participants. If you believe that there is minimal likely harm, please articulate why you believe this to be so. If there is potential for harm to the researcher (physical or psychological) please include attach a risk assessment.	The research will not induce psychological stress or anxiety, because the participants will be aware of the research they are undertaking. The research itself is not intrusive and will be there to improve wellbeing.  1. Initial Questionnaire and Interviews- Minimal risk 2. Mixed Reality Testing- Minimal risk 3. Brainstorming and Co-creation- Minimal risk 4. Concept Testing- Minimal risk 5. Cultural Probe- Minimal risk 6. Final Questionnaire and Interviews- Minimal risk  There will be no risk of harm to me.
<b>Does the project include any security sensitive information?</b> Please explain how processing of all security sensitive information will be in full compliance with the "Oversight of security - sensitive research material in UK universities: guidance (October 2012)" (Universities UK, recommended by the Association of Chief Police Officers)	No <input checked="" type="checkbox"/> Yes <input type="checkbox"/>  If yes, please provide further information.

**Retrospective applications.** If your application for Ethics approval is retrospective, please explain why this has arisen.  
  
N/A

SECTION C – SUMMARY OF ETHICAL ISSUES (TO BE COMPLETED BY THE STUDENT)

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Please give a summary of the ethical issues and any action that will be taken to address the issue(s).

N/A
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SECTION D – ADDITIONAL DOCUMENTS CHECKLIST (TO BE COMPLETED BY THE STUDENT)

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**Please supply to your supervisors copies of all relevant supporting documentation electronically. If this is not available electronically, please provide explanation and supply hard copy**

I have included the following documents

- |                    |   |  |
|--------------------|---|--|
| Information sheet  | Yes <input checked="" type="checkbox"/> | Not applicable <input type="checkbox"/>            |
| Consent form       | Yes <input checked="" type="checkbox"/> | Not applicable <input type="checkbox"/>            |
| Questionnaire      | Yes <input checked="" type="checkbox"/> | Not applicable <input type="checkbox"/>            |
| Interview schedule | Yes <input type="checkbox"/>            | Not applicable <input checked="" type="checkbox"/> |

**Interview schedule to be completed once Questionnaires have been completed.**

SECTION E – STATEMENT BY APPLICANT

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I confirm that the \_\_\_\_\_ information I have given in this form on ethical issues is correct.

*J. Allen*

Signature \_\_\_\_\_

Date: 27/11/2018

**Please note, you must obtain your supervisors signature before submitting this form.**

**Affirmation by Supervisor**

I can confirm that, to the best of my understanding, the information presented by the student is correct and appropriate to allow an informed judgement on whether further ethical approval is required

*[Handwritten Signature]*

Signature \_\_\_\_\_

Date: 27/11/2018

**SECTION F: SUPERVISOR RECOMMENDATION ON THE PROJECT'S ETHICAL STATUS (UG/PGT)**

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Having satisfied myself of the accuracy of the project's ethical statement, I believe that the appropriate action is:

Approve	
Approve subject to recommendations [please specify]	
Approve subject to conditions [please specify]	
The project proposal needs further assessment by xxx	
The project needs to be returned to the student for modification prior to further action (details of required modifications must be provided)	
Reject	

Taught Students

**Undergraduate and Taught Postgraduates- All documentation must be submitted to BrightSpace as part of the assessment submission.**

Research students/ Staff

**Staff and Research students- All documentation must be submitted electronically to school research office (sadapgradmin@hud.ac.uk).**

**All enquiries should be directed to school research office (sadapgradmin@hud.ac.uk).**



**Sample Information sheet  
(required for submission with application for ethical approval)**

**University of Huddersfield  
School of Art, Design and Architecture**

**Participant Information Sheet 1**

**Research Project Title:** How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

You are being invited to take part in a research project. Before you decide, it is important for you to understand why this research is being done and what it will involve. Please take time to read the following information and discuss it with others if you wish. Ask if there is anything that is not clear or if you would like more information. May I take this opportunity to thank you for taking time to read this.

**What is the purpose of the project?**

The research project is intended to provide the research focus for a module which forms part of my degree. It will attempt to find out if immersive technology (virtual reality) can improve the wellbeing of menopausal women who are affected by vasomotor symptoms (Hot flashes, night sweats, etc.).

**Why have I been chosen?**

You have been chosen to take part in this research as you experience vasomotor symptoms that affect your wellbeing.

**Do I have to take part?**

Participation on this study is entirely voluntary, so please do not feel obliged to take part. Refusal will involve no penalty whatsoever and you may withdraw from the study at any stage without giving an explanation to the researcher.

**What do I have to do?**

You will be invited to take part in the initial questionnaire and/or interviews. This should take no more than 30 minutes of your time.

**Are there any disadvantages to taking part?**

There should be no foreseeable disadvantages to your participation. If you are unhappy or have further questions at any stage in the process, please address your concerns initially to the researcher if this is appropriate. Alternatively, please contact Omar Ivan Huerta Cardoso; School of Art, Design & Architecture, at the University of Huddersfield.

**Will all my details be kept confidential?**

All information which is collected will be strictly confidential and anonymised before the data is presented in any work, in compliance with the Data Protection Act and ethical research guidelines and principles.

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

The results of this research will be written up in my final PhD thesis and possibly publications. If you would like a copy please contact the researcher.

**What happens to the data collected?**

The data collected will be written up in my final PhD thesis and possibly publications. If you would like a copy please contact the researcher.

**Will I be paid for participating in the research?**

No cash incentives will be given to any participants.

**Where will the research be conducted?**

Questionnaires will be conducted online, interviews will be conducted in a mutual environment which is comfortable for both parties.

**Criminal Records check (if applicable)**

N/A

**Who has reviewed and approved the study, and who can be contacted for further information?**

Omar Ivan Huerta Cardoso

Lecturer in Product Design, Department of Architecture and 3D Design

School of Art, Design and Architecture

Phone: 01484 472110

Email: [O.HuertaCardoso@hud.ac.uk](mailto:O.HuertaCardoso@hud.ac.uk)

**Name & Contact Details of Researcher:**

James Dennis Allen

Email: [James.Allen@hud.ac.uk](mailto:James.Allen@hud.ac.uk)

**University of Huddersfield**  
**School of Art, Design and Architecture**

**Participant Information Sheet 2**

**Research Project Title:** How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

You are being invited to take part in a research project. Before you decide, it is important for you to understand why this research is being done and what it will involve. Please take time to read the following information and discuss it with others if you wish. Ask if there is anything that is not clear or if you would like more information. May I take this opportunity to thank you for taking time to read this.

**What is the purpose of the project?**

The research project is intended to provide the research focus for a module which forms part of my degree. It will attempt to find out if immersive technology (virtual reality) can improve the wellbeing of menopausal women who are affected by vasomotor symptoms (Hot flashes, night sweats, etc.).

**Why have I been chosen?**

You have been chosen to take part in this research as you are able to test if body temperature can be affected due to immersive technology.

**Do I have to take part?**

Participation on this study is entirely voluntary, so please do not feel obliged to take part. Refusal will involve no penalty whatsoever and you may withdraw from the study at any stage without giving an explanation to the researcher.

**What do I have to do?**

You will be invited to take part in the mixed reality testing. This should take no more than 10 minutes of your time.

**Are there any disadvantages to taking part?**

There should be no foreseeable disadvantages to your participation. If you are unhappy or have further questions at any stage in the process, please address your concerns initially to the researcher if this is appropriate. Alternatively, please contact Omar Ivan Huerta Cardoso; School of Art, Design & Architecture, at the University of Huddersfield.

**Will all my details be kept confidential?**

All information which is collected will be strictly confidential and anonymised before the data is presented in any work, in compliance with the Data Protection Act and ethical research guidelines and principles.

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

The results of this research will be written up in my final PhD thesis and possibly publications. If you would like a copy please contact the researcher.

**What happens to the data collected?**

The data collected will be written up in my final PhD thesis and possibly publications. If you would like a copy please contact the researcher.

**Will I be paid for participating in the research?**

No cash incentives will be given to any participants.

**Where will the research be conducted?**

In a booked room at the University of Huddersfield.

**Criminal Records check (if applicable)**

N/A

**Who has reviewed and approved the study, and who can be contacted for further information?**

Omar Ivan Huerta Cardoso

Lecturer in Product Design, Department of Architecture and 3D Design

School of Art, Design and Architecture

Phone: 01484 472110

Email: O.HuertaCardoso@hud.ac.uk

**Name & Contact Details of Researcher:**

James Dennis Allen

Email: James.Allen@hud.ac.uk

**University of Huddersfield**  
**School of Art, Design and Architecture**

**Participant Information Sheet 3**

**Research Project Title:** How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

You are being invited to take part in a research project. Before you decide, it is important for you to understand why this research is being done and what it will involve. Please take time to read the following information and discuss it with others if you wish. Ask if there is anything that is not clear or if you would like more information. May I take this opportunity to thank you for taking time to read this.

**What is the purpose of the project?**

The research project is intended to provide the research focus for a module which forms part of my degree. It will attempt to find out if immersive technology (virtual reality) can improve the wellbeing of menopausal women who are affected by vasomotor symptoms (Hot flashes, night sweats, etc.).

**Why have I been chosen?**

You have been chosen to take part in this research as you are able to contribute to the project as you either have expert knowledge, experience vasomotor symptoms, or are a designer.

**Do I have to take part?**

Participation on this study is entirely voluntary, so please do not feel obliged to take part. Refusal will involve no penalty whatsoever and you may withdraw from the study at any stage without giving an explanation to the researcher.

**What do I have to do?**

You will be invited to take part in the brainstorming and co-creation. This should take no more than 30 minutes of your time.

**Are there any disadvantages to taking part?**

There should be no foreseeable disadvantages to your participation. If you are unhappy or have further questions at any stage in the process, please address your concerns initially to the researcher if this is appropriate. Alternatively, please contact Omar Ivan Huerta Cardoso; School of Art, Design & Architecture, at the University of Huddersfield.

**Will all my details be kept confidential?**

All information which is collected will be strictly confidential and anonymised before the data is presented in any work, in compliance with the Data Protection Act and ethical research guidelines and principles.

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

The results of this research will be written up in my final PhD thesis and possibly publications. If you would like a copy please contact the researcher.

**What happens to the data collected?**

The data collected will be written up in my final PhD thesis and possibly publications. If you would like a copy please contact the researcher.

**Will I be paid for participating in the research?**

No cash incentives will be given to any participants. Food and drink may be provided.

**Where will the research be conducted?**

In a booked room at the University of Huddersfield.

**Criminal Records check (if applicable)**

N/A

**Who has reviewed and approved the study, and who can be contacted for further information?**

Omar Ivan Huerta Cardoso

Lecturer in Product Design, Department of Architecture and 3D Design

School of Art, Design and Architecture

Phone: 01484 472110

Email: O.HuertaCardoso@hud.ac.uk

**Name & Contact Details of Researcher:**

James Dennis Allen

Email: James.Allen@hud.ac.uk

**University of Huddersfield**  
**School of Art, Design and Architecture**

**Participant Information Sheet 4**

**Research Project Title:** How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

You are being invited to take part in a research project. Before you decide, it is important for you to understand why this research is being done and what it will involve. Please take time to read the following information and discuss it with others if you wish. Ask if there is anything that is not clear or if you would like more information. May I take this opportunity to thank you for taking time to read this.

**What is the purpose of the project?**

The research project is intended to provide the research focus for a module which forms part of my degree. It will attempt to find out if immersive technology (virtual reality) can improve the wellbeing of menopausal women who are affected by vasomotor symptoms (Hot flashes, night sweats, etc.).

**Why have I been chosen?**

You have been chosen to take part in this research as you experience vasomotor symptoms that affect your wellbeing.

**Do I have to take part?**

Participation on this study is entirely voluntary, so please do not feel obliged to take part. Refusal will involve no penalty whatsoever and you may withdraw from the study at any stage without giving an explanation to the researcher.

**What do I have to do?**

You will be invited to take part in the concept testing and cultural probe. This should take no more than 15 minutes at a time.

**Are there any disadvantages to taking part?**

There should be no foreseeable disadvantages to your participation. If you are unhappy or have further questions at any stage in the process, please address your concerns initially to the researcher if this is appropriate. Alternatively, please contact Omar Ivan Huerta Cardoso; School of Art, Design & Architecture, at the University of Huddersfield.

**Will all my details be kept confidential?**

All information which is collected will be strictly confidential and anonymised before the data is presented in any work, in compliance with the Data Protection Act and ethical research guidelines and principles.

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

The results of this research will be written up in my final PhD thesis and possibly publications. If you would like a copy please contact the researcher.

**What happens to the data collected?**

The data collected will be written up in my final PhD thesis and possibly publications. If you would like a copy please contact the researcher.

**Will I be paid for participating in the research?**

No cash incentives will be given to any participants.

**Where will the research be conducted?**

In the participants own home.

**Criminal Records check (if applicable)**

N/A

**Who has reviewed and approved the study, and who can be contacted for further information?**

Omar Ivan Huerta Cardoso

Lecturer in Product Design, Department of Architecture and 3D Design

School of Art, Design and Architecture

Phone: 01484 472110

Email: O.HuertaCardoso@hud.ac.uk

**Name & Contact Details of Researcher:**

James Dennis Allen

Email: James.Allen@hud.ac.uk



Appendix 2

**Sample Participant Consent Form  
(required for submission with application for ethical approval)**

**University of Huddersfield  
School of Art, Design and Architecture**

Participant Consent Form

**Title of Research Study:** How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

**Name of Researcher:** James Dennis Allen

**Participant Identifier Number:**

- I confirm that I have read and understood the participant Information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study

**Name of Participant:** .....

**Signature of Participant:** .....

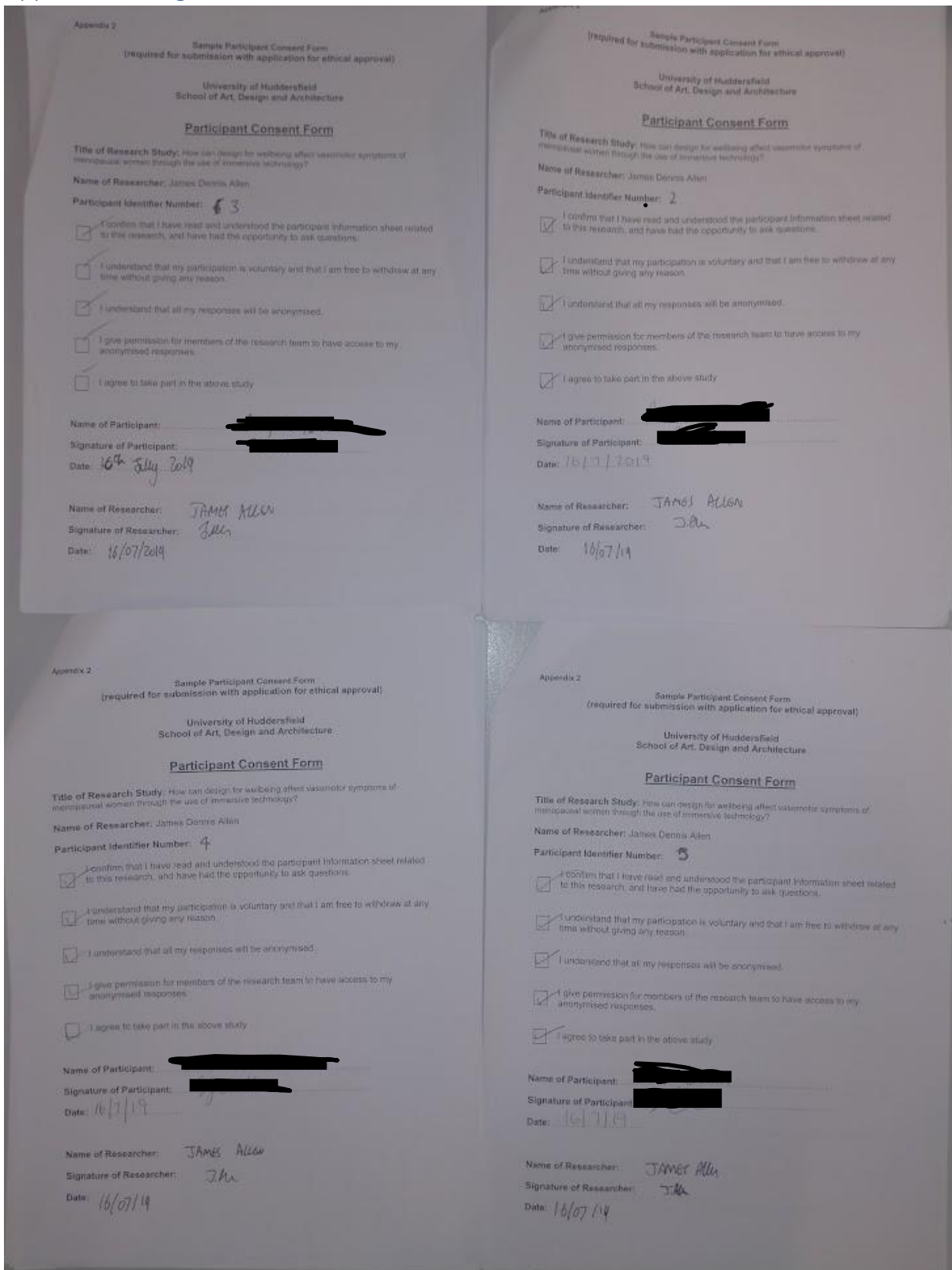
**Date:** .....

**Name of Researcher:**

**Signature of Researcher:**

**Date:**

Appendix 10- Signed Ethics Forms



Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

**Participant Consent Form**

**Title of Research Study:** How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

**Name of Researcher:** James Dennis Allen

**Participant Identifier Number:** 1

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

**Name of Participant:** [REDACTED]

**Signature of Participant:** [REDACTED]

**Date:** 16/7/19

**Name of Researcher:** JAMES ALLEN

**Signature of Researcher:** J. Allen

**Date:** 16/7/19

Participant Consent Form

**Title of Research Study:** How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

**Name of Researcher:** James Dennis Allen

**Participant Identifier Number:** 10

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study

**Name of Participant:** [REDACTED]

**Signature of Participant:** [REDACTED]

**Date:** 08 July 2019

**Name of Researcher:** JAMES ALLEN

**Signature of Researcher:** J. Allen

**Date:** 08/07/19

Appendix 2

Sample Participant Consent Form  
(required for submission with application for ethical approval)

Participant Consent Form

**Title of Research Study:** How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

**Name of Researcher:** James Dennis Allen

**Participant Identifier Number:** 8

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study

**Name of Participant:** [REDACTED]

**Signature of Participant:** [REDACTED]

**Date:** 08/07/19

**Name of Researcher:** JAMES ALLEN

**Signature of Researcher:** J. Allen

**Date:** 08/07/19

Participant Consent Form

**Title of Research Study:** How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

**Name of Researcher:** James Dennis Allen

**Participant Identifier Number:** 11

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study

**Name of Participant:** [REDACTED]

**Signature of Participant:** [REDACTED]

**Date:** 08/07/19

**Name of Researcher:** JAMES ALLEN

**Signature of Researcher:** J. Allen

**Date:** 08/07/19

Appendix 2

Sample Participant Consent Form  
(required for submission with application for ethical approval)

Participant Consent Form

**Title of Research Study:** How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

**Name of Researcher:** James Dennis Allen

**Participant Identifier Number:** 9

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study

**Name of Participant:** [REDACTED]

**Signature of Participant:** [REDACTED]

**Date:** 08/07/2019

**Name of Researcher:** JAMES ALLEN

**Signature of Researcher:** J. Allen

**Date:** 08/07/19

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 2

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 08/07/2019

Name of Researcher: JAMES ALLEN

Signature of Researcher: J. Allen

Date: 08/07/19

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 4

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 08/07/19

Name of Researcher: JAMES ALLEN

Signature of Researcher: J. Allen

Date: 08/07/19

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 6

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 8<sup>th</sup> July 2019

Name of Researcher: JAMES ALLEN

Signature of Researcher: J. Allen

Date: 08/07/2019

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 7

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 08/07/19

Name of Researcher: JAMES ALLEN

Signature of Researcher: J. Allen

Date: 08/07/19

Appendix 2  
Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

**Title of Research Study:** How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

**Name of Researcher:** James Dennis Allen

**Participant Identifier Number:** 1

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

**Name of Participant:** [REDACTED]

**Signature of Participant:** [REDACTED]

**Date:** 08/07/19

**Name of Researcher:** James Dennis Allen

**Signature of Researcher:** J. Allen

**Date:** 08/07/19

Appendix 2  
Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

**Title of Research Study:** How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

**Name of Researcher:** James Dennis Allen

**Participant Identifier Number:** 5

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

**Name of Participant:** [REDACTED]

**Signature of Participant:** [REDACTED]

**Date:** 08/07/19

**Name of Researcher:** James Allen

**Signature of Researcher:** J. Allen

**Date:** 08/07/19

Appendix 2

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

**Title of Research Study:** How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

**Name of Researcher:** James Dennis Allen

**Participant Identifier Number:** 3

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

**Name of Participant:** [REDACTED]

**Signature of Participant:** [REDACTED]

**Date:** 08 July 2019

**Name of Researcher:** James Allen

**Signature of Researcher:** J. Allen

**Date:** 08/07/19

Appendix 2

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

**Title of Research Study:** How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

**Name of Researcher:** James Dennis Allen

**Participant Identifier Number:** 13

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

**Name of Participant:** [REDACTED]  
**Signature of Participant:** [REDACTED]  
**Date:** 12/08/19

**Name of Researcher:** JAMES ALLEN  
**Signature of Researcher:** J. Allen  
**Date:** 12/08/19

Appendix 2

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

**Title of Research Study:** How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

**Name of Researcher:** James Dennis Allen

**Participant Identifier Number:** 14

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

**Name of Participant:** [REDACTED]  
**Signature of Participant:** [REDACTED]  
**Date:** 12<sup>th</sup> August 2019

**Name of Researcher:** JAMES ALLEN  
**Signature of Researcher:** J. Allen  
**Date:** 12/08/19

Appendix 2

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

**Title of Research Study:** How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

**Name of Researcher:** James Dennis Allen

**Participant Identifier Number:** 11

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

**Name of Participant:** [REDACTED]  
**Signature of Participant:** [REDACTED]  
**Date:** 12/08/2019

**Name of Researcher:** JAMES ALLEN  
**Signature of Researcher:** J. Allen  
**Date:** 12/08/2019

Appendix 2

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

**Title of Research Study:** How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

**Name of Researcher:** James Dennis Allen

**Participant Identifier Number:** 12

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

**Name of Participant:** [REDACTED]  
**Signature of Participant:** [REDACTED]  
**Date:** 12/08/19

**Name of Researcher:** JAMES ALLEN  
**Signature of Researcher:** J. Allen  
**Date:** 12/08/19



Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 9

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 12/08/19

Name of Researcher: JAMES ALLEN

Signature of Researcher: J.A.A.

Date: 12/08/19

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 10

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 12th of August 2019

Name of Researcher: JAMES ALLEN

Signature of Researcher: J.A.A.

Date: 12/08/19

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 7

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 12<sup>th</sup> August 2019

Name of Researcher: JAMES ALLEN

Signature of Researcher: J.A.A.

Date: 12/08/19

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 8

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 12/08/19

Name of Researcher: JAMES ALLEN

Signature of Researcher: J.A.A.

Date: 12/08/19

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 3

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 12/08/19

Name of Researcher: James Allen

Signature of Researcher: J.A.A.

Date: 12/08/19

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 6

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 12/08/19

Name of Researcher: James Allen

Signature of Researcher: J.A.A.

Date: 12/08/19

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 1

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 12/08/19

Name of Researcher: James Allen

Signature of Researcher: J.A.A.

Date: 12/08/19

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 5

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 12/08/19

Name of Researcher: James Allen

Signature of Researcher: J.A.A.

Date: 12/08/19

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

**Title of Research Study:** How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

**Name of Researcher:** James Dennis Allen

**Participant Identifier Number:** 4

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

**Name of Participant:** [Redacted]

**Signature of Participant:** [Redacted]

**Date:** 12/08/19

**Name of Researcher:** JAMES ALLEN

**Signature of Researcher:** J Allen

**Date:** 12/08/19

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

**Title of Research Study:** How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

**Name of Researcher:** James Dennis Allen

**Participant Identifier Number:** 2

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

**Name of Participant:** [Redacted]

**Signature of Participant:** [Redacted]

**Date:** 12/08/19

**Name of Researcher:** JAMES ALLEN

**Signature of Researcher:** J Allen

**Date:** 12/08/19

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 3

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 28<sup>th</sup> 09<sup>th</sup> 2020

Name of Researcher: JAMES ALLEN

Signature of Researcher: [Signature]

Date: 28/09/20

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 4

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 28/09/20

Name of Researcher: JAMES ALLEN

Signature of Researcher: [Signature]

Date: 28/09/20

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 2

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 28/09/20

Name of Researcher: JAMES ALLEN

Signature of Researcher: [Signature]

Date: 28/09/20

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 5

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 28/09/20

Name of Researcher: JAMES ALLEN

Signature of Researcher: [Signature]

Date: 28/09/20

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 1

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study

Name of Participant: [REDACTED]

Signature of Participant: [REDACTED]

Date: 28/09/20

Name of Researcher: JAMES ALLEN

Signature of Researcher: JDA

Date: 28/09/20

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

**Title of Research Study:** How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

**Name of Researcher:** James Dennis Allen

**Participant Identifier Number:**

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study

**Name of Participant:** .....

**Signature of Participant:** .....

**Date:** .. 26/11/20 ..

**Name of Researcher:** JAMES ALLEN

**Signature of Researcher:** J.A.A.

**Date:** 26/11/20

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 2

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 01/02/21

Name of Researcher: James Allen

Signature of Researcher: [Signature]

Date: 01/02/21

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 5

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 01/02/21

Name of Researcher: James Allen

Signature of Researcher: [Signature]

Date: 01/02/21

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 3

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 02/02/21

Name of Researcher: James Allen

Signature of Researcher: [Signature]

Date: 02/02/21

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 4

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 02/02/21

Name of Researcher: James Allen

Signature of Researcher: [Signature]

Date: 01/02/21

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

**Title of Research Study:** How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

**Name of Researcher:** James Dennis Allen

**Participant Identifier Number:** 2

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
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- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study

**Name of Participant:** .....

**Signature of Participant:** .....

**Date:** 02/03/22

**Name of Researcher:** JAMES ALLEN

**Signature of Researcher:** J. Allen

**Date:** 01/02/21



Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 4

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study

Name of Participant: [REDACTED]

Signature of Participant: [REDACTED]

Date: 03/03/21

Name of Researcher: JAMES ALLEN

Signature of Researcher: [Signature]

Date: 03/03/21

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 5

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
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- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study

Name of Participant: [REDACTED]

Signature of Participant: [REDACTED]

Date: 03/03/21

Name of Researcher: JAMES ALLEN

Signature of Researcher: [Signature]

Date: 03/03/21

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 2

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- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study

Name of Participant: [REDACTED]

Signature of Participant: [REDACTED]

Date: 03/03/21

Name of Researcher: JAMES ALLEN

Signature of Researcher: [Signature]

Date: 03/03/21

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 3

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- I understand that all my responses will be anonymised.
- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study

Name of Participant: [REDACTED]

Signature of Participant: [REDACTED]

Date: 03/03/21

Name of Researcher: JAMES ALLEN

Signature of Researcher: [Signature]

Date: 03/03/21

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

**Title of Research Study:** How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

**Name of Researcher:** James Dennis Allen

**Participant Identifier Number:** 1

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
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- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study

**Name of Participant:** .....

**Signature of Participant:** .....

**Date:** 03/03/21 .....

**Name of Researcher:** JAMES ALLEN

**Signature of Researcher:** JAA

**Date:** 03/03/21

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 15

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
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- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 26/08/21

Name of Researcher: JAMES ALLEN

Signature of Researcher: J. Allen

Date: 26/08/21

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 16

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
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- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 26/08/21

Name of Researcher: JAMES ALLEN

Signature of Researcher: J. Allen

Date: 26/08/21

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University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 3

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- I agree to take part in the above study.

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 26/08/21

Name of Researcher: JAMES ALLEN

Signature of Researcher: J. Allen

Date: 26/08/21

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 14

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- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 26/08/21

Name of Researcher: JAMES ALLEN

Signature of Researcher: J. Allen

Date: 26/08/21

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 11

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- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

Name of Participant: [REDACTED]

Signature of Participant: [REDACTED]

Date: 26/08/21

Name of Researcher: JAMES ALLEN  
 Signature of Researcher: J.A.A.  
 Date: 26/08/21

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 12

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- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

Name of Participant: [REDACTED]

Signature of Participant: [REDACTED]

Date: 26/08/21

Name of Researcher: JAMES ALLEN  
 Signature of Researcher: J.A.A.  
 Date: 26/08/21

Sample Participant Consent Form  
(required for submission with application for ethical approval)

University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 9

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
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- I agree to take part in the above study.

Name of Participant: [REDACTED]

Signature of Participant: [REDACTED]

Date: 26/08/21

Name of Researcher: JAMES ALLEN  
 Signature of Researcher: J.A.A.  
 Date: 26/08/21

Sample Participant Consent Form  
(required for submission with application for ethical approval)

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School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 10

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
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- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

Name of Participant: [REDACTED]

Signature of Participant: [REDACTED]

Date: 26 August 2021

Name of Researcher: JAMES ALLEN  
 Signature of Researcher: J.A.A.  
 Date: 26/08/21

Sample Participant Consent Form  
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University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 6

- I confirm that I have read and understood the participant information sheet related to this research, and have had the opportunity to ask questions.
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- I agree to take part in the above study.

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 26/08/21

Name of Researcher: JAMES ALLEN

Signature of Researcher: J. Allen

Date: 26/08/21

Sample Participant Consent Form  
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University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 7

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- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 26/08/21

Name of Researcher: JAMES ALLEN

Signature of Researcher: J. Allen

Date: 26/08/21

Sample Participant Consent Form  
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University of Huddersfield  
School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 5

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- I agree to take part in the above study.

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 26 August 2021

Name of Researcher: JAMES ALLEN

Signature of Researcher: J. Allen

Date: 26/08/21

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School of Art, Design and Architecture

Participant Consent Form

Title of Research Study: How can design for wellbeing affect vasomotor symptoms of menopausal women through the use of immersive technology?

Name of Researcher: James Dennis Allen

Participant Identifier Number: 8

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- I give permission for members of the research team to have access to my anonymised responses.
- I agree to take part in the above study.

Name of Participant: [Redacted]

Signature of Participant: [Redacted]

Date: 26 August 2021

Name of Researcher: JAMES ALLEN

Signature of Researcher: J. Allen

Date: 26/08/21