MSc in Engineering Management
Project Report

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Project Title: Improving Healthcare through Wearable Technology

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A year as a postgraduate student at the University of York has been full of unique experiences for me. I'm glad to have gotten this opportunity to study MSc in Engineering Management in this institution and by great professors.

First, I would like to thank my parents for believing in me when I chose this university and the course. Without them, I wouldn't have been here.

I would like to express my sincerest gratitude to my supervisor, Dr. Gayan Jayakody, who was always there for all of us in the group whenever we needed guidance. Furthermore, I would also like to thank Dr. John Robinson, another supervisor, for providing critical feedback. To all the lecturers who taught me in this past year, I would like to express my most heart-felt gratitude. I have learnt a lot in this course because of all of you.

I would finally like to thank my group members who have been there throughout the year in all group projects. It was a pleasure working with all of you.

ABSTRACT

The smartphone industry has started reaching a saturation point in recent years and sales volumes have reduced post-COVID. Wearable devices and wearable technology have seen a sharp rise in recent years and are projected for growth for another decade at least. The compact size, light weight and intriguing technological features attract customers. The use of wearable devices and technology has started to become an important factor in healthcare. Its advanced technology and sensors can help patients and medical experts create a plan of care and track outcomes. This data is collected in real-time through sensors and thus reveal physical and chemical properties of the body to evaluate wellness. Wearable devices can also warn people about potential risks associated with their health. Sleep and cardiovascular monitoring are one of the most common features of a wearable device and smartwatches/wrist wearables have the biggest market share in the wearables' market. Other common features of a smart wearable are detection of stress levels and suggestion of smart lifestyle plans. Pregnancy monitoring using wearable devices is also becoming a necessity due to the rise in population and increasing costs of health insurance. The market for pregnancy monitoring via wearable devices is also increasing every year as the demand is also increasing, but the devices require more improvements in terms of accuracy and features. Hence, this study aims to research the technology and business aspects of wearable devices in healthcare and develop a solution to solve a major problem in pregnancy.

First, the key objectives are defined, based on which the literature review is carried out. From this investigation, the challenges in technology and pregnancy are identified for further research. In order to find the right problem and solution for it, surveys and case studies are carried out. The research data is interpreted with the secondary research in order to obtain the final solution. The group functions as a startup in the healthcare wearables' market. Before entering the market, a few business factors are assessed to provide a complete overview of the industry. Finally, a roadmap to develop the solution is presented.

This report concludes with further recommended work based on the limitations faced in this study.

Contents

CHAPTER ONE – INTRODUCTION

1.1 PROJECT BACKGROUND

The first computer was created by Charles Babbage in 1822 i.e., 200 years ago (Jacobson, 2019) and the first commercial mobile phone was created in 1983 by Motorola (Goodwin, 2021). Since then, technology has completely transformed by becoming portable and these innovations have made billions of lives easier. Businesses split their technical focus on different user experiences (Anon., 2022) and with rising demands for more compact, sleek, portable and easier to use devices, wearable technology has become a recent trend in the market.

Wearable technology (or wearables) are small electronic devices like jewelry, accessories, medical equipment, virtual reality headsets, etc. worn on a user's body to generate and provide them with useful data or experiences by transmitting data to and from the body (Knox, 2022). Wearable technology has existed for almost 30 years but consumer adoption has only begun a decade ago (Knox, 2022). Figure 1 shows that the overall market has seen a rise in the last decade and is forecasted to grow from US$ 115.8 billion in 2021 to US$ 380.5 billion by 2028 (Globenewswire, 2022).

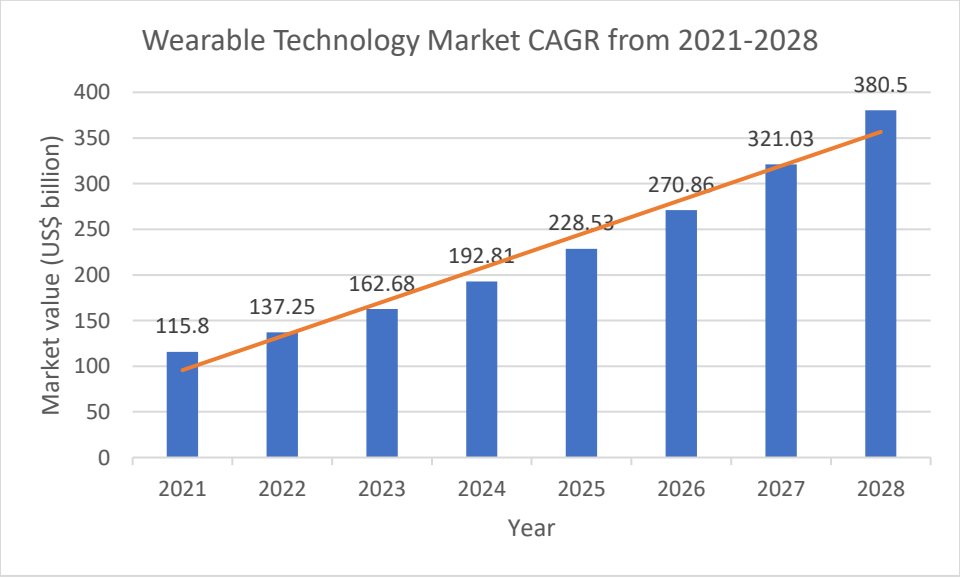


Figure 1: Wearables' Market Size Forecast (Globenewswire, 2022)

According to a study conducted by Insider Intelligence, 23.3% of the US population uses wearable devices (Phaneuf, 2022). Wearable healthcare devices are useful for sending health information to

doctors or healthcare professionals in real time. This upward trend in consumer application will influence companies, insurers and healthcare providers to take advantage of the benefits of the technology (Phaneuf, 2022). Constant use of wearable technology would reduce the frequency of going to a hospital for healthcare and a survey from Insider Intelligence suggests that 75% of the users agree that such devices help them engage with their own health. Data connectivity is set to expand as more accurate sensors are developed, thus opening doors for insurers and employers to promote healthy lifestyles and boost profitability (Phaneuf, 2022).

There is a lot of evidence that suggests that smartphones are reaching their maturity and stagnation. An analysis of Gartner's data by Statista shows that the number of smartphones sold globally to end users grew rapidly from 2007 to 2016, and has reached stagnation ever since (Sakpal, 2022; Statista, 2022). According to Lori Cameron from the IEEE Computer Society, wearable technology is surpassing smartphones as today's fastest growing technological innovation, making it the next big thing for consumers, investors and entrepreneurs alike (Cameron, n.d.). Over the past two decades, we have witnessed bulky technology being transformed into light-weight devices, and now into wearables, clothes and body patches. This trend indicates that wearable technology will dominate the market and current shipment statistics indicate the same. A report generated by Statista has highlighted that global wearable technology shipments have grown from 28.8 million units in 2014 to over 533 million units in 2021 i.e., almost 19 times (Statista, 2022). Wearable devices have a promising future in the world of technology and are the next big thing.

1.2 PROJECT MOTIVATION AND AIM

The global population is projected to reach 8 billion by mid-November 2022 and expected to exceed 10.4 billion by the start of the 22nd century (Gaigbe-Togbe, et al., 2022). As the population grows, so does the demand of access to healthcare. This rise in demand has driven real-time monitoring of various physiological signals and also the research and development of remote patient monitoring/wearable devices in healthcare (Loncar-Turukalo, et al., 2019).

Healthcare is a necessity for anyone and everyone, but also expensive. Countries like the USA, Switzerland, Germany, Australia, Canada, etc. have very high healthcare costs. In the current era of healthcare, everyone wants to be facilitated with the economical rates and great comfort by deploying the technology (Chawla, 2020). Figure 2 is a representation of how wearable technology predicts health problems.

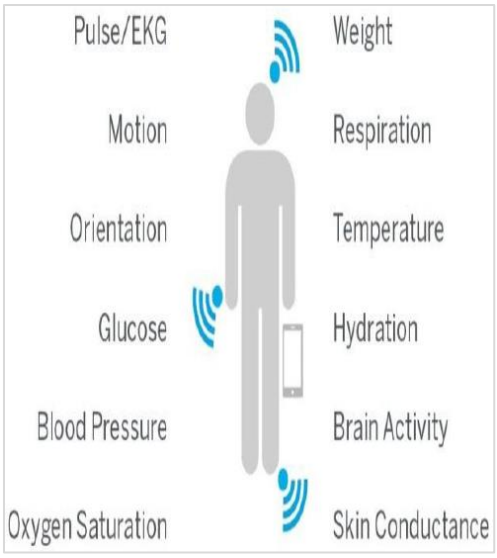


Figure 2: Prediction of health problems (Chawla, 2020)

Based on evidence already cited and technology trends, the researchers of this project believe that wearable devices are game changers and the best field to use and improve it would be in the healthcare industry. The researchers of this project chose three fields to improve the technology from its current standpoint:

- Cardiovascular Monitoring
- Sleep Detection
- Pregnancy and infant monitoring

According to the British Heart Foundation, the average mortality rate due to cardiovascular diseases in the UK is 1 death in every 3 minutes, which results to over 160,000 deaths every year (British Heart Foundation, 2022). Over 900,00 people in the UK live with heart failure and a patient is hospitalised every 5 minutes. Each day 13 babies are diagnosed with a congenital heart defect in the UK. Insufficient or fragmented sleep can result in gradual degradation of a person's heart and thus heighten the risk of cardiovascular diseases (Suni, 2022). We thought that if the condition in the UK was this bad, the statistics for the entire world would be catastrophic.

There are limitations with the current wearable technology and a huge scope for improvement, especially in the healthcare sector. In-home health monitoring has become a bigger necessity ever since the COVID-19 pandemic as people have become skeptic about going to hospitals/clinics for checkups or treatments. Hence, we decided to choose the above-mentioned fields for our research

and explore what possibilities there are for improvement by including technology and business aspects.

1.3 KEY OBJECTIVES

This report will identify the current limitations and challenges with healthcare wearables, from a technology and business perspective, and discuss technical and business solutions for improving these technologies. Six students from the MSc Engineering Management program at the University of York have worked together on this project. with two students choosing one field of wearable healthcare technology. However, all the data collected and literature reviewed was shared with each member in the team. We function as a startup who are working towards improving existing technology in healthcare and have a plan to release three types of wearable devices in the near future. The main research question and key objectives are mentioned below:

Project Topic: Improving Healthcare through Wearable Technology
Project Question: "What improvements should be made to wearable technology to increase consumer adoption, trust, and accuracy of these devices?"
Key Objectives: 1. Analyse pregnancy problems and technologies related to wearables (in general, in healthcare and in cardiovascular, sleep and pregnancy/infant monitoring) 2. Address current limitations and potential technology challenges to propose their solutions 3. Examine consumer acceptance 4. Identify the benefits of wearable technology in healthcare 5. Assess the potential challenges from a business point of view

Analysing and understanding technologies related to wearable devices is important to help us understand the technology better. With every problem there is a solution, which is why it would be important to assess the limitations and challenges with these products. Furthermore, examining consumer acceptance is necessary because there is no market or business without customers, and identifying the benefits of this technology would be effective for marketing the product effectively. Assessing the business challenges would help us develop effective business strategies as a company. These key objectives will help us answer our research question.

1.4 TOPIC DISTRIBUTION

Since we have three fields of research under the wearable technology industry, the team of six split into three pairs:

Technology	Researcher
Cardiovascular Monitoring	Yuechen Liu, Tushar Khandelwal
Sleep Detection/Monitoring	Xinyu Mao, Jingjin Li
Pregnancy and Infant Monitoring	Antariksh Kudal, Akash Pawar

Table 1: Topic Distribution between team members

1.5 REPORT STRUCTURE

The report starts with a literature review in chapter 2 which describes the technologies used in wearable devices. Chapter 3 is an explanation of our research methodology including the philosophy and tools for data collection and analysis. Chapter 4 would show our analysis, findings and results depending on the three tools used for data collection: surveys and case studies. Next, chapter 5 would be the most important part of our project i.e., solutions to technical and business challenges, a business model canvas and a roadmap based on our findings from the previous chapter. Chapter 6 would be a description of our project management tools and techniques used for successful completion of the project such as GANTT chart and risk management. Conclusions and further recommendations would be provided in chapter 7.

CHAPTER TWO – LITERATURE REVIEW

2.1 OVERVIEW

This chapter discusses a problem-based literature on foetal, pregnancy, sleep and cardiovascular monitoring. It also addresses the major technologies of wearable devices, how these technologies are actually used in these devices, its importance, as well as challenges.

2.2 FOETAL MONITORING

2.2.1 TRADITIONAL FOETAL MONITORING

It is defined as the continuous monitoring of heartrate, health status and other functions of the foetus during pregnancy or labour. (Dekker, 2018). There are two methods i.e., external and internal. External monitoring is done using either a fetoscope, which is a differently-shaped stethoscope or a doppler, which uses soundwaves and a computer to detect the foetal heartrate (Anon., n.d.). On the other hand, internal monitoring involves electrodes being put on the baby's head while it is inside the uterus. (Anon., n.d.).

According to the royal Australian and New Zealand College of Obstetricians and Gynaecologists, there are different types of external and internal foetal heartrate monitoring (The Royal Australian and New Zealand College of Obstetricians and Gynaecologists, 2014). Under external, the first one is intermittent auscultation, where a doctor or midwife make use of a doppler to listen to the baby's heartbeat in regular intervals of time. This mode is usually preferred when the mother and baby are healthy. The second one is intermittent cardiotocograph, which is considered when pregnant mothers have low risk of developing foetal compromise where intermittent auscultation is difficult (Queensland Clinical Guidelines, 2019). Foetal scalp blood sampling is an internal monitoring method which is done when pregnancy and labour is complicated. Few small drops of blood are collected from the baby's scalp and it is done through vaginal examination. This is effective when an immediate report on the foetus' health is required.

2.2.2 DOWNSIDES TO TRADITIONAL FOETAL MONITORING

There are certain risks associated to the traditional form of foetal heartrate monitoring. The most common risk during internal monitoring is infection (Nall, 2016). Doctors have to wear gloves before they insert electrodes inside the cervix and due to this, there is a high chance that the bacteria present on the gloves can spread to the mother's tissues and hence, to the baby. This is even riskier

when the mother is prone to or has already been subjected to a transmittable disease (HIV) (John Hopkins Medicine, 2022). In 2012, Adam J. Wolfberg said that even though foetal heartrate monitoring is the most common obstetric procedure, it is a frustrating technology because it is plagued by false positives and miscommunication between providers (Wolfberg, 2012). Another issue highlighted with this technology was that even though the baby's health data was accurate, details about injuries or potential injuries were not identified properly (Wolfberg, 2012).

A study carried out by Shenzhen Technology University, China describes the problems with hospital-based foetal and pregnancy monitoring (Li, et al., 2021). Intelligent real-time monitoring and detection is not possible at hospitals, which results in increased risk of high-risk pregnancy emergencies at the same time. In-home self-monitoring is crucial during the perinatal stage as mothers have an irreplaceable role in learning their babies. Traditional healthcare systems fail to satisfy the need for continuous pregnancy monitoring. In-hospital monitoring means providing printed results to the patients. These records, if not maintained properly, could be lost and would cause a lot of inconvenience to the patients, and the information would not be shared properly.

2.2.3 STRESS DURING PREGNANCY

Stress is one of the most common feelings during pregnancy and they occur due to physical and hormonal changes, physical discomfort and other biological as well as psychological changes (Anon., n.d.). According to Heidi Murkoff, the author of "What to expect when you are expecting", some of the major symptoms of stress during pregnancy are an increase in cortisol, epinephrine and norepinephrine levels i.e., hormones that increase blood-sugar levels, heart rate and blood pressure, increase in heart palpitations, excessive fatigue, loss of appetite, overeating, sleeping problems, mixed emotions, etc. (Luskin, 2022; Murkoff, 1984). Excessive stress can lead to anxiety, depression or other mental health conditions, which would have a negative impact on the pregnancy. Such conditions also force people to turn towards unhealthy coping mechanisms like consumption of drugs, alcohol and unhealthy eating habits, and this in turn leads to a possibility of preeclampsia, a hypertension-based complication during pregnancy (Lopez, et al., 2018).

A growing body of evidence-based research indicates the correlation of maternal stress and the unborn baby. Stress during pregnancy exerts strong influence on the development of the offspring (Bergh, et al., 2020). Research conducted at the Down Syndrome Federation of India suggested that stress in couples during conception could be a possible cause for down syndrome, a

chromosome defect, in a baby (Dharwadkar, 2018). Another study shows that maternal stress and depression is a factor in the development of autism in an unborn baby. Early personality development in children, emotional disturbance and schizophrenia risk are all impacted due to maternal stress. Another study shows the correlation of prenatal stress and miscarriage (Qu, et al., 2017). Researchers found that women who experienced major psychological stress and negative life-changing events were twice as likely to have early miscarriages. Furthermore, studies have also found links which show that prenatal stress and/or anxiety has a negative impact on the development of a child till adolescence, due to anxiety disorders in the offspring (Hettema, et al., 2001).

2.2.4 STRESS AND DEPRESSION COMBAT TECHNOLOGY

A study shows that even though many pharmacological treatments proved to be effective in treatment of panic disorder, post-traumatic stress disorder, anxiety, depression, etc., most patients weren't able to achieve remission with such methods (Freire, et al., 2020). Psychotherapy is effective but due to its limitations like availability, cost and commitment, most people are not able to complete their sessions. The relapse rate after successful pharmacological and psychotherapy treatment is high as well. Researchers suggest that neurostimulation is a more effective alternative or augmentation treatment to pharmacological and psychotherapies (Zugliani, et al., 2019). Non-invasive neurostimulation strategies could be effective for treatment of stress and depression during pregnancies because of their ability to treat depression and stress rapidly, without the risk of foetus being exposed to medication (Kim, et al., 2011). An increased interest in untilisation of various neurostimulation techniques has led researchers and scientists to discover multiple methods of non-invasive neurostimulation techniques. Repetitive transcranial magnetic stimulation is the most established of all the techniques. It modulates cognitive functions of the brain related to pathophysiology of stress and depression, with regional changes in neurotransmitter release, signaling pathways, transsynaptic efficiency and genetic (oestrogen) transcription (A.T.Barker, et al., 1985). People do not have to be hospitalised or sedated to undergo this treatment. Typically, patients must go to the doctor five times a week and the course lasts for four to six weeks (Brennan, 2021). In the first session, the doctor takes measurements to find the right place to position the electromagnetic coil. This coil is used to deliver the pulses to motor cortex, which is responsible for all the motor skills of a person i.e., muscle movement. The magnetic strength of the coil is increased till the point of twitching in the fingers which is known

as the patient's motor threshold (Brennan, 2021). After that, the coil is moved to a different part of the brain called the dorsolateral prefrontal cortex i.e., the area involved in stress and depression. Rest of the sessions last for about forty minutes.

There are a few temporary side effects to this process such as headaches, discomfort and lightheadedness. According to Brennan (2021), about 50% of the patients have headaches after their first session. He also highlighted a few risks with this technology such as hearing problems, seizures and worsening of bipolar disorder symptoms i.e., for patients who have bipolar disorder. In such cases, this treatment could trigger impulsive behaviour and racing thoughts.

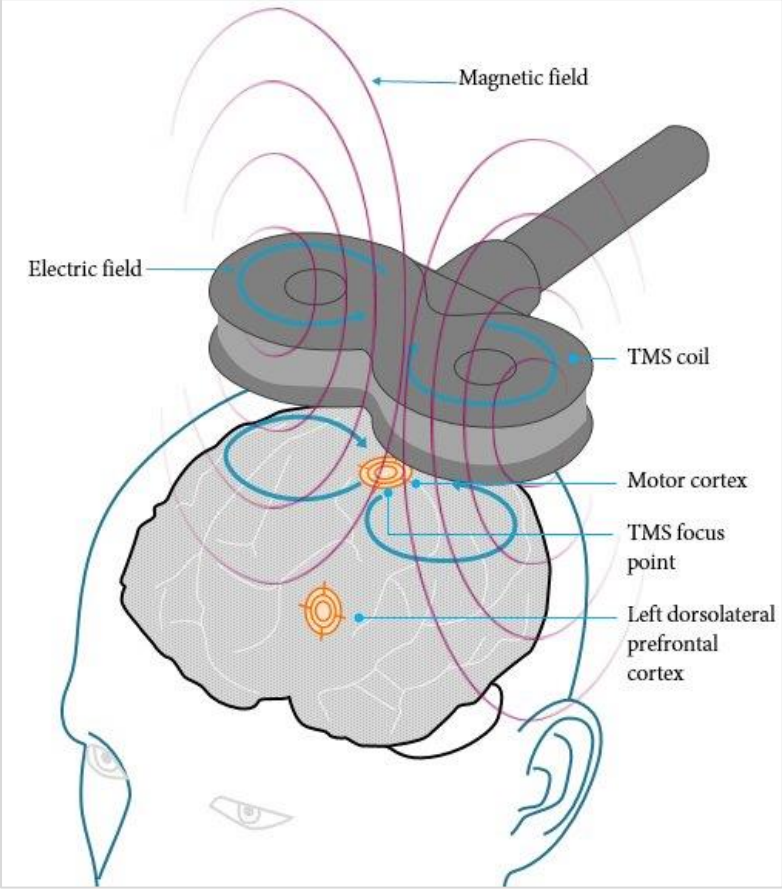


Figure 3: Transcranial Magnetic Stimulation (Fitzgerald, et al., 2018)

Vagus nerve stimulation is another neuromodulation technique which transmits mild electric pulses to the brain via the vagus nerve to alter neural activity (Cleveland Clinic, 2022). The vagus nerve is a pair of twelve cranial nerves that sends electrical signals between the brain, different parts of the neck, head and torso. The vagus nerve also links the neck, heart, lungs and abdomen

to the brain. A study conducted by Ding et al. (2021) concludes that vagus nerve stimulation is relatively safe and effective for pregnant women going through stress and depression (Ding, et al., 2021). However, an article by Cleveland Clinic (2022) suggests that pregnant women should not receive vagus nerve stimulation (Cleveland Clinic, 2022).

2.2.5 WEARABLE AND MOBILE TECHNOLOGY

A study conducted by the University of Technology Sydney identified heartrate variability as the most useful physiological determinant for stress and anxiety (Hickey, et al., 2021). The current wearable devices utilise average heartrate, which does not monitor stress as accurately as heartrate variability parameters. Electrodermal activity was another parameter which was assessed by multiple authors of this research. Mixed conclusions were drawn out about electrodermal activity as one author claimed that it was a useful metric for stress detection, whereas the other author was skeptic on the accuracy of results from these wearables due to motion artefact (Hickey, et al., 2021; Kim, et al., 2020; Chen, et al., 2021). Accurate detection of stress and depression using wearable devices and technology is an ongoing challenge. Wearable accelerometers and electroencephalograms are able to detect stress and depression levels as individual devices, but combining the two technologies successfully would yield highly accurate results.

Acute stress is also related to temporary rise in blood pressure (Health, 2022). Scientists from Spain and Columbia have developed an android-based wearable prototype that uses fuzzy logic to detect potential pregnant mothers with preeclampsia and the intensity of it (Espinilla, et al., 2017). They wearable device collected input values for preeclampsia attributes to monitor the patient through wireless media such as Bluetooth. Indicators such portable urine tests were also used in this method to collect the patient's information. Hypertension is huge contributor to preeclampsia. One study indicated that women with psychological stress, anxiety or depression, or all of them had a 3.1-fold increased risk for preeclampsia compared to those without them (Kurki, et al., 2000), whereas another study found that there was a 2.1-fold increased risk (Qiu, et al., 2009).

Researchers at Purdue College of Engineering are developing technology which makes use of a smartphone application and a wearable device (blood pressure cuff) (Goergen, et al., 2020). This technology would measure the mother's blood pressure on her side versus her back, also known as a supine pressor test. The shift in position would result in an acute rise in the blood pressure and would thus predict susceptibility to preeclampsia. The resting position and blood pressure are

compared to automatically detect mothers who could be prone to this problem (Goergen, et al., 2020). This technology would also be able to monitor sleeping positions and thus alert their users to correct their posture by recommending therapeutic positioning. Figure 4 shows how this technology would be used by pregnant mothers. The test assesses blood flow through the kidney, and 90 percent of women with a positive test eventually develop preeclampsia, according to the researchers (Haller, 2018).

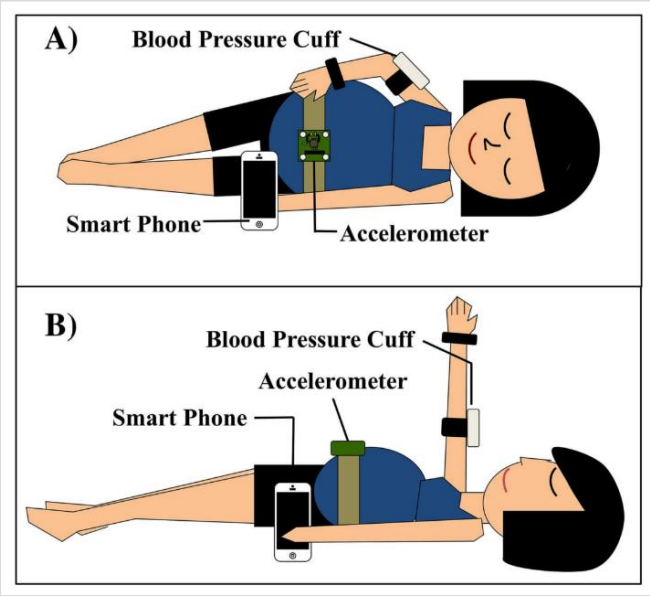


Figure 4: Automated supine pressor test procedure (Goergen, et al., 2020)

Multiple research studies and meta-analyses indicate that non-pharmacological treatment and techniques may be effective in preventing stress, depression, anxiety, nausea and vomiting (Lee & Done, 1999; White, et al., 2002). A study draws out the comparison between efficiency of a wearable and medication for treating nausea and vomiting (White, et al., 2002). Due to neuromodulation technology present in the wearable device, it had higher efficacy in treating and preventing these problems. Although the use of medication along with the wearable was recommended.

Smartphone applications have been introduced to alert pregnant mothers in case of high-risk or extreme situations, and also to keep them informed about their pregnancy status. Krapf et al. (2015) developed a smartphone application to monitor and collect blood pressure details and notify mothers when abnormalities were detected (Krapf, et al., 2015). Researchers in Canada proposed

a wireless body network to monitor pregnant mothers to identify the possibility of premature labour (Allahem & Sampalli, 2017). This non-invasive wireless body sensor network is used to monitor uterine contractions and notify mothers via smartphones if the threshold is crossed. Kumar et al. (2019) proposed an end-to-end self-adaptive health monitoring by facilitating big data analytics and real-time monitoring. This model is an integration of body sensors, mobile devices, cloud infrastructure and thin client of health care professionals (Kumar, et al., 2019). This system takes user input along with signal data through sensors to make accurate health predictions. Based on the results generated, patients would be provided with summarised reports of their health status whereas the doctors or health professionals would get a detailed technical report for in-depth diagnosis. Figure 5 shows a basic structure of how pregnancy is monitored using smartphones, wearable sensors and internet of things (IoT).

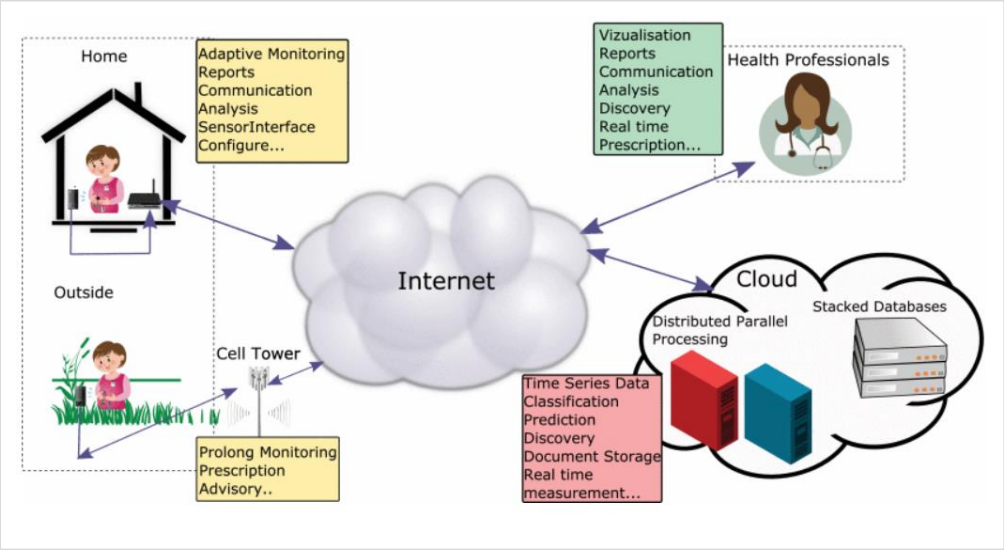


Figure 5: Architecture of pregnancy monitoring through sensors and smartphones (Kumar, et al., 2019)

All the above-mentioned studies and system designs for maternal monitoring are IoT-based, but they are restricted to niche areas for short periods of time and with limited data. An IoT-based pregnancy health-monitoring system is major requirement for pregnant mothers' health conditions (Sarhaddi, et al., 2021). These types of systems should be able to provide a comprehensive view of the pregnant mother's health, encourage healthy lifestyle habits and reduce the risk factors associated to pregnancy. According to a study conducted by Craig et al. (2014), neonatal deaths are most frequently caused by preterm birth complications (RUBENS, et al., 2014). Most of these cases occur without a known cause (Sentilhes, et al., 2017). Collection of stress-related factors and

behaviours in pregnancy could help uncover these health issues in pregnancy (RUBENS, et al., 2014). Artificial intelligence and machine learning should be integrated with IoT to compute accurate and real-time data to provide a personalised maternal experience.

2.2.6 IoT, CLOUD AND BIG DATA IN WEARABLE TECHNOLOGY

IoT-based healthcare monitoring architecture consists of four layers i.e., perception, gateway, cloud and application (Sarhaddi, et al., 2021). The first layer is the perception layer i.e., wearables, which collects data from users. Wearables such as smartwatches, rings and other such similar devices are the modes of data collection in such IoT-based systems. Wearables contain bio-sensors like gyroscopes, accelerometers, photoplethysmography which collect data health data. These signals are analysed and then used to obtain data on various health and psychological parameters such as sleep, stress, physical activity, etc. The second layer in this architecture is gateway. This acts as an interoperability medium between the perception and cloud layer. The gateway could either be a smartphone or a router. Smart e-Health gateways can also be used as they offer services like local storage, real-time data processing, data mining, reliability and security (Rahmani, et al., 2015). The cloud layer of the IoT architecture is in-charge of communication across all devices (Anon., 2020). Communication between devices and cloud services require networking technologies such as WiFi, Bluetooth, ethernet, cellular networks, etc. The cloud layer provides a secure central storage for all the massive inflow of data. Big data analytics and machine learning algorithms are combined to find trends and irregularities in the collected data. It analyses and provides personalised data for the users (Sarhaddi, et al., 2021). The final application layer provides a user interface to monitor and visualize the personal data via smartphone web applications.

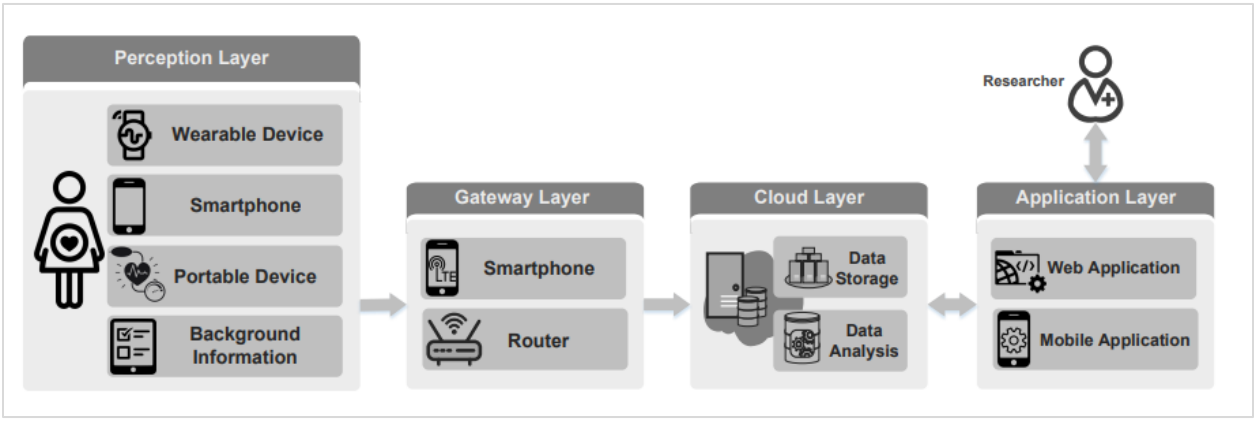


Figure 6: IoT-based health monitoring architecture (Sarhaddi, et al., 2021)

Big data is essential for predictive analytics as it can help healthcare specialists assess the patient's symptoms and vital characteristics, and thus help with earlier diagnosis of potential health problems. This would also increase the chance of appropriate care, prevention or even recovery (Pilkington, 2020). Collecting high-quality data requires the data collection tools in healthcare to be optimised.

2.3 SLEEP MONITORING USING WEARABLE TECHNOLOGY

We spend over 30% of our life asleep (Kwon, et al., 2021). Multiple research projects works and studies have indicated the negative influence of poor sleep quality on health conditions such as heart conditions, hypertension, mood disorders, etc. (Buysse, 2014; Hublin, et al., 2007; Patel, et al., 2004; Sigurdson & Ayas, 2007). Sleep assessment begins with brain activity monitoring by making use of electroencephalogram (EEG). Sleep monitoring at hospitals is inconvenient for patients as they have multiple electrodes attached to their scalps. But they make use of conductive gels to attach electrodes to the scalp which in turn deliver accurate data for analysis. On the other hand, wearables use the forehead for data collection and monitoring of sleep (Kwon, et al., 2021). Researchers from Advanced Brain Monitoring (California, USA) developed a wireless sleep monitoring device in a headband platform which is equipped with three frontopolar electrodes on the forehead along with photoplethysmography (PPG) sensor, triaxial accelerometer and a microphone to monitor body movement, snoring and blood pressure (Levendowski, et al., 2017). Figure 7 shows the working model of this device.

Figure 7: Wearable for sleep monitoring – Forehead (Levendowski, et al., 2017)

Despite the challenges with putting a wearable on the scalp (hair), studies have made breakthroughs with electrodes and a structure to reliably measure EEG via the scalp (Arnal, et al., 2019). This device uses the same sensors as compared to the model that Levendowski et al. (2017) created. The key difference is that the model proposed by Arnal et al. (2019) the electrodes are made of soft and flexible silicone protrusions which penetrate through the hair to make contact with the scalp. The prototype of this device is shown in figure 8.

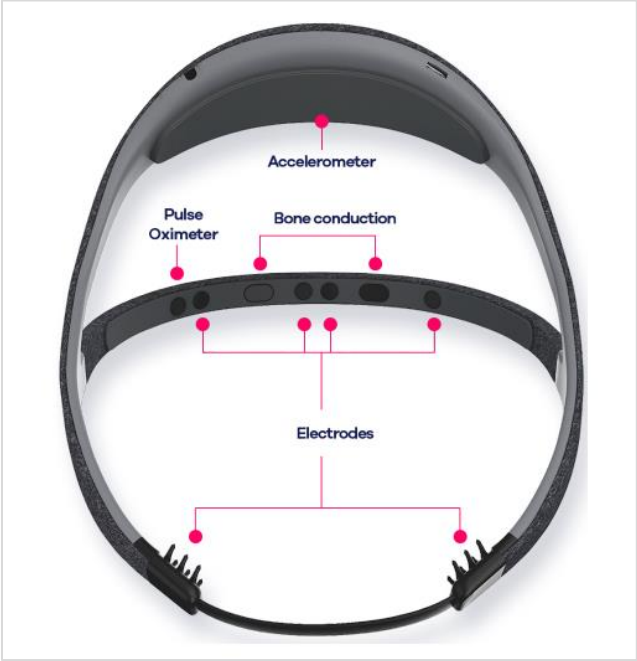


Figure 8: Wearable for sleep monitoring – Scalp (Arnal, et al., 2019)

Other parts of the body have also been discovered for non-interfering sleep monitoring. The ear is the most popular location amongst other body parts (Kwon, et al., 2021). Figure 9 shows an in-ear type EEG measurement which has two fabric-based electrodes integrated into a memory-foam substrate (YD, et al., 2018). Memory foam was used in this model due to its unique mechanical property and comfort fit to the user's ears. Along with the comfortable fit, it also makes reliable electro-to-skin contact and reduces the signal artefacts that are caused due to blood vessel pulsation movements caused by the ear.

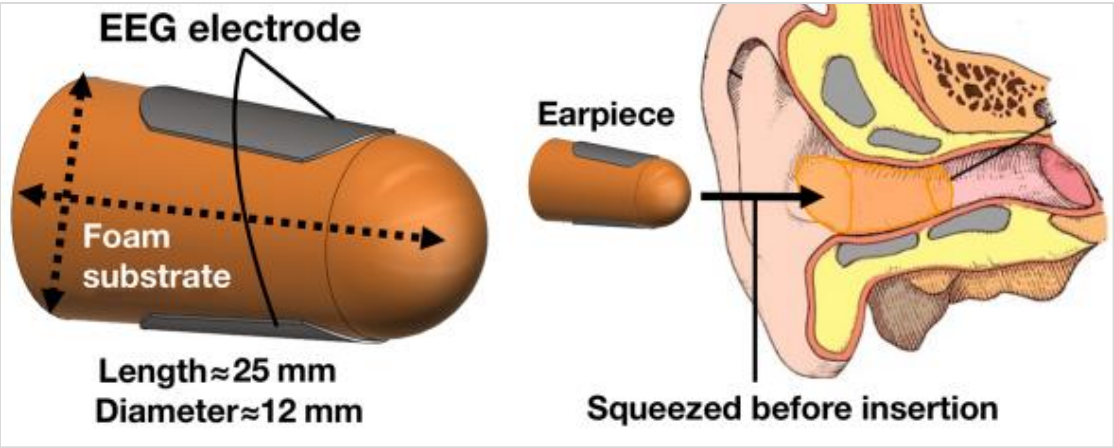


Figure 9: Wearable device for sleep monitoring – In-ear (YD, et al., 2018)

2.4 CARDIOVASCULAR MONITORING USING WEARABLES

Cardiovascular diseases are responsible for the highest number of deaths globally, but wearable devices and technology have the potential to change how these diseases are diagnosed and managed (Chen, et al., 2021). Wearable sensors are required for non-invasive and continuous real-time monitoring of signals, without any interference with daily tasks. Polymers or substrate films are generally used for wearable sensors due to their lightweight, flexibility, scalability and low-cost advantages (Economou, et al., 2018). Existing studies highlight that monitoring arrythmia, physical activity, blood pressure and sleep are the key factors for efficient cardiovascular monitoring (Pevnick, et al., 2018). Studies show that under ideal conditions, wrist-worn devices can monitor heartrates with less than 10% error (Wang, et al., 2017; Cadmus-Bertram, et al., 2017; Pevnick, et al., 2018). These heartrate monitors transmit data to smartphones, servers and electronic health records. This has clinical benefits as well as a challenge. Mary Jo Deering (2013), in her paper said that patient-initiated data violates a central principle of clinical testing i.e., initiating of testing without awareness of the impact the result may have on health management (Deering, 2013).

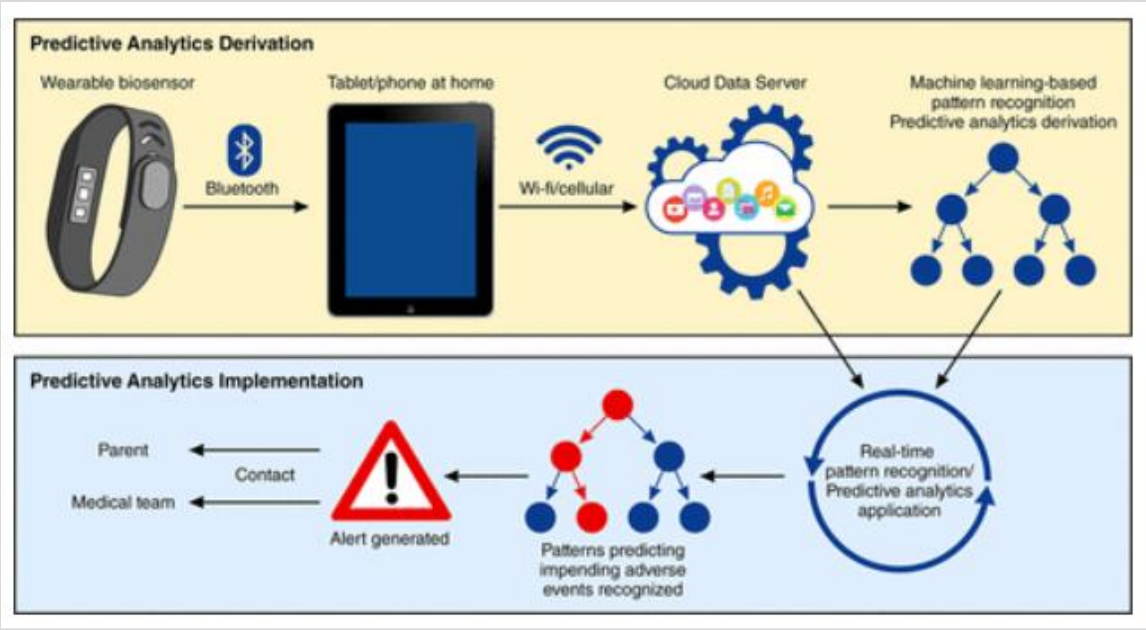


Figure 10: Wearable cardiovascular monitoring technology (Tandon & Ferranti, 2019)

2.5 CHALLENGES ASSOCIATED WITH WEARABLES

The challenges associated to remote health monitoring can be classified into two perspectives i.e., user experience and integration of system with newer technologies (Sarhaddi, et al., 2021). From the user point of view, keeping them motivated to use the wearable device for long periods of time is indeed a challenge (Meyer, et al., 2017; Sarhaddi, et al., 2021). Long-term usage of the device is essential to enhance user experience and generate accurate results. On the other hand, the technical challenge is integrating multiple devices (Mykola & Oleksandr, 2021). Data aggregation becomes difficult due to different communication protocols. This slows down the internal process even though the devices are connected. Another major technical challenge is security. Private data is susceptible to cyber-crime as there is diversity in communication protocols and lack of clarity of data ownership. This leads to the threat of personal health info abduction, its public exposure, or even identity theft (Mykola & Oleksandr, 2021). Data overload is an issue because IoT-based wearables collect huge amounts of data which causes problems for data analysis. The increase in data and amount of health data leads to higher complexities in decision making. The final challenge with such technology is internet disrupting (Mykola & Oleksandr, 2021). Since the products cannot be protected from critical errors or malfunctioning, the device in its offline stage could possibly lead to violation of data transmissions, thus becoming life-threatening.

2.6 RESEARCH GAP SUMMARY

Through the literature review showcased in this chapter, the challenges associated with health and remote health-monitoring (pregnancy, sleep and cardiovascular) using wearables and IoT were clearly identified. It was observed that monitoring and controlling emotional and psychological health during pregnancy is critical for a mother's as well as foetus' life. Another analysis from this literature was that even though there are medical treatments and medicines for dealing with these health factors, there is a high relapse rate with patients as they are unable to complete their treatment for a number of reasons. Also, the wearable devices that help pregnant mothers deal with these issues are very limited and only give them temporary relief, which is not the long-term solution. It was also observed that there are ambiguities surrounding vagus nerve stimulation for pregnant women, which is why further research needs to be conducted. A final trend was observed that improper sleep is a big factor for psychological and emotional distress, and these problems contribute to cardiovascular problems.

The following chapters in this study will discuss a possible solution to these challenges and will analyse them jointly with business aspects of wearable devices.

CHAPTER THREE – Research Methodology

3.1 OVERVIEW

The whole project starts with a discussion to decide a topic and finishes with results of data analysis presented in a report (figure 11). This research design follows the 'Research Onion Model' approach created by Saunders et al. (2009). The following section covers the research philosophy behind this project and the methodologies used for solving the research problem, based on the above-mentioned research model.

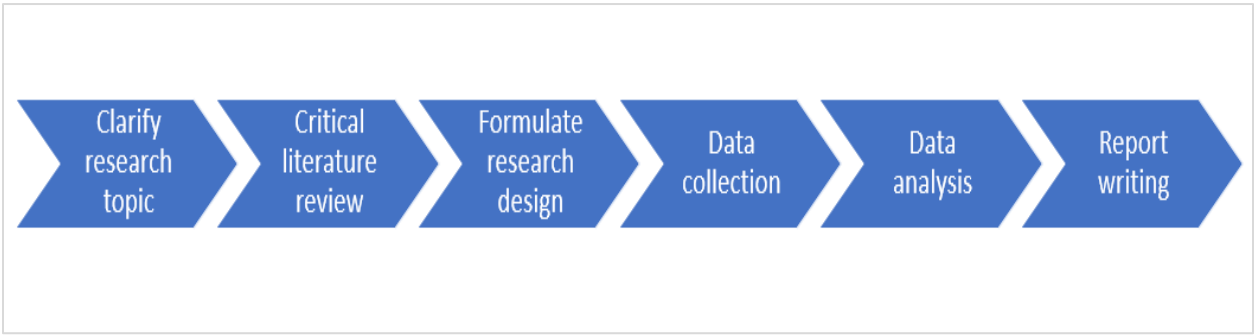


Figure 11: The research process (Saunders, et al., 2009)

3.2 RESEARCH DESIGN

3.2.1 PHILOSOPHY

The outermost layer of the research model is philosophy and there are three kinds – positivism, constructivism and pragmatism. Positivism adheres to the view that only factual knowledge gained through observations and measurement through the traditional method of quantitative research is trustworthy (Collins, 2010). On the other hand, constructivism uses qualitative data to understand the research problem from a participant's point of view. This philosophy is used to see the world through other people's perception. This project carries out positivist approaches using quantitative research to observe the general population's perception around wearable devices in healthcare, problems that pregnant mothers face or have faced in their pregnancy and their views on acceptance, concerns and preferences. However, constructivist studies are worth carrying out because it would help with identification of other technological, mental and physical health, as well as business challenges, that could possibly lead to a better solution. This could be done through qualitative research. Thus, pragmatism, which is a combination of both philosophies, would be the most appropriate philosophy for this project.

3.2.2 RESEARCH APPROACH

This research makes use of the deductive approach to derive a theory based on the literature reviewed, but uses inductive approach in the overall research. The theory is linked to the literature review and is used to develop a conceptual framework (Saunders, et al., 2009). The inductive approach is used after the quantitative and qualitative data has been collected. A comparative analysis can be conducted from the literature review as well as the collected data, based on which a solution can be proposed.

3.2.3 METHODOLOGY

Based on the pragmatic philosophy, this research uses a mixed method of combining quantitative and qualitative research to fully explore all aspects of wearable technology and business. A final analysis will be drawn from quantitative as well as qualitative data. The benefit of this method is that it uses primary as well as secondary data. Primary data is obtained from the quantitative and qualitative research whereas secondary data is the information obtained from others' studies, research work, experiments and verified articles. The secondary data will be fully used to support the primary data's analysis.

3.2.4 STRATEGIES

Two strategies were used for combining qualitative and quantitative research – surveys and case studies. Surveys fall under the quantitative research category whereas case study fall under qualitative research. These studies are carried out parallelly to acquire sufficient data for meaningful solutions. Each strategy is designed to achieve the key objectives of this project. The survey is used for understanding the acceptance and trust around wearable healthcare devices, which then filters down to key problems in pregnancy, sleep and cardiovascular monitoring. The case study focuses on business aspects by analysing the limitations with previous wearable devices. All the data obtained from primary and secondary research strategies are combined and analysed to provide a meaningful business solution i.e., a new line of products particularly targeted towards remote maternal-health monitoring. Figure 12 shows the research process for data collection.

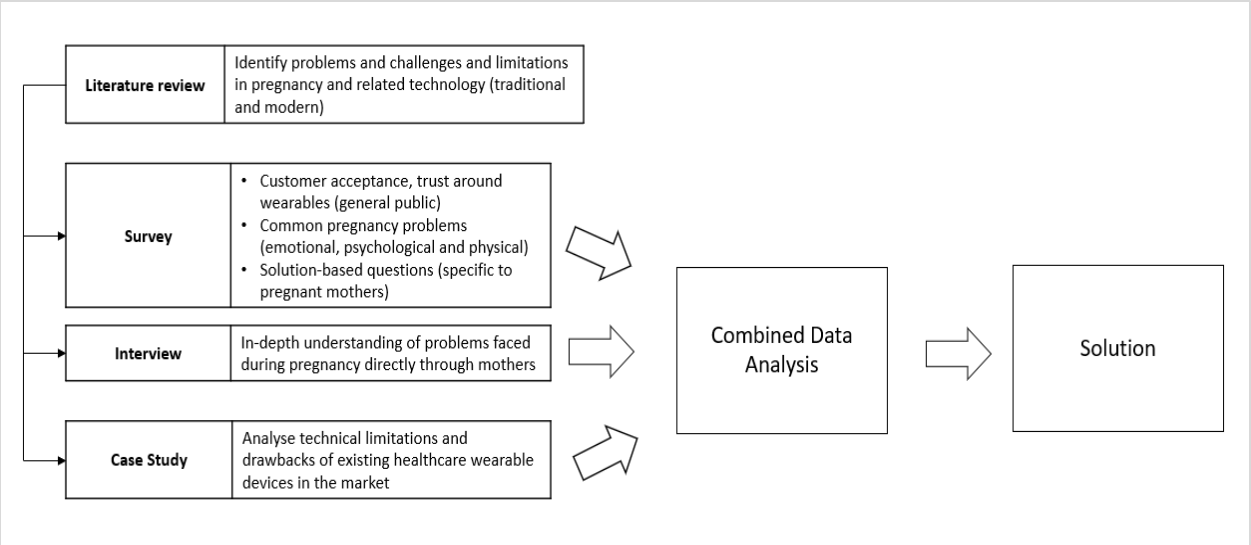


Figure 12: Research design - Primary and Secondary data collection

Survey design: There are two surveys for this research. The first one contains questions to understand people's perception about wearable technology in healthcare, demographics, trust factor, acceptance factor, whether they've used it, if they're willing to invest in it and how much would they invest. These questions help analyse the customer segment for a wearable technology company. The second survey was particularly designed for the pregnant customer base. It starts with questions about the current duration of their pregnancy, problems that they are facing or have faced, frequency of these problems, awareness about wearable technology and its types, potential solutions for improvement in pregnancy monitoring technology based on the types of health problems that are currently not solved by wearable devices. This questionnaire would be useful to derive statistical relationships between the frequency of problems faced by pregnant women and the possible solution to combat those problems.

Case study: This part of the research aims to identify why existing wearable device manufacturing companies are unable to provide a solution for pregnant mothers to help them combat health problems. This section discusses the limitations in commercial wearable devices and the data obtained from this study would be used to be used as a reference to avoid failure.

3.2.5 TIME HORIZON

This project has a limited time frame because there are a lot of companies working towards developing an ideal product for pregnant women. To launch our solution commercially, research

and development of the solution needs to be faster than the competitors. Hence, the time horizon for this research is 'cross-sectional' (Saunders, et al., 2009). But this study would gradually progress towards a longitudinal time horizon because of continuous updates, changes in technology and customer requirements.

3.2.6 DATA COLLECTION AND ANALYSIS

3.2.6.1 Data Collection

Sampling: Sampling for two surveys was required. The first one was the general customer-acceptance survey for wearable technology. This group survey was distributed to the general public and the last recorded number of responses was 114. The second survey was specific to pregnant women and new mothers, and the last recorded number of responses was 23. Lamaze classes as well as nurseries were approached to distribute the survey to pregnant women and recently new mothers.

Collecting and recording: Google forms were used to collect responses. The case study was performed by online research materials, articles and papers.

3.2.6.2 Data Analysis

Data analysis of survey: The collected data was first cleaned and then analysed using Microsoft Excel. Data analysis was carried out using the descriptive analysis method, which checks for statistical characteristics or patterns for each answer.

Data analysis of case study: The product's history, features and reasons for discontinuation were studied. After analysis, it was safe to conclude that the technological limitations of the product aligned with the data obtained through other sources.

3.3 ETHICAL CONSIDERATIONS

All ethical considerations and regulations were maintained during the data collection process of this research. The ethics fast-track form was submitted to our supervisor for data collection and was approved by the 'Physical Sciences Ethics Committee' at the University of York. Participant anonymity and confidentiality was maintained throughout the research.

3.4 LIMITATIONS

Not being able to get in touch with gynaecologists and healthcare specialists could limit my understanding of health issues from a medical standpoint. The initial plan for a case study was to

speak to industry experts and product owners/managers in companies that develop pregnancy wearables. There was no response from their end which is why the case study was carried out via online papers and articles. The sampling of pregnant women and new mothers for the survey was also limited because not all candidates were willing to take the survey. Some did not answer all questions. Since the total number of participants were 114 in the first and 23 in the second survey, this would also be a limitation since the sample size is small. For the pregnancy-specific survey, Lamaze classes and children's nurseries were approached for data collection. The surveys were distributed via the managers of these places, and they were the link to other customers. But the response was limited, hence, resulting in a small sample size. Thus, this study makes use of the survey results but does not generalise its outcomes.

CHAPTER 4 – Data Analysis

4.1 OVERVIEW

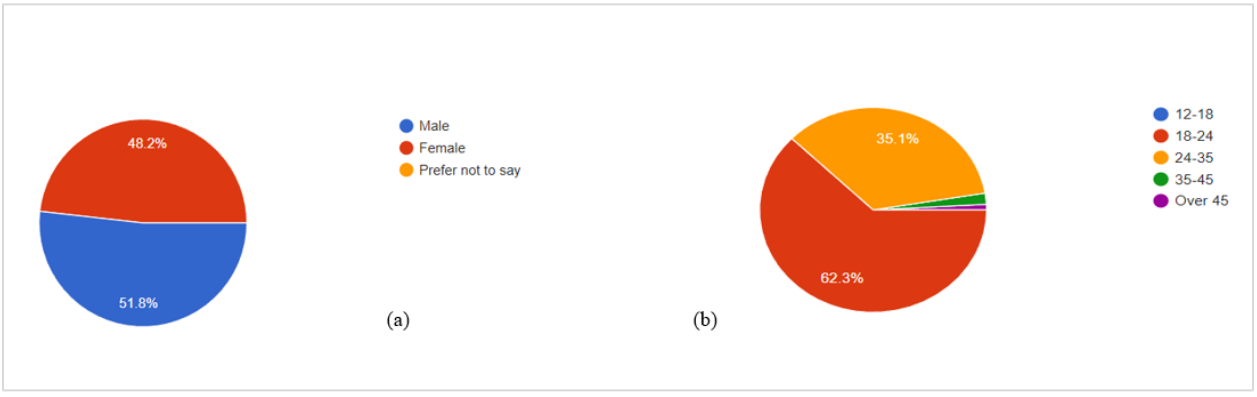
This chapter presents the findings obtained from quantitative and qualitative data analysis. Quantitative data analysis is based on results obtained from two surveys. The first one being a group survey on general wearable technology and consumer acceptance and the second one being a pregnancy-specific survey. Qualitative data analysis is based on the case study conducted on a neurostimulation wearable device.

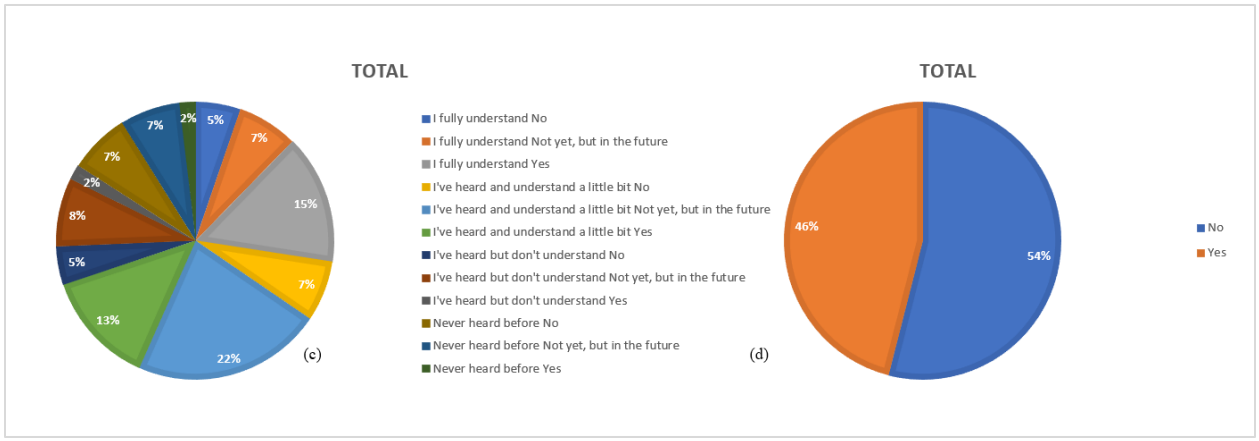
4.2 QUANTITATIVE DATA ANALYSIS – Survey

4.2.1 PARTICIPANTS

4.2.1.1 Group Survey

In the consumer acceptance survey, 51.8% of the respondents were male and 48.2% were female (figure 13a). This indicates that gender of the participants is almost equally divided. On the other hand, the participants' age group is skewed towards the 18-24-year category with 62.3% falling under it (figure 13b). This is because most of the participants were from universities around the world. Out of these participants, 63% people have heard about wearable devices and either understand the concept a little bit or completely (figure 13c). Another characteristic is that 54% of the respondents do not own any wearable devices but 52% of them intend on buying it either now or in the future (figure 13d). 71.1% of the respondents gave a rating of 7 and above out of 10 for trust on results and accuracy, and 85% of the respondents rated it 6 and above (figure 13e). This indicates that there was a high trust factor towards wearable devices and thus a higher acceptance rate.





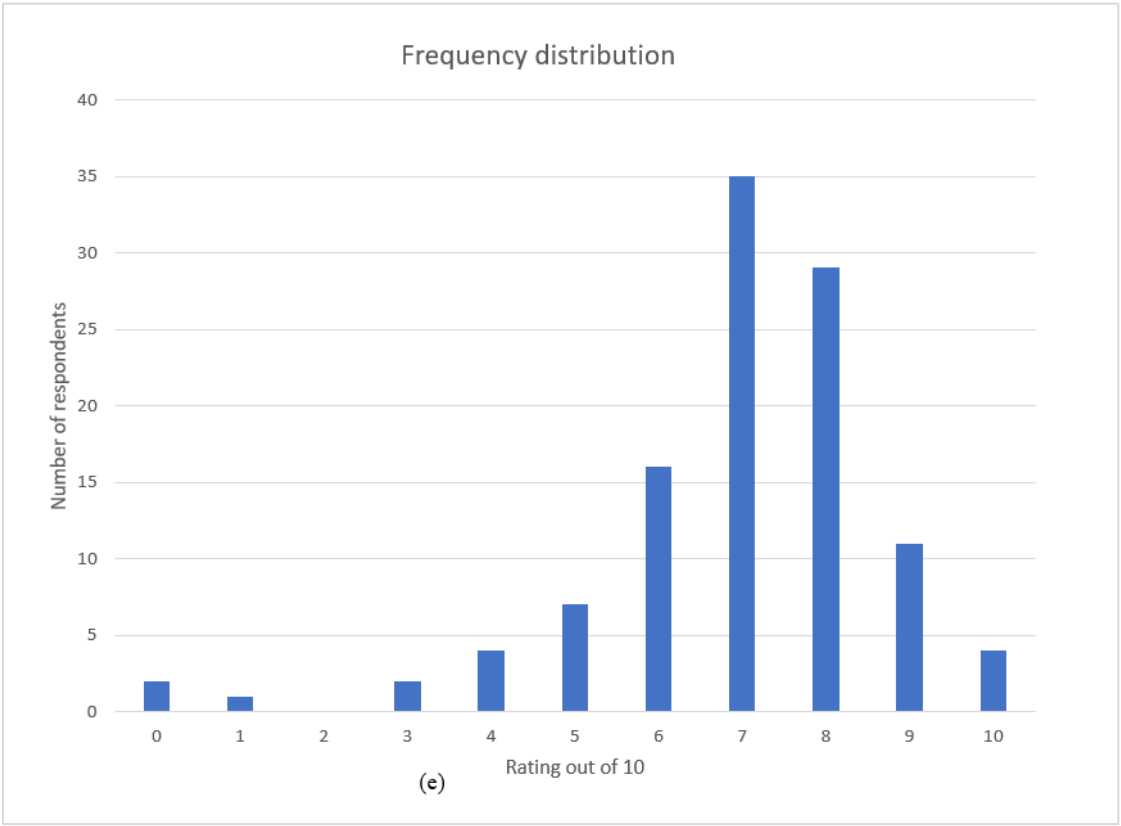


Figure 13: Consumer acceptance

4.2.1.2 Pregnancy-specific

In this survey, the pregnancy duration varied from 4 weeks to recently new mothers (post-delivery). 69.6% of the mothers understood the concept of wearable technology. 87% of the participants rated their trust on wearable technology between 5-8 out of 10. This again is a good indication towards their acceptance of this technology.

4.2.2 FINDINGS FROM THE SURVEY

4.2.2.1 Group survey

Most preferred wearable: This question addresses the type or style of wearable device that consumers would prefer. Smart watches and wrist-wearables was the most preferred wearable device and 62.2% of the participants chose this (figure 14a). Following wrist wearables was a ring-type wearable sensor which was preferred by 45% of the respondents. 50.9% of the respondents preferred to purchase these devices online i.e., via Amazon or a company website (figure 14b). Purchasing from a physical store was preferred by 26.4% of the participants and hospitals or pharmacies were preferred by 21.8%. The rest fell into social media categories.

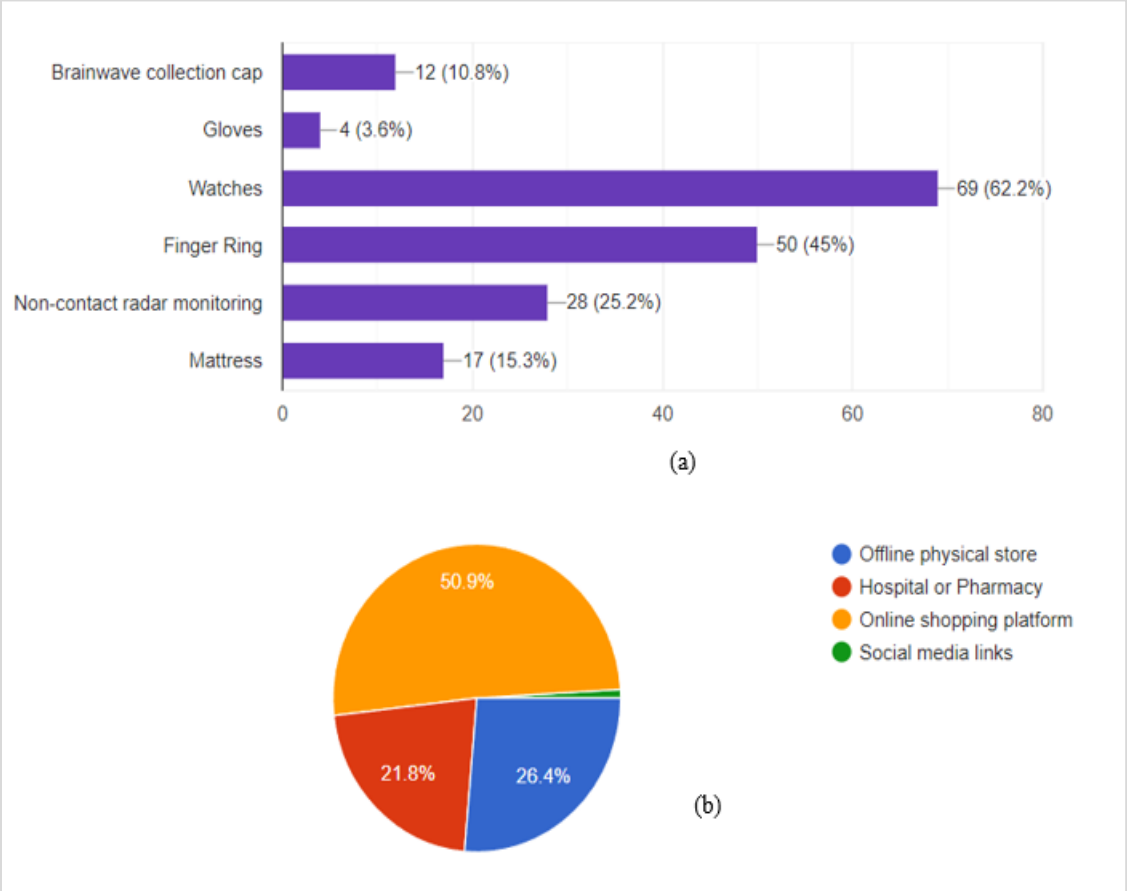


Figure 14: Consumer preferences

4.2.2.2 Pregnancy-specific

Table 2 addresses the technological gaps in current pregnancy wearables, the trust factor as well as acceptance by pregnant mothers for each potential solution using wearable technology.

Technology Gap	Response
Pregnancy detection without traditional testing	39.1% of the participants rated this solution 6/10 and only 8.7% gave a 9/10 for their trust in this solution (figure 15a)
IVF detection before conceiving	26.1% rated their trust factor 5/10, 21.7% rated it 4/10 and only 8.7% gave a 9/10 for their trust in this solution (figure 15b)
Stress, depression and anxiety reduction	78.2% of the participants rated their trust factor 7 and above out of 10 (figure 15c)
Hypertension control	60.8% of the respondents gave a 7 and above trust rating for this solution (figure 15d)

Table 2: Acceptance and trust factors for wearable solutions based on pregnancy-related problems

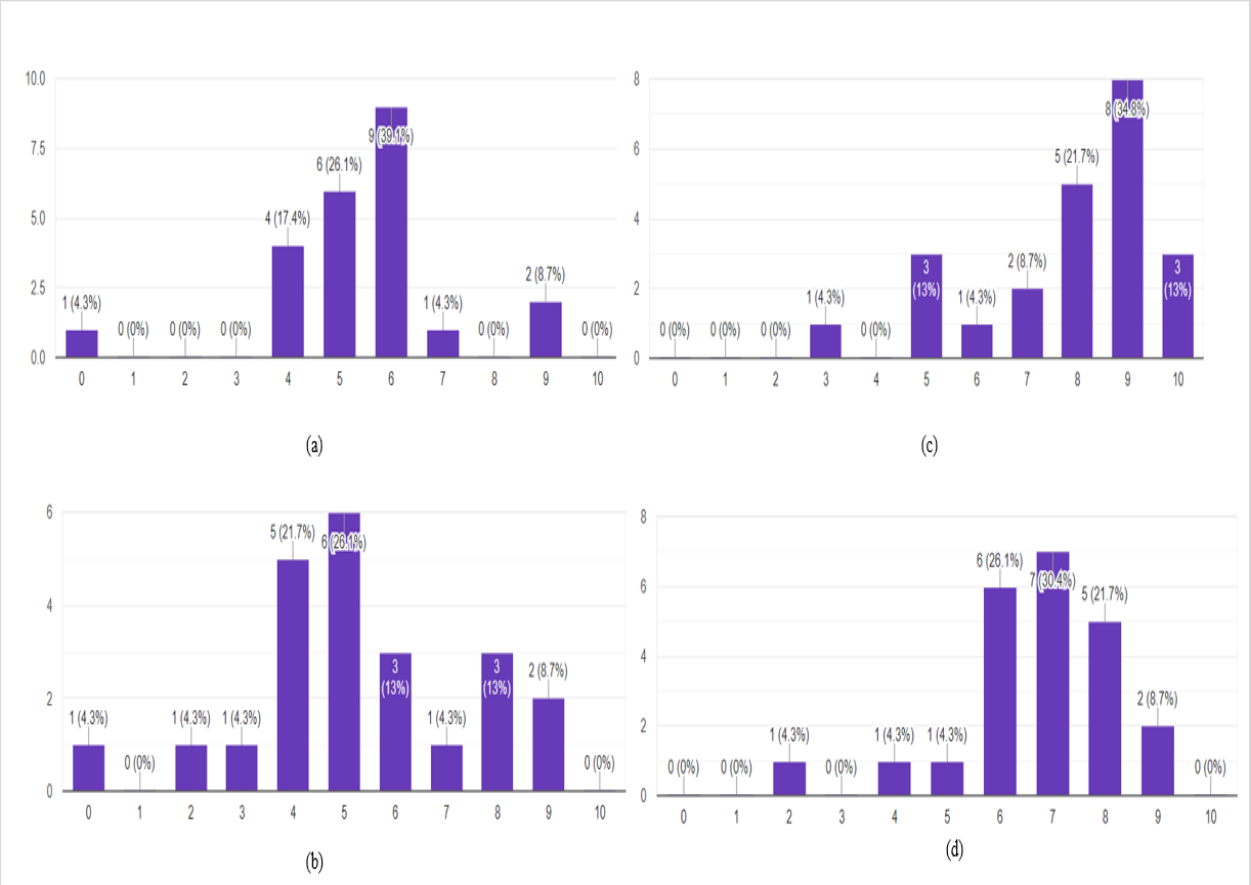


Figure 15: Potential solutions

4.3 QUALITATIVE ANALYSIS – Case Study

4.3.1 OVERVIEW

All the information is obtained from the articles and the official company website, based on which an analysis about the technology is drawn from them.

4.3.2 NUROSYM

It is a certified medical device created by an Estonia-based company called Parasym. It is an in-ear wearable device which harnesses the power of advanced neuromodulation into a handheld remote-like device (Nurosym Editorial Team, 2021). Nurosym focuses on the immune pathway that generates excessive inflammation and irritation by halting inflammatory signals, hence pausing their effect on the brain and resulting in improvements in temperament and energy. Nurosym also balances the autonomous nervous system by lowering the fight or flight response and thus bringing the body back to a state of homeostasis or stability.

4.3.2.1 Pros

Nurosym is the most accessible and affordable medically certified neuromodulation device in the market (Nurosym Editorial Team, 2021). The non-invasive technology prevents ingestion of medicinal cocktails to counter stress, anxiety and depression. Its compact design does not restrict any movement or any decision-making ability. The neuromodulation levels are easy to control via a control pad. Since the body is brought to a state of homeostasis after each session, it triggers the body to rest, digest and recover.

4.3.2.2 Cons

It is an hour-long daily process and if not done every day, the effects only last for a week. It is an in-ear wearable which is directly in contact with the vagus nerve. If not operated properly or under guidance, it could damage the nerve thus leading to possible neurological disorders. Other risks involved with using this device are burning of skin at the stimulation site, light-headedness/dizziness, shortness of breath, fatigue, abnormal heart rhythm and headaches (Nurosym, 2022).

4.3.2.3 Contraindications

The main contraindication with this product is that the company does not intend for pregnant women to use this device (Nurosym, 2022). The possible factors could be of potential impacts that the neuromodulation technique could have on the baby.

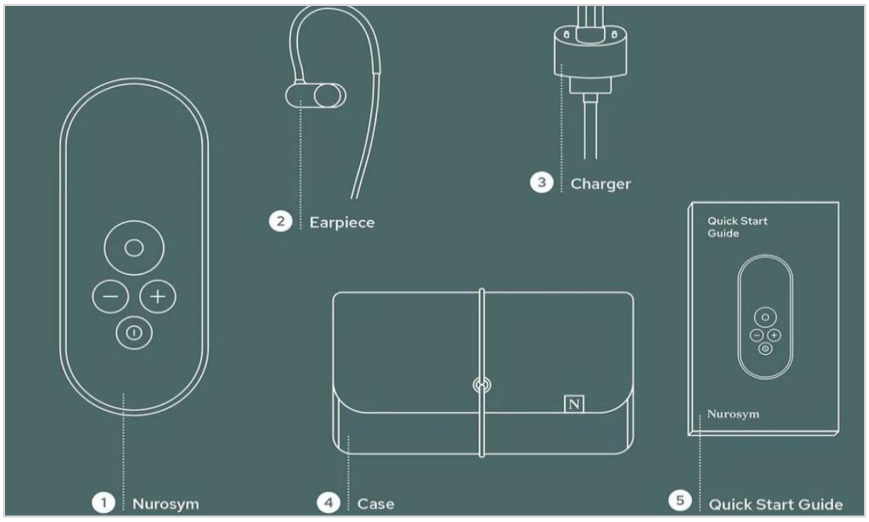


Figure 16: Nurosym (Nurosym, 2022)

4.3.3 TOUCHPOINT

It is a device created by Touchpoint Solution, a US-based company which specialises in developing patented wearables that reduce stress levels through advanced neuromodulation (LinkedIn, 2022). Touchpoints are two devices that can be worn on multiple places on both sides of the body as such as wrists, ankles, etc. The company focuses on using these devices to tackle more than just stress i.e., sleep, performance, focus, irritability and Parkinson's disorder (Touchpoint Solution, 2022). Touchpoints make use of patented Bi-Lateral Alternating Stimulation-Tactile Technology (BLAST) to reduce stress and anxiety. These are vibrations from each wrist that stimulate both sides of the brain in order to align both branches of the nervous system to bring the body to a state of equilibrium (Kummer, 2021).

Figure 17: Touchpoints (The TouchPoint Solution, 2022)

4.3.3.1 Pros

According to customer reviews and a case study conducted by the company itself (Touchpoint Solution, 2022; Kummer, 2021), touchpoints' ability to relieve stress is great. By using these devices for 30 minutes daily, people who were initially obsessive, constantly worried, insomniac, and had relationship problems, were able to solve all of these problems.

4.3.3.2 Cons

There were no technological problems or downsides associated with this device and neither were there any contraindications.

The only limitation with the scope of this product research is that there is no known evidence on the impact it has on pregnant women and foetus.

4.3.4 FINDINGS FROM THE CASE STUDY

Vagus nerve stimulation was a great way to relieve stress and had no major side effects on its users, but was not advised for pregnant women. Bilateral tactile stimulation was safe and a fast way to relieve stress, depression and anxiety. It also solved sleeping problems and improved cardiac rhythm in some cases (Touchpoint Solution, 2022).

CHAPTER 5 – Business Strategy

5.1 OVERVIEW

This chapter describes a technological solution based on results combined from the analysed data and the reviewed literature. A macroenvironmental analysis and competitive assessment is carried to understand the business' potential opportunities as well as risks. A business model canvas is shown to understand the target market, market need, and the role of the proposed solution in the market. This chapter ends with a roadmap for developing the device.

5.2 TECHNOLOGY SOLUTION

Table 3 shows the conclusions drawn from literature review and the data analysis conducted in the above chapters.

Tool	Challenges	Solution
Primary research (Group survey)	Preference of type of wearable device	Wrist-wearable
Primary research (Individual survey)	Pregnant mothers had a lot of stress and anxiety, and would prefer wearable devices that could reduce it	Wrist-wearable device that controls stress, depression and anxiety
Primary research (Case Study)	Vagus nerve stimulation was not advised for pregnant women in one device. Bilateral tactile stimulation was extremely effective for relieving stress, anxiety and depression	Integrate vagus nerve stimulation with bilateral tactile stimulation
Secondary research	Stress, depression and anxiety are not controlled by wrist-wearable devices yet	Wrist-wearable device for pregnant women that uses integrated vagus nerve stimulation and bilateral tactile stimulation to control stress, depression and anxiety

Table 3: Solution generated from each research phase

Based on this analysis, the proposed solution is to develop a wrist-wearable device that can control and reduce stress levels, depression and anxiety by integrating vagus nerve stimulation with bilateral tactile stimulation. A smartphone app linked to the data obtained from this device would also be essential to monitor pregnancy effectively. Based on the data generated, the app would also make recommendations on improving lifestyle and diet habits. The combined stress controller device and the pregnancy app would be the solution to improve pregnancy monitoring through wearable technology.

5.3 PESTEL ANALYSIS

Figure 13 shows the macro-environmental analysis of the wearable technology industry through the use of PESTEL analysis tool.

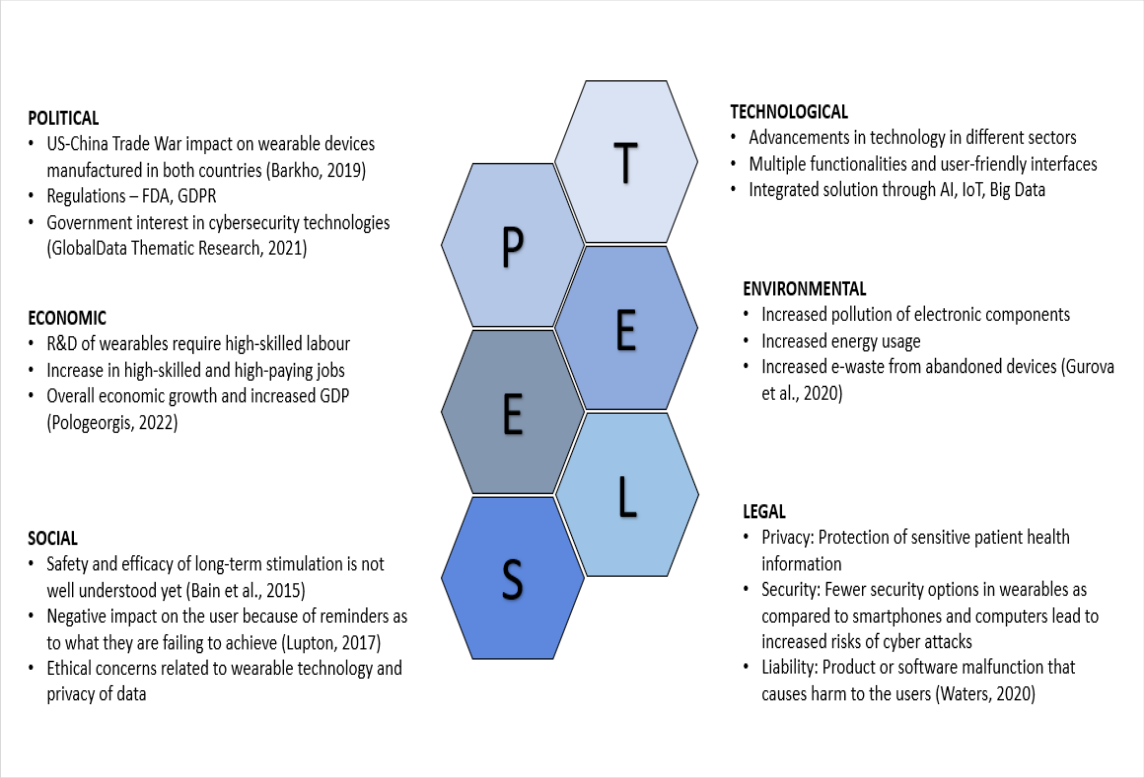


Figure 18: PESTEL Analysis for the wearable market

Political: Due to the US-China trade war, tariffs on imports could force manufacturers of wearable devices and other electronic devices to pass the rising costs to their customers (Barkho, 2019). Since the electronics supply chain is interconnected globally, the US-China trade war contributes to shortage of electronic components (ReboundEU, n.d.).

Economic: Development of wearable devices and technology requires high-skilled labour. An increased number in high-skilled results in an increase the GDP. In the healthcare industry, wearable devices also will also contribute to saving money which is spent on hiring workforce that carries out the process of health checkups and data collection (Sibanda, 2019).

Social: Wearable devices have started being adopted by consumers more in recent years. But a study conducted by Gartner in 2016 shows that there is also a high abandonment rate with these devices (Moore, 2016). Adoption rates of wearables as compared to smartphones and other devices

are lower due to lack of trust in data privacy and security. Wearable technology is becoming more ubiquitous and it will penetrate and spread through every aspect of human life (Vaajakari, 2018).

Technological: Continuous advances are being made in wearable technology. A near-future guarantee for wearables is increased battery life and these devices may incorporate energy harvesting i.e., converting body heat to raw electrical power (Suzuki, 2022). The variety of different wearables in the market is also increasing.

Environmental: Wearable devices can heighten the impact on the environment and health through increasing power consumption and generating hard-to-recycle electronic waste components (Vaajakari, 2018). Implementing circular economy for the sustainable development of wearable devices would be beneficial for the environment.

Legal: Manufacturers and developers of wearables need to acquire Food and Drug Administration (FDA) clearances on technology. There are certain standards that wearable medical devices must meet as these tests help manufacturers overcome regulatory constraints. Security and privacy concerns are about user data being hacked, manipulated and misused. There is also lack of encryption grouped with other vulnerabilities (Kalia, 2017).

5.4 PORTER'S FIVE-FORCE ANALYSIS

A competitor analysis has been carried out in figure 14 with respect to our proposed 'stress-controller' wearable device.

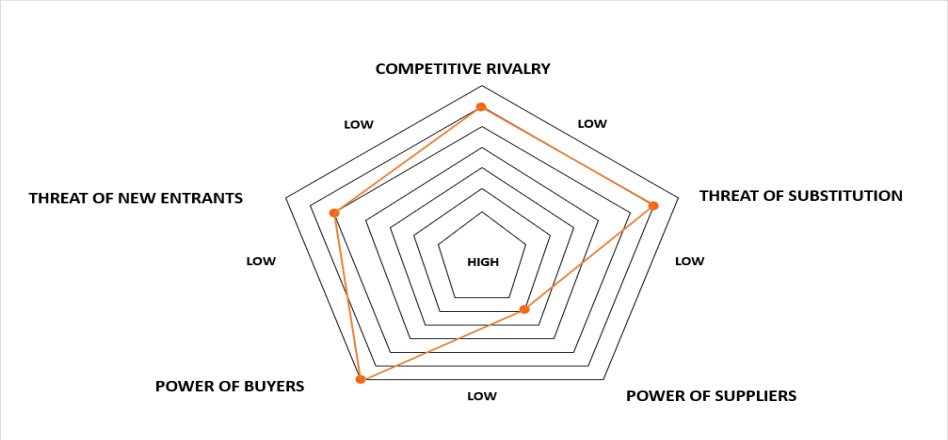


Figure 19: Porter's five-force analysis

Competitive rivalry: This has been ranked between low and medium as there is currently no product in the marketing which carries out neurostimulation for stress using wearable devices.

Threat of new entrants: This has been ranked medium because of two factors – importance of mental health and growing wearables' market. Maternal emotional and psychological health is as important as their physical health because stress, depression and anxiety lead to complications before, during and after pregnancy. This factor along with the rising market is an opportunity for other companies to introduce similar lines of products.

Power of buyers: This is marked low because after the product has been successful in clinical testing, getting FDA clearance and successful marketing, the customers would buy our product as there would be no alternative.

Power of suppliers: This is ranked between medium and high as our product would be the only of its kind, which is why we would have a competitive advantage over other companies developing wearable devices for pregnancy monitoring.

Threat of substitution: This has been ranked between low and medium because there aren't many technologies that can reduce stress levels and control depression.

5.5 BUSINESS MODEL CANVAS

Figure 17 visualises the business model through a canvas.

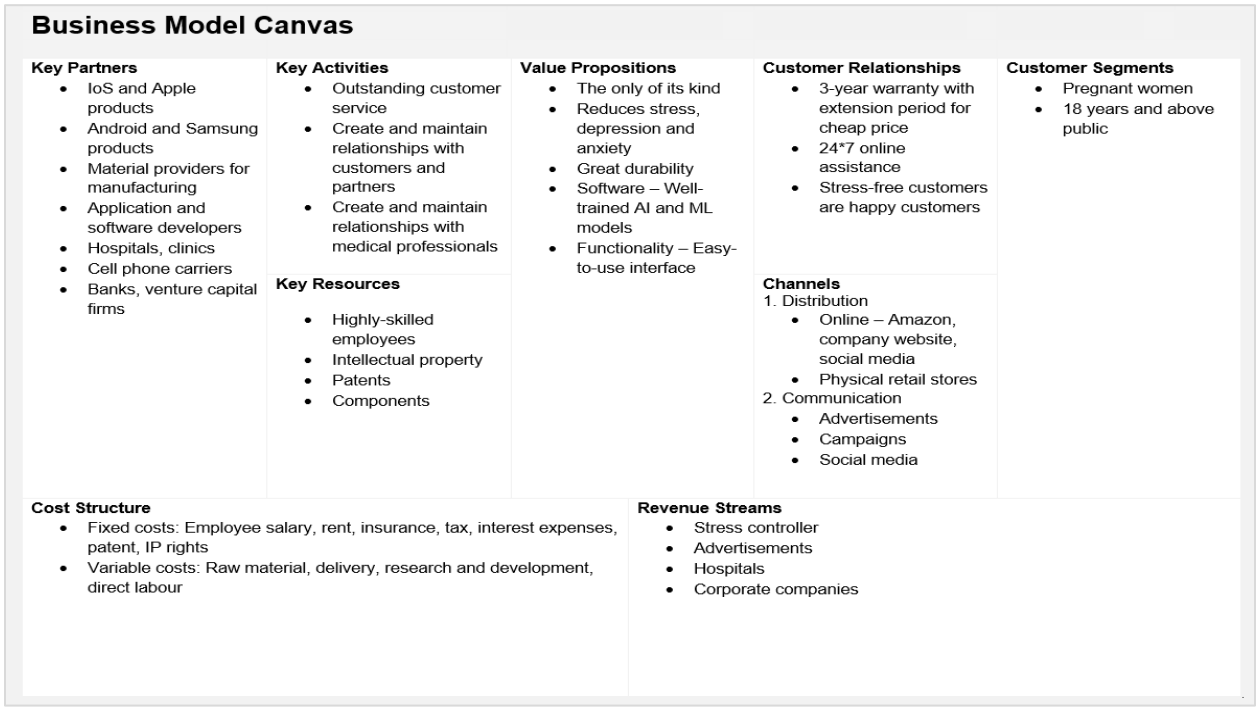


Figure 20: Business Model Canvas for stress controller

5.6 ROADMAP FOR TECHNOLOGY DEVELOPMENT

The development of this device is divided into six phases i.e., research, proof-of-concept, alpha, beta, pilot production and manufacturing phase (DeviceLab, 2020). Figure 15 shows the technology roadmap.

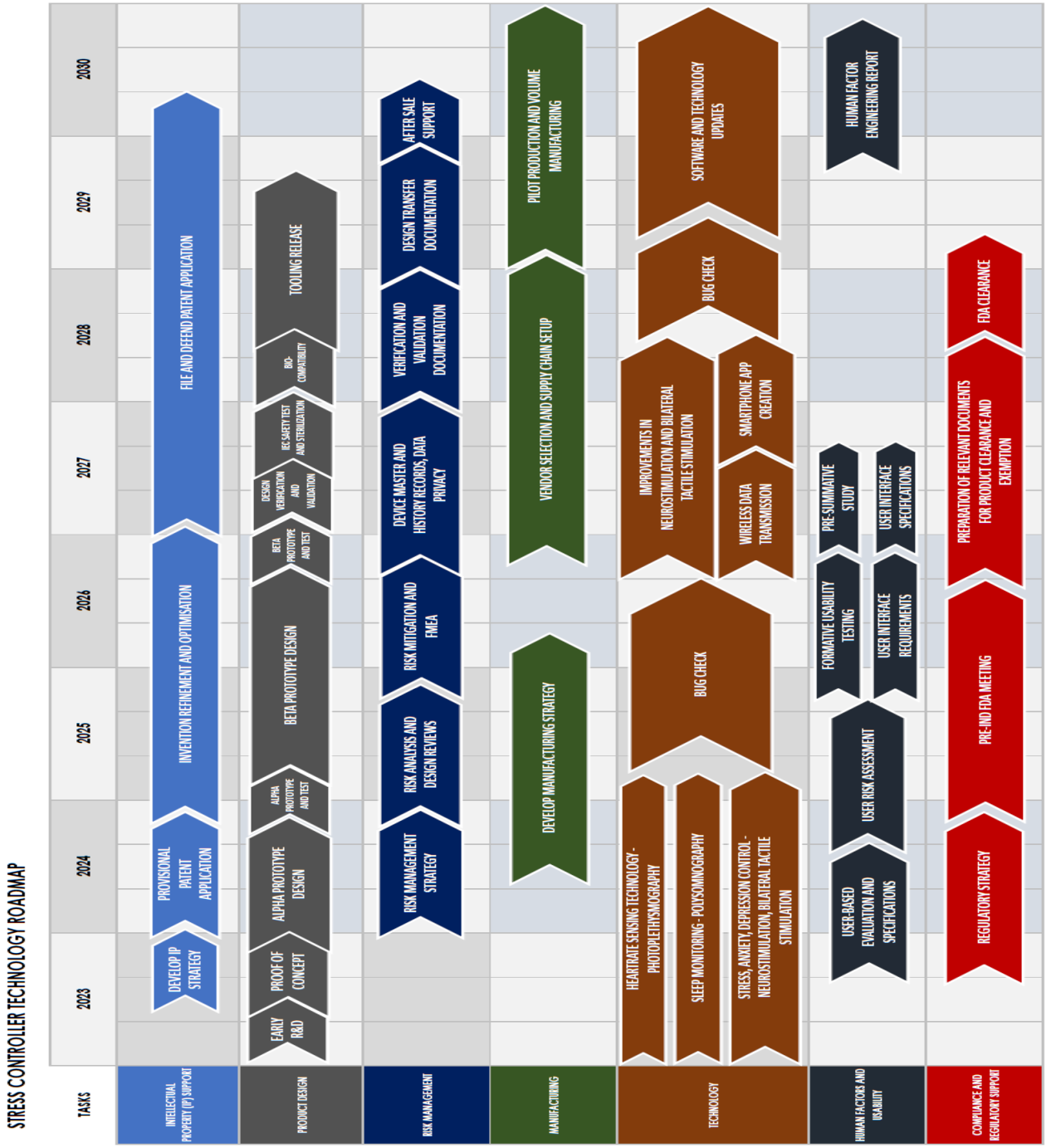


Figure 21: Roadmap for development of Stress Controller (DeviceLab, 2020)

PHASE 1 - Research

This is the initial phase for the product where data based on consumer requirements and acceptance are considered as the metrics for product development. The market for the product and technology would be assessed via qualitative and quantitative research. The results will help the initiate their prototype development. The key objectives to be met in this phase are market analysis (finance, industry, competition), early risk assessment, checking for similar intellectual property rights and patents. Medical experts would also need to be approached to understand whether the product and technology would require clinical trials. This would also be linked with the financial analysis of the project as it would help determine whether the venture's feasibility due to high costs involved. An initial mock-up of the prototype would also be created in this phase to present to key stakeholders and potential investors. Evaluation of known hazards with the technology would also need evaluation as it is a key determinant of safety in the product (DeviceLab, 2020). Research on how to develop sensors for the product would also begin in this process.

PHASE 2 – Proof-of-concept

In this phase, weaknesses would be eliminated from the design which was created in the research phase. Design controls would also be invoked during this phase such as fail-safe features. Since lithium-ion batteries would be used in this device, the risks associated to it will also be dealt with in this phase. Hazard analysis is developed based on the conceptual design by factoring intended use and predicting misuses associated to the device. The development of heart rate monitoring, sleep monitoring and stress, anxiety as well as depression sensors would commence in this phase. Vendors and suppliers would be contacted for purchasing of components and sensors for developing these technologies. After identifying the problems, risks and solutions for the design, a prototype of the device is built. This is the key deliverable of this phase.

PHASE 3 – Alpha

This is the experimental stage where the prototype is tested. All the three technologies i.e., photoplethysmography, polysomnography, neurostimulation and bilateral tactile stimulation will be integrated in the device and then tested for results. Through tests, the efficiency of these sensors will be continuously evaluated for accuracies and bugs. The risks in the design would require thorough analysis and that would be done using Failure Modes, Effects and Criticality Analysis

(FMECA) test. This would help with critical evaluation of the technology and remove risks before it is supplied to the users. The deliverable from this phase should be a convincing alpha prototype that indicates that an actual product with the integration of all three technologies can be made. A well-developed alpha prototype would allow for allow more in-depth data collection which would be useful for implementation. This is an important step while graphical user interface (GUI) evaluation, patient's touchpoints and other physical user interfaces (Astero Starfish, 2019).

PHASE 4 – Beta

In this stage, the device would be developed and tested further after identifying faults from the alpha prototype. This would help mitigate regulatory risks. This phase delays product introduction in the market but also buys time to make the device technologically perfect and thus improve device reputation. Perfecting the integrated neurostimulation and bilateral tactile stimulation through the wrist will require a lot of trial and tests before its launch and require FDA clearance. The right materials for manufacturing would be selected in this phase as well. Integration of device with smartphone application would also be conducted in this phase and then tested. Intellectual property rights and patents would be filed before beginning the manufacturing process. The design documentation would then be assembled into a Device Master Record. Risk mitigation and verification of mitigation would also be a key objective in this phase. The deliverable from this phase would be a successfully tested and validated beta prototype.

PHASE 5 – Pilot production

Final bugs in the software would be checked and then the device would undergo intense verification and validation testing. The patent-filing process would also be completed during this phase. This is one of the most critical phases in product roadmap as the device will go through a lot of clinical trials before full-scale production. If successful in a pilot market, the device would be ready for full-scale production. If not, then the errors would have to be rechecked and mitigated before another clinical trial round. Using the pilot-production prototypes, a summative study would be formed which would demonstrate the proper and safe usability of the stress controller device. By the end of this phase, the product would be ready to sell as it would be verified and validated, have had complete risk mitigation, all intellectual property and patents would be secured, fulfill all regulatory requirements, be intuitive, ergonomic and safe to use. The stress

controller would be more expensive than other smart wearables in its field because it would be the only device of its kind. The key deliverable for this phase would be a pilot-ready model.

PHASE 6 – Manufacturing

A full-scale production will begin in this phase and the company would have to be in a prepared situation for negative customer reviews. This would open more opportunities for improvement in the software. Device functionality would be continuously improved by launching software updates, taking user input and training the AI model with more stress controlling algorithms.

CHAPTER 6 – Project Management

6.1 OVERVIEW

This chapter summarises how the entire project was carried out in the group. Furthermore, risk management at different stages in the research is also outlined.

6.2 TARGET ITEMS

Each phase of the research was set a timeline which everyone in the team had to follow. Figure 19 describes each phase of the project and the amount of time taken to finish it.

6.2.1 GROUP MEETINGS

The team had meetings weekly meetings every Tuesday with Dr. Gayan Jayakody, our supervisor, to discuss ideas for the project. We usually had just the one meeting every week until the final few weeks of our project, where we had to discuss our action plans.

6.2.2 WEEKLY TASKS

Every week, each team member had to study literature for their field of research and report their progress in the weekly project management report.

6.2.3 RESEARCH

The group collaborated to create one survey to assess the market for wearable devices globally. The survey contained questions from all three fields of research i.e., sleep detection, cardiovascular and pregnancy monitoring. Xinyu Mao and Jingjin Li contributed to the questions for sleep detection, Tushar Khandelwal provided questions for cardiovascular monitoring and Antariksh Kudal provided questions on general consumer acceptance for wearable devices. Pregnancy monitoring questions did not align with the group survey and hence, an individual survey was designed for a specific customer base.

After the results obtained from the group survey, each member took the required data for their analysis and continued with the research in their field individually.

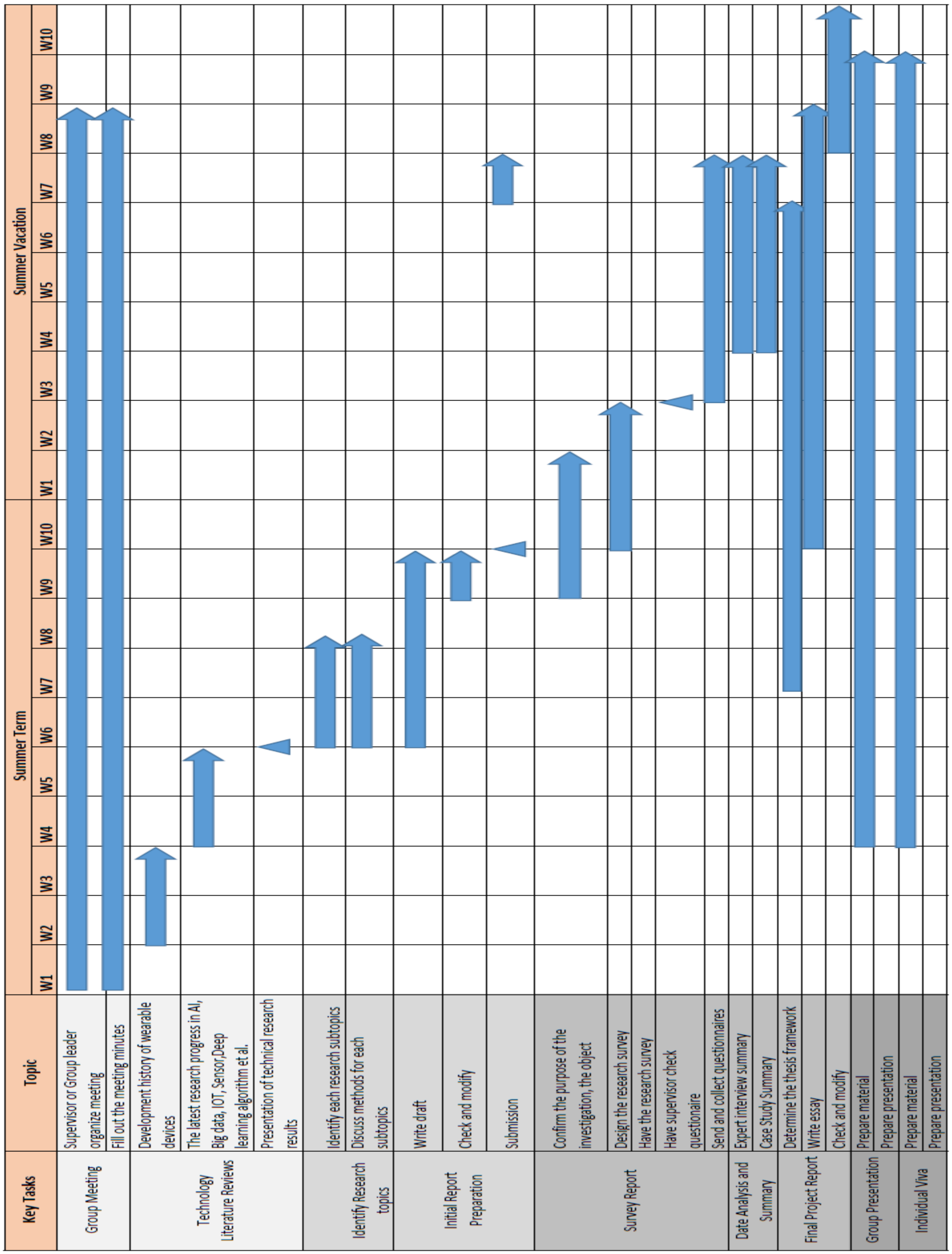


Figure 22: Project GANTT Chart

6.3 PROJECT RISK MANAGEMENT

Since the beginning, we had three different fields of research under the common industry i.e., wearable technology in healthcare. The challenges and risks faced throughout the project have been summarised in a probability and impact matrix in table 4.

Sr. no.	Risks	Probability (P)	Impact (I)	Total Score (P*I)	Actions to mitigate risks
1	Lack of survey participants	5	5	25	Approaching Lamaze classes, pregnancy centers and pregnant women in general was difficult. Convincing them to participate in the survey was also difficult since the survey had to be distributed via an intermediary. The group survey was distributed via email, WhatsApp and WeChat. Maintaining a friendly and respectable approach while talking to a potential participant is necessary.
2	Difficulty in reaching out to medical and industry experts	5	5	25	Emails and messages were sent but there was no response from anybody's end. Gaining an insight from a proper expert would've improved the case study and the overall solution from a technical, medical as well as business perspective. They must be approached through mutual acquaintances next time and cold emailing needs to start much before.
3	Team coordination	5	5	25	Due to three different fields of research, we did not know how to integrate our research. Thorough literature review at the very beginning and more frequent discussions about project ideas should be discussed in the team.
4	Team communication	4	5	20	There was always a language barrier in the team that restricted flow of ideas and understanding with each other. Each member should speak in English and be well-prepared before every meeting to be able to convey their ideas in a flow.
5	Incomplete survey data	4	5	20	Quality of survey questions could've been more specific to the proposed solution and also could've been designed in a way where participants will answer all.
6	Inadequate participation of	3	5	15	Group tasks should be distributed equally and everyone should contribute to team discussions.

	individual in team meetings				
7	Unprecedented situations	1	5	5	In situations where members are unavailable for meetings or physically unavailable for the entirety of the project, work must be allocated and the group leader should be in loop with the absentees in order to guide them.

Table 4: Probability and Impact matrix for risk assessment and mitigation

CHAPTER 7 – Conclusion and Further Recommended Work

Stress has a negative impact on everybody's lives irrespective of gender, age, race, etc. It is one of the root causes of almost all physical as well as psychological problems. Stress management is absolutely necessary in every situation, be it at the workplace, at home, school, or university. The global stress management market was valued at US $18.6 billion in 2020 and is expected to grow at a compound annual growth rate of 3.5% until 2030 (Quince Market Insights, 2021). Adoption of wearable devices is increasing in daily lives as well as in healthcare and the market for this is increasing as well. This study indicates the impact of stress, anxiety and depression on pregnant mothers and highlights how wearable technology can be used to monitor heartrate and sleep to detect stress levels. It also shows stress is related to abnormal heartrate variability and improper sleep schedules, and the impact it has on pregnant mothers as well as the foetus. The current technology has its perks as well as its limitations with respect to monitoring pregnancy, detecting stress levels and reducing it. This study concludes that developing a wrist-wearable device which integrates vagus nerve stimulation and bilateral tactile stimulation to control and reduce stress, would be a solution in improving healthcare wearable technology.

Furthermore, if a larger sample size is considered globally, it would help analysing the market by providing more accurate mean values for factors considered in developing this technology. The sample size in this research was very small due to limitations mentioned, which is why the results from data analysis can indicate that the wearable stress controller is the right way to improve the existing technology. But these results cannot generalise the outcome as the only solution, which is why a huge sample size should be considered for global market analysis.

APPENDIX

1. Group Survey

MARKET RESEARCH FOR WEARABLE TECHNOLOGY IN HEALTHCARE

We, the students from MSc in Engineering Management at the University of York are carrying out a market research to understand how trusted and helpful wearable technology is for the people.

We have chosen the following research areas:

1. Sleep monitoring

2. Cardiovascular monitoring

In this survey, we aim to understand sleep problems and heart-related problems that people of various age groups face, and then assess the results to develop a solution using wearable technology.

You have the right to avoid any question(s) you are not comfortable answering. Data anonymity and integrity will be maintained throughout the research.

What is your age group?

12-18
18-24
24-35
35-45
Over 45

What is your gender?

Male
Female
Prefer not to say

Do you know the concept of **wearable devices**?

Never heard before
I've heard but don't understand
I've heard and understand a little bit
I fully understand

Do you own any smart healthcare devices (wearable technology)?

Yes
No

Do you plan on buying/renting/using any smart healthcare devices (wearable technology)?

Yes
Not yet, but in the future
No

How much would you trust the results obtained from these devices?

No trust

0
1
2
3
4
5
6
7
8
9
10

Full trust

Would you trust wearable technology/devices that could detect and monitor sleep?

Yes
No
Maybe

Do you have (or know somebody who has) any sleep disorders?

Yes
No
Maybe

If yes, which sleep disorders are they?

Snoring
Insomnia
Light sleeper
Narcolepsy (vivid dreams - unsure between dream and reality)
Other:

Would you like to wear a smart device while you sleep?

Yes
No

Maybe

Do you think using wearable devices is important for your health?

Yes
No
Maybe

What features would you like to see in a wearable device for health monitoring?

Sleep monitoring
Heart-rate monitoring
Fall monitoring
Maternal and child monitoring
Exercise status monitoring

Would you be willing to pay for smart healthcare devices?

Yes
No
Maybe

How much would you be willing to pay?

£50 - £100
£100 - £150
£150 - £200
£200 - £250
£250 - £300
Over £300

Statement: I have been sleeping well for the last week.

Strongly agree
Agree
Neutral
Disagree
Strongly Disagree

Would you be willing to pay for a smart sleep monitoring device?

Yes
No
Maybe

How much would you be willing to pay?

£50 - £100
£100 - £150
£150 - £200
£200 - £250
£250 - £300

Over £300

Which type of device would you prefer?

Brainwave collection cap
Gloves
Watches
Finger Ring
Non-contact radar monitoring
Mattress
Other:

Where would you prefer to buy your smart healthcare device from?

Offline physical store
Hospital or Pharmacy
Online shopping platform
Social media links
Other:

Are you suffering from any cardiovascular disease?

Yes
No

Would you trust smart wearables for the diagnosis of cardiovascular disease, for Ex - Heart rate, ECG.

Yes
No

Do you or anyone in your family have cardiovascular disease? If yes, How often do you go to the hospital?

Once in a month
Once in 3 month
Once in 6 months
Once in a year
Other:

Do you Prefer buying a smart wearable or renting one?

Buying
Renting

2. Individual Survey

CUSTOMER SURVEY

MARKET RESEARCH

This study is being carried out only for research purposes and data obtained from these results will solely be used for educational purposes. We are trying to understand common problems faced by pregnant women and develop a solution using wearable technology. Wearable technology are devices like smart watches, smart patches, smart clothing etc. which are used to track health and fitness data, and provide users with lifestyle improvements.

How long is your pregnancy currently?

Your answer

How often do you face morning sickness? (scale is based on number of days i.e., 0 days a week to 7 days a week)

Never

0
1
2
3
4
5
6
7

Daily

How often do you have nausea?(scale is based on number of days i.e., 0 days a week to 7 days a week)

Never

0
1
2
3
4
5
6
7

Daily

How often do you have hypertension?(scale is based on number of days i.e., 0 days a week to 7 days a week)

Never

0
1
2
3
4
5
6
7

Daily

How often do you have irregular vaginal bleeding/discharge?(scale is based on number of days i.e., 0 days a week to 7 days a week)

Never

0
1
2
3
4
5
6
7

Daily

How often do you have stomach-related problems (constipation/indigestion/loose-motions)?(scale is based on number of days i.e., 0 days a week to 7 days a week)

Never

0
1
2
3
4
5
6
7

Daily

How often do you have sleeping problems?(scale is based on number of days i.e., 0 days a week to 7 days a week)

Never

0
1
2
3
4
5
6
7

Daily

How often do you have fever?(scale is based on number of days i.e., 0 days a week to 7 days a week)

Never

0
1
2
3
4
5
6
7

Daily

How often do you have heart-related problems (high/low blood pressure, blockage, etc.)?(scale is based on number of days i.e., 0 days a week to 7 days a week)

Never

0
1
2
3
4
5
6
7

Daily

How often do you have respiratory (breathing) problems?(scale is based on number of days i.e., 0 days a week to 7 days a week)

Never

0

1
2
3
4
5
6
7

Daily

How convenient is it for you to travel to your doctor for checkup?

Not convenient

0
1
2
3
4
5
6
7
8
9
10

Absolutely convenient

Do you understand what wearable technology is?

Yes
No
Maybe

Would wearable technology/devices be more convenient for monitoring and checkup?

Not convenient

0
1
2
3
4
5
6
7
8
9
10

Absolutely convenient

Would you trust wearable technology/devices for monitoring and checkup results?

Not at all

0
1
2
3
4
5
6
7
8
9
10

Absolutely

Would you trust wearable technology/devices that could detect pregnancy?

Not at all

0
1
2
3
4
5
6
7
8
9
10

Absolutely

Would you trust wearable technology/devices that could detect and monitor the health of unborn baby?

Not at all

0
1
2
3
4
5
6

7
8
9
10

Absolutely

Would you trust wearable technology/devices that could detect possibility of having to undergo an IVF (In Vitro Fertilization - assisted pregnancy in lab)?

Not at all

0
1
2
3
4
5
6
7
8
9
10

Absolutely

Would you trust wearable technology/devices that could reduce stress and anxiety?

Not at all

0
1
2
3
4
5
6
7
8
9
10

Absolutely

Would you trust wearable technology/devices that could reduce hypertension?

Not at all

0
1
2

3
4
5
6
7
8
9
10

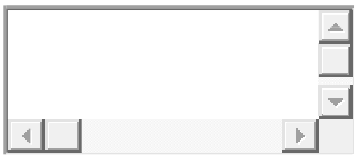
Absolutely

Are there any other problems you have faced during pregnancy?

Your answer

Do you think wearable technology/devices could solve these problems as well?

Your answer



Please leave your name if you are interested in using wearable technology for pregnancy monitoring.

Your answer

Please leave your contact number if you are interested in using wearable technology for pregnancy monitoring.

Your answer

3. Weekly Project Management Template

Project Weekly Report - MSc Engineering Management

Week 6	
Team identity Group 5	
Present: ak2004,tk986, xm950, yl5840	
Apologies for absence: Personal reasons	
Meeting 3 minutes accurate: 30	Proposed: Supervisor
Matters arising: *Project scope discussion, report expectations*	
Meeting 1 notes: Discussion of scope	
Any other business: *(you may shorten this to AOB)* N.A.	
Date, Time and Venue of next meeting: Tuesday, 31/05/2022; 3pm, Zoom/Google Meet	
Meeting closed at: 10:30 pm	

Progress report from each team member

Please give your personal progress/engagement report with the group work for this week

Name of Team member	Progress notes
Akash Avinash pawar	Searched some papers published and learned about the technology. I looked at monitoring technology available in the market for all kind monitoring use. I also looked at the feedback of the products in the market.
Yuechen Liu	Read the essays which related to medical innovation and cardiac disease armarium market, intend to find out new opportunities of business blue ocean. Obtained data and information of cardiac disease, intend to find out intrinsic connection between this phenomenon.
Tushar khandelwal	I researched on the no. Of people getting cardiovascular problems based on demographics also people who get blockages which leads to bypass surgery.
Jingjin Li	Last week I investigated related sleep monitoring devices and compared their sales data to get a general understanding of the market of these sleep monitoring devices.
Xinyu Mao	Check the literature on the development status of intelligent sleep products, and record the relatively new sleep quality detection

	technology and monitoring technology in recent years. Also look for limitations and open issues with these technologies.
Antariksh Kudal	I researched information on the global market share of wearable pregnancy devices and how it is predicted to grow by 2024. I made a flowchart on how to search information because I was getting confused with multiple research papers and articles. So, I started with the big umbrella i.e., wearable technology (WT). Then I funneled it down to WT in health care, and then to pregnancy, neonatal and infant monitoring. I read about smart jacket technology for neonatal monitoring, identification of problems during pregnancy using WT and hypertension tracking using WT. I just skimmed through the research papers and found some useful information. Will continue reading these research papers further.

Team leader's overall summary on group progress for the week:

Everyone is aware of the topics and how the literature review must be conducted. We discussed our individual progress with our supervisor and discussed ideas on how our management aspect of the project would look like.

4. Ethics Form

FAST-TRACK ETHICAL APPROVAL FORM (STUDENTS)

This fast-track system for is for taught students only. Research students and staff must complete the full Ethical Approval Form.

If you answer **YES** to any of the following you must complete either this Fast-track ethical approval form, to be signed off by your supervisor, or a full Ethical approval application, to be approved by the Physical Science Ethics Committee (allow at least two weeks for this process).

Note that the outcome of the Fast-track system may result in you needing to complete a full ethical approval application.

Does your project involve any of the following?

Human participants (adults or children	YES	✓	NO	
Human material (e.g. tissue or fluid samples)	YES		NO	✓
Human data (e.g. surveys and questionnaires on issues such as lifestyle, housing and working environments, attitudes and preferences)	YES	✓	NO	
Vertebrates, especially mammals and birds	YES		NO	✓
Any other organisms not previously mentioned	YES		NO	✓
Military or defence context	YES		NO	✓
Funding sources with potential to adversely affect existing relationships or bring the University or Department into disrepute.	YES		NO	✓
Restrictions on dissemination	YES		NO	✓
Overseas countries under regimes with poor human rights record or identified as dangerous by the Foreign & Commonwealth Office	YES		NO	✓
Applications that could potentially involve unethical practice, including potential dual-use applications which could be unethical	YES		NO	✓

Students: you should discuss the ethical considerations of your project with your project supervisor and, if necessary, fill in a full ethics form to be submitted to the Physical Sciences Ethics Committee.

Supervisors: Please ensure you are familiar with the University's 'Code of practice and principles for good ethical governance' in order to guide your student effectively. Please seek guidance from the Departmental Ethics Officer if you are uncertain about any ethical issue arising from this application.

FAST-TRACK ETHICAL APPROVAL FORM (STUDENTS)

Project Information: MSc in Engineering Management Project [ELE00052M]

Student Name: Antariksh Kudal, Tushar Khandelwal, Akash Pawar, Jingjin Li, Yuechen Liu, Xinyu Mao

Course Title: MSc in Engineering Management

***Tick one box**:*

Undergraduate project □ Postgraduate project ✓

Undergraduate module assignment □ Postgraduate module assignment □

Other (Please state……) □

Title of project: Business Plan for Wearable Technology in Healthcare

Project supervisor / module leader name: Dr. Gayan Jayakody/Prof. Tony Ward

Protocol:

a): *If you answer **NO** to any of the following you must submit a full ethical approval form*

	If you answer yes to any of the following, this must be explicit in any supporting literature (e.g. consent forms, information sheets and questionnaires)	YES	NO	N/A
1	Will you describe the procedures to participants in advance, so that they are informed about what to expect?	✓		
2	Will you tell participants that their participation is voluntary?	✓		
3	Will you inform the participants of the purpose / background of the study?	✓		
4	Will you obtain written consent for participation?	✓		
5	If the research is observational, will you ask participants for their consent to being observed?			✓

6	Will you tell participants that they may withdraw from the research at any time and for any reason?	✓		
7	With questionnaires and interviews will you give participants the option of omitting questions they do not want to answer?	✓		
8	Will you tell participants that their data will be treated with full confidentiality and that, if published, it will not be identifiable as theirs?	✓		

Protocol:

b): *If you answer **YES** to any of the following you must submit a full ethical approval form.*

		YES	NO	N/A
9	Is your study designed to be challenging/disturbing (physically or psychologically)?		✓	
10	Will you deliberately mislead your participants?		✓	
11	Does your study involve taking bodily samples?		✓	
12	Is your study physically invasive?		✓	
13	Is there any obvious or inevitable adaptation of your research findings to ethically questionable aims?		✓	
14	Could the methodologies or findings of your study damage the reputation of the University of York?		✓	

Health and Safety:

Please identify any risks to the participants and state any precautions you will take to ensure their health and safety: N/A

Participants: *If you answer **YES** to any of the following you must submit a full ethical approval form. If you have ticked **YES** to 15 and your participants are **patients**, in addition to the full ethical application you must follow the Guidelines for Ethical Approval of NHS Projects.*

			YES	NO	N/A
15	Does your project involve work with animals			✓	
16	Will any of the participants be from one of the following vulnerable groups? **Note that you may also need to obtain satisfactory DBS clearance (or equivalent for overseas students)**	Children under 18		✓	
		People with learning difficulties			
		People who are unconscious or severely ill			
		NHS patients			
		Other vulnerable groups (specify)			

Data Protection: *If you answer **NO** to any of the following you must submit a full ethical approval form*

		YES	NO	N/A
17	Any personal / sensitive data will be stored in password protected folders on computers.	✓		
18	Any hard copies of personal data (including consent forms) will be stored in a secure place.	✓		
19	Only the student and supervisors will have access to the data generated from the study. (The supervisor may share the anonymised data with other researchers at the University of York)	✓		
20	The data will be preserved beyond the study in line with University policy and will be placed in the custody of the supervisor at the end of the project.	✓		
21	All data will be anonymised prior to analysis.	✓		

	Please state your method of anonymisation: Anonymous google forms			

FOR THE STUDENT TO COMPLETE:

Please complete and sign the following section and submit to your supervisor alongside any supporting documentation (this includes consent forms, information sheets and questionnaires where necessary).

Provide a brief summary of the participants and procedures of your project (max 100 words)

The field of our research is biotechnology and under that, wearable technology for sleep, cardiovascular, pregnancy and neonatal/infant monitoring. We intend to interview field experts and take customer surveys to help us understand the current limitations in technology. Based on data obtained, we will come up with a hypothetical solution to improve existing technology/new product and make a business case out of it. The data collected will abide by all ethical rules and regulations and will be only used for educational and research purposes.

I have considered the ethical implications of this project and have identified no significant ethical implications requiring a full ethics submission to the Physical Sciences Ethics Committee ✓

I have included all relevant paperwork (e.g. consent form, information sheet, questionnaire/interview schedules) with this application ✓

Signed…… Date 24/07/2022

Print name: Yuechen Liu, Xinyu Mao, Antariksh Kudal, Tushar Khandelwal, Akash Pawar, Jingjin Li

FOR THE SUPERVISOR TO COMPLETE:

By signing this form you are taking responsibility for the ethical conduct of this project

The student has taken all reasonable steps to ensure ethical practice in this study and I can identify no significant ethical implications requiring a full ethics submission to the Physical Sciences Ethics Committee ✓

I have checked and approved all relevant paperwork required for this proposal ✓

STATEMENT OF ETHICAL APPROVAL

This project has been considered using the Physical Sciences Ethics Committee Fast-track ethical approval procedure, agreed by the Physical Sciences Ethics Committee of the University of York, and is now approved.

Signed Print name Dr. Gayan Jayakody Date 15/08/2022

(Supervisor/Module leader)

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