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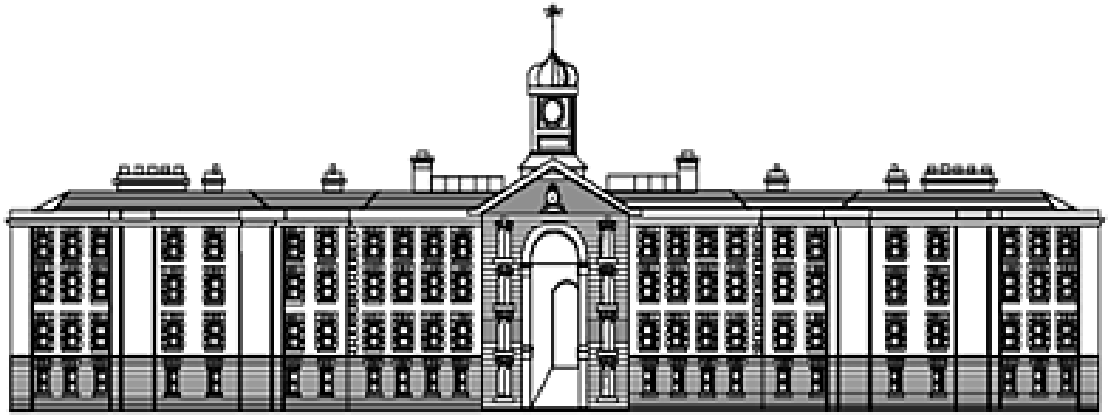
An Evaluation of User Feedback on the Effectiveness of Smartwatches from a Health Perspective in Ireland



GRIFFITH COLLEGE

A Dissertation submitted in Partial fulfilment of the Requirements for the Degree of

MSc in Medical Device Technology and Business

AARADANA KANAKARAJ

3123863

Dissertation Supervisor: Dr. Javed Iqbal

DECLARATION

I declare that the dissertation entitled "An Evaluation of User Feedback on the Effectiveness of Smartwatches from a Health Perspective in Ireland", which I am submitting as part of the requirements for the award of the MSc in Medical Device Technology and Business, represents my own original work. It is the outcome of my independent effort, and it is based solely on my own research and analysis. Where the ideas, theories, or findings of other scholars or sources have been used, they have been accurately and transparently acknowledged through appropriate references.

I further confirm that this dissertation has not been copied, in whole or in part, from the work of any other author, researcher, or fellow student. I affirm that the work presented herein has been carried out with diligence, academic honesty, and respect for ethical research practices.

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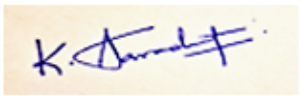
Candidate Signature: 

Date: 24/08/2025

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Date: 24/8/2025

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LIST OF ABBREVIATIONS

FDA – Food and Drug Administration

AFib/AF – Atrial Fibrillation

ECG - Electrocardiograms

BP - Blood Pressure

COVID-19 - Coronavirus Disease 2019

IRN - Irregular Rhythm Notification

iCBT - Cognitive Behavioural Therapy

iECG - Intelligent Electrocardiogram

RHR- Resting Heart Rate

GDPR – General Data Protection Regulation

VO2 max - Volume of Oxygen Consumption at Maximum

HR – Heart Rate

ABSTRACT

This study evaluates the user feedback on the effectiveness of FDA/CE-cleared smartwatches from a health perspective in Ireland. The research adopts a mixed-method approach, employed a survey-based strategy with a cross-sectional time horizon. Primary data were collected through online questionnaires structured into five sections comprising 24 questions. Quantitative data were analyzed using descriptive statistics in Excel, while qualitative responses were examined through thematic analysis. The study aimed to evaluate the effectiveness of FDA/CE-cleared smartwatches in tracking essential health metrics, investigate their role in motivating healthier habits, evaluate their impact on health outcomes, measure user satisfaction, and explore differences in users feedback across demographics and health status. The quantitative findings showed that smartwatches were widely trusted for tracking heart rate, blood oxygen, ECG, and stress, though sleep tracking received mixed evaluations. Both healthy users and users with medical conditions reported that alerts, reminders, and fitness tracking motivated healthier behaviours, though users with health conditions emphasized disease management benefits (e.g., improved heart rate and blood pressure control, greater reassurance in monitoring), while healthy users highlighted fitness, stress reduction, and lifestyle regulation. Overall satisfaction was very high, with usability, comfort, and perceived benefits strongly endorsed, although battery life and sleep monitoring were noted as areas for improvement. Younger adults were the most frequent users, while older adults were underrepresented. While the qualitative findings showed that FDA/CE-approved smartwatches serve a dual function: For Users with medical conditions, they serve as supportive healthcare tool, aiding in disease management and offering emotional comfort and for healthy users, they serve as motivational lifestyle enhancement tool, encouraging fitness, routine-building, and wellness optimization. In conclusion, this study highlights the growing role of FDA/CE-cleared smartwatches in bridging the gap between personal health management and formal healthcare systems. While not a substitute for medical care, they are valued for their clinical and wellness needs, FDA/CE-cleared smartwatches demonstrate the potential of digital health innovation to support individuals, complement healthcare systems, and advance public health goals in Ireland.

Keywords: FDA/CE-cleared smartwatches, user feedback, health monitoring, digital health, Ireland.

An Evaluation of User Feedback on the Effectiveness of Smartwatches from a Health Perspective in Ireland

CHAPTER 1 – INTRODUCTION

1.1. Research background

Over the last decade, the integration of technology into healthcare has driven significant advancements, enabling people to engage more proactively with their health and overall wellbeing. Among these advancements, smartwatches have become one of the most commonly embraced types of wearable health technology. Initially it promoted as accessories for convenience and communication, now smartwatches have transformed into all-encompassing health monitoring tools that can monitor physical activity, sleep patterns, heart rate, oxygen levels, and even identify irregular heartbeats. These features align with the worldwide transition from reactive to preventive healthcare, and from episodic to continuous health monitoring.

Approval from regulatory agencies like the FDA and CE marking has been vital for the development of smartwatches as credible health monitoring tools. For example, smartwatches approved by the FDA and CE—such as the Apple Watch, Fitbit, and others—have included features like ECG recording, atrial fibrillation (AFib) detection, and monitoring of blood pressure. These features are based on clinical validation and extensive studies that show a significant level of accuracy compared to conventional medical devices. (Gsap, 2024).

Also, smartwatches facilitate ongoing patient observation at minimal expenses and allow for the collection of patient-generated data even when physically distant from healthcare facilities in everyday situations, offering healthcare providers access to insights that were once unreachable or only available via patient self-reporting. For example, when a doctor inquiry about a patient's sleep over recent weeks, conventional responses would rely on subjective estimates. Conversely, a smartwatch is capable of providing objective and unbiased data detailing the amount and quality of sleep, along with its relationship to other vital signs monitored simultaneously. This major improvement in the accuracy and dependability of health evaluations is undeniable and signifies a transformative change in the provision of care. (Köhler *et al.*, 2024).

In Ireland, there is a robust willingness to adopt digital health solutions. The 2023 EY Ireland Consumer Health Survey reveals that a majority of Irish consumers are willing to share health data generated by wearables with healthcare providers, highlighting their trust and willingness for a digitally integrated health service. However, the healthcare system in Ireland is currently struggling to incorporate the valuable data generated by smartwatches into clinical care processes. In spite of these systemic obstacles, Irish users are utilizing smartwatches to gain insights into and control factors such as aerobic capacity, VO2 max, and resting heart rate—elements linked to mortality risk and overall health. (Mary Coghlan, 2023).

Even with the increasing adoption of smartwatches, there remains a restricted comprehension of how users assess their efficacy in actual health situations. The majority of current research emphasizes technical performance or clinical validation, placing less priority on user-centred insights like perceived usefulness, trustworthiness, usability, and behavioural effects. This dissertation seeks to address this gap by examining user feedback on smartwatches through a health lens, analyzing how people in Ireland view the function of these devices in their daily health management.

1.2. Research purpose:

The purpose of this study is to thoroughly assess user feedback on the health effectiveness of FDA/CE-cleared smartwatches in Ireland, focusing on comprehending the lived experiences, perceptions, and satisfaction levels of those who utilize these devices for health/fitness tracking. As smartwatches progress from simple fitness monitors to medically relevant tools—capable of detecting health conditions like abnormal heartrate, oxygen deprivation, ECG or reduced physical activity and etc —their role in everyday life and healthcare becomes increasingly vital. Although their prevalence and potential are increasing, evidence supporting their clinical efficacy in community-based, non-hospital environments remains scarce and varied, with ongoing challenges related to technological precision, user adherence, and data interpretation. As the utilization of these health monitoring tools in the healthcare sector increases, it is crucial to evaluate their usability, dependability, and overall efficacy from the standpoint of the users. This analysis can provide significant understanding regarding the actual effects of these tools, their ability to enhance health outcomes, and the opportunities for further advancement and incorporation into healthcare practices. This study evaluates and assesses the impact of FDA/CE-cleared smartwatches on enhancing health and wellness based on user

feedback. Its main aim to assess user perceptions of the effects of smartwatches on their health and if these devices fulfill their health-related expectations. The findings from this research will be crucial in promoting wearable technology by identifying key aspects that need enhancement in user experience, data precision, and health results, aiding the development of smartwatches as an effective health monitoring tools in healthcare.

1.3. Research significance and Justification:

The growing availability of FDA- and CE-approved smartwatches marks a significant development in incorporating digital technology into healthcare services. In contrast to typical consumer wearables, these regulated devices comply with medical standards for safety, precision, and effectiveness. Their functionalities—like detecting irregular heart rates, reading electrocardiograms (ECGs), and monitoring blood oxygen levels—offer considerable potential to improve preventive care, remote patient monitoring, and early diagnosis, particularly within vulnerable groups.

In Ireland, the public's readiness to share health data from wearable devices with healthcare professionals is significant, indicating a shift toward digital-first healthcare and self-care. (Mary Coghlan, 2023). As smartwatch usage rises worldwide, especially after the COVID-19 pandemic, these health monitoring tools could greatly aid in chronic health condition management, promote healthier living, and also alleviate strain on the national healthcare system. However, while technical and clinical studies have shown the precision and regulatory adherence of FDA/CE-approved smartwatches (Rajakariar *et al.*, 2020), less is known about how end users view and utilize these medically approved smartwatches in daily health management. Obtaining regulatory approval alone does not ensure practical impacts—factors such as user satisfaction, experience, motivation, and perceived effectiveness are crucial in determining if these technologies truly enhance health outcomes.

This research is justified in its aim to examine user feedback, since most current studies focus on clinical trials or sensor validation instead of the actual experiences of typical users. This study offers vital information regarding the human aspect of adopting digital health by exploring the perceptions, motivations, and satisfaction reported by users of FDA/CE-approved smartwatches.

1.4. Research Question and Objectives:

The research objectives of this study are;

1. To assess the effectiveness of FDA/CE-Cleared smartwatches in tracking important health metrics like heart rate, blood oxygen saturation levels, ECG, physical activity, sleep habits, and stress levels.
2. To investigate how FDA/CE-Cleared smartwatch functionalities (e.g., alerts, reminders, fitness tracking) impact users' motivation to adopt healthier habits, including enhanced physical activity or better sleep patterns.
3. To assess whether regular usage of FDA/CE-cleared smartwatches results in observable enhancements in users and patients' health outcomes, like improvements in disease management among cardiac and diabetic patients, such as improved heart rate (HR) control, better blood pressure regulation, blood glucose control, increased fitness levels, improved sleep quality, and better mental wellness.
4. To evaluate general user satisfaction with the health-related features of FDA/CE-cleared smartwatches, encompassing usability, comfort, and perceived benefits.
5. To assess differences in user feedback based on demographics (age, gender) and health status (healthy vs diseased).

The research question is.

"What is the perceived health effectiveness of FDA/CE- cleared smartwatches based on users' experiences and feedback in Ireland?"

1.5. Structure of dissertation:

This dissertation is structured into five interconnected chapters to ensure a clear, logical, and cohesive flow. Every chapter contributes progressively to a comprehensive insight into user perceptions of FDA/CE-approved smartwatches regarding health in Ireland. The framework starts with the foundation of contextual significance and theoretical basis, proceeds through a critical literature review and detailed methodological approach. The later chapters present and analyze the study's findings, ultimately leading to practical conclusions and actionable recommendations. An overview of each chapter's focus is provided in Table 1 below.

Chapter	Title	Overview
Chapter I	Introduction	Outlines the research background, defines the problem, articulates research aim, objectives, and question. Justifies the study's significance and relevance to Ireland's health context.
Chapter II	Literature Review	Examines literatures on FDA/CE-cleared smartwatches, Users insights on wearable technology, and its effectiveness in health monitoring.
Chapter III	Research Methodology	Describes the overall research design, methodology, participant selection, data collection instruments (such as surveys) and ethical considerations.
Chapter IV	Findings & Analysis	Presents the results from users' survey including quantitative and qualitative data. Discusses key findings on perceived effectiveness, users' satisfaction, and motivation.
Chapter V	Conclusion	Summarizes main findings, outlines the study's contributions, suggests direction for future research.

CHAPTER 2: LITERATURE REVIEW

2.1. Effectiveness of wearable devices on the user's health

User satisfaction is essential for ongoing smartwatch usage. Studies show that users prioritize convenience, simplicity, health tracking, and integration into their daily routines. For example, (Almuwais and H. Alharbi, 2022) discussed the effects of wearable technology, particularly smartwatches and fitness trackers, on the health and wellness of users in Saudi Arabia. The study focused on how these devices influence health behaviours, motivation, and overall health outcomes in users, which is highly relevant to my study aim. They gathered information involving only 12 female participants (narrowed research) from Saudi Arabia, which was a major limitation of this study. The Findings revealed that wearable devices positively contributed to increased physical activity levels, improved self-monitoring, and greater user awareness of lifestyle behaviours. Additionally, user acceptance was influenced by factors such as device usability, trust in the technology, and integration into daily routines. The conclusion of the study showed that wearable devices positively influence users' health and assist users in adjusting their daily habits, resulting in enhanced healthcare provision. Thus, this article provides me a clearer insight into users perceived benefits from smart watch usage, which will be beneficial for my research work.

2.2. Users' demographic and attitudinal insights on wearable technology use

Comprehending the demographic factors and user attitudes that influence wearable device adoption is significant for creating effective digital health innovations. For example, (Venn et al., 2024) conducted a large-scale study within the Mass General Brigham healthcare system, examined the demographic characteristics and views of 11,121 adults receiving ongoing cardiovascular care. The findings revealed that more than half of the participants (55.8%) regularly utilized wearable devices, and there was a significant interest from nonusers (95.3%) in embracing these technologies if they were offered for no cost. Notably, even with high usage rates, merely a small fraction of users (29.8%) provided their wearable data to healthcare professionals, indicating a gap in data integration and clinical involvement. The research also emphasized demographic differences, observing increased device usage among younger

individuals, female groups, and also higher socioeconomic status, and cardiovascular care were associated with higher adoption rates. These observations highlight both the opportunities and challenges in utilizing wearables for health tracking and patient engagement. While this study provides valuable information regarding user perspectives, demographic factors, and data-sharing behaviours, all of which influence the effectiveness of wearable technology in real-world healthcare settings. However, the research primarily focused on general consumer-grade wearables rather than regulatory-approved devices, making a critical gap that my research addresses.

2.3. Effectiveness of CE-cleared smart watch in blood pressure monitoring

The precision and practical applications of wearable devices for health tracking have been seen as growing areas of research, especially as smartwatches become more popular for their potential in remote health monitoring. In a notable study, (Falter et al., 2022) thoroughly evaluated the effectiveness of the Samsung Galaxy Watch Active2, a CE-marked smartwatch, in assessing blood pressure (BP) using a cuffless technique. This research included participants with normal and high blood pressure who concurrently wore a smartwatch and a validated 24-hour ambulatory BP monitor to compare measurement results. In contrast to anticipated outcomes for a regulatory-approved device, the findings revealed that the smartwatch's BP readings were not clinically accurate enough, showing notable discrepancies when compared to the standard ambulatory measurements. These results emphasize the inherent challenges associated with cuffless BP monitoring technology, encompassing concerns regarding calibration, sensor sensitivity, and the effects of external factors such as motion artifacts and physiological variability. Although (Falter et al., 2022) present significant findings about the technical constraints of wearable BP monitors, their study mainly focused on device accuracy metrics and did not consider user-centered aspects like usability, motivation, or health behaviour outcomes.

2.4. Evaluation of ECG performance and reliability in FDA/CE-cleared smartwatch

The prospective observational study conducted by (Kader et al., 2025) to evaluate the reliability and performance of an FDA/CE-cleared smartwatch (Apple Watch Series 7 Watch OS 8 model) capable of performing electrocardiograms (ECGs). The research on evaluating the precision of

ECG recordings, collected from smartwatch in relation to standard clinical ECG devices. Participants utilized the smartwatch in real-world settings, and the results showed high concordance between the smartwatch ECG recordings and conventional ECG measurements. The research emphasized the smartwatch's capability as a reliable tool for ongoing heart monitoring, aiding in the prompt identification of arrhythmias and various heart-related irregularities. This study is particularly relevant to my research as it offers evidence for the clinical reliability of smartwatches in monitoring essential health metrics, especially cardiac performance. Additionally, in contrast to research carried out in clinical environments, Kader et al. emphasize real-world application, which aligns with my objective.

2.5. Accuracy of FDA/CE-cleared smartwatch (apple watch) feature for atrial fibrillation detection

(Wasserlauf et al., 2023) conducted a multicentre study to assess the Apple Watch's irregular rhythm notification (IRN) capability in identifying atrial fibrillation (AF) in patients who already have cardiac monitors. The study analyzed the performance of the device in comparison to clinically validated diagnostic methods across diverse patient population. The findings demonstrated that Apple watch could identify AF with high 100% specificity, and a 100% positive predictive value for AF episodes duration of one hour or longer. It was supporting its role as a supplementary tool for AF detection in real-world settings. While the high specificity confirms the device's accuracy in recognizing actual AF instances, but the moderate 72% sensitivity indicates that some occurrences may be missed. However, despite strong diagnostic performance, limitations were observed, including variable sensitivity in certain subgroups and challenges related to inconclusive readings. This study is highly relevant to my work, as it specifically evaluates the diagnostic precision of a regulatory-approved smartwatch, highlighting the capability of these devices to aid in clinical decision-making. However, while it confirms the feasibility of smartwatch-based AF detection, the research primarily focuses on clinical accuracy rather than exploring user feedback or broader health perspectives, thereby highlighting a gap that my study aims to address.

2.6. Diagnostic accuracy of smartwatches for cardiac arrhythmia detection

Evaluating the effectiveness of wearable devices in detecting clinically significant conditions is essential for understanding their potential in healthcare management. For example, (Scarlet Nazarian *et al.*, 2021) performed a systematic review and meta-analysis investigating the diagnostic precision of smartwatches in identifying cardiac arrhythmias, especially atrial fibrillation. The research combined data from several clinical trials and observational studies, evaluating effectiveness across different smartwatch models. The results showed that smartwatches exhibited encouraging sensitivity and specificity in identifying arrhythmic events, though accuracy differed considerably among devices. Elements like sensor technology, algorithm development, and user demographics impacted device performance, underscoring the necessity of careful device selection for clinical applications. Despite their potential as accessible monitoring tools, the study emphasized that smartwatch-based detection should complement, not replace, traditional clinical assessments. Moreover, the authors emphasized the necessity for additional extensive, real-world validation to ensure consistent diagnostic reliability. Although these results offer important insights into clinical effectiveness, the study predominantly concentrated on regulatory-approved devices for detecting arrhythmias and did not investigate user perceptions or engagement beyond controlled research settings. This research is significant to my study as it establishes a foundation for evaluating FDA/CE-approved smartwatches, emphasizing the clinical functionalities of these devices and the importance of assessing user feedback to comprehend their real-world effectiveness.

2.7. Patient acceptance of self-monitoring on smartwatches in digital therapy

Understanding patient acceptance of wearable devices is important for designing effective digital health interventions. For instance, (NadalCamille *et al.*, 2023) performed a mixed-methods study to explore patient interactions with a Mood Monitor smartwatch app during an 8-week online Cognitive Behavioural Therapy (iCBT) course for depression. The research included 35 patients from the UK's National Health Service and gathered information through three online surveys and interviews conducted after the study. The findings showed that patients generally accepted the smartwatch app, identifying factors that encouraged or hindered its use. The study also demonstrated that integrating the smartwatch into routine digital therapy was feasible and could support self-monitoring and patient engagement. However, the study

concentrated on a specific therapeutic context and a limited patient cohort, restricting its broader applicability. This study is relevant to the current research as it highlights the role of user acceptance and engagement in the use of smartwatches for health monitoring. A research gap persists since it did not assess FDA/CE-approved smartwatches, resulting in limited evidence regarding patients' perceptions or use of regulatory-cleared devices in actual healthcare environments.

2.8. Impact of wearable activity trackers on elderly health

Wearable activity trackers have become effective health monitoring tool for encouraging physical exercises and minimizing sedentary behaviour, especially in older individuals. A comprehensive systematic review and meta-analysis conducted by (Wu et al., 2023) combined data from 45 studies and found that wearable trackers considerably boosted daily step counts and moderate-to-vigorous physical activity, in addition to decreasing sedentary time. The research emphasizes how behavioural interventions incorporated into wearable technology-like reminders, goal setting, and progress updates - can positively influence lifestyle behaviours. However, despite its significant contributions, the review has limitations when compared to my research study. Wu et al. concentrated mainly on elderly individuals in controlled clinical environments, and assessed general activity trackers, not distinguishing between devices that have regulatory approval (e.g., FDA or CE-marked) and those that do not. Additionally, the results primarily focused on objective metrics such as physical activity levels and did not consider users' personal experiences, motivation, or health outcomes over time.

2.9. Diagnostic accuracy of regulatory-approved smartwatch (withings scanwatch) for cardiac arrhythmia detection

The research conducted by (Badertscher *et al.*, 2022) assessed the diagnostic effectiveness of the Withings ScanWatch (Withings SA, Issy les Moulineaux, France), an approved smartwatch that can capture an intelligent electrocardiogram (iECG) featuring automated detection of atrial fibrillation (AF).It was conducted as a prospective, observational study at University Hospital Basel, consecutive patients with suspected cardiac arrhythmias received simultaneous iECG recordings from their smartwatch and 12-lead ECGs interpreted by cardiologists. Out of 319

patients, roughly 1 in 7 tracings (14%) were deemed unreadable by the device's algorithm, a figure lowered to 4.1% upon examination by cardiologists. This level of unreadable output aligns with previous research on different smart devices, which indicated rates ranging from 6% to 52%. Automatic rhythm classification was less effective than manual analysis of iECGs. The sensitivity for detecting AF with the Withings iECG feature was found to be lower than that reported for other smart devices. However, the interpretation of the iECG by cardiologists demonstrated excellent reliability, achieving a diagnostic accuracy of 98% when compared to the gold standard. The iECG algorithm in this new smartwatch for distinguishing sinus rhythm from AF has limited clinical value on its own, necessitating physician oversight and manual interpretation to attain adequate diagnostic accuracy for AF detection. Limitations included testing only one device, no at-home environments, and absence of patient perception evaluation. Finally, the authors conclude that while these devices may act as effective mobile monitors for AF documentation, incorporating them into clinical workflows necessitates clear strategies for managing data and allocating resources. This study is highly relevant to the present research as it demonstrates both the diagnostic accuracy and practical limitations of a regulatory-approved smartwatch, providing essential insights into clinical applicability. However, a research gap exists since the study was hospital-based and did not explore the effectiveness, usability, or patient perceptions of such devices in broader real-world settings.

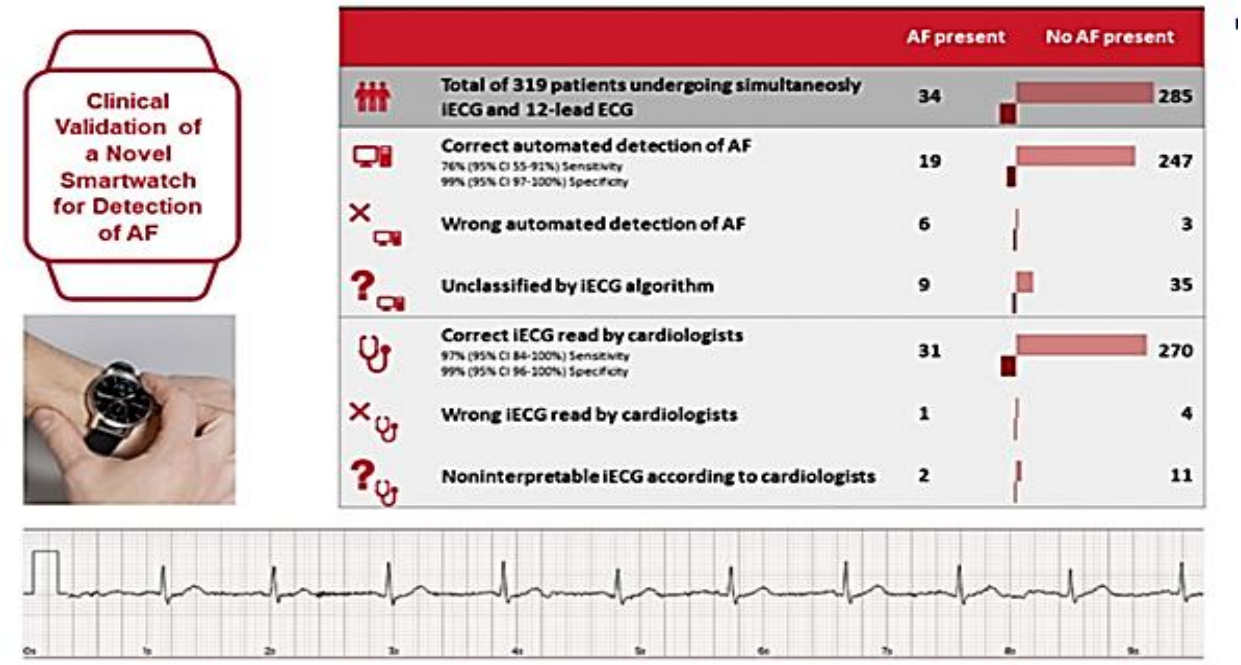

Fig 1: Diagnostic accuracy of the withings scanwatch iECG function for atrial fibrillation detection compared to 12-lead ECG (badertscher *et al.*, 2022)

CHAPTER 3: METHODOLOGY

3.1. Introduction

This study employs a structured and systematic approach to examine the perceived effectiveness of FDA/CE-approved smartwatches regarding health perspective among users in Ireland. Recognizing the dual nature of the research emphasis— comprising quantifiable user behaviours and personal health viewpoints—a mixed-method research approach has been utilized. This method enables the combination of quantitative information, including usage trends and satisfaction levels, with qualitative understandings gained from individual experiences, motivations, and observed health outcomes. The approach is based mainly on a positivist research philosophy, with supplementary elements of interpretivism to address the richness and diversity of individual viewpoints. A cross-sectional time frame has been chosen to gather data at a particular moment, offering an up-to-date and pertinent overview of user interactions with smartwatch health-monitoring functionalities. To maintain methodological rigor, the research specifies distinct protocols for choosing participants, sampling methods, sample size determination, and data gathering. These elements together enhance the validity and reliability of the study and enable a comprehensive assessment of the utilization of regulatory approved smartwatches as a health monitoring tool in real-world contexts.

3.2. Research Design:

A mixed-method approach is employed to gather and examine both quantitative and qualitative data. This design is selected to ensure a comprehensive understanding of smartwatch usage from a health perspective. This research utilizes a mixed-methods strategy that integrates quantitative information obtained via Likert scale surveys with qualitative perspectives gained from thematic analysis of open-ended responses. Employing Likert scales facilitates the structured assessment of user views on the effectiveness, motivation, and satisfaction linked to FDA/CE-cleared smartwatches within a health context. This quantitative aspect aids in recognizing trends and patterns in user feedback, along with descriptive comparisons across demographic groups such as age, gender, and health status.

The mixed-method approach is especially appropriate for this research because of the intricate and subjective aspects of health perceptions, behavioural changes, and technology adoption. Combining both types of data strengthens the validity and depth of the results and allows for cross-validation of results. (John W. Creswell & Plano Clark, 2018).

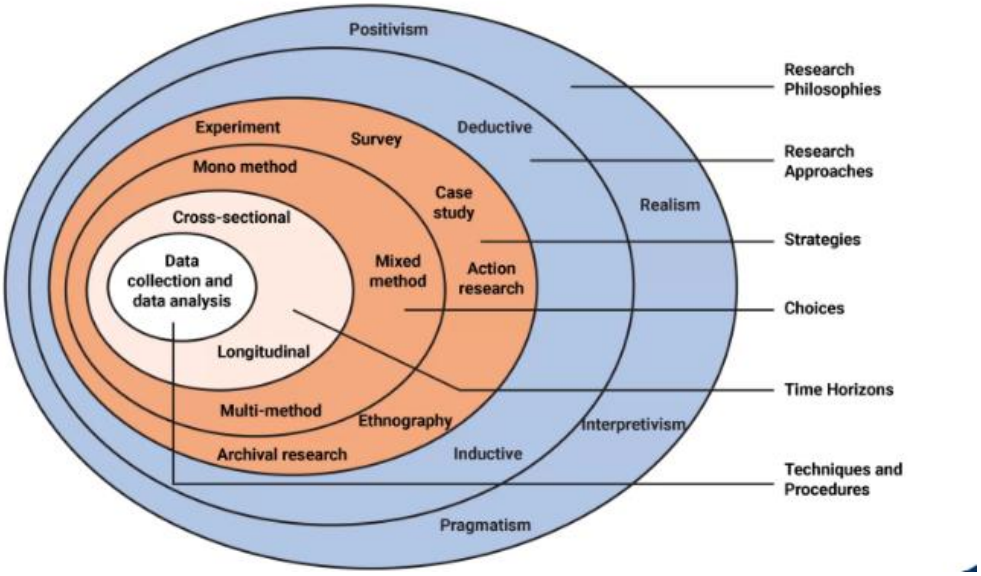

Fig 2 : Research Onion by (Saunders et al., 2015)

The Research Onion framework, created by Saunders, Lewis, and Thornhill (2009), offers a systematic approach to assist researchers in navigating the essential components of research design, ranging from selecting philosophical underpinnings to identifying particular methodologies. (Saunders et al., 2015)**.**

Table 1: Methodological Framework of survey-based research

Primary Data	**Method**
Research Approach	Mixed Method approach
Research Philosophy	Pragmatism
Research Strategy	Survey based Research
Time – Horizon	Cross-sectional
Data Collection Techniques	Online Survey Questionnaires
Structure of survey	5 Sections comprise of 24 Questionnaires
Data Analysis	Descriptive statistics using excel and Thematic analysis

3.3. Justification for research design

The decision to utilize a mixed-method strategy in this research is grounded in the need to bridge the gap between objective assessment with subjective perception when analyzing the health-related effectiveness of FDA/CE-approved smartwatches in Ireland. Wearable health technologies inherently function at the convergence of clinical usefulness, individual lifestyle, and user involvement—each requiring a distinct perspective for analysis. From a research standpoint, solely utilizing quantitative methods can reveal trends in device usage, demographic relationships, and generalized patterns in satisfaction or perceived health advantages. However, these approaches frequently fail to fully address the personal significance, everyday incorporation, and behavioural outcomes linked to wearable health technologies. Users' motivations, experiences, and real-world effects—like lifestyle adjustments are often subtle and highly individualized, requiring qualitative investigation.

3.4. Research Approach:

This research mostly utilizes a deductive method, which involves evaluating established theories and assumptions regarding the effectiveness of FDA/CE-approved smartwatches in monitoring health metrics, promoting healthier behaviours, and enhancing health outcomes. The research objectives build on existing studies and evidence indicating that these devices can benefit user health by delivering precise monitoring of vital signs, promoting physical activity, and assist in managing chronic diseases.(Niwarinda Arnold, 2025). By systematically assessing these propositions through user feedback in Ireland, the study aims to verify the applicability and validity of these established concepts. Simultaneously, the study includes an inductive element, especially via the qualitative examination of open-ended feedback from users' response. This enables the development of new themes, insights, or patterns that might not have been foreseen in the current literature, including distinctive motivational factors, usability issues, or demographic differences in smartwatch usage.

3.5. Research Philosophy:

This research is mainly based on the positivist research philosophy, indicating it emphasizes gathering data that can be quantified and examined in a scientific, objective way. Positivism

works effectively for studies that use tools like surveys with closed-ended questions, where responses can be counted and compared easily. This aligns with the aim of the study to assess the effectiveness of smartwatches on user health outcomes, behaviours, and satisfaction through clear numerical data. However, due to the presence of a few open-ended questions, the research additionally includes some aspects of interpretivism. Interpretivism recognizes the personal significance of human experiences, which are most effectively understood through qualitative responses. These open-ended responses allow participants to share personal insights, motivations, or concerns that provide context to the numerical data, particularly crucial when evaluating perceived effectiveness, satisfaction, or health impacts. Therefore, although the research is mainly positivist, the dual aspect of the data collection tool adds a supplementary interpretivist dimension, improving the depth of the results. (John. W. Creswell, 2018).

3.6. Time Horizon:

This research employs a cross-sectional study design, noted for gathering and analyzing data from a specified population at one moment in time or during a brief, defined duration. This method offers a snapshot of user feedback on the health-related effectiveness of FDA/CE-approved smartwatches in Ireland. Cross-sectional studies are commonly employed to assess the frequency of specific outcomes and to gather pertinent data on individual characteristics and exposures within the study population. This type of study is especially valued for its simplicity, cost-effectiveness, and the ability to be conducted within a relatively short time horizon, without the need for extended follow-up of participants. (İrday, 2024).

3.7. Study Participants:

This research encompasses a carefully selected group of participants who meet specific inclusion criteria to ensure the relevance and integrity of the gathered data. Participants will include individuals who are 18 years or older, living in Ireland, and who have utilized FDA- or CE-approved smartwatches.

Inclusion Criteria:

The targeted population includes:

i. FDA/CE-cleared smartwatch users (normal users)
ii. Fitness enthusiasts (fitness users) and
iii. People with chronic disease conditions, especially cardiac and diabetic patients, who utilize FDA/CE-cleared smartwatches (users with medical conditions) to track vital signs or manage health metrics such as heart rate, ECG, blood pressure, and blood glucose levels.

It is important to note that data gathering will be completely non-clinical. Participants will be recruited through online platforms, including forums, fitness apps, and social media. This study will not access or utilize any clinical records or hospital-based information, thereby preserving ethical standards related to medical data privacy.

Exclusion Criteria:

Participants will be excluded if:

i. They are under 18 years of age.
ii. They are not using FDA/CE- cleared smartwatches.
iii. Participants not willing to participate the study.

3.8. Sample size Determination:

The sample size for this research was determined using the SurveyMonkey sample size calculator, a trusted and commonly utilized online resource for identifying suitable sample sizes in survey-related studies. As the overall number of FDA/CE-approved smartwatch users in Ireland is not known, a conservative estimate was applied by establishing the population proportion at 50%, which ensures maximum variability and results in the largest necessary sample size. A confidence level of 95% was chosen to ensure a high level of certainty in the findings, accompanied by a margin of error of 8%, deemed acceptable for initial investigations in public health and technology studies. This calculation yielded a suggested sample size of 150 participants, which strikes a balance between statistical validity and feasibility, considering the study's time and resource limitations. This sample size is adequate to identify significant trends and associations among various user groups, such as regular users, fitness enthusiasts

and those with chronic health issues, and supports both descriptive and comparative studies. Furthermore, it aligns with the study's mixed-method methodology, providing adequate quantitative data for descriptive statistics, while also allowing for qualitative depth through open-ended responses.

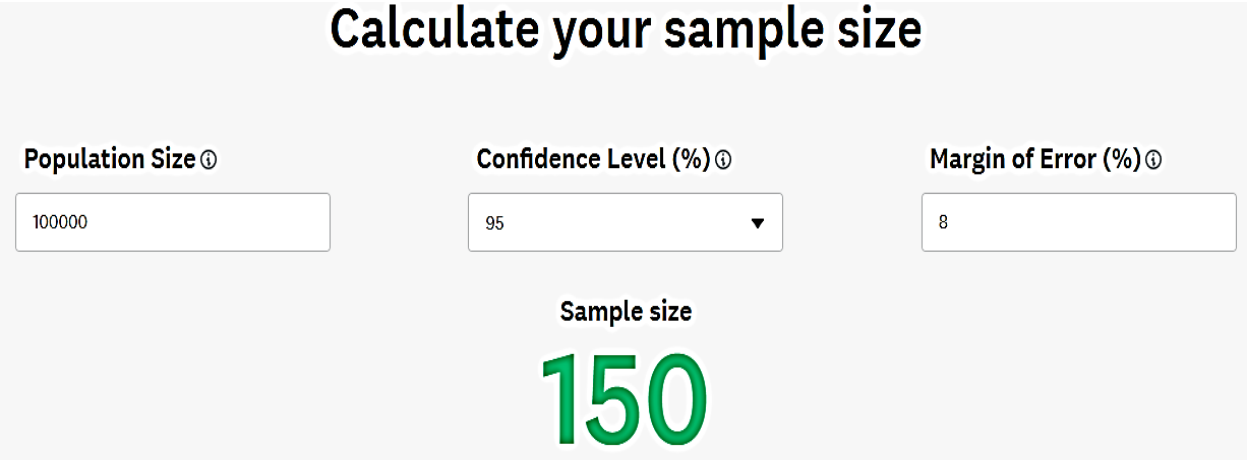

Fig 3 : Sample Size Calculator (Survey Monkey, 2025)

3.9. Data Collection:

The study gathered primary data via a structured online survey created and conducted with Google Forms. The number of questionnaires included were 24 questions, which corresponds with the research aim and to gather both quantitative and qualitative data. Closed-ended questions—such as Likert scales, multiple-choice questions, yes/no selections, and frequency scales—were employed to collect measurable data on smartwatch utilization, perceived benefits, satisfaction levels, and feature utilization among various demographic groups. Simultaneously, open-ended questions were incorporated to obtain detailed qualitative insights concerning users' individual experiences, motivations for utilizing health-monitoring features, and their perceived health outcomes. This combination enabled thorough insight into user engagements with FDA/CE-approved smartwatches. The survey addressed multiple topics, such as demographic information, frequency of smartwatch usage, how often users engage with health features (e.g., ECG, heart rate monitoring), and overall satisfaction and trust in the device's health measurements. Participants were recruited through online platforms, including forums, fitness apps, and social media. Participation was voluntary, and informed consent was acquired digitally prior to accessing the survey.

3.10. Data Analysis:

Quantitative Data Analysis:

The quantitative data for this study were collected through various closed-ended survey questions, including yes/no questions, multiple-choice items, and several types of Likert-type scales such as “Very Accurate” to “Very Inaccurate,” “Strongly Agree” to “Strongly Disagree,” and “Significant Improvement” to “No Change.” The data were extracted from Google Forms and imported into Microsoft Excel for analysis. Likert-type scale responses were analyzed using descriptive statistics, specifically by counting the number of responses in each category and convert them into percentages to assess participants’ perceptions of the accuracy, effectiveness, and health impact of FDA/CE-cleared smartwatches. Descriptive comparisons across demographic groups such as age, gender, and health status were conducted.

To provide deeper insight, responses were further disaggregated into two key participant groups: (i) individuals with diagnosed health conditions and (ii) normal smartwatch users/fitness users. This separation allowed for meaningful comparisons between groups, highlighting whether smartwatch features had different impacts depending on health status. In addition to categorical breakdowns, summary tables and visual representations (e.g., bar graphs and pie charts) were used to display findings in a more interpretable manner. While the analysis remains primarily descriptive in nature, this approach is particularly suited to the exploratory design of the study, as it reveals general trends, user perceptions, and satisfaction levels without imposing statistical assumptions. Together, the use of descriptive statistics and Likert-scale analysis provided a robust framework to address the study’s objectives and to assess the role of FDA/CE-cleared smartwatches in supporting health monitoring and lifestyle management.

Qualitative Data Analysis:

Qualitative responses from open-ended questions will be examined through thematic analysis, highlighting common themes and user emotions regarding their experiences, motivations, and health results. This complementary method facilitated a more profound insight into the context surrounding the numerical data, providing a comprehensive interpretation of the perception of FDA/CE-cleared smartwatches in aiding personal health management.

The results from both data types were integrated to validate and enhance the findings. Quantitative data provided broad insights and measurable trends, while qualitative data enriched understanding by uncovering personal narratives, emotional responses, and contextual details. This combined method improved the overall credibility, validity, and comprehensiveness of the research findings, ensuring that both the measurable trends and the personal experiences related to FDA/CE- cleared smartwatch use in a health context were thoroughly explored.

3.11. Ethical Considerations:

Ethical integrity will be maintained throughout the study. Participation is completely voluntary, and informed consent will be obtained through an introductory part of the survey form. Participants will be ensured of anonymity and confidentiality, with no personal identification details gathered. Data will be kept securely; all the research information including gathered survey responses and documents related to analysis/findings will be stored securely in a password-protected Google Drive account in an electronic device(laptop). Data will be kept securely, and it is utilized exclusively for academic purposes in line with institutional regulations and kept in accordance with General Data Protection Regulations (GDPR) and Ethical research standards.

3.12. Conceptual framework:

The conceptual framework guiding this research was structured around a mixed-methods design, combining both quantitative and qualitative approaches to gain a comprehensive insight into smartwatch usage. The research focused on three participant groups: regular users of FDA/CE-approved smartwatches, fitness users, and people with chronic health conditions, especially those with cardiac conditions and diabetes. Primary data were gathered via a structured 24 online questionnaire, aimed at evaluating smartwatch effectiveness, satisfaction, functionalities, and perceived benefits. Quantitative data provided deeper insights into users' experiences, motivations, and behavioural changes associated with smartwatch use. This framework demonstrates the user feedback on the effectiveness of FDA/CE-cleared smartwatches from a health perspective in Ireland.

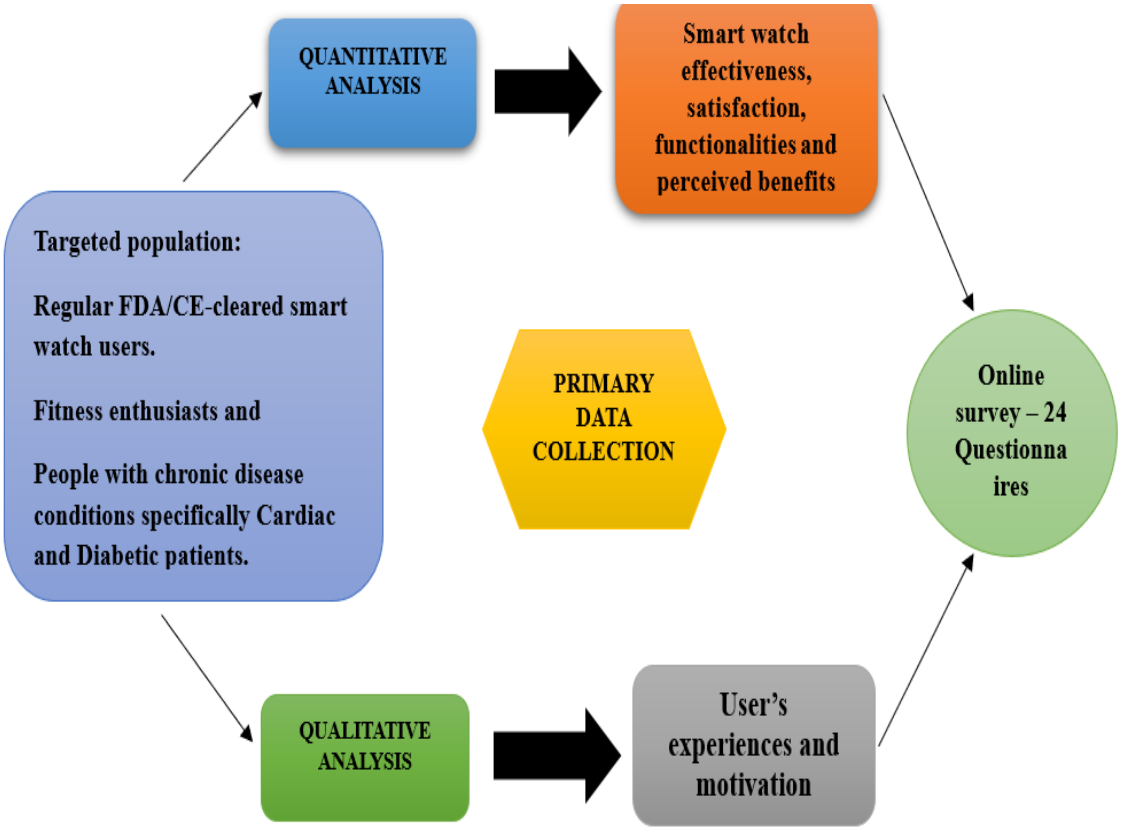

Fig 4: Conceptual framework for data collection and analysis of smartwatch usage

CHAPTER 4 - FINDINGS AND ANALYSIS

4.1. Overview:

This chapter delivers the findings from the mixed-method survey carried out among users of FDA/CE-approved smartwatches in Ireland. The survey comprised both quantitative questions rated on Likert scales and qualitative open-ended questions, capturing detailed user feedback on smartwatch health features, motivation, outcomes, and satisfaction. Out of the **152 participants** who accessed the survey, 2 individuals chose not to participate by declining consent, resulting in a **final sample size of 150 respondents.**

4.2. QUANTITATIVE FINDINGS:

4.3. Demographic Profile of Respondents

The demographic profile is important as it highlights how age, gender, and health status influence smartwatch perceptions and usage, ensuring findings are interpreted within context. It further enables comparison across groups to identify who benefits most and where gaps in adoption remain.

AGE:

Among FDA or CE-cleared smartwatch users in Ireland who participated in the survey, the largest proportion were aged 25–34 years (42%). This was followed by 18–24 years (19.3%) and 35–44 years (18.7%), 44 – 54 years (12%), 55–64 years (4.7%%), and 65 years or older (3.3%). This indicates that smartwatch adoption from a health perspective is most prevalent among younger to mid-adult age groups, with representation steadily declining among older age groups.

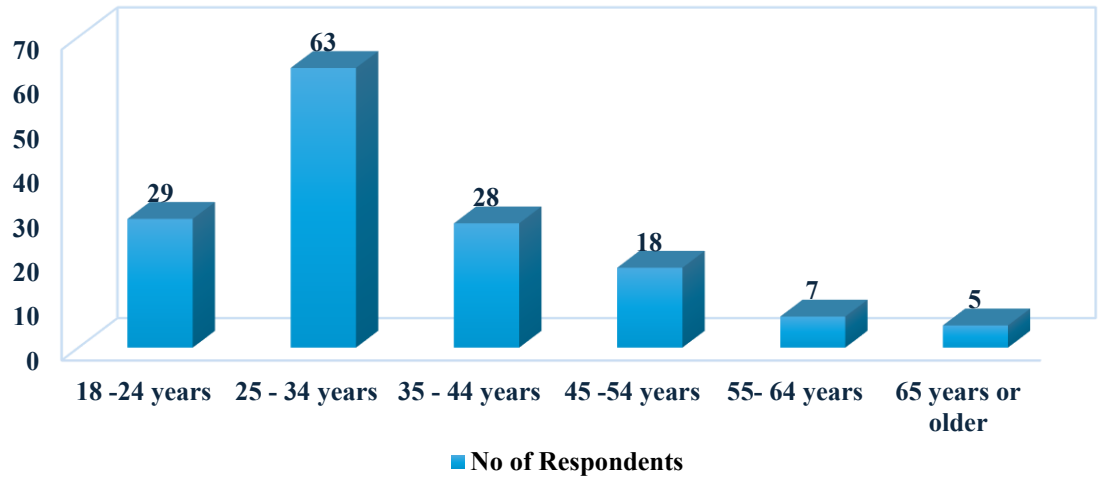

Fig 5: Age Distribution

Table 2: Age Distribution

AGE	NO OF RESPONDENTS	PERCENTAGE
18–24 years	29	19.3%
25–34 years	63	42%
35–44 years	28	18.7%
44-54 years	18	12.0%
55–64 years	07	4.7%
65 years or older	05	3.3%
Total	**150**	**100%**

GENDER DISTRIBUTION OF RESPONDENTS:

Among smartwatch users in Ireland, females accounted for 50% of respondents, while males made up 47.3%. This suggests a relatively balanced gender representation, with a slightly higher proportion of female users.

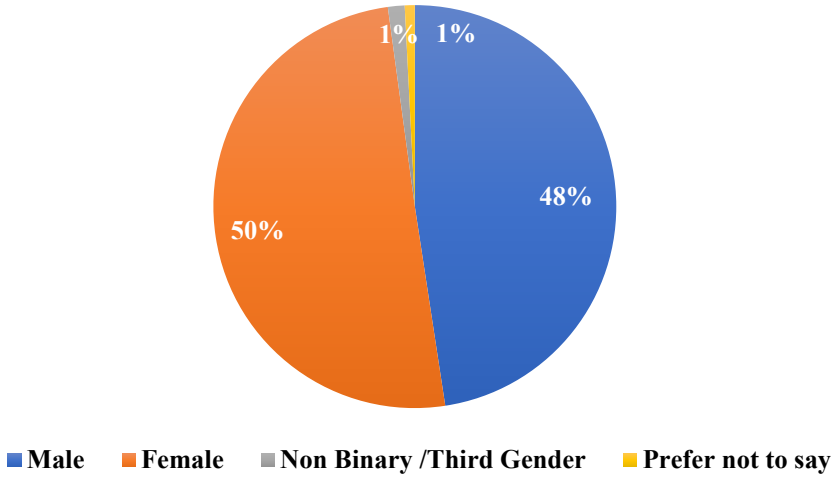

Fig 6: Gender Distribution on Smartwatch adoption

Table 3: Gender Distribution on Smartwatch adoption

GENDER	NO OF RESPONDENTS	PERCENTAGE
Male	71	47.3%
Female	75	50.0%
Non-Binary/third gender	02	1.33%
Prefer not to say	02	1.33%
Total	**150**	**100**

FDA/CE-CLEARED SMART WATCH USERS:

Out of the 150 respondents, **127 (84.7%)** reported currently using an FDA/CE-cleared smartwatch, while 23 (15.3%) indicated they do not use/ use non regulatory approved smartwatches, which are not evaluated in this study.

Table 4: Categorization of Regulatory approved smart watch users vs Non - Regulatory approved smartwatch users

CATEGORY	NO OF RESPONDENTS	PERCENTAGE
FDA or CE-cleared smart watch users	127	84.7%
Non-regulatory approved smart watch users	23	15.3%
TOTAL	150	100%

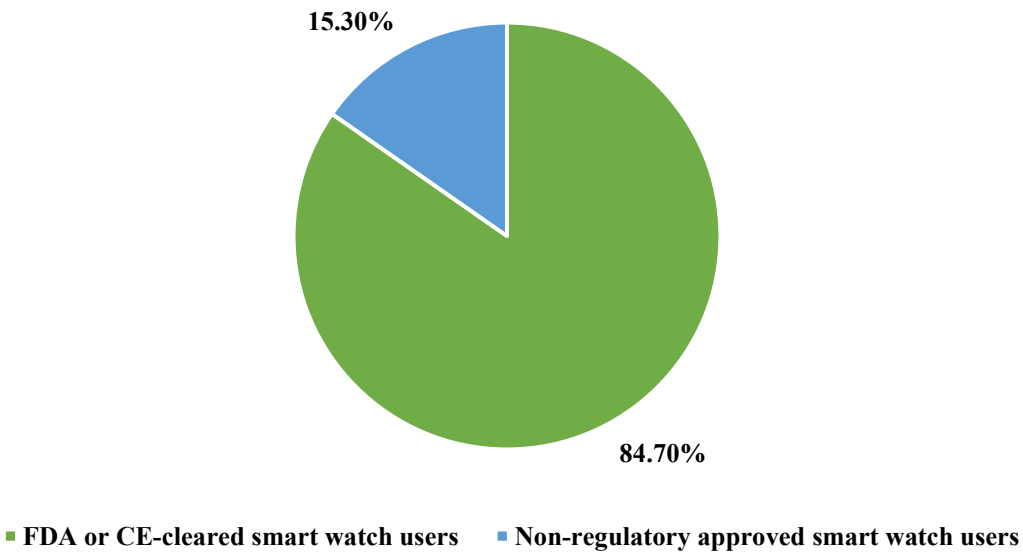

Fig 7: Categorization of Regulatory approved smart watch users vs Non-regulatory approved smartwatch users

USAGE PATTERNS OF FDA/CE-CLEARED SMARTWATCHES:

Among the 150 participants, 127 respondents (84.7%) reported that they were currently using an FDA/CE-cleared smartwatch. And analysis of usage patterns revealed that most users had been wearing their devices for a period exceeding six months, with a significant proportion using them for more than one year. In terms of device preference, Samsung Galaxy watches and Apple Watches were the most frequently reported models, followed by Fitbit Sense and

other brands. Regarding usage frequency, **over half of the users (57.5%) indicated they used their smartwatch daily,** with many others reporting usage several times per day. These findings suggest sustained engagement with smartwatches among the majority of users.

HEALTH STATUS

Among the 127 respondents, 59 (46.5 %) reported having diagnosed health conditions, while 68 (53.5%) reported they do not have any diagnosed/Pre-existing health conditions.

Table 5: Health Status of Participants

HEALTH STATUS	NO OF RESPONDENTS	PERCENTAGE
Yes, to diagnosed health conditions	59	46.5%
No, to diagnosed health conditions	68	53.5%
Prefer not to say	0	0%
TOTAL	**127**	**100%**

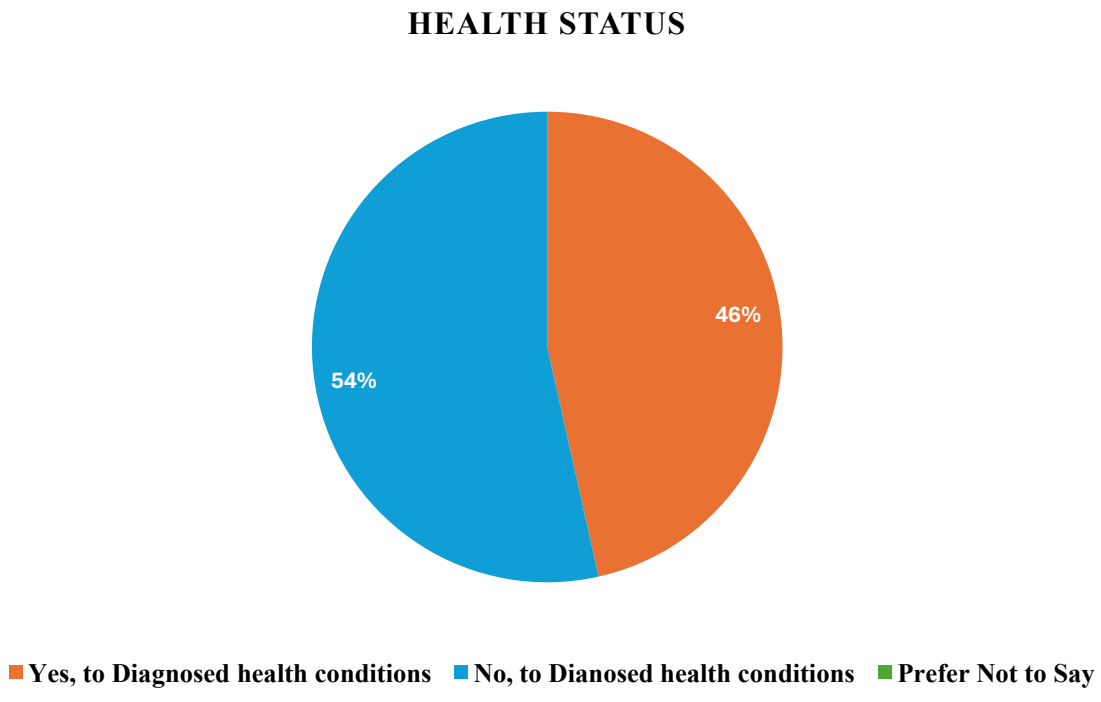

Fig 8: Health Status of Participants

<u>Responses from Participants with Pre-existing Health Conditions:</u>

Among the 127 respondents, **59 (46.5%)** of participants who reported having diagnosed health conditions and who currently use FDA/CE-cleared smartwatches, the most reported

ailments included **Heart conditions (28.3%) and Diabetes (20%)**. Other conditions identified were obesity (11.7%), mental health conditions such as anxiety and depression (10%), and various other illnesses (16.7%). Notably, 18.3% of respondents in this group preferred not to specify their condition.

Participants without Pre-existing Conditions:

Remaining **68 (53.5%)** respondents who reported "No" or "Prefer not to say" to having diagnosed health conditions were directed to continue with questions related to general smartwatch usage and health tracking, excluding illness-specific queries. These participants were subsequently asked whether they would describe themselves as fitness or gym enthusiasts. Among this group of healthy users**, 51.5% identified as fitness enthusiasts**, while **48.5% considered themselves normal regular users**. This approach enabled the study to capture health and activity perspectives specifically from individuals without chronic illnesses.

Table 6: Categorization of Normal users and Fitness users'

CATEGORY	NO OF RESPONDENTS	PERCENTAGE
Fitness enthusiasts	33	48.5%
Normal smartwatch users	35	51.5%
TOTAL	**68**	**100%**

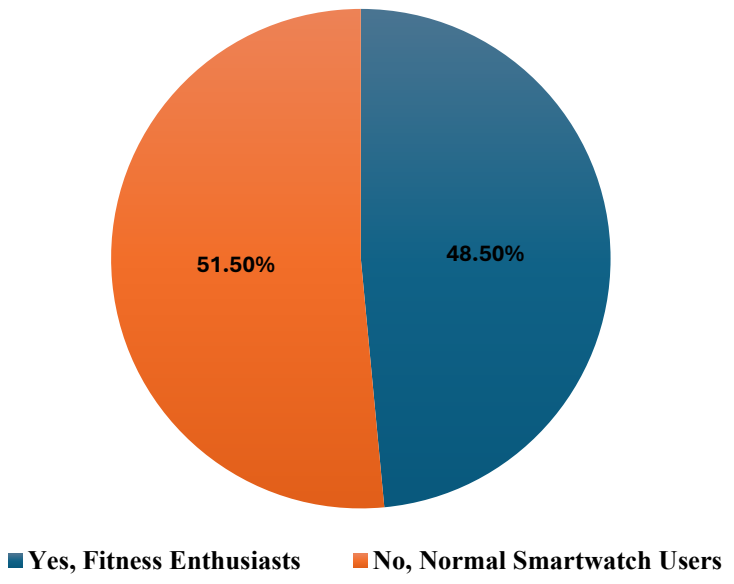

Fig 9: Categorization of Normal users and Fitness users'

4.4. Objective1: Effectiveness in tracking Health Metrics

Q.1. Rating Smartwatch Accuracy and Usefulness

Responses from Participants with Pre-existing Health Conditions:

Among 59 respondents, **67.8%** rated the accuracy and usefulness of their smartwatch in tracking health metrics (heart rate, blood oxygen saturation,ECG, physical activity, sleep habits, and stress levels) as 'Somewhat Accurate" **27.1%** rated it as 'Very Accurate,' **5.1%** were neutral, and no respondents selected 'Somewhat Inaccurate' or 'Very Inaccurate.'

Table 7: Rating Smartwatch Accuracy and Usefulness (Diagnosed Group)

SCALE	NO OF RESPONDENTS	PERCENTAGE
Very accurate	16	67.8%
Somewhat accurate	40	27.1%
Neutral	03	5.1%
Somewhat inaccurate	0	0%
Very in accurate	0	0%
TOTAL	**59**	**100%**

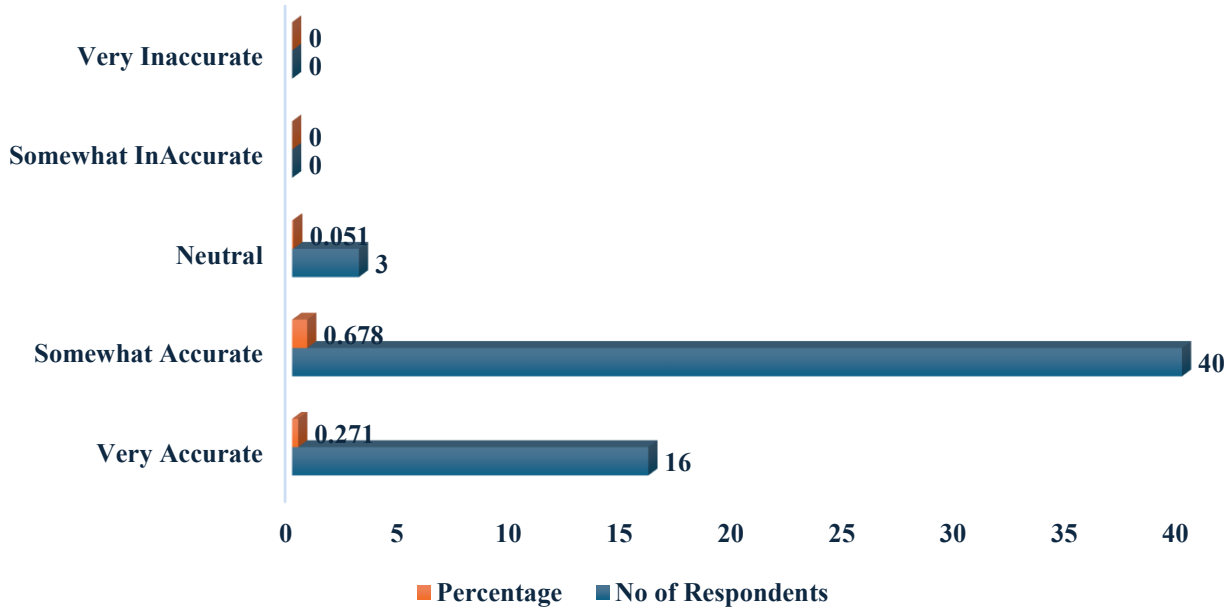

Fig 10: Rating Smartwatch Accuracy and Usefulness (Diagnosed Group)

Responses from Normal/ Fitness Users:

Among healthy participants, 34 (50%) rated the smartwatch's tracking accuracy as Somewhat Accurate, 23(33.3%) as Very Accurate, 8(11.8%) selected Neutral, and 3 (4.4%) selected Somewhat Inaccurate. No participants chose Very Inaccurate. This distribution indicates a generally positive perception of accuracy, though with slightly more variability compared to participants with pre-existing health conditions.

Table 8: Rating Smartwatch Accuracy and Usefulness (Healthy Group)

SCALE	NO OF RESPONDENTS	PERCENTAGE
Very accurate	23	33.80%
Somewhat accurate	34	50.00%
Neutral	08	11.80%
Somewhat inaccurate	03	4.40%
Very inaccurate	0	0.00%
Total	68	100 %

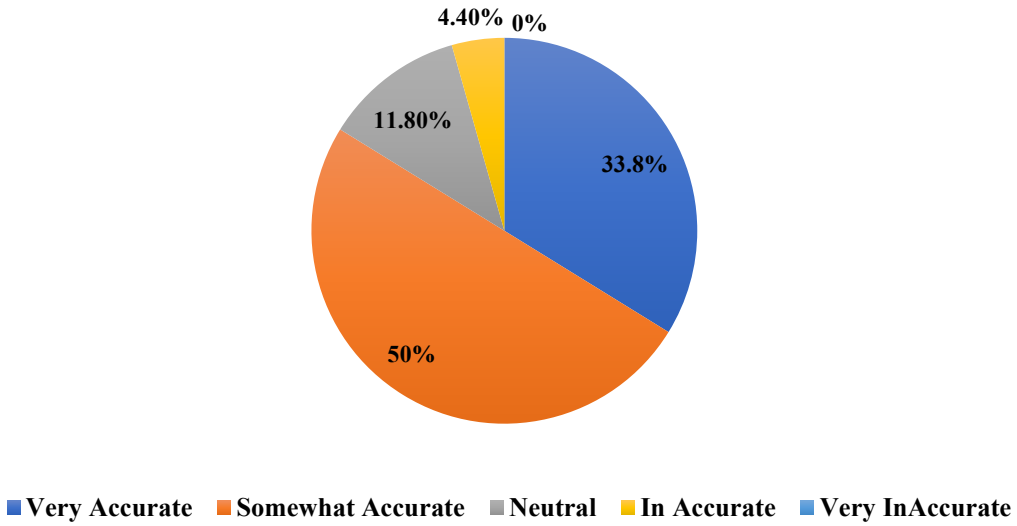

Fig 11: Rating Smartwatch Accuracy and Usefulness (Healthy Group)

Interpretation for Objective 1:

The findings for Objective 1 indicate that both healthy and unhealthy user groups expressed generally positive perceptions of the accuracy and usefulness of FDA/CE-cleared smartwatches in tracking health metrics such as heart rate, blood oxygen saturation, physical activity, sleep habits, and stress levels. Within the patient group, a notably high proportion (67.8%) considered the devices "Somewhat Accurate," and 27.1% rating "Very Accurate" with

a further 5.1% rating them as "Neutral." This indicates that although there is significant confidence in technology, patients might still hold some concerns regarding its accuracy, potentially due to prior exposure to clinical-grade monitoring equipment for comparison.

Among normal/fitness users (Healthy group), the distribution was slightly more varied, with half rating "Somewhat Accurate" and one - third indicating "Very Accurate." The presence of 4.4% reporting "Somewhat Inaccurate" suggests that healthy users may be more critical or have higher performance expectations, possibly due to a focus on optimization for training, fitness goals, or lifestyle monitoring rather than medical necessity. The absence of "Very Inaccurate" ratings in both groups highlights an overarching confidence in the core tracking capabilities of FDA/CE-cleared smartwatches. This finding supports the proposition that these devices are perceived as reliable tools for everyday health monitoring across diverse user groups, although patients appear slightly more accepting of minor inaccuracies than their healthy counterparts.

4.5. Objective 2: Impact on Motivation to adapt Healthier Habits:

Q.2. Impact of Smartwatch use on Physical activity motivation

Response from Participants with Pre-existing Health Conditions:

Among the patient group, a significant number of participants indicated that their smartwatch had motivated them to enhance their physical activity levels. 33.9% indicated "Strongly Agree," whereas 61.0% chose "Agree." Merely 5.1% stated a neutral opinion, and no respondents indicated disagreement. This positive response highlights the motivational role of FDA/CE-cleared smartwatches in supporting physical activity engagement among individuals with pre-existing health conditions.

Table 9: Impact of Smartwatch use on Physical activity motivation (Diagnosed Group)

SCALE	NO OF RESPONDENTS	PERCENTAGE
Strongly Agree	20	33.9%
Agree	36	61.0%
Neutral	03	5.1%
Disagree	0	0.0%
Strongly Disagree	0	0.0%
TOTAL	**59**	**100%**

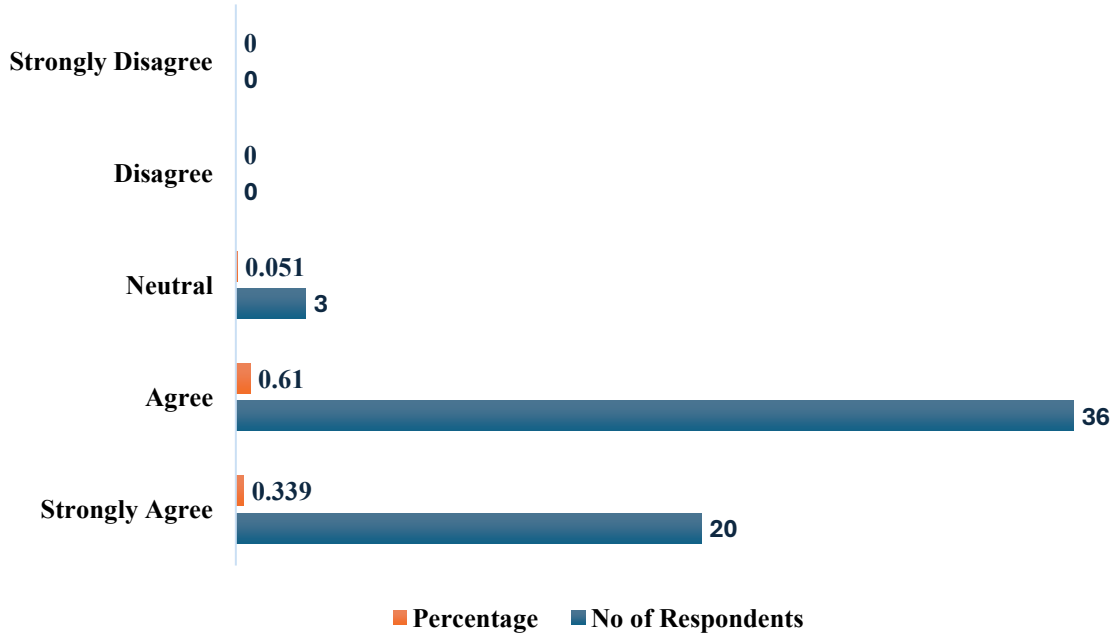

Fig 12: Impact of Smartwatch use on Physical activity motivation (Diagnosed Group)

Response from Normal/ Fitness Users:

In the normal/fitness group, a significant majority of respondents recognized that their smartwatch had contributed to motivating them to engage in more physical activity. Over One-third 36.8% strongly agreed with this statement, and almost half of the respondents i.e., 48.5%, agreed it and a small percentage, 14.7% maintained neutrality, and no participants reported disagreement. These results suggest that, even among people without pre-existing health conditions, FDA/CE-approved smartwatches serve as a strong motivator for physical activity engagement.

Table 10: Impact of Smartwatch use on Physical activity motivation (Healthy Group)

SCALE	NO OF RESPONDENTS	PERCENTAGE
Strongly Agree	25	36.8%
Agree	33	48.5%
Neutral	10	14.7%
Disagree	0	0.0%
Strongly Disagree	0	0.0%
TOTAL	**68**	**100%**

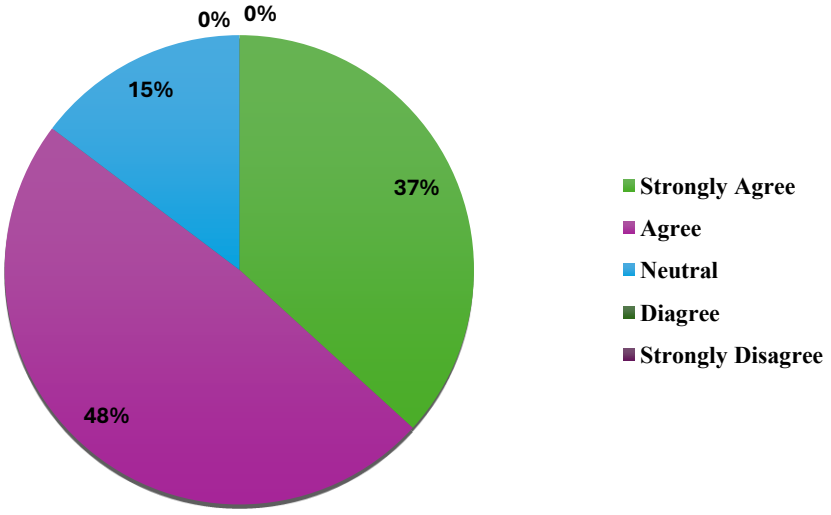

Fig 13: Impact of Smartwatch use on Physical activity motivation (Healthy Group)

Objective 2:

Q.3. Heart monitoring features have motivated me to make lifestyle

Response from Participants with Pre-existing Health Conditions:

Most respondents in the patient group, 72.9%, indicated that heart-monitoring features on their FDA/CE-cleared smartwatch encouraged them to embrace their healthier lifestyle practices, with an additional 18.6% strongly agreeing. Only a minor percentage, 8.5%, remained neutral, and none expressed disagreement. This distribution indicates a clear and consistent positive impact of smartwatch heart-monitoring functionalities on health-related behavioral changes among patients with diagnosed health conditions.

Table 11: Motivation from Heart monitoring features (Diagnosed Group)

SCALE	NO OF RESPONDENTS	PERCENTAGE
Strongly Agree	11	18.6%
Agree	43	72.9%
Neutral	05	8.5 %
Disagree	0	0.0%
Strongly Disagree	0	0.0%
TOTAL	**59**	**100%**

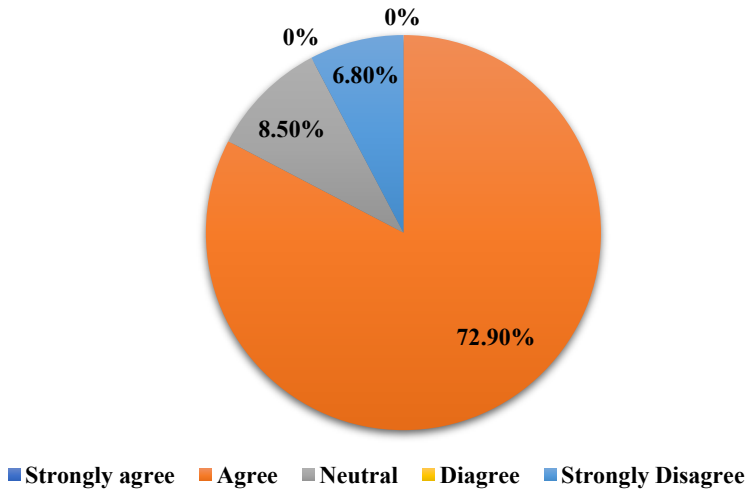

Fig 14: Motivation from Heart monitoring features (Diagnosed Group)

Response from Normal/ Fitness Users:

Among the normal/fitness user group, a significant majority indicated that the heart-monitoring features of their FDA/CE-cleared smartwatch inspired them to alter their lifestyles, with half (50.0%) choosing "Agree" and more than a third (33.8%) choosing "Strongly Agree." A small percentage (16.2%) stayed neutral, suggesting that although the majority of participants considered these features helpful for promoting healthier behaviors, a few might need extra motivation or supportive tools to better meet their expectations.

Table 12: Motivation from Heart monitoring features (Healthy Group)

SCALE	NO OF RESPONDENTS	PERCENTAGE
Strongly Agree	23	33.80%
Agree	34	50.0%
Neutral	11	16.20 %
Disagree	0	0.0%
Strongly Disagree	0	0.0%
TOTAL	**68**	**100%**

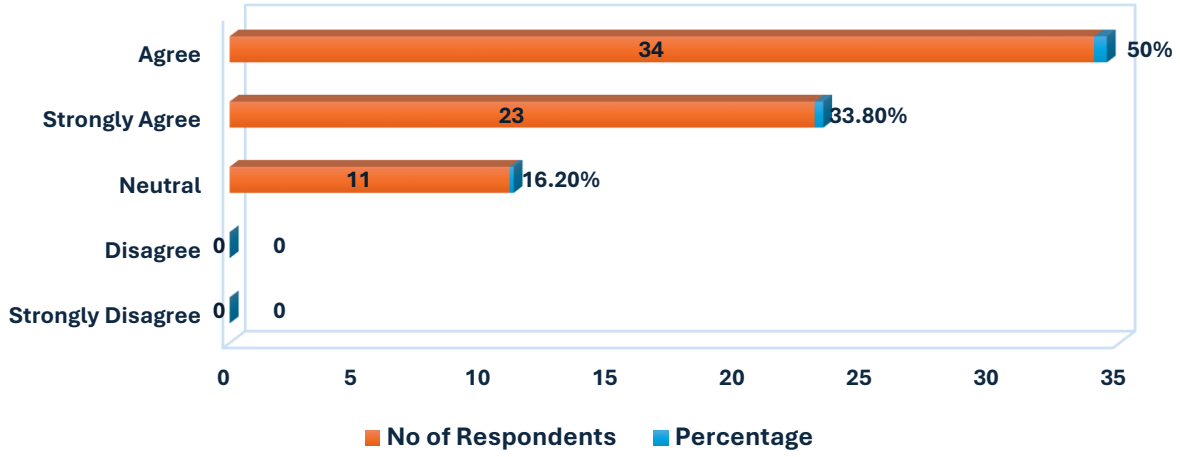

Fig 15: Motivation from Heart monitoring features (Healthy Group)

Objective 2:

Q.4. Effectiveness of Smartwatch in support Sleep Quality:

Response from Participants with Pre-existing Health Conditions:

Within the patient group, showed stronger overall agreement, with 64.4% (n = 38) acknowledging (both "Strongly Agree" and "Agree") that smartwatch use had contributed to better sleep management. Only 17% (n = 10) disagreed, and 18.6% (n = 11) were neutral. These findings indicate that for patients—who may require closer monitoring of sleep because of health issues, smartwatch functionalities are more likely viewed as helpful for enhancing sleep quality.

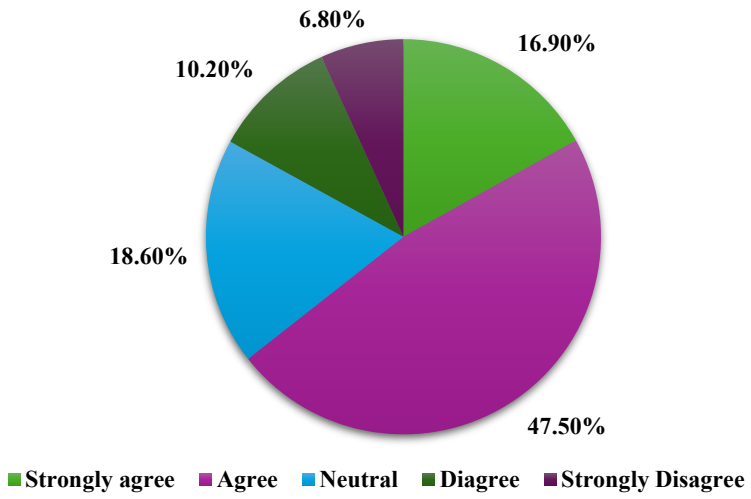

Fig 16: Smartwatches in supporting Sleep Quality (Diagnosed Group)

Response from Normal/ Fitness Users:

In contrast, normal/fitness user responses were more evenly distributed compared to other motivation-related questions. While 42.7% (n = 29) expressed agreement (including both "Strongly Agree" and "Agree") that their smartwatch helped them manage or improve sleep, a sizeable portion, 33.8% (n = 23), remained neutral, indicating uncertainty or inconsistent perceived benefits. Notably, 23.5% (n = 16) disagreed to some degree, suggesting that a notable minority finds the sleep-related features of the smartwatch to be ineffective or unhelpful.

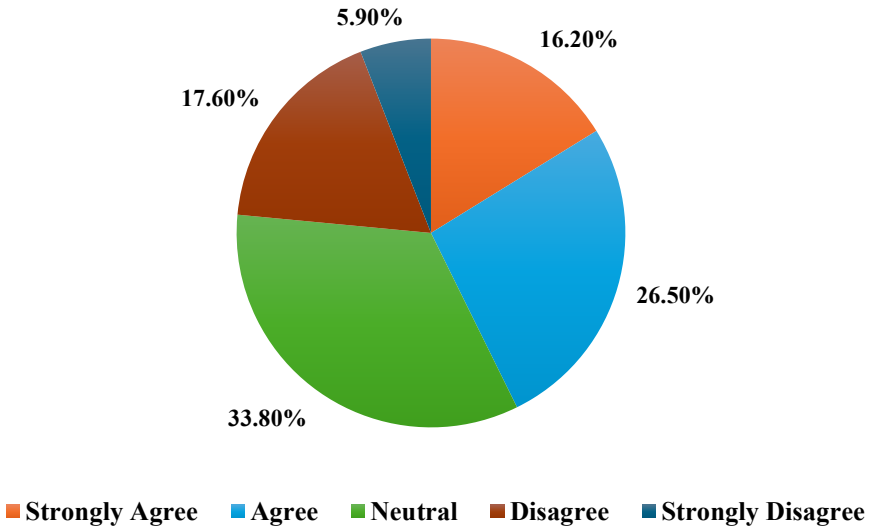

Fig 17: Smartwatches in supporting Sleep Quality (Healthy Group)

Table 13: Smartwatches in supporting Sleep Quality (Both Diagnosed and Healthy Groups)

Users with Pre-Existing Health Conditions			Normal /Fitness Users	
SCALE	**NO OF RESPONDENTS**	**PERCENTAGE**	**NO OF RESPONDENTS**	**PERCENTAGE**
Strongly Agree	10	16.9%	11	16.2%
Agree	28	47.50%	18	26.5%
Neutral	11	18.60 %	23	33.8%
Disagree	06	10.20%	12	17.6%
Strongly Disagree	04	6.80%	04	5.9%
TOTAL	**59**	**100%**	**68**	**100%**

Objective 2:

Q.5. Smartwatch features like Reminders and Alerts help maintain Healthier routines

Both groups demonstrated a strong positive perception of smartwatch reminders and alert features in maintaining healthier routines. Among Users with Pre-existing health conditions, a significant portion 49 respondents (83.0%) either agreed or strongly agreed, indicating high acceptance of this functionality for health management. The normal/fitness group showed a very similar pattern, with 58 respondents (85.3%) in agreement. Neutral responses were minimal in both groups, and active disagreement was negligible, suggesting that reminder and alert features are broadly valued across health status categories.

Table 14: Smartwatch features like Reminders and Alerts help maintain Healthier routines

Users with Pre-Existing Health Conditions			Normal /Fitness Users	
SCALE	**NO OF RESPONDENTS**	**PERCENTAGE**	**NO OF RESPONDENTS**	**PERCENTAGE**
Strongly Agree	15	25.40%	20	29.40%
Agree	34	57.60%	38	55.90%
Neutral	10	17.00 %	09	13.20%
Disagree	0	0.0%	0	0.0%
Strongly Disagree	0	0.0%	01	1.5%
TOTAL	**59**	**100%**	**68**	**100%**

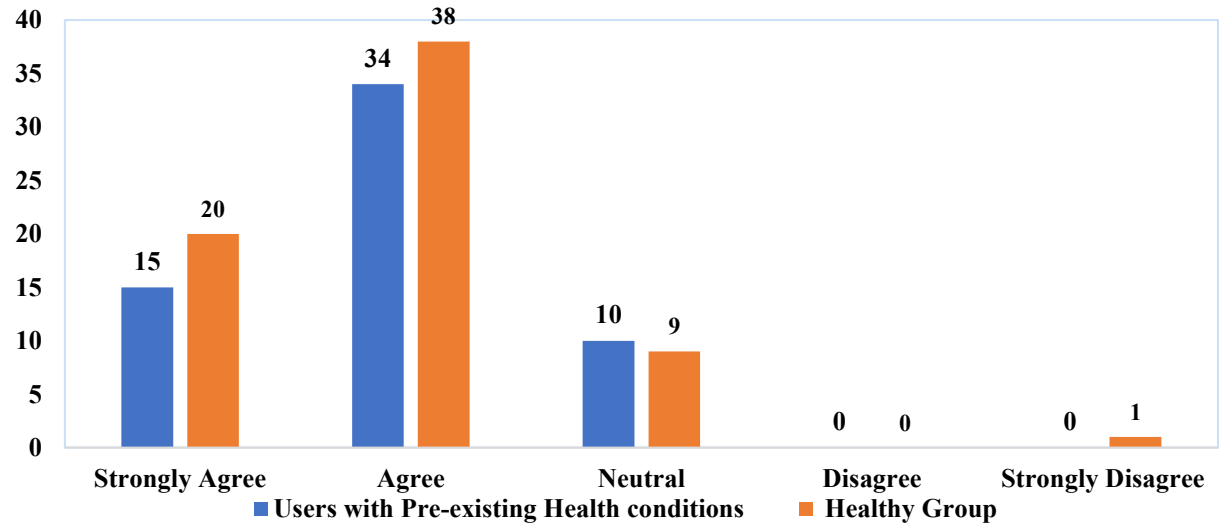

Fig 18: Smartwatch features like Reminders and Alerts help maintain Healthier routines (Both groups)

Interpretation for Objective 2:

The Findings for objective 2 demonstrate that both Users with Pre-existing health conditions and Normal/Fitness users generally perceive FDA/CE-cleared smartwatch functionalities – such as physical activity motivation, Heart monitoring features, sleep management tools and reminders/alerts as valuable for promoting healthier lifestyles. From all these features, most participants from both groups chose "Agree" or "Strongly Agree", reflecting strong endorsement of the smartwatch's role in motivating positive health behaviors**.**

Users with Pre-existing health conditions consistently reported high agreement rates, particularly for features supporting physical activity (94.9%) and lifestyle modifications through heart monitoring (91.5%), emphasizing the perceived clinical significance of these capabilities in managing the disease. Similarly, the normal/fitness group expressed strong support, with the highest ratings observed for physical activity encouragement (85.3%) and maintenance of healthy routines through reminders (85.3%).

Sleep-related features received slightly lower agreement across both groups, with more respondents indicating neutral or negative positions, suggesting that sleep tracking may be perceived as less impactful compared to activity or monitoring functionalities. However, the overall trend indicates that FDA/CE-cleared smartwatch features are widely recognized as contributing to improved self-management, routine adherence, and motivation for healthier habits, regardless of health status.

4.6. OBJECTIVE 3: Perceived Health Outcomes

Q.6. Have you seen improvements in your health?

Response from Participants with Pre-existing Health Conditions:

Evaluation of feedback from the Users with pre-existing health condition (n = 59) revealed a clear pattern of perceived health benefits associated with the use of FDA/CE-cleared smartwatches. For heart rate management, a combined 93.2% of participants reported either significant (35.6%) or somewhat (57.6%) improvement, indicating strong perceived efficacy in this area. Likewise, 86.4% indicated better blood pressure management, with significant improvement noted by 35.6% and somewhat improvement by 50.8%. Blood glucose management showed the highest "somewhat improvement" proportion (61.0%), and a further

33.9% indicated significant improvement, bringing the total to 94.9% perceiving benefits. In terms of overall health, 42.4% reported significant improvement and 52.5% somewhat improvement, while only 5.1% observed no change.

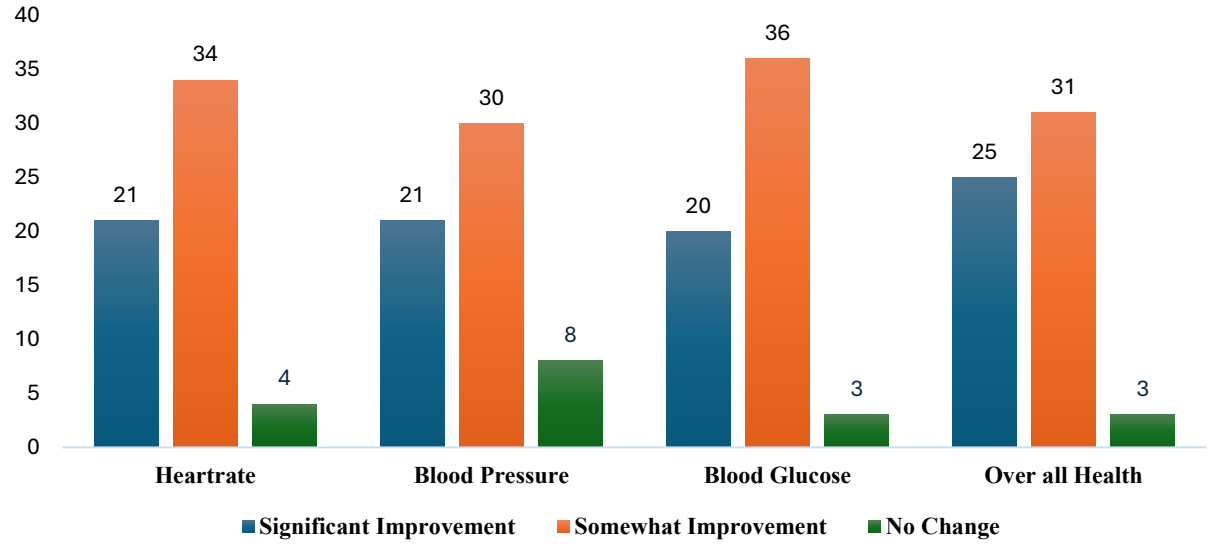

Fig 19: Health Improvements after Smart watch usage (Diagnosed Group)

These findings suggest that users with existing health conditions commonly view smartwatch usage as beneficial for various health outcomes, especially in managing heart rate, blood pressure, and blood glucose levels. The relatively high "somewhat improvement" percentages may reflect that while users acknowledge these benefits, they may experience them as gradual or incremental rather than immediate.

Response from Normal/ Fitness Users:

For normal/fitness smartwatch users (n = 68), the perceived health impacts were also largely positive, though with some differences compared to the patient group. In heart rate monitoring, 88.2% of respondents reported improvement, with 39.7% indicating significant improvement and 50.0% somewhat improvement, while 10.3% reported no change. Blood pressure control showed slightly lower perceived benefits, with 36.8% reporting significant improvement and 45.6% somewhat improvement, leaving 17.6% observing no change. In blood glucose monitoring, 39.7% indicated significant improvement and 42.6% somewhat improvement, with 17.6% noting no change. Regarding overall health, 39.7% reported significant improvement and 55.9% somewhat improvement, with only 4.4% seeing no change.

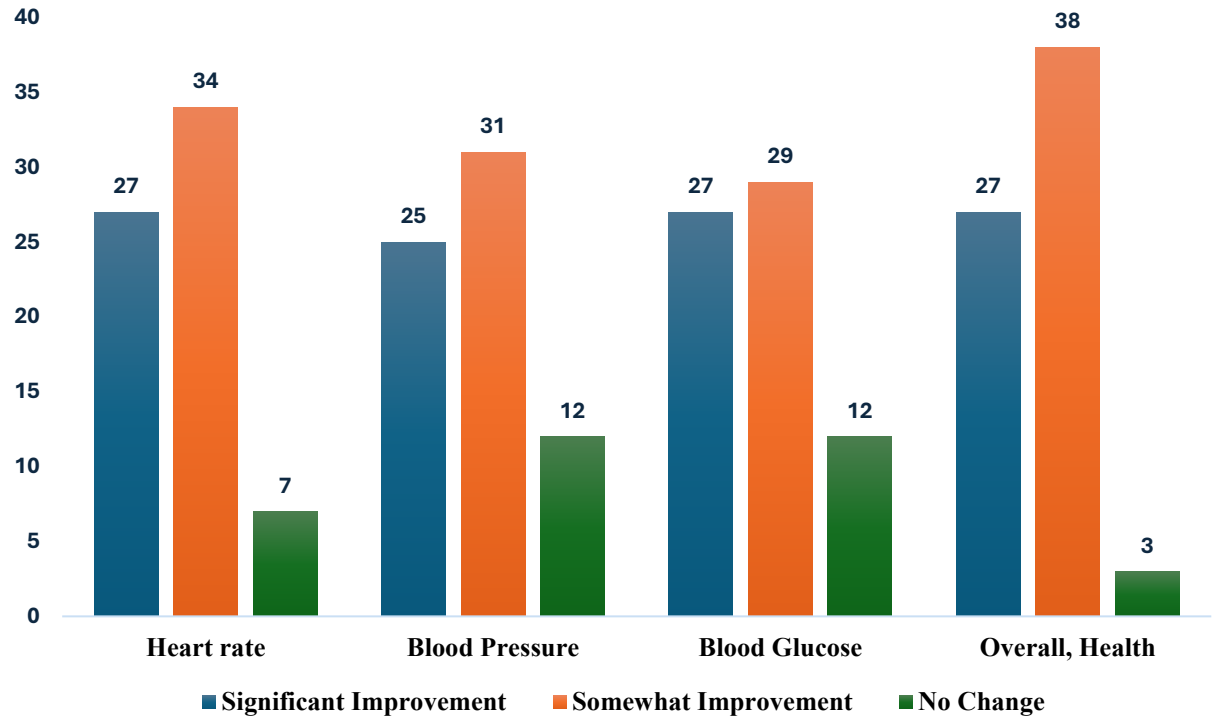

Fig 20: Health Improvements after Smart watch usage (Heathy Group)

Overall, these results suggest that healthy smartwatch users also perceive clear benefits from health tracking features, particularly in heart rate monitoring and overall health. However, the proportion of "no change" responses was consistently higher than in the patient group, especially for blood pressure and blood glucose, possibly reflecting that individuals without chronic conditions may have fewer noticeable health changes to track over time.

Table 15: Health Improvements after Smart watch usage (Both groups)

HEALTH METRICS	SCALE	Users with Pre-existing Health conditions		Normal/ Fitness Users	
		No of Respondents	Percentage	No of Respondents	Percentage
HEART RATE	Significant Improvement	21	35.6%	27	39.7%
	Somewhat Improvement	34	57.6%	34	50.0%
	No Change	4	6.8%	7	10.3%

BLOOD PRESSURE	**Significant Improvement**	21	35.6%	25	36.8%
	Somewhat Improvement	30	50.6%	31	45.6%
	No Change	8	13.6%	12	17.6%
BLOOD GLUCOSE	**Significant Improvement**	20	33.9%	27	39.8%
	Somewhat Improvement	36	61.0%	29	42.6%
	No Change	03	5.1%	12	17.6%
OVERALL, HEALTH	**Significant Improvement**	25	42.4%	27	39.8%
	Somewhat Improvement	31	52.5%	38	55.8%
	No Change	03	5.1%	3	4.4%

Interpretation: When compared, Users with Pre-existing health conditions tended to report slightly higher rates of significant improvement across most health outcomes, possibly due to greater baseline health challenges and therefore more noticeable gains from smartwatch use. In contrast, healthy users, while still reporting substantial benefits, often rated their changes as "somewhat" rather than "significant," suggesting that improvements for this group may be more incremental and preventive in nature rather than corrective.

Objective 3:

Q.7. Smartwatch use helped to reduce stress and improve Mental well-being

Response from Participants with Pre-existing Health Conditions:

Among Users with pre-existing health condition group, the majority expressed a positive perception of the smartwatch's role in supporting mental well-being. Specifically, 10.2% (n = 6) strongly agreed and 55.9% (n = 33) agreed with the statement, suggesting that two-thirds of participants identified benefits related to stress relief or mental well-being. Only 11.9% (n = 7)

disagreed, and none selected “strongly disagree,” highlighting that negative perceptions were minimal. An additional 22% (n = 13) maintained a neutral position, indicating uncertainty or a limited perceived effect. This distribution indicates that, for the majority of patients, using a smartwatch correlates with some degree of enhancement in mental well-being, although for a significant number, the impact may be slight or unclear.

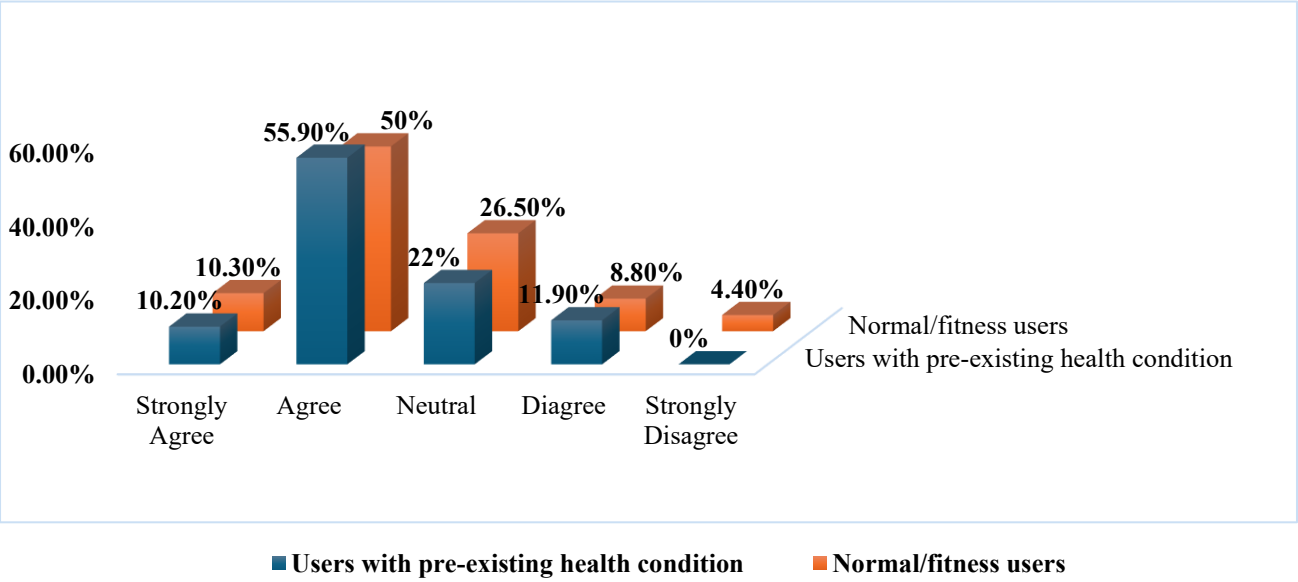

Fig 21: Improvement in Mental Health (Both groups)

Table 16: Improvement in Mental Health (Both groups)

Users with Pre-Existing Health Conditions			Normal /Fitness Users	
SCALE	**NO OF RESPONDENTS**	**PERCENTAGE**	**NO OF RESPONDENTS**	**PERCENTAGE**
Strongly Agree	06	10.20%	07	10.30%
Agree	33	55.90%	34	50.00%
Neutral	13	22.00 %	18	26.50%
Disagree	07	11.90%	06	8.80%
Strongly Disagree	0	00.00%	03	4.40%
TOTAL	**59**	**100%**	**68**	**100%**

Within the normal/fitness user group, 50.0% of the participants (n = 34) expressed that using a smartwatch contributed to stress alleviation or enhanced their mental health, whereas 10.3% (n = 7) strongly agreed. This suggests that approximately 60% of healthy individuals experienced

at least some mental health benefits. However, a considerable portion (26.5%, n = 18) remained neutral, suggesting ambivalence or limited perceived impact. Negative responses were also slightly more evident in this group compared to patients, with 8.8% (n = 6) disagreeing and 4.4% (n = 3) strongly disagreeing.

Interpretation:

In comparison, both groups showed a mostly positive perspective, but users with pre-existing health conditions, reported a stronger perception of mental well-being benefits (66.1% positive vs. 60.3% for normal/fitness users). Simultaneously, healthy users exhibited greater levels of neutrality and disagreement, indicating that although the smartwatch may provide stress management assistance, its psychological effects seem to be more significant and appreciated by those dealing with diagnosed health conditions.

4.7. OBJECTIVE 4: General User satisfaction with Smartwatch features:

Q.8. General User satisfaction with Smartwatch features:

Smartwatch satisfaction among users with pre-existing health conditions was predominantly positive, with more than 90% indicating they were satisfied or very satisfied with their user-friendliness and overall health benefits. Comfort and design were also positively rated, whereas battery life indicated comparatively lower satisfaction, with about one-fifth expressing neutral opinions. Dissatisfaction was minimal across all features, signifying a generally overall positive user experience.

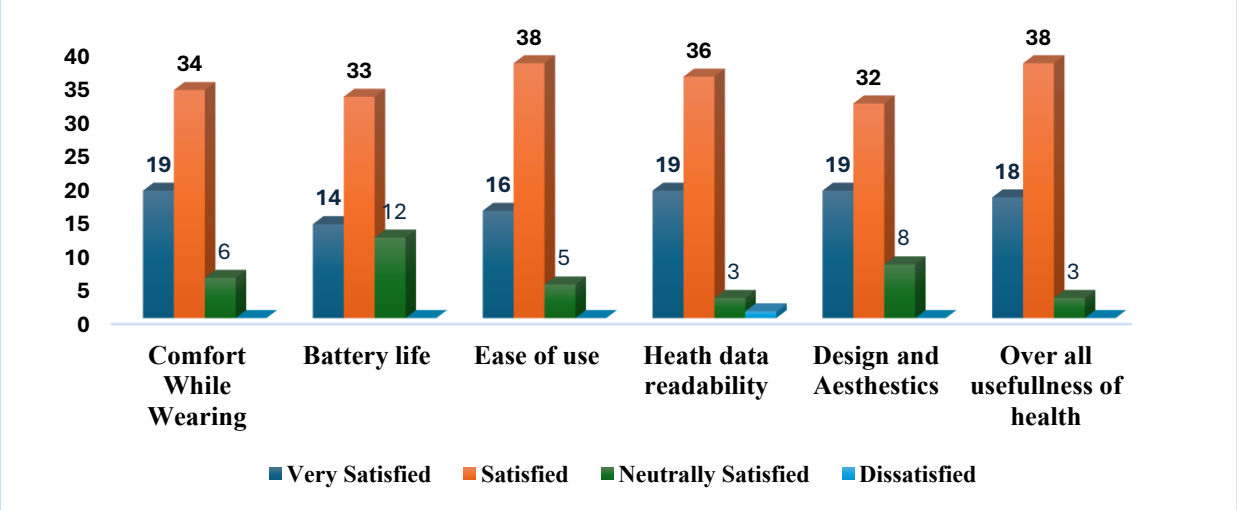

Fig 22: User satisfaction (Diagnosed group)

For normal/fitness users, satisfaction was significantly high, especially regarding ease of use, overall health benefits, comfort, and design, with more than 90% expressing positive ratings. Battery life again received slightly lower satisfaction, with more neutral responses compared to other features. Dissatisfaction was minimal, highlighting broadly favorable perceptions of smartwatch usability and value.

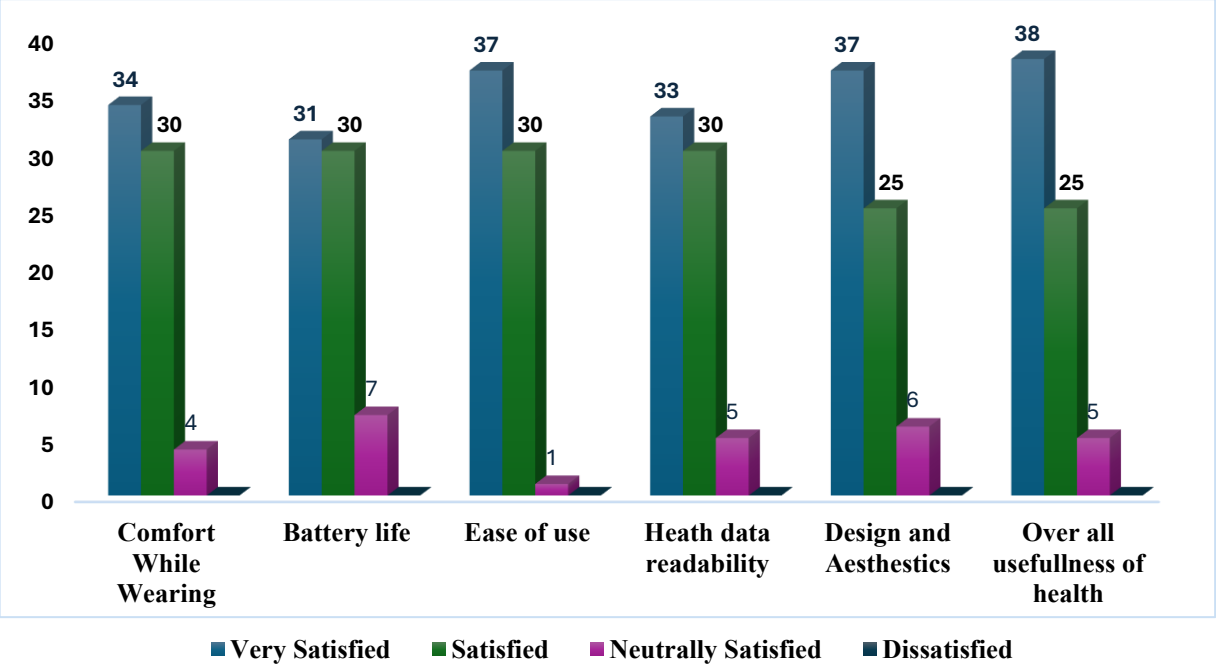

Fig 23: User satisfaction (Healthy group)

Table 17: User satisfaction (Both groups)

CATEGORY	SCALE	Users with Pre-existing Health conditions		Normal/ Fitness Users	
		No of Respondents	Percentage	No of Respondents	Percentage
COMFORT WHILE WEARING	Very Satisfied	19	32.2%	34	50.00%
	Satisfied	34	57.6%	30	44.10%
	Neutrally Satisfied	6	10.2%	04	5.90%

	Dissatisfied	0	0.0%	0	0.0%
BATTERY	**Very Satisfied**	14	23.8%	31	45.60%
	Satisfied	33	55.9%	30	44.10%
	Neutrally Satisfied	12	20.3%	07	10.30%
	Dissatisfied	0	0.0%	0	0.0%
EASE OF USE	**Very Satisfied**	16	27.1%	37	54.4%
	Satisfied	38	64.4%	30	44.1%
	Neutrally Satisfied	05	8.5%	1	1.5%
	Dissatisfied	0	0.0%	0	0.0%
HEALTH READABILITY	**Very Satisfied**	19	32.2%	33	48.5%
	Satisfied	36	61.0%	30	44.1%
	Neutrally Satisfied	03	5.1%	5	7.4%
	Dissatisfied	01	1.7%	0	0.0%
DESIGN & AESTHETICS	**Very Satisfied**	19	32.2%	37	54.4%
	Satisfied	32	54.2%	25	36.8%
	Neutrally Satisfied	08	13.6%	6	8.8%
	Dissatisfied	0	0.0%	0	0.0%
OVERALL, USEFULLNESS FOR HEALTH	**Very Satisfied**	18	30.5%	38	55.9%
	Satisfied	38	64.4%	25	36.8%
	Neutrally Satisfied	03	5.1%	05	7.3%
	Dissatisfied	0	0.0%	0	0.0%

Interpretation:

Overall satisfaction with smartwatch features was consistently high across both patients and normal/fitness users. Ease of use, overall usefulness for health, comfort, and design were the most positively rated aspects, with over 90% of respondents in both groups expressing satisfaction. Battery life, while still generally well-rated, drew comparatively more neutral responses, suggesting it as a minor limitation. Importantly, dissatisfaction across all features was rare, highlighting generally positive user experiences and the acceptance of smartwatches for health and lifestyle uses. Thus, the Findings highlight that smartwatches are broadly accepted and valued by both patients with diagnosed health conditions and fitness-oriented users. While minor usability concerns such as battery performance remain, the overall satisfaction levels reinforce the role of smartwatches as effective, user-friendly, and motivating tools for health management and daily activity support.

4.8. Objective 5: Demographic and Health Status Differences in User Feedback

The following information fulfils the objective 5 by analysing user feedback by demographics and health status:

Age: Younger adults (25–34 years) constituted the largest user group (42%), followed by 18–24 years (19.3%) and 35–44 years (18.7%). Smartwatch adoption was therefore most prevalent among young and middle-aged adults, with limited uptake among older users (≥55 years, 8%). Younger respondents tended to report higher motivation and lifestyle changes from smartwatch use compared to older participants.

Gender: The sample was relatively balanced (50% female, 47.3% male). No major differences were found between genders in perceptions of accuracy, usefulness, or satisfaction, suggesting smartwatch benefits are consistent across both groups.

Health Status: Among 127 smartwatch users, 59 (46.5%) reported a diagnosed health conditions while 68 (53.5%) reported they do not have any pre-existing health conditions.

Users with health conditions were more likely to value clinical features such as heart monitoring, reminders, and health data readability, reporting higher lifestyle changes and health management improvements. While Normal/fitness users emphasized motivation for physical

activity and fitness goals, though their feedback showed slightly more neutral or mixed ratings for clinical health metrics (e.g., blood pressure, blood glucose).

Overall, both groups reported positive smartwatch experiences, but users with health conditions group viewed them more as tools for health management, while normal/fitness users saw them as tools for motivation and lifestyle enhancement.

4.9. THEMATIC ANALYSIS OF QUALITATIVE FINDINGS

Introduction:

In addition to the quantitative analysis, this research included a qualitative aspect to gain a deeper understanding of users' experiences with FDA/CE-approved smartwatches. For this purpose, three open-ended questions were asked to both sets of respondents: users with health conditions and users from the normal/fitness group. The questions were designed to explore (i) any health changes or improvements noticed after smartwatch use, (ii) motivations for regularly using the smartwatch for health or fitness, and (iii) the ways in which the smartwatch has positively impacted health habits.

This qualitative analysis provides a deeper insight into user viewpoints that emphasizing individual experiences, motivations, and perceived health benefits. Thematic analysis was employed to recognize common themes, perspectives, and experiences throughout the responses. Themes were created to highlight both the benefits of smartwatch use and the challenges and limitations mentioned by participants.

RESPONSES FROM USERS WITH PRE-EXISTING CONDITIONS:

Initially, the feedback from users with health conditions was analyzed. Their observations were categorized and structured into themes, which are outlined in the next section. These themes offer insight into how patients view FDA/CE-cleared smartwatches regarding health management, lifestyle control, and mental wellness.

Key Themes Identifies are:

1.Health Monitoring and Clinical Support:

FDA/CE-cleared Smartwatches are widely valued for monitoring vital signs (heart rate, blood pressure, glucose, SpO_2, stress levels, and sleep etc.,) and supporting in medical consultations. Several users reported early detection of irregularities (e.g. abnormal resting heart rate), which prompted timely medical intervention.

Examples:

"The watch showed changes in my resting heart rate. It made me book a check-up and we caught a problem early."

"I can show my doctor my heart rate and step history right from the app."

Sub-themes: Disease Management, Early detection of disease and Sharing data with healthcare providers.

2. Motivation for physical activity and lifestyle changes:

FDA/CE-cleared Smartwatches offered alerts and encouragement for physical activity, tracking steps, and maintaining daily movement routines. The visual tracking of progress (calories, steps, heart rate, sleep data) reinforced healthier routines.

Examples:

"Daily step count keeps me moving."

"I feel energetic and active since I started jogging with the help of smartwatch."

Sub-themes: Increased physical activity and exercise consistency, Weight loss and calorie control and Awareness of sleep habits and improvement in sleep quality.

3. Reminders, Routine, and Self-Management:

Reminders for medication, hydration, movement, and rest were especially valued by users managing chronic conditions. This theme overlaps with memory support, where some users used the FDA/CE-cleared smartwatch as a tool to manage their cognitive impairment.

Examples:

“It reminds me to take medications, do exercises and so on.”

“I can’t remember my important tasks without its help.”

Sub-themes: Medication adherence, Hydration and nutrition reminders, and Cognitive support for memory loss.

4. <u>Psychological and Emotional Benefits:</u>

Users reported reduced anxiety, better stress control, increased confidence, and a feeling of safety from smartwatch use. The confidence from fall detection, health notifications, and stress/mindfulness tracking helped patients feel mentally supported.

Examples:

“Knowing my watch can detect irregular heart rates, oxygen deprivation gives me peace of mind.”

“The stress and mindfulness tracking features help me slow down and be more present.”

Sub-themes:

Mental wellbeing (reduced stress and anxiety), Safety reassurance (fall alerts, irregular heart rate alerts), and sense of control and confidence.

<u>5. External Influence and Adoption Factors:</u>

The adoption and consistent use were frequently associated with recommendations from doctors, advice from physicians, or support from family and friends. Although certain patients started using smartwatches because of their appearance or interest, ongoing usage was motivated by health benefits.

Examples:

“My doctor advised me to use.”

“It was gifted by my brother.”

6.Mixed or Neutral Experiences:

Not all users reported improvements. Some mentioned concerns regarding accuracy, challenges in data interpretation, or technical issues. Several respondents indicated no significant health changes despite usage.

Examples:

"I've lived fine without it. I don't trust it to tell me something a doctor wouldn't."

"It tells me my steps, but that doesn't mean much to me. I don't feel motivated just because a screen says so."

Thematic analysis summary of users with pre-existing conditions:

In general, Users with health conditions emphasized the diverse effects of FDA/CE- cleared smartwatches on well-being. The greatest advantages were in managing diseases, monitoring cardiovascular and metabolic health, regulating lifestyle, and enhancing psychological wellbeing. Smartwatches aided patients in increasing their activity levels, following routines, and feeling more secure about their health condition. The responses illustrate how FDA/CE-cleared smartwatches function as both preventive health tools (detecting irregularities, promoting exercise) and daily management aids (reminders for medication, hydration, and sleep). Importantly, the psychological benefits of confidence, stress reduction, and safety extended beyond physical health. However, not all patients perceived equal value — a minority reported technical barriers, concerns, or lack of improvements, highlighting that while smartwatches offer promising health benefits, their effectiveness can vary depending on individual trust, usability, and medical circumstances.

RESPONSES FROM NORMAL/FITNESS USERS:

Following the analysis of patient responses, the same three open-ended questions were examined for the normal/fitness user group. Thematic analysis was again applied to identify key patterns, focusing on how FDA/CE-cleared smartwatches influenced their fitness routines, lifestyle habits, and overall health perceptions. The findings below present the themes that emerged from this group, allowing comparison with those of users with medical conditions.

Key Themes Identifies are:

1.Fitness, Exercise and Physical Activity Motivation:

Smartwatches primarily functioned as motivators for workouts, step counts, and calorie tracking. Users appreciated the accountability provided by goals, activity rings, and daily feedback, which helped them maintain consistent exercise routines.

Examples:

"I've become way more consistent with my workouts since I can track progress daily."

"It motivates me to hit my step and calorie burn goals every day."

"Exercise heart rate zones help optimize workouts and track cardiovascular improvements."

Sub-themes:

Exercise consistency and structured workouts

Step counts and daily activity reminders

Calorie tracking and weight loss

Increased energy and reduction in sedentary time.

2. Lifestyle regulation and routine building:

Normal/Fitness users emphasized that smartwatches aided them in creating and sustaining healthy habits by offering reminders, prompting schedules, and tracking daily progress.

Examples:

"It really helps me keep control of my daily routine."

"The smartwatch has most positively impacted my health habits by keeping me consistently active through step goals and reminding me to move throughout the day."

"Not major changes but I'm doing my routine properly."

Sub-themes:

Enhanced daily schedule and organization

Consistent exercise, sleep, and hydration practices

Tracking meals and mindful calorie consumption

3. Psychological Benefits:

Smartwatches were valued for their contribution to mental health assistance, stress relief, and enhancements in sleep quality. Multiple users reported experiencing increased relaxation, mindfulness.

Examples:

"My stress levels are reduced."

"Tracking my sleep has been eye-opening. I've improved my bedtime routine and started getting more consistent rest."

"The stress and mindfulness tracking features help me slow down and be more present."

Sub-themes:

Improved sleep patterns and recovery awareness

Stress reduction through breathing/mindfulness reminders

Mental wellbeing (peace of mind, motivation, reduced anxiety).

4. Self-Monitoring and Awareness

Users valued the real-time health monitoring features (steps, heart rate, calories, sleep, VO_2 max) that provided them with increased insight and control over their fitness journey.

Examples:

"I feel more in control of my health data."

"It gives me peace of mind monitoring my health."

"Viewing long-term trends in heart rate, fitness level, or sleep helps me stay engaged."

Sub-themes:

Self-awareness of activity and fitness levels

Data-driven decision-making for workouts and diet

Progress tracking and motivation through feedback.

5.Style, Technology, and Adoption Factors:

Beyond health, smartwatches were frequently linked to fashion, luxury, and interest in new technology, impacting their adoption and consistent use.

Examples:

"I use smart watch for stylish look and as well as for fitness."

"Initially I bought for my stylish appearance, now it is useful for my fitness also."

"I bought it for exploring new technology."

Sub-themes:

Dual motivation: health + style

Appeal of modern technology

Influence of branding/advertisement.

6. Mixed or Neutral Experiences

Not all users experienced strong benefits. A minority reported no significant health changes, irregular usage, or concerns regarding data accuracy.

Examples:

"I'm not using regularly, so I haven't seen any changes."

"It tracks my steps, but it doesn't really feel like it matters."

"No significant changes seen."

Sub-themes:

Inconsistent usage limiting benefits

Limited perceived impact

App overload or complexity as barriers.

Thematic analysis summary of Normal/Fitness users (Healthy group):

For Normal/fitness users, smartwatches acted as fitness motivators, lifestyle regulators, and self-tracking tools. The most significant reported impacts included more consistent exercise, enhanced daily habits, effective calorie/weight control, improved sleep, and reduced stress. The psychological benefits of accountability, motivation, and peace of mind also stood out.

Compared with users with medical conditions, this group placed greater emphasis on fitness, exercise goals, and physical appearance, while still recognizing benefits in mental health and wellbeing. However, a smaller proportion expressed neutral or minimal changes, often due to inconsistent usage or lack of deeper engagement with the features.

Summary:

Overall, the findings suggest that FDA/CE-cleared smartwatches serve as comprehensive health supportive tool:

For users with health conditions, they act as preventive and supportive healthcare tool.

For normal/fitness users (healthy users), they act as motivational and lifestyle enhancement tools.

Together, these perspectives demonstrate that while the core technology is the same, its value is shaped by user context, goals, and engagement, making smartwatches both healthcare facilitator and fitness motivators in everyday life.

CHAPTER 5

5.1. Conclusion:

This research aimed to evaluate user feedback on the effectiveness of FDA/CE-cleared smartwatches from a health perspective in Ireland, employed a mixed-methods cross-sectional approach. The research involved 150 participants, comprising 127 FDA/CE-cleared smartwatch users, and explored perceptions of device accuracy, motivational influence, health outcomes, usability, and demographic differences. By integrating quantitative survey data with qualitative insights, this study provides a holistic view of how these devices are used and valued within the Irish population.

The findings suggest that FDA/CE-cleared smartwatches are widely accepted as reliable, motivating, and beneficial tools for both health management and lifestyle enhancement. Users extensively reported satisfaction with device accuracy, usability, and comfort, while also recognizing the role of smartwatch features in motivating healthier behaviours. Importantly, perceived benefits were shaped by users' health status: Users with health conditions emphasized the value of monitoring and disease management, while healthy users highlighted fitness, motivation, and lifestyle regulation.

The first objective, focused on accuracy and health monitoring, revealed a strong level of trust in the ability of smartwatches to track heart rate, blood oxygen levels, ECG, sleep, and stress. Although minor doubts were expressed, no participants viewed the devices as highly inaccurate, demonstrating overall confidence in FDA/CE-cleared devices.

The second objective explored the impact on motivation, showing that alerts, reminders, and tracking features motivated both unhealthy and healthy people to adopt healthier behaviours. While fitness features were strongly appreciated across groups, but sleep tracking features received neutral or negative perceptions from some healthy users.

The third objective focused on perceived health outcomes, Users with health conditions indicating enhancements in heart rate and blood pressure regulation, blood glucose control, and general disease management. Healthy individuals, on the other hand, emphasized improvements in fitness, reduced stress levels, and enhanced management of daily activities. Both groups identified psychological reassurance and peace of mind as meaningful benefits.

The fourth objective evaluated user satisfaction, which was exceptionally high in terms of usability, comfort, and perceived health benefits. Only battery life generated noticeable neutrality, though even here dissatisfaction was minimal.

The fifth objective examined differences in demographics and health status, revealing that smartwatch usage is predominantly seen in younger adults, while older individuals exhibit minimal adoption. Differences in gender were minimal, but health status strongly influenced perceptions: users with health conditions considered smartwatches as helpful health monitoring tool, whereas healthy individuals viewed them mainly as motivational and fitness tools.

The qualitative analysis provided richness by capturing real-world experiences. Users with medical conditions viewed smartwatches as essential for tracking chronic illnesses, aiding in medication compliance, and reducing stress relief. A minority of respondents expressed limited perceived impact, uncertainty about data accuracy and technological barriers, yet overall feedback remained strongly positive.

In conclusion, the research shows that FDA/CE-approved smartwatches serve a dual function:

For Users with medical conditions, they serve as supportive healthcare tool, aiding in disease management and offering emotional comfort.

For healthy users, they serve as motivational lifestyle enhancement tool, encouraging fitness, routine-building, and wellness optimization.

Although there are limitations in sleep tracking accuracy and battery life, the vast majority of participants expressed satisfaction and trust in the devices. FDA/CE-cleared smartwatches therefore represent a significant step in the integration of digital health technologies into everyday life, offering both preventive and supportive health benefits in Ireland.

5.2. Recommendations:

According to the findings, several recommendations can be made for health care practice, policy and technology development.

<u>Recommendations for Healthcare practice:</u>

Integration into Chronic Disease Management: Smartwatches should be considered as supportive tools in managing patients with heart conditions and diabetes. Their monitoring

capabilities may aid in the early identification of irregularities and improve patient self-management.

Patient Education and Training: Healthcare professionals should guide patients on proper usage, understanding of readings, and incorporating smartwatch data into clinical decision-making to prevent overreliance or misinterpretation.

Doctor–Patient Interaction: Smartwatch data could be incorporated into consultations, allowing for more personalized and data-informed healthcare interactions.

Recommendations for Public Health and Policy:

Focusing on Elderly people: Engagement among older adults stays minimal, even though they could gain significant advantages from health tracking. Health campaigns and training programs could bridge this gap.

Equity of Access: Policymakers should explore strategies to make smartwatches more affordable and accessible, reducing the digital divide in healthcare technology.

Incorporation into Preventive Health Initiatives: Smartwatches could support national efforts to encourage people to do physical exercise, minimize stress, and enhance preventive health services, aligning with broader public health goals.

Recommendations for Technological Development:

Improved Sleep Tracking: Manufacturers should invest in enhancing the accuracy and utility of sleep-monitoring features, given the mixed user experiences in this area.

Battery Life Improvement: Enhancing battery efficiency would increase satisfaction and usability among users, especially for ongoing health monitoring.

Personalization of Health Alerts: Providing more personalized health alerts could improve user engagement and reduce alert fatigue.

5.3. Limitations and Directions for future Research:

Although this study provides valuable insights into the effectiveness of FDA/CE-cleared smartwatches in Ireland, it is important to acknowledge its limitations and identify areas where additional research can expand on its findings.

One limitation is the smaller sample size; it reduces the generalizability of the results to the broader Irish population, so future research with larger groups is necessary to validate and expand upon these findings. In addition, while all devices examined were FDA/CE-cleared, participants used a various smartwatch brands and models, each with differing levels of functionality, accuracy, and usability, making it difficult to isolate feedback related to specific devices. Ultimately, although this study emphasized numerous perceived advantages of smartwatch usage, it did not capture in detail the challenges and limitations. These gaps suggesting the need for a more balanced exploration of both positive and negative experiences of smartwatch usage.

These limitations point toward important avenues for future research. Longitudinal studies are required to determine whether self-reported improvements translate into measurable clinical outcomes over time. Comparative validation studies that directly compare smartwatch data with medical-grade devices would enhance trust in their clinical reliability. Finally, targeted studies on older adults could help identify barriers and facilitators to adoption among populations most likely to benefit from health-monitoring technologies.

5.4. Final Reflection:

This study highlights the growing role of FDA/CE-cleared smartwatches in bridging the gap between personal health management and formal healthcare systems. While not a substitute for medical care, FDA/CE-cleared smartwatches are valued by users for their accuracy, motivational influence, and contribution to well-being. For users with medical conditions, they serve as supportive healthcare tool and aid in managing chronic health conditions; for healthy users, they act as catalysts for healthier lifestyles.

By addressing both clinical and wellness needs, FDA/CE-cleared smartwatches represent the potential of digital health innovation supporting individuals, complementing healthcare systems, and advancing public health goals in Ireland.

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APPENDIX

SURVEY QUESTIONNAIRE

An Evaluation of User Feedback on the Effectiveness of Smartwatches from a Health Perspective in Ireland

You are invited to take part in a research study led by AARADANA KANAKARAJ, a post graduate student in the MSc in Medical Device Technology and Business program at Griffith College, Dublin. The purpose of the research is to collect users' feedback on the health-related effectiveness of FDA/CE-cleared smartwatches in Ireland.

Participation in this study is entirely voluntary, and you have the right to refuse or withdraw at any point before submitting your answers, without incurring any penalties or negative consequences. If you decide to participate, you will need to fill out a brief online survey, which will take around 20 minutes. Make sure to read each question thoroughly before providing your answers.

Your responses will be kept anonymous and confidential. No personal information like your name, email, or IP address will be gathered. The survey questions will be about your perspectives on the health-related effectiveness of FDA/CE-cleared smartwatches. And among the questions, you will be asked whether you have any diagnosed health conditions, and if applicable, to select the type(s) of condition (e.g., heart disease, diabetes, mental health). These questions are optional, and you may choose "Prefer not to say" if you do not wish to disclose the information.

All information given will be utilized solely for academic purposes and will be kept safe in compliance with GDPR and ethical research guidelines. By proceeding to the next page, you acknowledge that you comprehend the study's nature and consent to take part.

Section 1: Consent and Demographics

1. Do you consent to participate in this survey?

a. Yes

b. No

(Saying 'Yes' takes you to survey)

2. What is your age group?

a. 18 – 24

b. 25 – 34

c. 35 – 44

d. 44 – 54

e. 55 – 64

f. 65 or older

3. What is your Gender?

a. Male

b. Female

c. Non-binary/ third gender

d. Prefer not to say

4. Do you currently use an FDA/CE-cleared smartwatch?

a. Yes

b. No

5. How long have you been using your FDA/CE-cleared smart watch?

a. Less than 3 months

b. 3 – 6 months

c. More than 6 months

d. More than 1 year

6. What is the model of the FDA/CE-cleared smartwatch do you currently use?

   a. Apple watch series

   b. Samsung Galaxy watch

   c. Fitbit Sense

   d. Withings Scan Watch

   e. Others

7. How often do you use your smartwatch?

   a. Daily

   b. Several times a week

   c. Once a week

   d. Rarely

   e. A few times a month

8. Do you currently have any diagnosed health conditions?

   a. Yes (Skip question 10 and move to section 2)

   b. No (Skip question 9 and continue with question 10)

   c. Prefer not to say (Skip question 9 continue with question 10)

9. If yes, which of the following chronic conditions do you have?

   a. Heart conditions

   b. Diabetes

   c. Obesity

   d. Mental health conditions (eg; anxiety, depression)

e. Others

f. Not applicable

g. Prefer not to say

10. Would you describe yourself as a fitness or gym enthusiast?

a. Yes

b. No

Section 2: Effectiveness in tracking health metrics

11. How would you rate the accuracy and usefulness of your smartwatch in tracking the following health metrics? (Heartrate, Blood Oxygen saturation levels, ECG, Physical activity, Sleep habits, Stress levels)

a. Very accurate

b. Somewhat Accurate

c. Neutral

d. Somewhat Inaccurate

e. Very Inaccurate

Section 3: Impact on Motivation to adapt healthier habits

12. The smart watch has encouraged me to increase physical activity.

a. Strongly agree

b. Agree

c. Neutral

d. Disagree

e. Strongly disagree

13. Heart monitoring features have motivated me to make lifestyle changes (e.g.: more exercise, less stress and proper sleep habits).

a. Strongly agree

b. Agree

c. Neutral

d. Disagree

e. Strongly disagree

14. Do you find that your smartwatch helps you manage or improve your sleep during the night?

a. Strongly agree

b. Agree

c. Neutral

d. Disagree

e. Strongly disagree

15. Smartwatch features like reminders and alerts helps me maintain healthier routines

a. Strongly agree

b. Agree

c. Neutral

d. Disagree

e. Strongly disagree

Section 4: Perceived Health Outcomes

16. Do you feel your smartwatch helps you manage your health better?

a. Yes, Significantly

b. Yes, Somewhat

c. Not really

d. Not at all

17. Since using the smartwatch, have you seen improvements in the following areas?

	Health Area	Significant improvement	Some Improvement	No Change
a.	Heart rate Control	☐	☐	☐
b.	Blood Pressure control	☐	☐	☐
c.	Blood glucose Control	☐	☐	☐
d.	Overall, Health	☐	☐	☐

18. Smartwatch use helped me reduce stress or improve my mental well-being.

a. Strongly agree

b. Agree

c. Neutral

d. Disagree

e. Strongly disagree

Section 5: User Satisfaction

19. How satisfied are you with the following aspects of your smartwatch?

Aspect	Very Satisfied	Satisfied	Neutrally Satisfied	Dissatisfied
a. Comfort while wearing	☐	☐	☐	☐
b. Battery life	☐	☐	☐	☐
c. Ease of Use	☐	☐	☐	☐
d.Health data readability	☐	☐	☐	☐
e. Design and Aesthetic	☐	☐	☐	☐
f. Overall usefulness for health	☐	☐	☐	☐

20. Do you face any challenges when using your smartwatch that you believe are related to your age group or gender or health status?

a. Yes

b. No

21. Would you recommend an FDA/CE-cleared smartwatch to others for health tracking?

a. Definitely Yes

b. Probably Yes

c. Not Sure

d. Probably No

e. Definitely No

22. Please describe any specific health changes / improvements you have noticed after smartwatch use?

23. What motivates you to regularly use your smartwatch for health or fitness?

24. In What ways has the smartwatch most positively impacted your health habits?

ETHICS APPLICATION & DECLARATION FORM

Innopharma education

GRIFFITH COLLEGE

Ethics Application & Declaration Form

DISSERTATION TITLE: An Evaluation of User Feedback on the Effectiveness of Smartwatches from a Health Perspective in Ireland.

RESEARCHER'S NAME: AARADANA KANAKARAJ

PROGRAMME OF STUDY: MSc in Medical Device Technology and Business

SUPERVISOR'S NAME: Dr. Javed Iqbal

DECLARATION:
The information in this application form is accurate to the best of my knowledge. I undertake to abide by the principles outlined by Innopharma/Griffith College ethics policy in my research dissertation. I confirm that I have completed a full ethics assessment for my research dissertation as per the college guidelines. I will not begin my primary research until such approval from my supervisor and/or ethics Committee has been obtained.
I pledge to carry out my research according to the Innopharma/Griffith College academic integrity standards. Any results presented in my dissertation will be from my own, original research, I will reference and/or acknowledge any material or sources used in its preparation and I will not plagiarise the work of anyone else.

For Student:
STUDENT SIGNATURE: (Aaradana Kanakaraj)

DATE: 10/07/2025

The research contained within this research dissertation proposal has been approved.

For Supervisor:
Ethics Committee Approval Required: Yes [ ] No [x]

SUPERVISOR SIGNATURE:

DATE: 10/07/2025

For Ethics Committee (if required):
Ethics Committee Approval Given: Yes [ ] No [ ]

ETHICS COMMITTEE MEMBER SIGNATURE:

DATE:

NOTE: Supervisors are responsible for ensuring their students fill in this form correctly and that all ethical areas have been considered.

SECTION 1: DESCRIPTION OF RESEARCH STUDY

1.1 **Purpose and objectives of research:**

Purpose: The Study of "An Evaluation of User Feedback on the Effectiveness of Smartwatches from a Health Perspective" has been selected due to the growing popularity of these health monitoring tools and their significant potential to influence personal health management. Smartwatches have evolved from mere lifestyle accessories into sophisticated health monitoring tools, leading to substantial growth in the consumer market. As the utilization of these health monitoring tools in the healthcare sector increases, it is crucial to evaluate their usability, dependability, and overall efficacy from the standpoint of the users. This analysis can provide significant understanding regarding the actual effects of these tools, their ability to enhance health outcomes, and the opportunities for further advancement and incorporation into healthcare practices.
This study evaluates and assesses the impact of smartwatches on enhancing health and wellness based on user feedback. Its main aim to assess user perceptions of the effects of smartwatches on their health and if these devices fulfill their health-related expectations. The findings from this research will be crucial in promoting wearable technology by identifying key aspects that need enhancement in user experience, data precision, and health results, aiding the development of smartwatches as an effective health monitoring tools in healthcare.

Objectives:

- To assess the effectiveness of FDA/CE-Cleared smartwatches in tracking important health metrics like heart rate, blood oxygen saturation levels, ECG, physical activity, sleep habits, and stress levels.
- To investigate how FDA/CE-Cleared smartwatch functionalities (e.g., alerts, reminders, fitness tracking) impact users' motivation to adopt healthier habits, including enhanced physical activity or better sleep patterns.
- To assess whether regular usage of FDA/CE-cleared smartwatches results in observable enhancements in users and patients' health outcomes, like improvements in disease management among cardiac and diabetic patients, such as improved heart rate control, better blood pressure regulation, blood glucose control, increased fitness levels, improved sleep quality, and better mental wellness.
- To evaluate general user satisfaction with the health-related features of FDA/CE-cleared smartwatches, encompassing usability, comfort, and perceived benefits.
- To assess differences in user feedback based on demographics (age, gender) and health status (healthy vs diseased).

1.2 **Research methodology:** This research is mainly based on a mixed method approach to gather and examine both quantitative and qualitative data. The study employs mainly of positivist research philosophy and due to the presence of a few open-ended questions, the research additionally includes some aspects of interpretivism. The primary data will be gathered via an online survey, created by using Google Forms, which will include demographic and Likert scale questionnaires to assess the users' feedback, experiences, motivation, and perceived benefits in smartwatch usage. The collected data will be analysed by using MS Excel for descriptive statistical analysis ensuring comprehensive understanding of the research aim.

The survey questionnaires are given below in appendix I.

SECTION 2: POSSIBLE ETHICAL ISSUES

Answer 'yes' or 'no' to the following questions.

SUBJECT MATTER

Does the research proposal involve:

Research into specific company activities that would be deemed sensitive or confidential	No
Research into politically and/or racially/ethnically and/or commercially sensitive areas	No
Sensitive, personal, professional or corporate issues	No

RESEARCH PROCEDURES

Does the research proposal involve:

Research that might damage the reputation of companies or participants	No
Research that may negatively affect the reputation of Griffith College/Innopharma	No

Use of personal records without consent	No
Use of company data without consent	No
The offer of any inducements to participate	No
Audio or visual recording without consent	No
Using a language other than English	No

PARTICIPANTS

Does the research proposal involve:

People who are not competent and/or fluent in English	No
Does your research group include any of the following vulnerable groups	No

(Adults with psychological impairments; Adults with learning difficulties; Adults under the protection/control /influence of others (e.g. in care/prison); Relatives of ill people (e.g. parents of sick children); Hospital or GP participants recruited in a medical facility; persons under the age of 18)

If you have answered NO to ALL questions, please go straight to Section 4.

If you have answered YES to ANY question in SECTION 2, you must fill in SECTION 3.

SECTION 3: STEPS TAKEN TO AVOID ETHICAL ISSUES

3.1. If your ethics relates to ***Subject Matter***, outline your action plan to work around any sensitive issues.

3.2. If your ethics relates to ***Research Procedures***, outline your action plan to deal with possible ethical issues in your research procedures.

3.3. If your ethics relates to ***Participants***, outline how you will protect vulnerable persons or those that do not have English as their first language.

SECTION 4: ABOUT YOUR PARTICIPANTS

4.1. Outline your participant profile and why you have chosen them for this:

The participants for this research will be adults aged 18 and above living in Ireland who have been using FDA/CE-cleared smartwatches for a minimum of 3months. Participants will consist of normal users, Fitness Enthusiasts, and those with chronic health conditions – particularly cardiac and diabetic patients who utilizes these smartwatches to track heart rate, ECG, blood oxygen levels, blood pressure, sleep monitoring, physical activity, and stress levels. This group has been chosen as they can provide direct and relevant experiences regarding the perceived effectiveness and real health-related outcomes of using smartwatches. Recruiting this group online is feasible and ethically appropriate, and no identifiable personal information will be gathered. Furthermore, this study will not access or utilize any clinical records or hospital-based information, thereby preserving ethical standards related to medical data privacy.

4.2 How do you plan to gain access to/contact/approach your participant(s).

I will utilize an online survey form like Google form to reach a broader participant base and I plan to distribute those survey forms through social media platforms like LinkedIn, forums, and fitness - related apps or communities. The survey link will be provided with detailed explanation of the study, purpose, what participation involves and a section for informed consent at the beginning of the survey. Participation will be completely voluntary and confidential.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

5.1 **Participant Information Letter (PIL) for participants**

The Participant Information Letter is given below in Appendix II.

Please confirm below that your information letter covers:

Description of the research topic and method	Yes
Details of what participation will involve	Yes
Rights to anonymity	Yes
Confidentiality	Yes
Rights to withdraw from the research	Yes

The contact details of the researcher and supervisor (if necessary) Yes

5.2 **Informed Consent Form (ICF) for participants**

Please indicate below if your research requires a signed consent form by selecting the relevant option only:

No: my research study involves an online survey only and/or does not require signed consent

SECTION 6: STORAGE OF DATA

6.1. How will you store the research data and for how long? How will you manage data protection issues?
All research information including gathered survey responses and documents related to analysis/findings will be stored securely in a password-protected Google Drive college account in an electronic device(laptop). Data will be kept securely, and it is utilized exclusively for academic purposes in line with institutional regulations. All the research data will be kept for a period of up to two years following the completion of study. After that all the data will be permanently deleted from the device. Participants will be notified of these measures in the Participant Information Letter to ensure transparency and ethical management of their data.

SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

7.1 **Non-Disclosure Agreement (NDA)**
Will the final dissertation contain any information pertaining to any source what would warrant the use of a Non-Disclosure Agreement (NDA) e.g. industry-based research?

No

7.2 **Student consent**
If a Non-Disclosure Agreement (NDA) is not required, does the Student consent to allow their completed dissertation to be held/published by Innopharma/Griffith College?

Yes

SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

8.1 **Viva Recording**
The Dissertation viva will be recorded. This recording may be used to facilitate assessment by Innopharma staff, a third reader if necessary and/or if requested by the external examiner for the Programme. The recording will be held in line with current GDPR guidelines and will not be made publicly available.

SECTION 9: DOCUMENT CHECKLIST

NOTE: Applicants must attach the following documents in electronic format to the appendix.

Which documents are added to the appendix? Please tick N/A if not applicable:

9.1 Participant Information Letter (PIL) for participant	Yes
9.2 Informed Consent Form (ICF) for participant	N/A
9.3 Questions/survey for interviewees/focus groups etc *(can be in draft form)*	Yes
9.4 Any other documents e.g. Non-Disclosure Agreement	N/A

I confirm that this application is complete, and all required documents are included in the appendix.

For Student:

STUDENT SIGNATURE:  (Aaradana Kanakaraj)

DATE:10/07/2025

PARTICIPANT INFORMATION LETTER

TITLE OF THE STUDY: An Evaluation of User Feedback on the Effectiveness of Smartwatches from a Health Perspective in Ireland.

I would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part.

WHO I AM AND WHAT THIS STUDY IS ABOUT

I am Aaradana Kanakaraj, pursuing an MSc in Medical Device Technology and Business at Griffith College, Dublin. I am conducting this research to evaluate the health-related effectiveness of smartwatches, particularly FDA/CE-cleared smartwatches in Ireland. This includes assessing users' experiences, motivation, and perceived benefits in smartwatch usage among different demographics.

WHAT WOULD TAKING PART INVOLVE?

The information gathered from this research will be crucial in assessing the use of FDA/CE-approved smartwatches for health monitoring and encouraging healthier living. Your answers will assist in determining which health-related features users perceive as most beneficial, how smartwatches influence behaviour (including enhancing physical activity, sleep, or managing illnesses), and how experiences differ among various user groups. This study aims to contribute to the growing body of research on digital health technologies and facilitate future advancement and utilization of smart health devices in managing personal health. The findings might also be presented in academic presentations, research publications, or conferences, yet all information will stay anonymous - no single participant will be recognized in any report or publication.

WHY HAVE YOU BEEN INVITED TO TAKE PART?

You are being asked to participate in this research because you are an adult (18 years or older) living in Ireland with experience using a smartwatch that has received FDA or CE clearance and includes health-monitoring features. Your insights are crucial for understanding how these devices influence users' health behaviours and outcomes in daily life.

DO YOU HAVE TO TAKE PART?

Participation in this study is entirely voluntary, and you have the right to refuse or withdraw at any point before submitting your answers, without incurring any penalties or negative consequences.

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

Participating in this study poses no major risks. The questionnaire is confidential, and no personal or sensitive details will be gathered. However, certain participants might experience slight discomfort when considering their health behaviours or conditions. If any question makes you feel uneasy, you can choose to skip it or leave at any moment. There are no direct personal benefits, but your involvement will provide useful insights on how smartwatches aid in promoting health and wellness. These results could enhance upcoming health technologies and guide research, or healthcare practices.

WILL TAKING PART BE CONFIDENTIAL?

Yes, your participation in this study will be entirely confidential and anonymous. The survey does not gather any personal information including your name, email address, or IP address. All responses will be kept safe and utilized solely for Academic purpose.

Since the research is survey based and will not involve interviews or recordings, there will be no collection of signed consent forms or personal audio information. Thereby assuring that confidentiality is never broken in this study.

HOW WILL INFORMATION YOU PROVIDE BE STORED AND PROTECTED?

All research information including gathered survey responses and documents related to analysis/findings will be stored securely in a password-protected Google Drive account in an electronic device(laptop). Data will be kept securely, and it is utilized exclusively for academic purposes in line with institutional regulations and kept in accordance with GDPR and Ethical research standards.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The findings from this study will be used solely for the completion of a master's dissertation within an MSc in Medical Device Technology and Business program at Griffith College Dublin. A copy of the completed dissertation will be provided to the college and made available in the Griffith College library. It might also be part of the college's digital repository or electronic journals, if applicable.

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

Name: Aaradana Kanakaraj

Contact: +353 894293003

Email ID: aaradana.kanakaraj@student.griffith.ie

[THANK YOU]