SPECIFIC AIMS

Breast cancer remains one of the most prevalent malignancies threatening the health of women both in the US and globally. In the US alone, one in eight women may develop breast cancer during their lifetime , with more than 3 million breast cancer survivors and more than $260,000$ new cases projected every year [7, 6, 2]. An estimated 8% of cancer patients are at risk of cardiotoxicity due to their treatment methods [6], necessitating an innovative approach to monitor symptoms and promote preventative health behaviors effectively. The proposed project aims to adapt an existing digital health system to provide integrated symptom monitoring and health lifestyle information support specifically tailored for cancer patients. This integration is crucial for the prevention of cardiotoxicity and further enhancing patients' quality of life by equipping them with knowledge and tools for proactive health management.

Specific Aim 1: Adapt and Refine the existing System for Cardiotoxicity Monitoring and Prevention

We will adapt the existing system, a LLM-powered communication system to support patient-provider communication, to focus on the needs of early diagnosis of cardiotoxicity. This adaptation will involve:

- Integrating clinician (estimated a total of 5 oncologists and cardiologists) and patient feedback (up to 15 patients) through a participatory design.
- Conducting formative research to ensure the system aligns with the needs of this patient group.
- Expanding system capabilities to capture and monitor physiological data.
- Providing targeted educational content on cardiotoxicity risks and prevention methods, leveraging existing guidelines and materials.

An iterative process of system evaluation will be utilized, first from physicians and then from cancer patients, to finalize a patient-centered solution.

Specific Aim 2: Design User-Centric Features and Interface

We will focus on creating accessible, intuitive system features and an interface that ensures high usability and patient engagement. By acknowledging the preferences and needs of patients at high risk of cardiotoxicity, the goal is to deliver an easy-to-use system that effectively provides critical information and tools for managing health.

Specific Aim 3: Conduct Pilot User Study

For 6 weeks, 15 patients that have recently take cancer treatment and have a high risk of cardiotoxicity will engage with the proposed system. This pilot study aims to evaluate:

- System usage patterns and user engagement.
- The feasibility of integrating the system into daily life.
- The system's immediate impact on health outcomes, including patient self-reported quality of life, patient activation score and awareness regarding cardiotoxicity, assessed using validated measures including the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30 [5]).

Metrics including adherence to symptom reporting, alerts issued, and engagement with educational content will be closely monitored. The System Usability Scale (SUS [3]) will be employed to quantitatively assess the system's usability from the patients' perspective. The Patient Activation Measures (PAM [4]) will be used to evaluate patient's knowledge, skills, and confidence in managing their health.

This comprehensive study will not only identify areas for further system improvement but also verify the system's effectiveness in enhancing patient engagement, increasing awareness, and potentially reducing the risk of cardiotoxicity. It aims to establish definitive evidence on the Talk2Care system's impact on specific health outcomes, providing a solid foundation for broader implementation.

A SIGNIFICANCE

A.1 Cardiotoxicity in Cancer Treatment: A Silent Threat

The nexus between cancer treatment and the resultant risk of cardiotoxicity presents a significant health challenge. It is estimated that up to 8% of patients receiving certain types of cancer therapies are at risk of developing cardiotoxicity, impacting their cardiac function and, consequently, their overall quality of life [6]. This issue underscores the crucial need for innovative monitoring and intervention strategies to mitigate these risks and enhance patient outcomes [1].

A.2 The Gap in Current Monitoring and Intervention Approaches

While current clinical practices involve regular monitoring of cardiac function in patients undergoing cancer treatment, there exists a notable gap in continuous, patient-centric monitoring, and intervention. Traditional methods often rely on periodic assessments that may not fully capture the dynamic nature of cardiotoxicity risk. Additionally, there is a lack of integrated systems that empower patients with information and tools to actively participate in preventing cardiotoxicity.

A.3 The Potential of Digital Health Solutions in Cardiotoxicity Prevention

Digital health technologies, especially those enabling symptom monitoring and health information delivery, hold vast potential in addressing the identified gaps in cardiotoxicity management. These solutions can offer continuous, real-time monitoring, personalized health information, and proactive intervention strategies, potentially transforming the landscape of cardiotoxicity prevention in cancer patients [8].

B INNOVATION

B.1 The Incorporation of Smartwatch Technology for Real-Time Biometric Data Collection

The proposed system introduces the innovative use of smartwatch technology to gather real-time biometric data including heart rate and electrocardiogram (ECG). This integration fosters an enriched narrative of the patient's state of health and advances the documenting of significant physiological changes.

B.2 Enhanced Daily System-Patient Interactions with Biometric Data

Daily check-ins not only provide a touchpoint for symptom inquiry and patient queries but are also enhanced with real-time biometric data. This enhancement allows the system to combine conversational information with physiological data to offer a more comprehensive understanding of the patient's health status. This synergistic approach presents a robust method to identify and track cardiotoxicity symptoms better.

B.3 Centralized Reporting and Data Analysis

The addition of a specialized clinician dashboard is another innovative feature. It provides a centralized, user-friendly interface for reviewing patients' interaction logs, symptom reports, and biometric data. This platform streamlines the complex data generated from various sources, facilitating a smooth data analysis process and providing critical insights into patient progress and health trends.

B.4 Amplified System-Clinician Communication through Integrated Dashboard

The proposed system facilitates seamless information sharing between the system and healthcare providers. With conversation summaries and symptom reports readily accessible via the clinician dashboard, providers

gain a clear and concise understanding of the patient's health status. This transparency fosters informed decision-making and the provision of timely and pertinent care, ultimately improving health outcomes.

B.5 Personalized Patient Engagement and Support Informed by Biometric Data

The system's innovative feature of utilizing real-time biometric data from smartwatch devices enhances its potential to offer personalized patient engagement. Patients who don't have enough biomedical knowledge are often confused about their symptoms and health status – whether it's normal or not. The system will be able to provide personalized feedback based on the patient's biometric data, assuring them about their normal symptoms and alerting them when necessary. Leveraging this data helps tailor engagement strategies, heightens the relevancy of interaction, and fosters improved patient adherence, affirming this proposed system as a beacon of innovation in the field of digital health.

C APPROACH

C.1 Rigor and Replicability in Research

To ensure scientific rigor and reproduce-ability, our proposed research will fully embrace open science practices. All protocols, collected raw data, and analysis codes will be publicly accessible after the study's completion. Additionally, every step of our study will be pre-registered on a comprehensive clinical trials registry.

C.2 Implementatino of the system

The system implementation will be participatory, combining system design and user experience enhancements with technical considerations. The system will be designed to facilitate easy patient-system communication while allowing for effective capture of relevant user metrics. A specialized dashboard will offer healthcare providers a clear report of patients' interaction summaries and symptom reports.

C.3 Pilot Usability Study and In-home Evaluation

This study will undertake a evaluation of the system's usability and real-world efficacy. Participants who meet our specific inclusion criteria (at least 18 y.o., have recently accepted cancer treatment) will be carefully selected through a validated recruitment and screening process. We'll ask clinicians to refer patients who meet the criteria to participate in the study. We'll randomlize them into two groups: one group, INTERVENTION, will use the system, and the other group, CONTROL, will use the tradional asynconous messaging method. Once recruited, the INTERVENTION group will engage with the system in their home environment over a period of four weeks, which serves as both the pilot usability study and the in-home evaluation phase.

Throughout this period, the system's functionality and user satisfaction will be extensively assessed using robust measures and tools. This dual-focused approach allows us to observe participants' interactions with the system during their after-treatment recovery and gather actionable data on health outcomes, usability, and overall satisfaction. Interim analyses at the midpoint of the trial will provide preliminary insights into the system's impact, guiding any necessary enhancements to optimize the user experience

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