ASSIST:

App Supported toxicity Surveillance using minimal Invasive wearables during Systemic cancer Treatment: A Pilot Study

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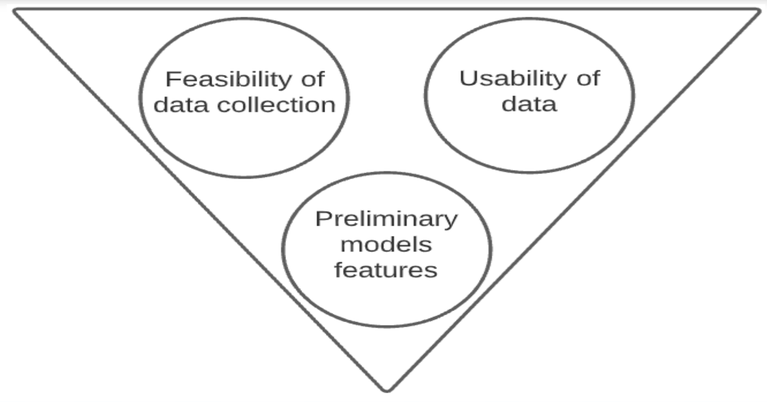
Background

- People treated for cancer are often exposed to highly toxic treatments.
- Treatment-induced toxicities can lead to adverse events.
- Routine symptom monitoring via a mobile app can decrease adverse events by enabling supportive care or dose reduction.
- Novel wearable sensor technology enables continuous measurement of physical and physiological functions, opening the door to identification of subclinical signs of toxicity which might be even more beneficial.

Aim



Methods

- Prospective pilot study with patients who start treatment receiving:
  - Chemoradiation therapy for advanced head and neck cancer
  - Targeted therapy for advanced melanoma.

Intervention

- Participating patients will be wearing a medical-grade biosensor (VitalPatch) as well as a consumer-grade activity monitor (Fitbit) for 12 weeks from the start of their treatment.
- During this period, data of bodily functions and physical activity, will be measured and collected in real-time (i.e., heart-rate, body-temperature, skin temperature, posture, step-count, ECG, heart rate variability, activity).
- During the same time period, patients will fill in PROMs via a mobile app or web page to self-monitor treatment toxicity.

Study Outcomes and Statistical Analysis

Primary study endpoints:

The primary endpoints will be summarized descriptively

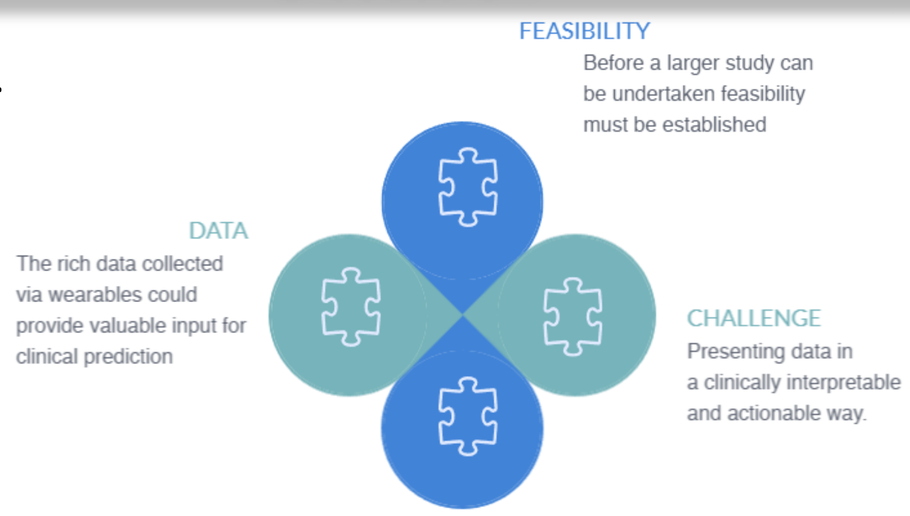
- Recruitment rate
- Patient adherence to Fitbit and VitalPatch wear-time
- Technical feasibility of continuous measurements (data loss).
- Patient retainment
- PRO-CTCAE adherence rate

Secondary study parameter: Machine learning models

1. Cleaning data
2. Development and usage of feature engineering approaches
3. Analysis of relationships of wearable data with the occurrence of adverse events
4. Generation of predictive models and analysis of these models

Discussion

- Patient inclusion will start 14 March 2022.



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