Understanding a Patient's Daily Experience Through Mobile Devices and Wearables

The MIPACT Study

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March 11, 2022

Disclosures

- The presenters' institution (University of Michigan) receives sponsored funding from PCORI, NIH, Apple, Blue Cross Blue Shield of Michigan, American Heart Association, Merck, and Becton Dickinson

- Sachin Kheterpal and other MIPACT co-investigators have held or may hold publicly traded Apple stock.

- No personal financial, consulting, or other relevant equity relationships

Overview

01	MIPACT Overview & Protocol Design
02	In-person vs all-remote Enrollment
03	Preliminary Inferences
04	The VALENTINE Study
05	THRIVE

01

Overview & Protocol Design

The MIPACT Study

- Goal: Understand how modern person-centered data may inform understanding of health, wellness, and disease trajectories.
- This study combines Apple Watch sensor data with blood pressure monitoring, survey data, health records, and genetic information.
- Sponsors: Apple, UM

The MIPACT Study Design

Phase 1 (45 day period)

Daily Tasks

Wear Apple Watch ≥12 hours per day

Take 2 sets of blood pressures per day

Complete breathing task 2 times per day

Requirements

Complete baseline surveys

Donate a blood sample

Protocol Completion

Basic Protocol Completion: Complete the tasks for at least 15 days

Compensation: Ownership of Apple Watch and blood pressure montitor

Comprehensive Protocol Completion: Complete the tasks for at least 30 days

Phase 2 (monthly periods)

Basic Protocol Completion

Wear Apple Watch ≥12 hours for 15 days

Take 1 set of blood pressures

Complete breathing task 1 time

Comprehensive Protocol Completion

Wear Apple Watch ≥12 hours for 15 days

Take 1 set of blood pressures for at least 3 weeks

Complete breathing task 1 time for at least 3 weeks

Surveys are administered on a quarterly basis and are required to receive study compensation.

MIPACT

16 months

6,765

Remote MIPACT

10 months

925

02

Recruitment and Enrollment

mipact
MICHIGAN PREDICTIVE ACTIVITY AND CLINICAL TRAJECTORIES

Recruitment and Enrollment Overview

Most recruitment tasks completed virtually

- Phone calls
- Emails
- Social media advertisement
- Postal mail

Enrollment visits were conducted via videoconferencing and screen-sharing software. Participants were required to have a secondary device (tablet, laptop, desktop, etc.), other than their iPhone, for the video visit.

Visit 1

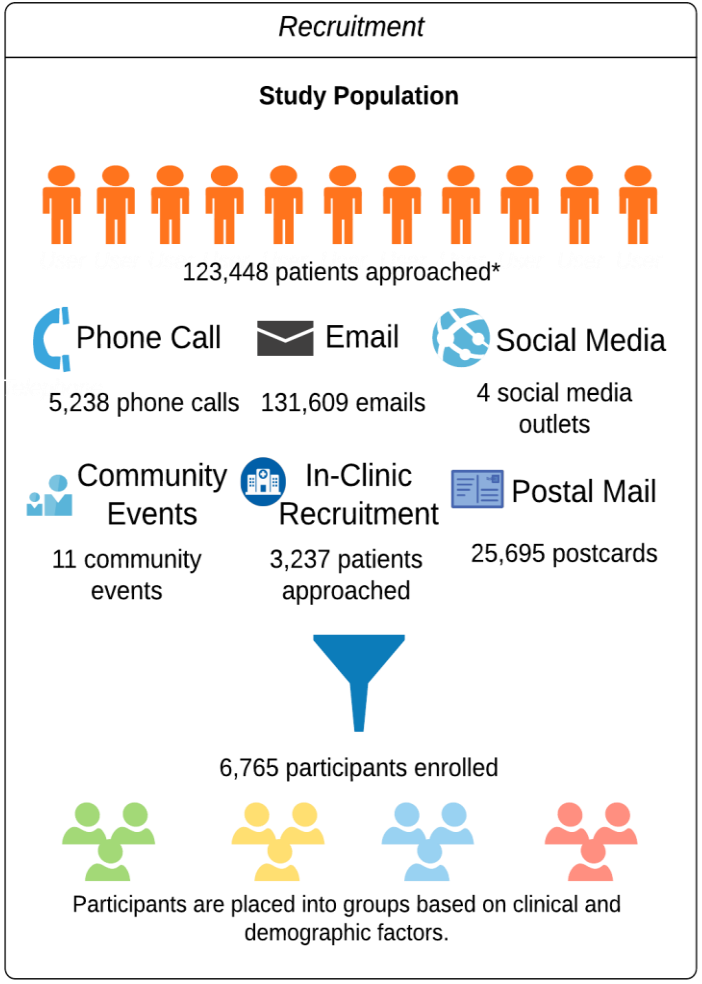
- Informed consent
- Assessment of protocol understanding
- Download required study apps

Ship devices to participant

~2 weeks later

Visit 2

- Device configuration
- Practice study tasks
- Place lab orders



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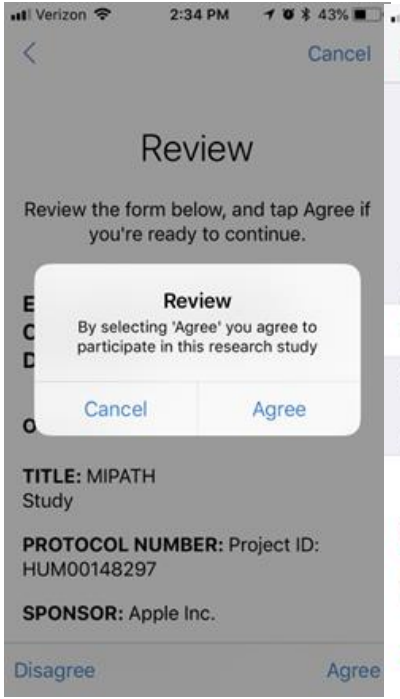
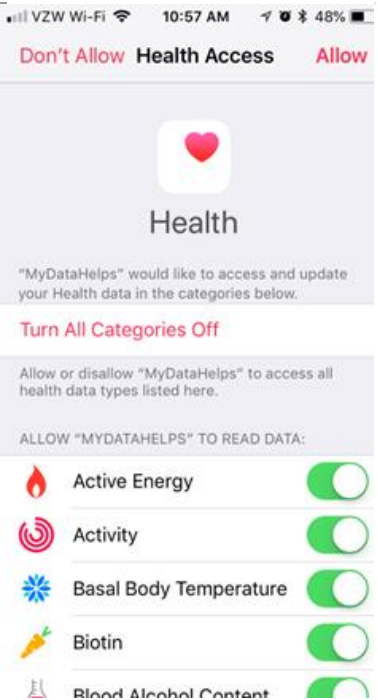
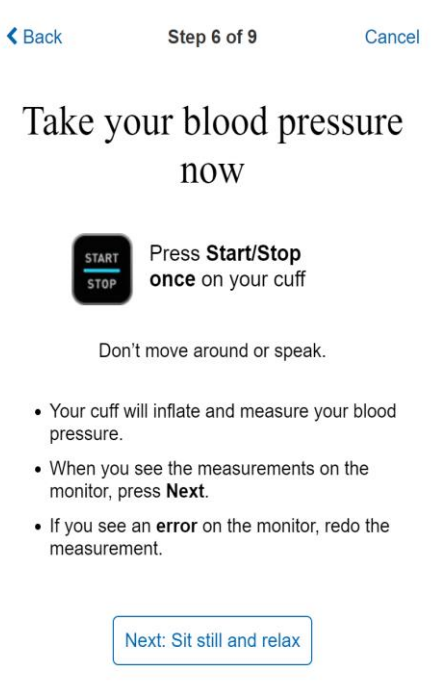
Informed Consent and Data Collection

Nearly all study activities are conducted through a mobile application, MyDataHelps.

- Informed Consent (no paper)
- Guided study tasks
- Surveys
- Mobile health data collection (step count, blood pressure, heart rate, etc.)
- Compliance reminders
- EHR data integration







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Comparing Methodologies

	In-Person	Virtual
Enrolled Participants	6,765	925
Withdrawal/Protocol Failure Rate	7%	3.5%
Basic Completion Reached in Phase 1	98%	98%
Basic Completion Reached in 80% of Phase 2 Months	50%	50%
Rescheduled Appointments	6%	11%
Cancelled or No-show Appointments	8%	8%

03

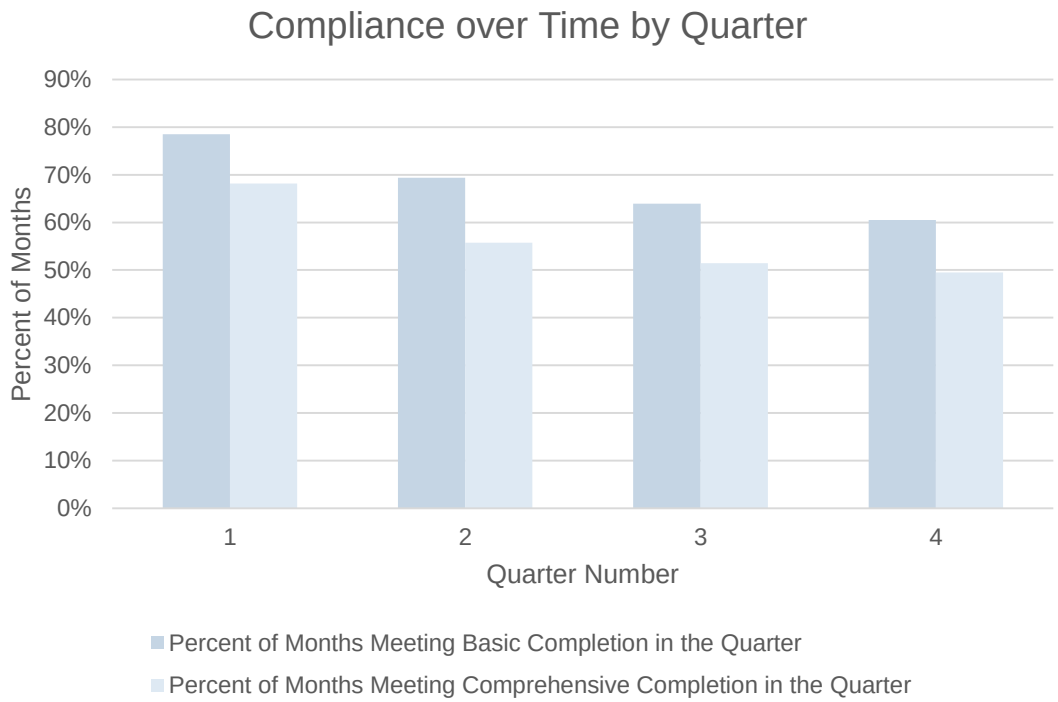
Preliminary inferences

Focus on diverse enrollment yields results

Age	
18-40	2,265 (35%)
41-64	3,036 (47%)
65+	1,153 (18%)
Race	
White	3,657 (57%)
Asian	1,094 (17%)
Black	1,090 (17%)
Other	615 (9%)

Ethnicity	
Hispanic	737 (11%)
Non-Hispanic	5,717 (89%)
Clinical diagnoses	
Diabetes	666 (10%)
Depression	1734 (27%)
Hypertension	2105 (33%)

Compliance high despite study burden



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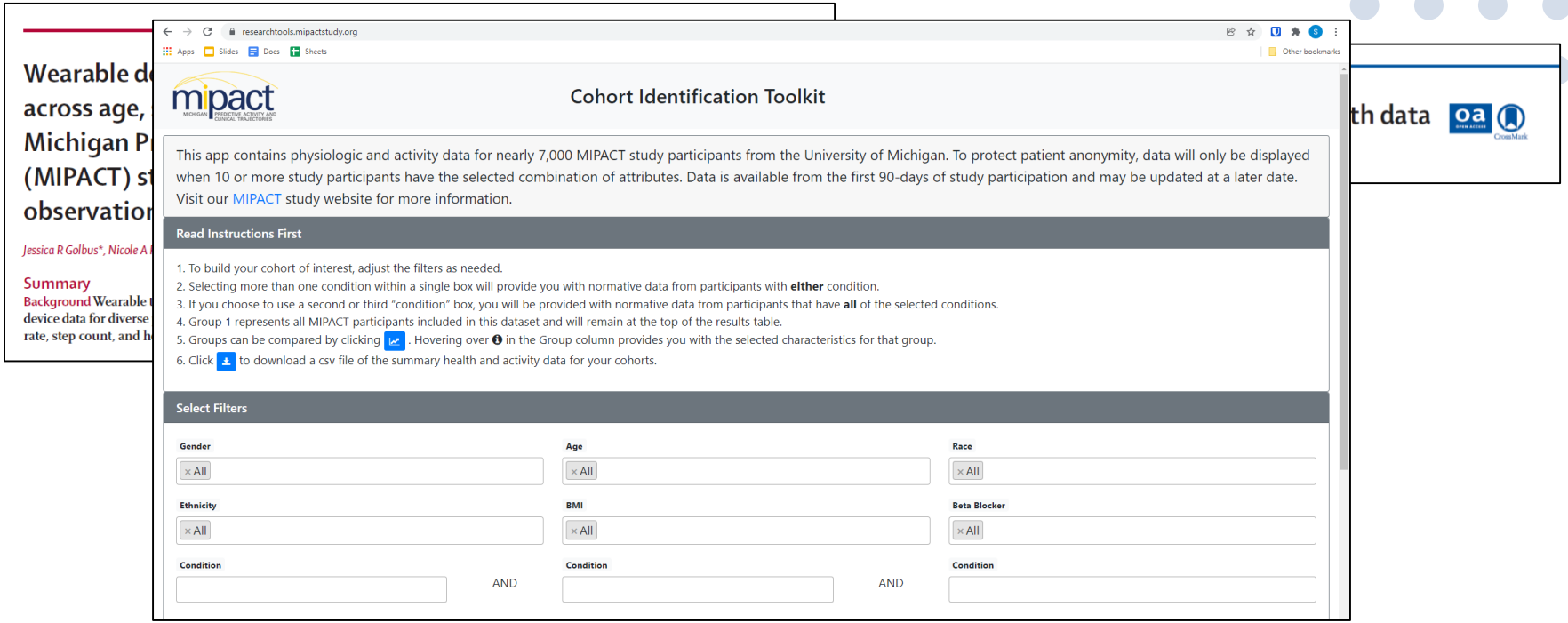
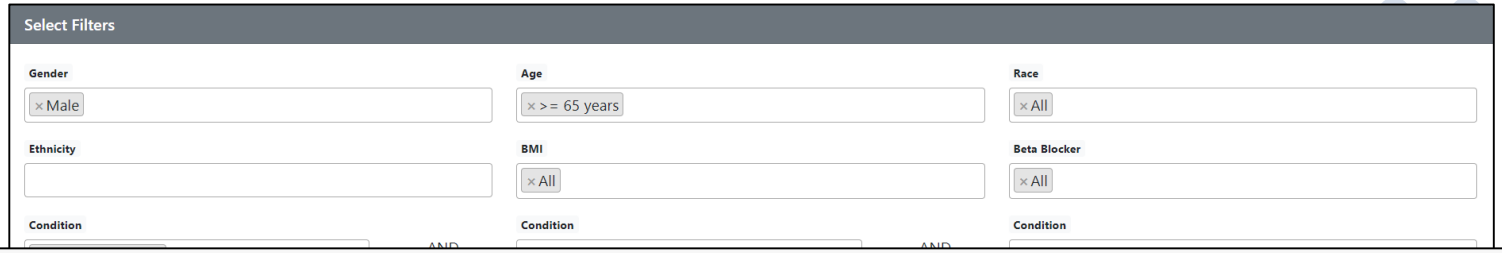
Data availability



https://researchtools.mipactstudy.org

Power analysis assumptions using real data

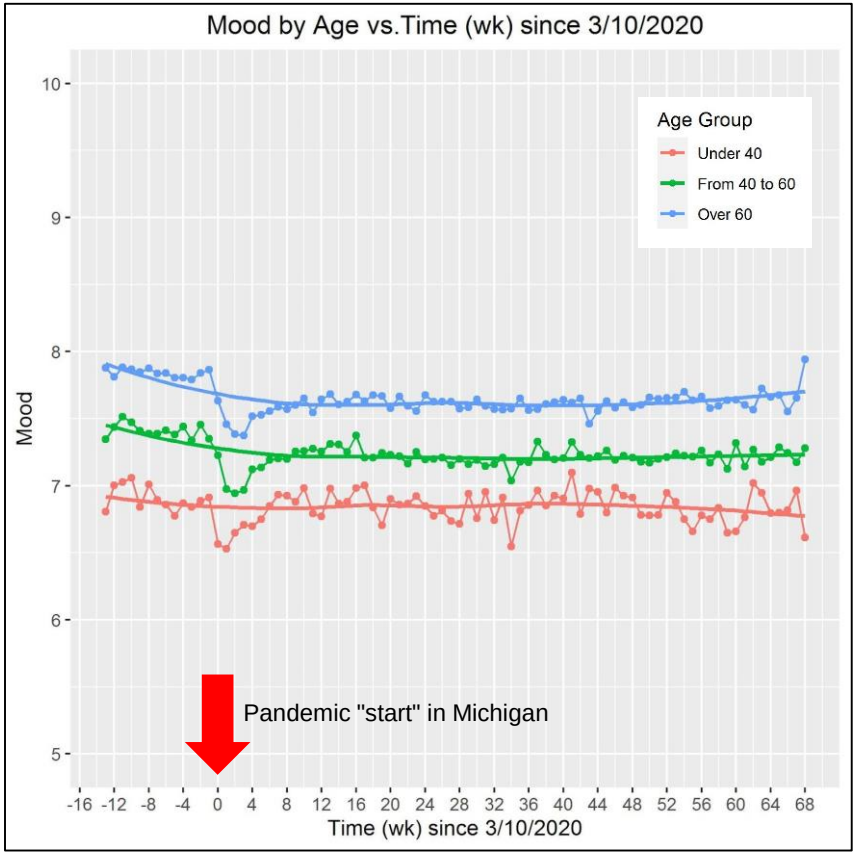


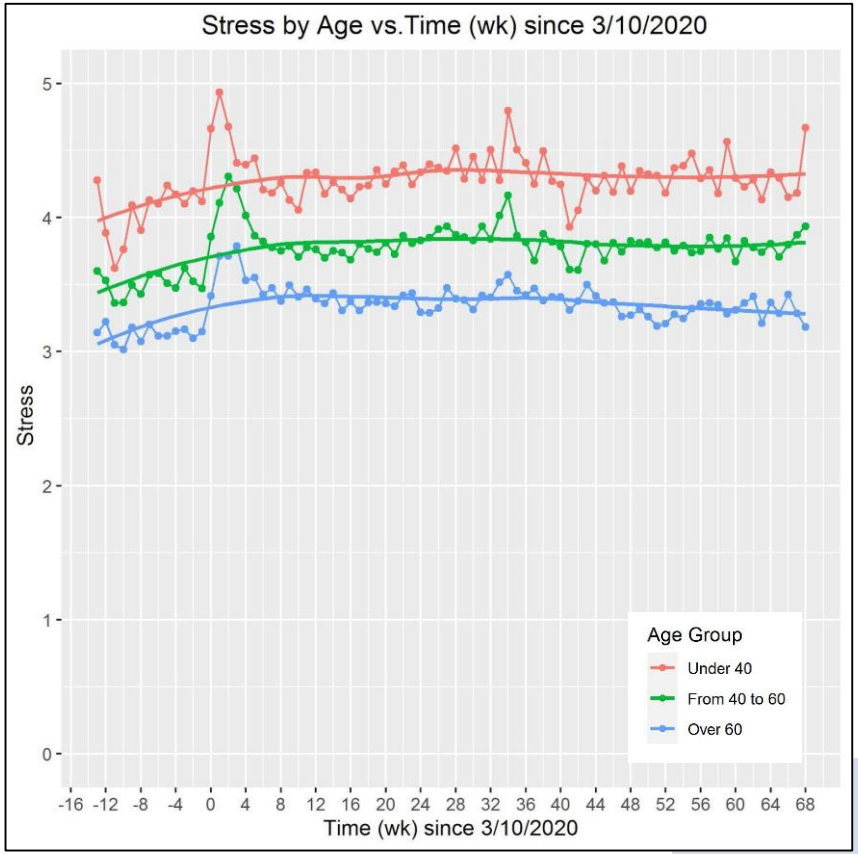
View Results

Group	Heart Rate (All) (beats / min)	Resting Heart Rate (beats / min)	Systolic Blood Pressure (mmHG)	Diastolic Blood Pressure (mmHG)	Step Count	Exercise Minutes
#1 Total 6454	Mean: 81 Median: 81 Std: 9 IQR: 12	Mean: 64 Median: 64 Std: 8 IQR: 11	Mean: 122 Median: 121 Std: 10 IQR: 14	Mean: 77 Median: 76 Std: 8 IQR: 10	Mean: 7511 Median: 7202 Std: 2805 IQR: 3436	Mean: 29 Median: 24 Std: 20 IQR: 21
#2 Total 83	Mean: 75 Median: 73 Std: 9 IQR: 11	Mean: 61 Median: 61 Std: 7 IQR: 7	Mean: 131 Median: 130 Std: 10 IQR: 11	Mean: 78 Median: 77 Std: 6 IQR: 6	Mean: 6206 Median: 5797 Std: 2677 IQR: 3274	Mean: 24 Median: 20 Std: 17 IQR: 17

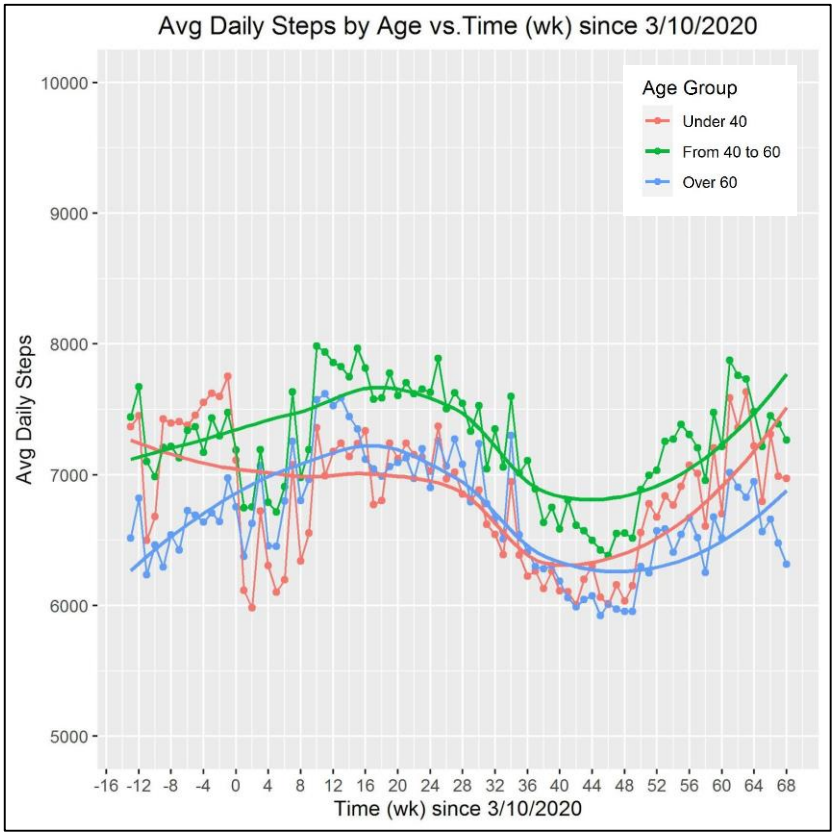
https://researchtools.mipactstudy.org

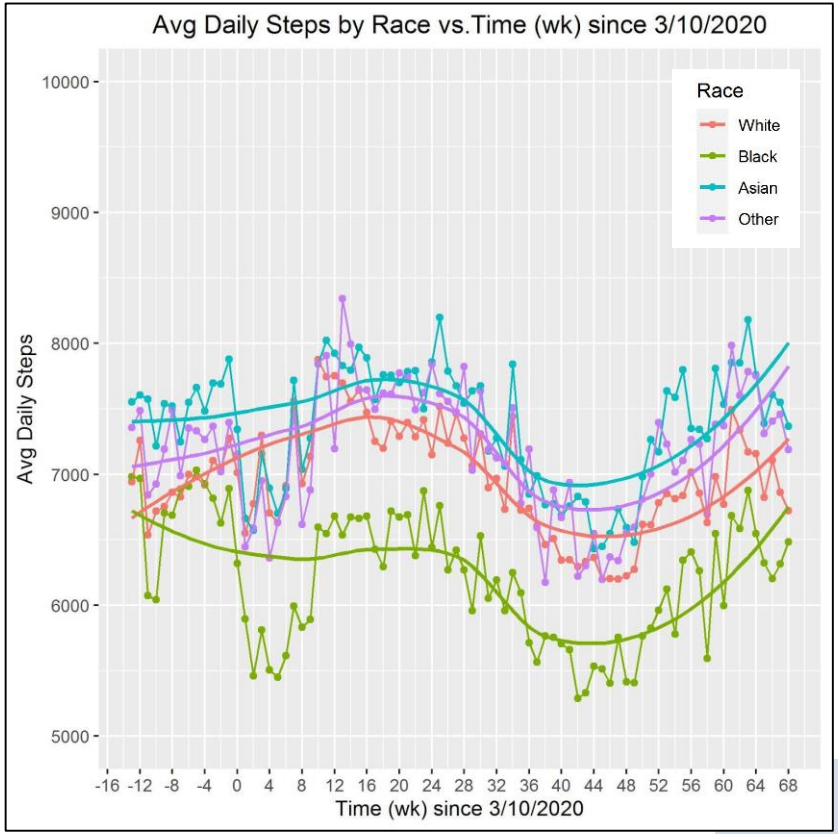
Mood and stress changes during the pandemic





Activity changes during the pandemic





Key Takeaways

1. Large scale completely digital recruitment and enrollment is feasible
2. Protocol compliance comparable across both designs
3. Historical biases regarding digital tools may be inaccurate
4. Prospective trials should be powered using real data
5. Impact of COVID 19 pandemic on participants controversial

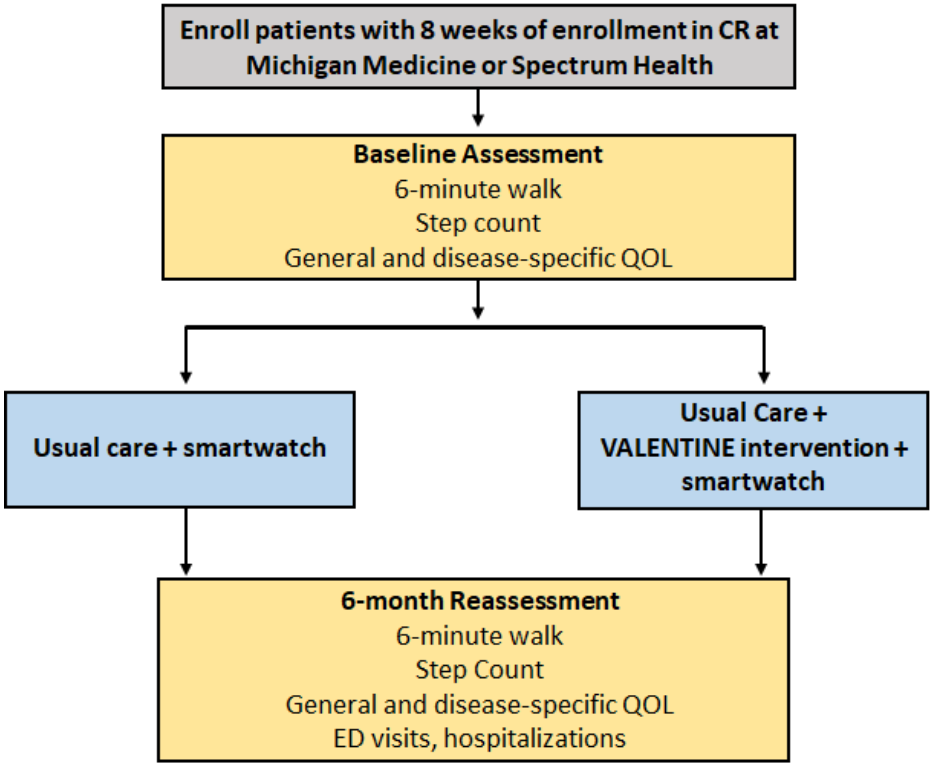
04

The VALENTINE Study

VALENTINE

Cardiac Rehabilitation Study

The VALENTINE Study Design



Telehealth Intervention

- Smartphone application with behavior tracking capabilities.
- Micro-randomized notifications focused on activity and goal-setting.
- Weekly emails to patients and exercise physiologists with a summary of past week's activity

Primary (bold) and Secondary Study Measures

Domain	Measurement
Functional assessments	**Distance on 6-minute walk distance (primary)**
	Average step count (secondary)
	Minutes in target heart rate zone
Quality of Life	SF-12, EQ-5D-5L
	PHQ-8
Process measures	System usability scale
Disease-specific questionnaires	Kansas City Cardiomyopathy Questionnaire, Seattle Angina Questionnaire
Safety endpoints	All-cause and cardiovascular hospitalization
	All-cause and cardiovascular death

Golbus et al. *American Heart Journal.* 2022. In-Press.

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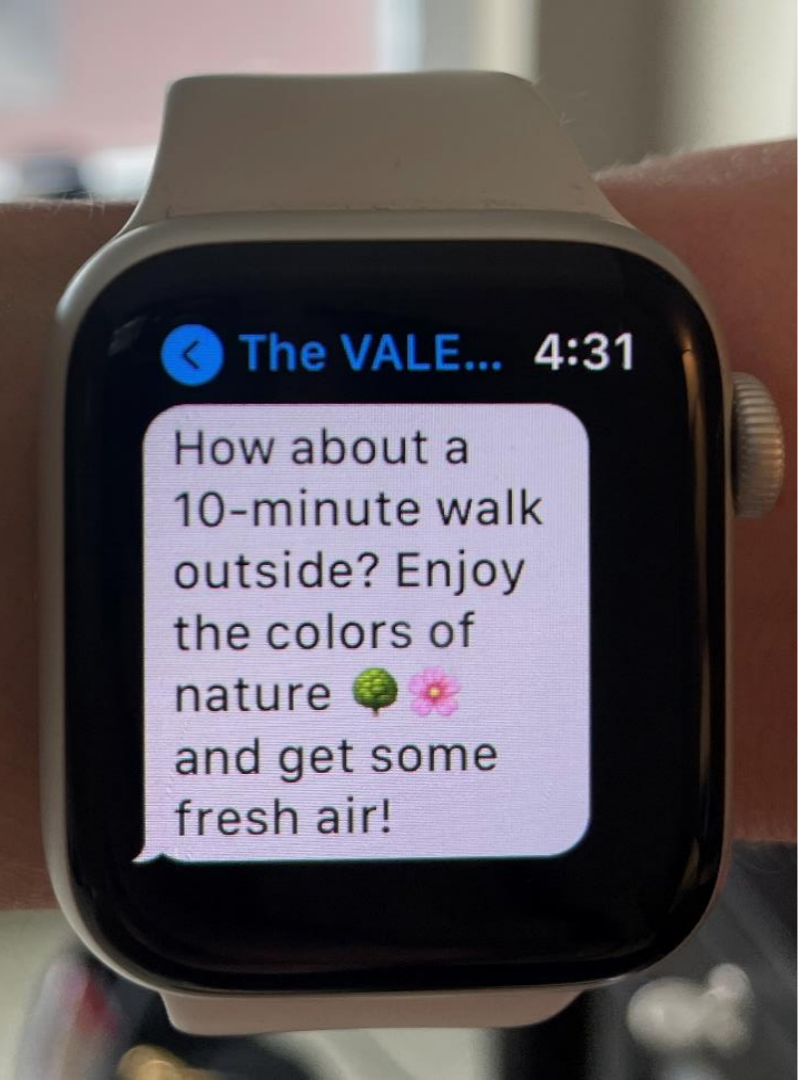

Just-In-Time Adaptive Intervention

Activity Notifications:

- Promote low-level physical activity appropriate for current environment.
- Tailored on weather, time of day, day of week, phase of cardiac rehabilitation.

Exercise Notifications:

- Encourage participants to plan their exercise and suggest new activities.
- Tailored on season, phase of cardiac rehabilitation.

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The VALENTINE Population

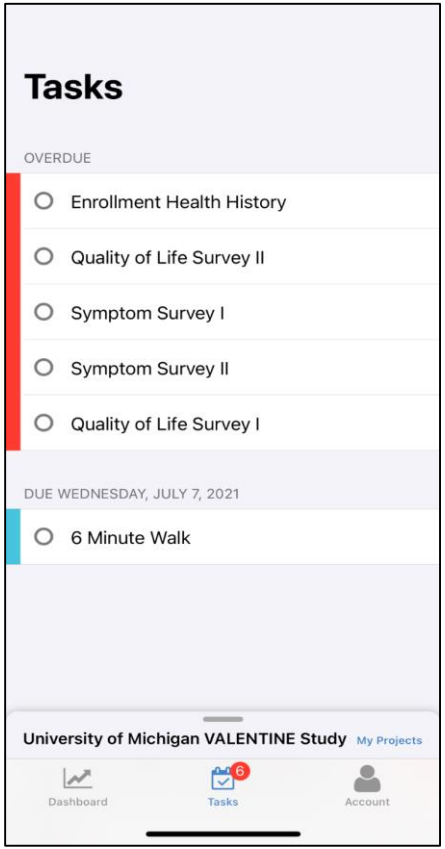
	N	Mean (SD or %)
Age, years	211	59.7 (10.6)
Sex		
Female	66	31%
Male	145	69%
Race		
Asian	7	3%
Black	12	6%
White	178	84%
Phone type		
iPhone (Apple Watch)	132	63%
Android phone (Fitbit Versa 2)	79	37%
Indication for cardiac rehabilitation		
s/p PCI or CABG	136	64%
Valve repair or replacement	48	23%
Valve repair/replacement + PCI/CABG	6	3%
CAD or ACS, not revascularized	21	10%

VALENTINE Study: Baseline Data

	N	Mean (SD)
Select Functional Endpoints		
6-minute walk distance, meters (remote)	202	493 (141)
Average daily step count (watch)*	206	6831 (3377)
Select Quality of Life Endpoints		
KCCQ, overall summary score	80	80.2 (16.1)
SAQ, physical limitation scale	157	87.2 (17.0)
SAQ, quality of life scale	166	75.1 (20.9)
EQ-5D VAS (0-100)	210	72.8 (18.1)

* Baseline step count based on compliant days during the first week of study, defined by 8 or more hours of watch wear.

Lessons Learned



Data Management

- **Active data management is essential:** Automated texts and an eDashboard.
- **Participants must use app to ensure data syncs.**

Digital Endpoints

- **6-minute walk test:** Clinically accepted though frequent technical challenges.
- **Step count:** Easy to collect though compliance is essential.
- **Surveys:** Easy to complete, high adherence

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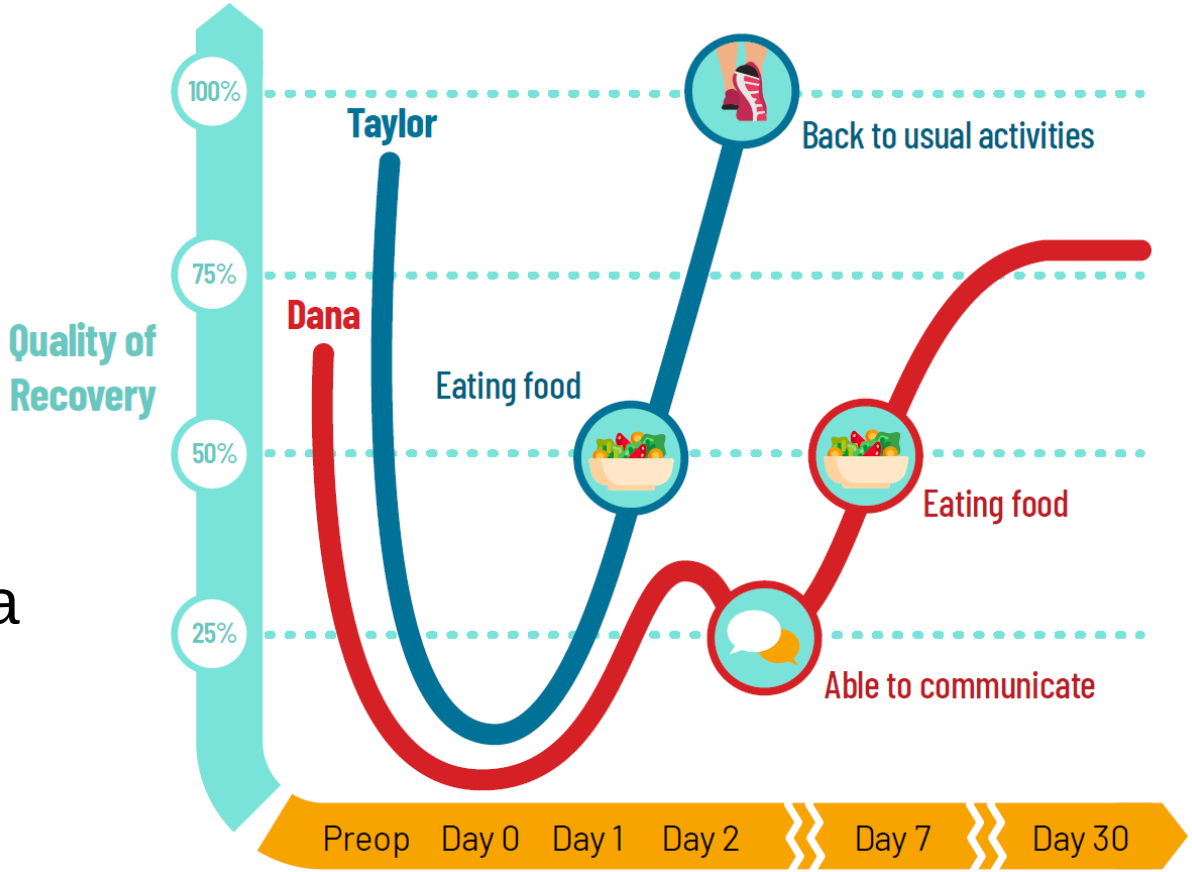
05

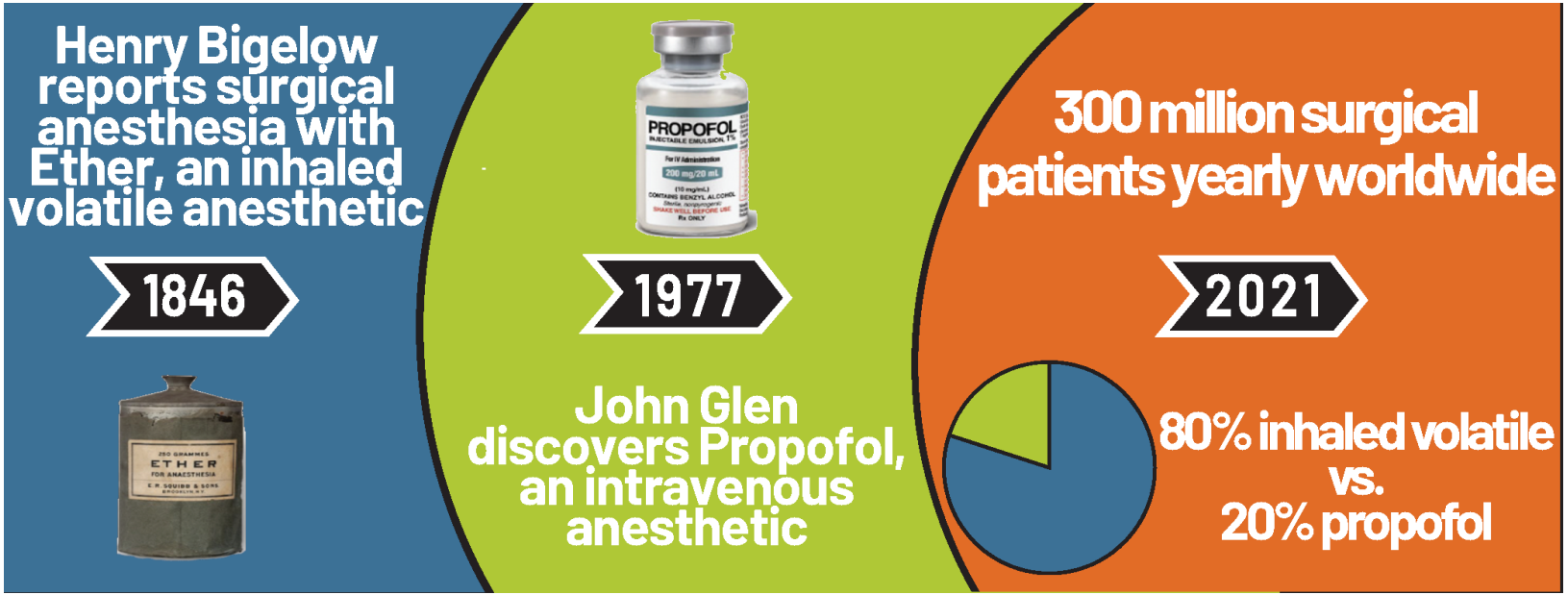
Trajectories of Recovery after Intravenous propofol versus inhaled VolatilE anesthesia

Recovery after surgery is not linear

- One patient back to baseline in 2 days
- Another patient takes more than a week



General anesthesia is ubiquitous



Propofol TIVA Advantages

Decreased postoperative nausea and vomiting

Fewer side effects

Gaps in our Knowledge

Awareness risk

Cognitive recovery

Sense of well-being

Postoperative pain

Ability to communicate

Return to usual activities

Sleep and restfulness

Enjoyment of food

Inhaled Volatile Advantages

Predictable dose-response relationship

Technical ease of administration

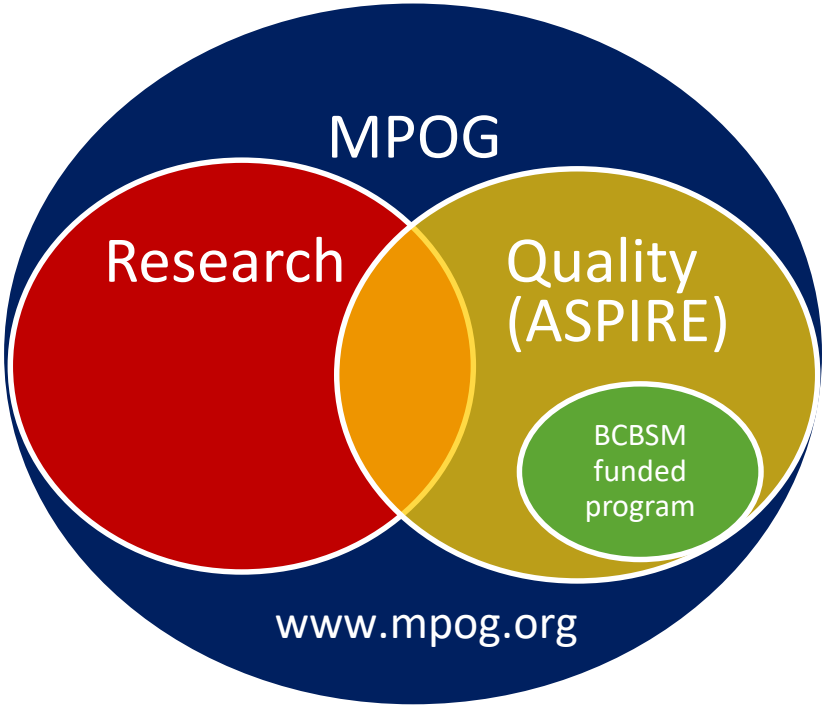
THRIVE: Trajectories of Recovery after Intravenous propofol vs inhaled VolatilE anesthesia

- Multicenter, pragmatic randomized control trial to evaluate superiority of propofol TIVA over inhaled volatile general anesthesia for patient experience and outcomes
- Support from the Patient-Centered Outcomes Research Institute (PCORI). $29.6 M total over 6.5 years
- 12 MPOG enrollment centers, 12,500 patients
- Led by UMichigan, Wash U, UPenn, Stanford

Multicenter Perioperative Outcomes Group

MPOG
MULTICENTER PERIOPERATIVE OUTCOMES GROUP

- 17 Million perioperative patient records extracted, mapped, de-identified, and available for research and performance improvement
  - Every medication administration and outpatient prescription
  - Every physiologic, every 60 seconds
  - Laboratory values 365 days pre/post
  - Discharge ICD9/10
  - Readmissions, long term costs, patient reported outcomes for a subset
- 26 health systems, 60+ hospitals, 22 states, 2 countries, 6 EHR vendors
  - 35 BILLION vital signs for these patients…this is BIG data
- > 5500 providers receiving monthly email feedback across 40 performance measures



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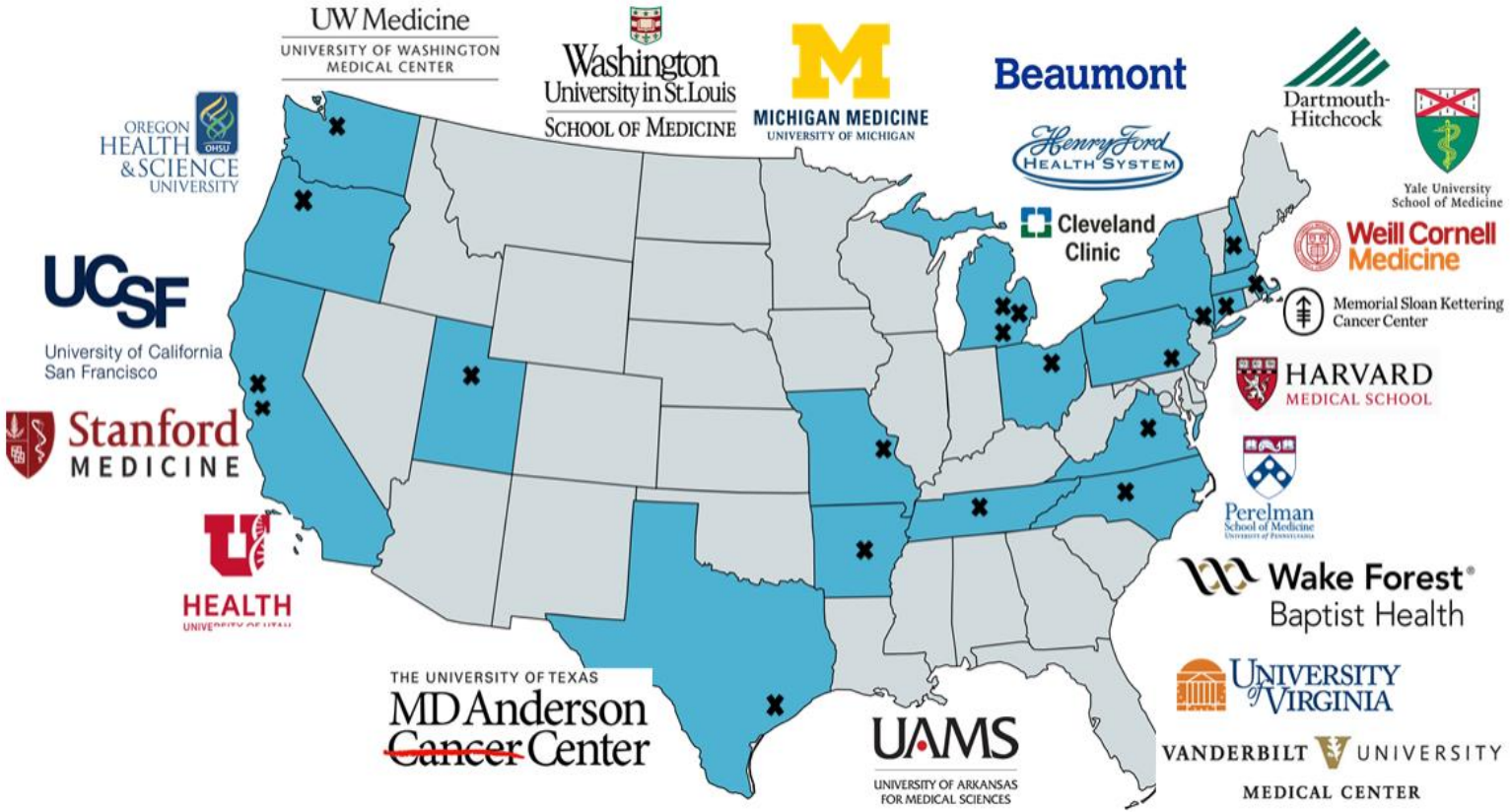
THRIVE candidate centers



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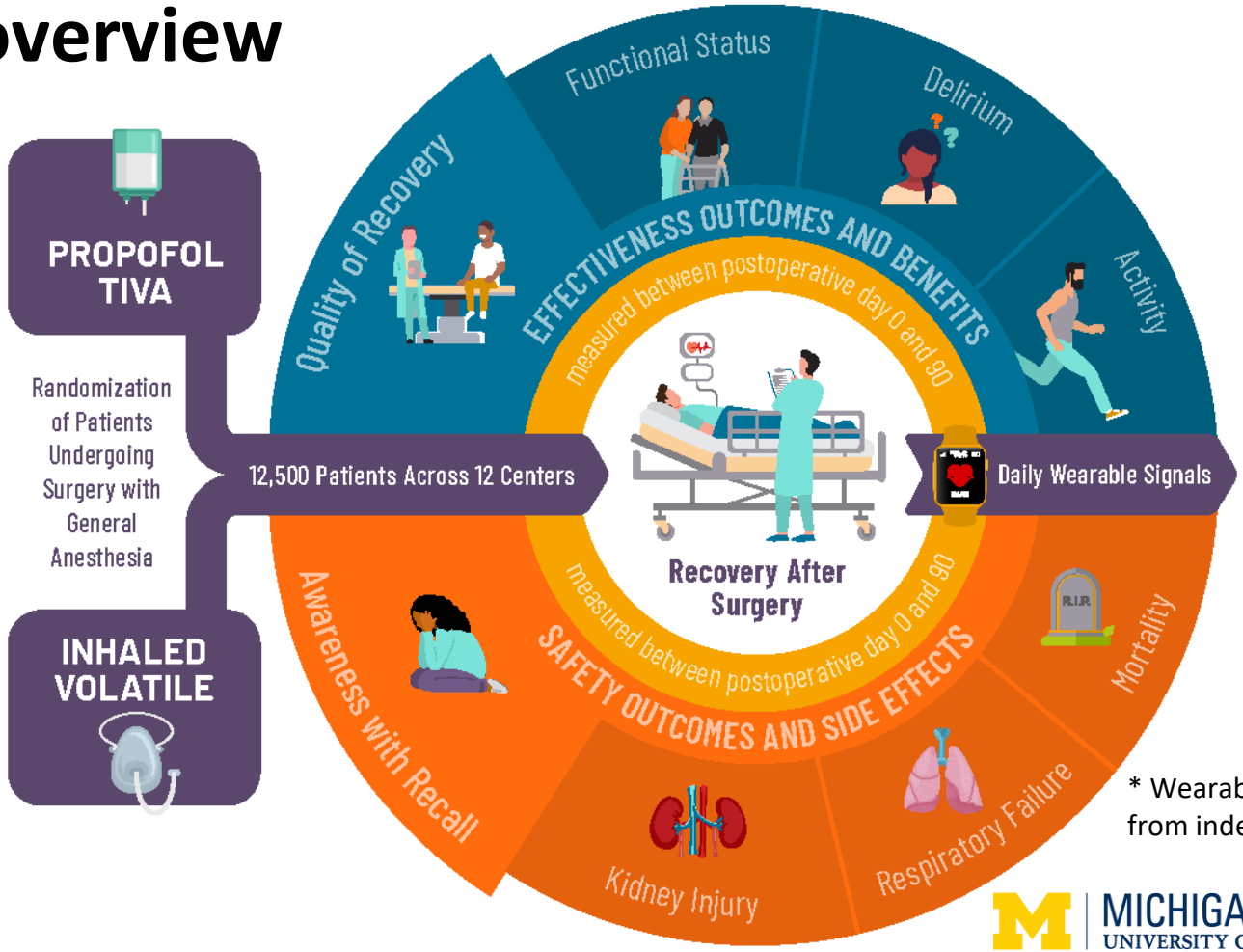
Study overview



* Wearable devices acquired from independent funds

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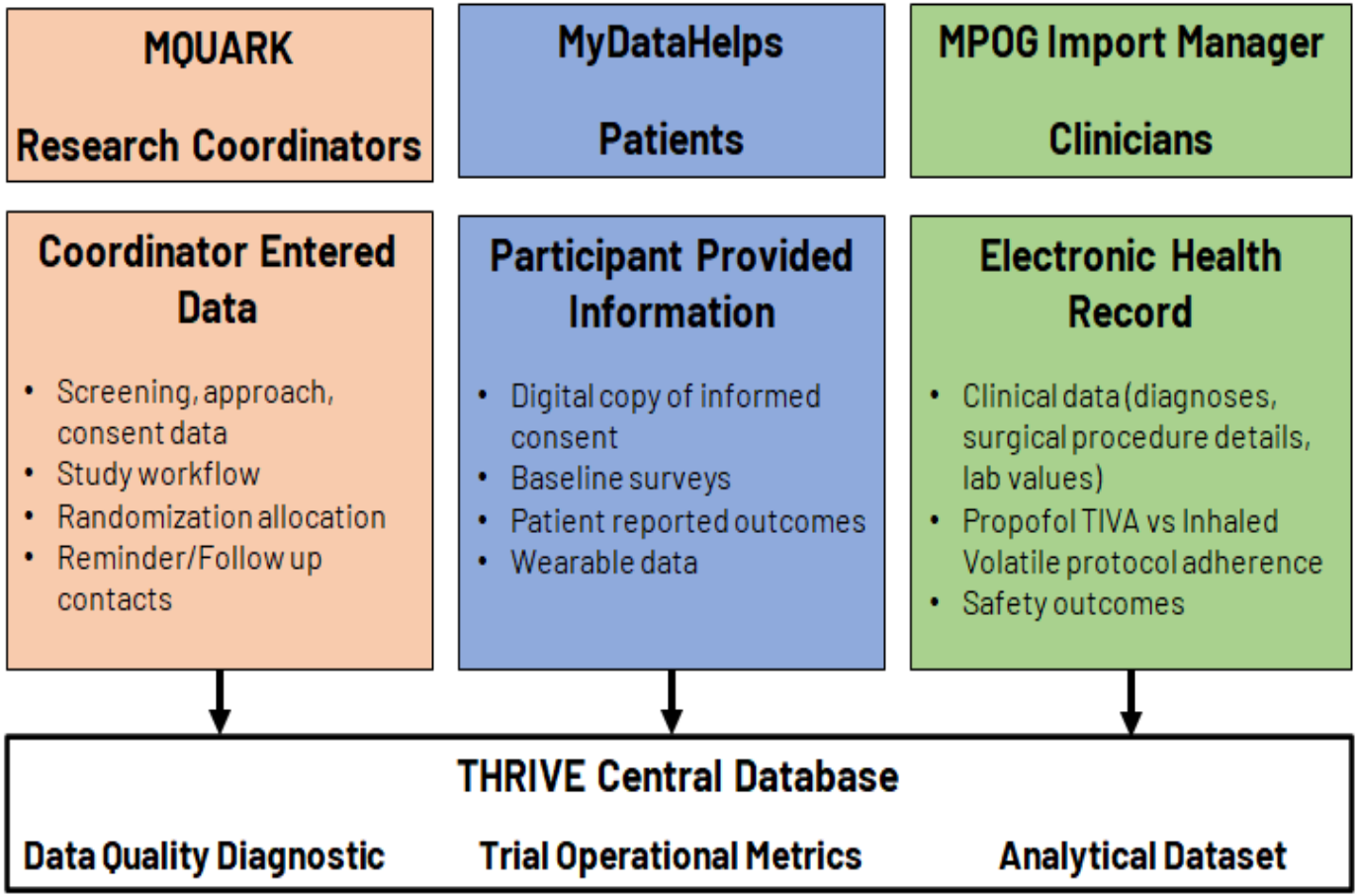
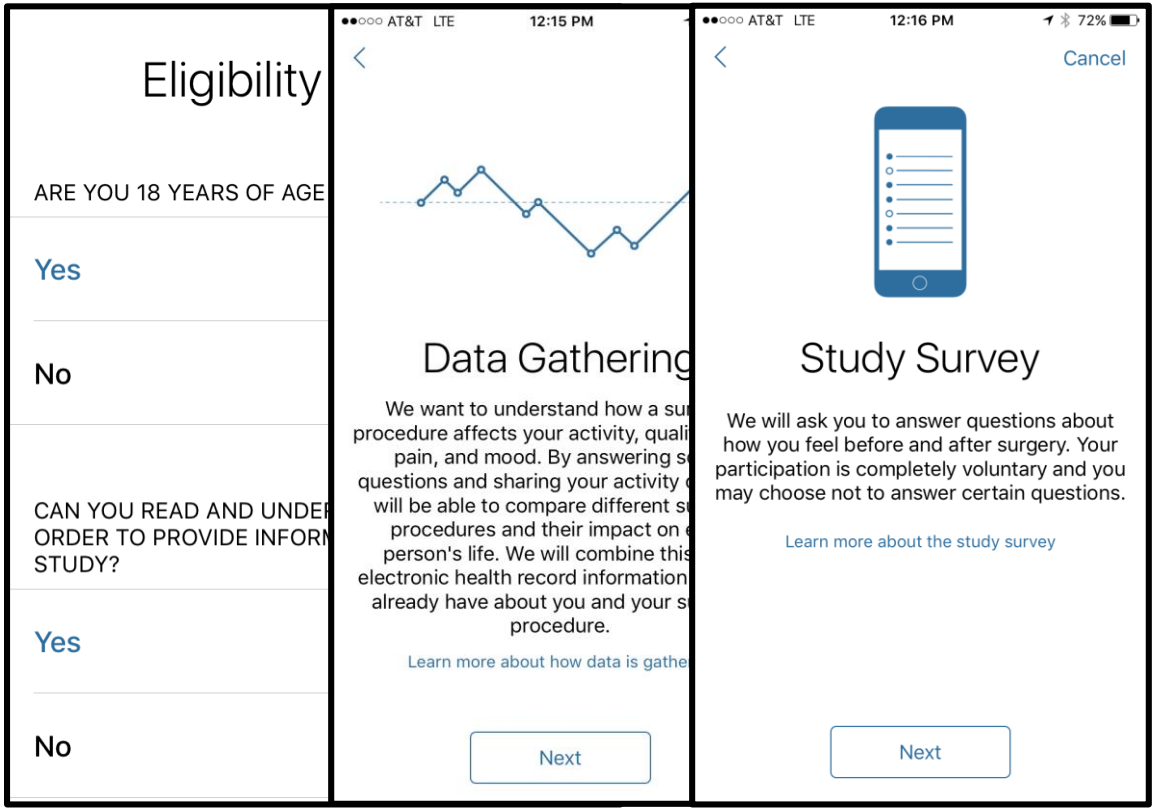
Data Sources and Systems



Mobile Health & Wearables

MyDataHelps implemented via iPhone, Android, tablet, and responsive web

- Informed Consent
- PROs
- Bring your own device wearables (BYOD)
- Compliance reminders
- Return of results
- Independently funded wearables for subset of participants



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Why mobile devices & wearables?

- Recovery assessment at pre-specified timepoints belies dynamic reality
- Significant PRO burden already (Day 0, 1, 2, 7)
- Patient "expectations" of recovery may bias reporting
- Objective (yet exploratory) data from wearables

Sleep Duration

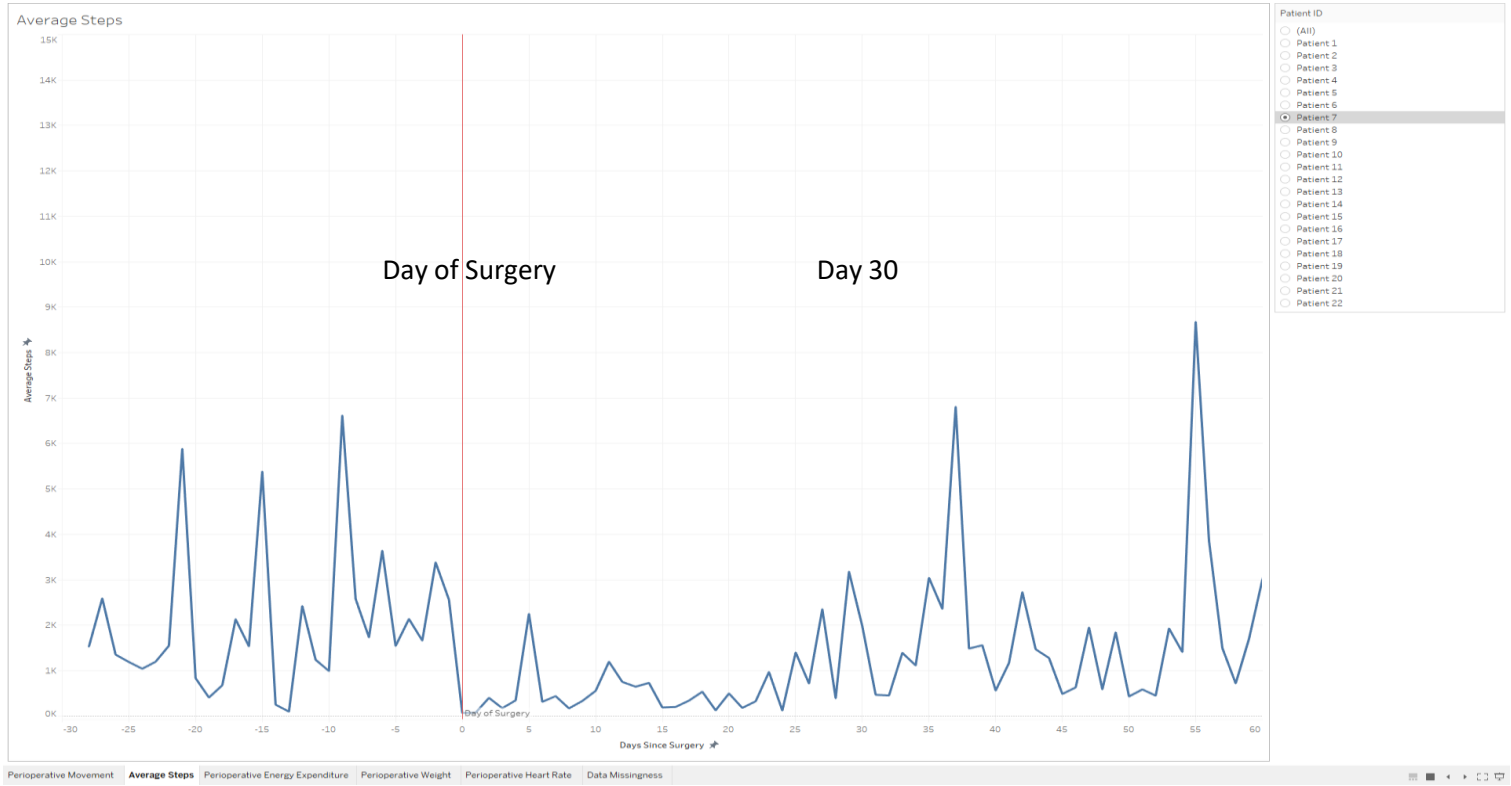

Sleep Quality


Step Count


Exercise Minutes


Stand Hours

PROSPER pilot study – steps per day



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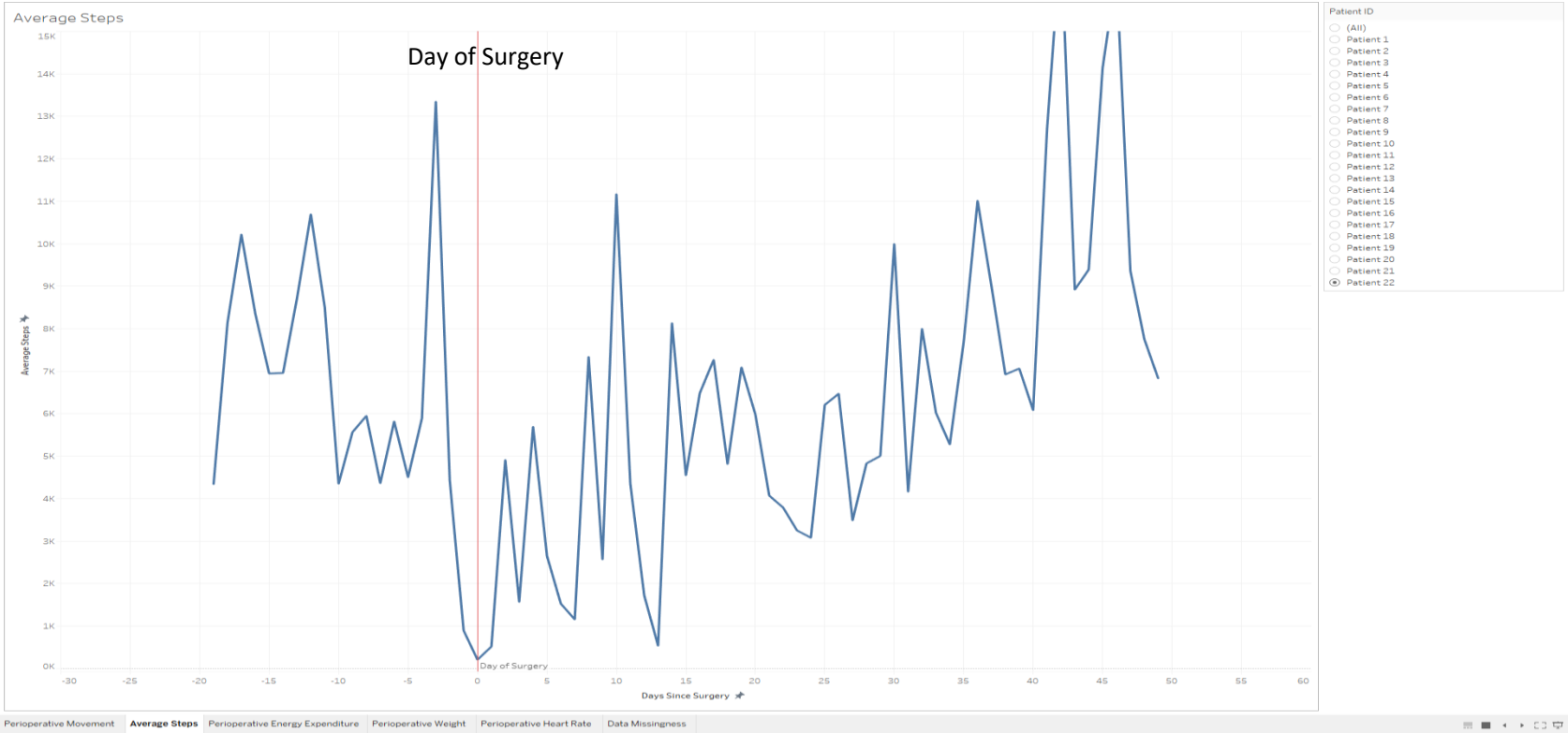
There is hope…



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Key Takeaways

1. Mobile health tools are viable across diverse populations
2. In person and remote enrollment scalable despite technical complexity
3. Wearable data research can use valid power analyses
4. Integration of pragmatic trials techniques, EHR data, smartphones, and wearables reflects comprehensive patient experience

Thank you to the MIPACT, MPOG, and THRIVE team

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MIPACT study team – pre-COVID

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