Overview

● Motivation for the study

● MyHeart Counts platform

● Data portal

● Findings from observational study of physical activity in 50000 app users

● Randomized controlled trial of coaching strategies to increase user step count

● Genomewide association study in collaboration with 23andMe

● Lessons learned

● Future directions
**Health Behavior**  |  **Percentage “At Risk”**
---|---
Smoking | 7.2%  
Alcohol use | 19.1%  
Dietary behavior | 17.2%  
Physical activity | **22.9%**  
Sedentary behavior | 25.0%  
Sleep duration | 23.1%  

N=650k US  

N=230k Australians  
Ding. 2015. Plos Med

N=1.1 Million UK Women  
Armstrong. Circulation. 2015

N = 60k  
Blair. BJS M. 2009; ERI 2013
Feasibility of Obtaining Measures of Lifestyle From a Smartphone App
The MyHeart Counts Cardiovascular Health Study
Michael V. McConnell, MD, MSEE; Anna Shcherbina, ME; Aleksandra Pavlović, BS; et al.

Physical activity, sleep and cardiovascular health data for 50,000 individuals from the MyHeart Counts Study
Steven G. Hershman, Brian M. Bot, Anna Shcherbina, Megan Doerr, Yasbanoo Moayed, Aleksandra Pavlović, Daryl Waggott, Mildred K. Cho, Mary E. Rosenberger, William L. Haskell, Jonathan Myers, Mary Ann Champagne, Emmanuel Mignot, Dario Salvi, Martin Landray, Lionel Tarassenko, Robert A. Harrington, Alan C. Yeung, Michael V. McConnell & Euan A. Ashley

myheartcounts.stanford.edu
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Data Descriptor | OPEN | Published: 11 April 2019

Physical activity, sleep and cardiovascular health data for 50,000 individuals from the MyHeart Counts Study

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Scientific Data 6, Article number: 24 (2019) | Download Citation

Make your heart count!
What keeps your heart its healthiest? Help us find out.
New version of MyHeart Counts App now available for download at the App Store

myheartcounts.stanford.edu
Goodbye Fliers

Have you ever experienced a traumatic or life-threatening event?

Since the trauma, have you:

- Had nightmares or flashbacks?
- Tried to avoid thinking or talking about it?
- Felt jumpy or anxious?
- Become less connected with people around you, or less interested in activities you used to enjoy?

If so, you may be suffering from post-traumatic stress disorder or PTSD. The Mood and Anxiety Disorders Program at the Icahn School of Medicine at Mount Sinai is conducting a study of an investigational medication that may help relieve your PTSD symptoms. You may be eligible to participate if you have PTSD and are 18-65 years old.

Participation involves a telephone assessment and medical screening. Please contact 212-241-7910.

Pr. James Murrough, MD/PhD 11/14/11. IIIB Approved 11/15/11

Participation will be compensated.

If interested, please contact Sarah Burns at 212-241-7910 or sarah.burns@mnosin.edu.

[Website URL]
Onboarding: find RK studies through the App Store

ResearchKit Section of Medical Apps

Search
# Onboarding: Eligibility Criteria

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are you 18 or older?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you have asthma as confirmed by a doctor?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are you currently taking any medicines (including inhalers, aerosols or tablets) for asthma?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you live in the United States of America?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are you pregnant?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N/A</td>
</tr>
</tbody>
</table>

You are eligible to join the study.

Tap the button below to begin the consent process.

Start Consent
A research study is when scientists try to answer a question about something that we don’t know enough about. Participating may not help you or others. People volunteer to be in a research study. The decision about whether or not to take part is totally up to you. You can also agree to take part now and later change your mind. Whatever you decide is okay. It will not affect your ability to get medical care at Mount Sinai.

We have provided the contact information for the study’s principal investigator above. If you have questions, please ask them. Feel free to ask all the questions you want before you decide. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

Basic information about this study will appear on the website http://www.ClinicalTrials.gov. There are a few reasons for this: the National Institutes of Health (NIH) encourages all researchers to post their research; some medical journals only accept articles if the research was posted on the website; and, for research studies the U.S. Food and Drug Administration (FDA) calls “applicable clinical trials” a description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The purpose of this study is to understand whether using an asthma mobile health application Version 2.0 (AMHA2.0 or “asthma app”) that you download onto your iPhone will help you to monitor your asthma. Although “apps” have been made to help people monitor certain health problems, medical researchers still do not know if they really work well or if they really can help improve your health. This research study will be different in that unlike typical research studies, your will not need to come to a hospital clinic or a study center. Part of this research is to see if we can study the use of the “asthma app” completely by phone without visits to a study center or clinic and to study how well the “asthma app” features work. Since you will be using the app for up to 6 months, we cannot be certain that the app will help you with your asthma. We will use information about how you use the app to make the app better and see if the “asthma app” helps you with your asthma. If you join this study you will still be able to join future studies if you choose.

Funds for conducting this research are provided by the Icahn School of Medicine at Mount Sinai, with technology support from Apple, Sage Bionetworks, and LifeMap Solutions.

Your participation in this research study is expected to last for six months.

The number of people expected to take part in this research study is difficult to predict but may be hundreds to tens of thousands of people.

This consent form tells you about the study to help you make your choice on whether or not to take part. Please take the time to read this carefully before making your choice. If you have any questions or anything is unclear please contact the study team. If you choose to participate in this study you will be asked to give permission by using your phone to sign the consent form electronically. You should not give consent or start any part of the study until your questions are answered and you are ready and able to begin. If you participate in this research study, you should also tell any health care providers who treat you that you are in the study.

Asthma is a very common condition, and patients with asthma do best if they monitor or take care of their asthma. Some things patients can do to take care of their asthma are to use regular medication as prescribed by their doctor, keep track of their own symptoms, and stay away from certain situations that may make their asthma symptoms worse (we sometimes call these asthma triggers). The “asthma app” is designed to help you do all of these things right on your mobile phone. The “asthma app” will help you learn more about your asthma, take your asthma medicine as prescribed, and learn what triggers your asthma. The “asthma app” does not replace your usual medical care. Our goal is that you will be able to use the “asthma app” to learn more about asthma. This consent will give you more details about what types of things you will be asked to do in this study. The information about your asthma that you give us through this “asthma app” will be joined together with information from other study participants so researchers can learn more about asthma and how an app can help monitor asthma. This information will be separated from your name and other ways to identify you or know it is you.

You may qualify to take part in this research study because you are 18 years of age or older, have asthma, own an iPhone, and are not currently pregnant.

If you agree to participate in this research study, this is what you will be asked to do:
- Download a mobile app (free): You need to have the AMHA2.0 app on your iPhone in order to participate in this study
- View a brief optional video that describes the purpose of the study and introduces the study team
- Complete a screening questionnaire on the iPhone.
Onboarding: Consent Vignettes with “learn more” link

Secure Database

Your study data will be stored in a manner that maintains strict information technology procedures to safeguard your information and to prevent improper access.

Learn more

Study data will be stored on Amazon Web Services servers under the control of Mount Sinai and Sage Bionetworks, a non-profit research institution. No one at Amazon Inc. will have access to the data.
Automated mobile study consent

Activities
This study will ask you to perform tasks and respond to surveys.
Learn more

Sensor and Health Data
This study will also gather sensor and health data from your iPhone and personal devices with your permission.
Learn more

Data Processing
Collected data may allow researchers, as well as you, to understand patterns and details about heart health.

Protecting your Data
Your data will be encrypted and sent to a secure database, with your name replaced by a random code. Learn more about how your privacy and identity are protected.

Data Use
Your coded study data will be used for research by Stanford and may be shared with other researchers approved by Stanford. Learn more about how data is used.

Issues to Consider
Your initial participation in this study will take 10-15 minutes per day for a week. We hope that you can contribute to the study for one week every three months. Learn more about the study’s impact on your time.

Surveys
Some of the tasks in this study will require you to answer survey questions about health and lifestyle factors.

MyHeart Counts app will ask you to do 3 activities:
1. Use your phone, or any wearable activity device you have, to collect activity data for 7 days.
2. If you are able, perform a 6-minute walk test.
3. Enter information about your weight, blood pressure, and heart rate.

There are sensors in your phone that can help assess activity, and Apple’s Health app on your phone can be linked with other devices to collect health and activity data, with your permission.

We will NOT access your personal contacts, other applications, personal photos, texts, or email messages.

We will use a random code instead of your name on all your study data. The coded study data are also encrypted and stored on a secure server to prevent improper access. This data server is run by Sage Bionetworks, a non-profit research organization. Stanford has secure servers that will maintain your consent and personal information.

Your coded study data will be combined with data from other participants for analysis. This provides a rich database for research. It also provides a safe way to share the data with other researchers approved by Stanford to learn more about cardiovascular disease. Study data will never be sold to any third party.

We will ask you survey questions and have you use your phone or wearable device to collect activity data for 7 days. After that, if you are able, there is a 6-minute walk test. You will also need to have your blood pressure and cholesterol information in order to determine your risk score and heart age. You can continue to use the app for activity monitoring and it will ask you to update your data every 3 months.
Anatomy of a ResearchKit App

Activities list (tasks)

Dashboard (patient feedback)

Learn

Asthma Health

- About This Study
- How This Study Works
- Who Can Participate?
- Who is Running This Study?
- Asthma Overview
- Treatment Options

Engaging Features
ie. Newsfeed

- The Coldest Day of the Year
- Resolved
- Asthma over the Holidays
- Asthma, the movie

Stanford University
Sage Backend Stack: De-identification via Bridge; Distribution with Synapse
MyHeart Counts

General

<table>
<thead>
<tr>
<th>Study name *</th>
<th>Short name (10 chars or less)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MyHeart Counts</td>
<td></td>
</tr>
</tbody>
</table>

Sponsor name *

- The MyHeart Counts Team

Youngest allowable age for participants

- 18

Minimum Supported App Versions

- iPhone: #
- Android: #

Leave blank or set to zero if you support all versions that have been released

The identifier for this study is cardiovascular. Your technical staff will need this identifier to integrate with the Bridge server.

Please do not disable strict upload validation unless instructed to do so. If your application submits corrupted data, you will have to fix it after the data is collected.

If your study no longer supports an older app version on a particular platform, lock that version out by setting a minimum supported app version. Apps older than this version on that platform will receive a 410 response from the server. Your app should prevent the user from doing anything but upgrading when it receives this response.

The CMS key is provided to encrypt data you send to the Bridge server. The encryption key (specific to your study) ensures that the data cannot be read on the phone, or in transit to the Bridge server.
### Upload Schemas

Schemas are also produced for published surveys. View these schemas under the schema tab in the survey editor. Common metadata fields can be configured study-wide through shared upload metadata configuration.

<table>
<thead>
<tr>
<th>Name</th>
<th>Type</th>
<th>Latest Revision</th>
<th>Matching Criteria</th>
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<tr>
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<td>iOS Data</td>
<td>6</td>
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</tr>
<tr>
<td>6MWT Displacement Data</td>
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<td>No criteria</td>
<td></td>
</tr>
<tr>
<td>ABTestResults</td>
<td>iOS Data</td>
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<td>No criteria</td>
<td></td>
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<td>ActivitySleep</td>
<td>iOS Survey</td>
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<td>displacement</td>
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<td>1</td>
<td>No criteria</td>
<td></td>
</tr>
<tr>
<td>HealthKitDataCollector</td>
<td>iOS Data</td>
<td>1</td>
<td>No criteria</td>
<td></td>
</tr>
</tbody>
</table>
Synapse - Data access

6-Minute Walk Test_SchemaV4-v6

SELECT * FROM syn12182118
Full stack is much more complicated
Data collected by ResearchKit-enabled health studies

- Mobile Analytics
- Tasks
  - Surveys
  - Active Tasks
  - Third party integrations (23andMe)
- Passive Data collection
  - CoreMotion
  - HealthKit
  - Other (ie Locations)
Mobile Analytics: App QA/QC & Engagement research

- Amazon Pinpoint (was Mobile Analytics) is a service for collecting, visualizing, understanding, and extracting app usage data at scale
  - Captures both standard device data and custom events
  - Automatically calculates reports on your behalf
  - Caveat: Data transfer is not guaranteed
Data collected by ResearchKit-enabled health studies

- Mobile Analytics
- Tasks
  - Surveys
  - Active Tasks
  - Third party integrations (23andMe)
- Passive Data collection
  - CoreMotion
  - HealthKit
  - Other (ie Locations)
ResearchKit enables a variety of surveys

Many question types including select-multiple multiple choice and Integer input question

Boolean question with skip logic

Bounded values
Example Survey: EuroQol

- Validated instrument
- Used with foundation’s approval
- Worked with organization to translate Palm Pilot PDA specs to iPhone
Active Tasks

- Active tasks uses sensors to collect data, ie
  - Accelerometer
  - Screen
  - Microphone
Active Task: Image Capture
Data collected by ResearchKit-enabled health studies

- Mobile Analytics
- Tasks
  - Surveys
  - Active Tasks
  - Third party integrations (23andMe)
- Passive Data collection
  - CoreMotion
  - HealthKit
  - Other (ie Locations)
Passive Data collection: HealthKit

- HealthKit is a central data store for iOS that allows users to share their health data between apps
- Many ResearchKit apps vacuum up all these data
HealthKit Enabled EMR Integration

Health Provider
Enroll/Order

Patient

Asthma App
Enroll within app
Allow data sharing

MyChart App
Allow data sharing
with Health App

Asthma App data is
shared with Health App

Health App data is
shared with MyChart
App

Epic

Health Provider alerted

Readings stored in epic. Period summaries of patient data is sent to providers. Providers are also alerted of abnormal results via notifications.
Passive Data collection: CoreMotion

- The iOS CoreMotion accelerometry library has a MotionActivityManager that detects when the user is walking, running, in a vehicle, or stationary.
- MyHeart Counts uses these states to provide the participant has a 7 Day activity assessment.
Users complete a weekly protocol of surveys and activity monitoring.

1. Download the app. Learn about the study. Review consent information.
2. Start following your daily activity with your phone or wearable activity device.
3. Do a walk test and enter labs to see your heart risk. Learn how to improve your heart health.

Consent for Study
Health Quest.
Activity state Activity state Activity state Activity state Activity state Activity state Activity state
Day 1 Day 2 Day 3 Day 4 Day 5 Day 6 Day 7

6 Minute Walk Test Heart Age Quest.
MHC app integrates three sources of physical activity data

Daily step count and distance walked from Apple platform

Core motion activity detection from phone accelerometry

Self-reported survey responses about daily and weekly physical activity levels
MHC app integrates three sources of physical activity data

Daily step count and distance walked from Apple platform

Core motion activity detection from phone accelerometry

Self-reported survey responses about daily and weekly physical activity levels
<table>
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<th>#Ind.</th>
<th># Per.-Days.</th>
<th>HealthKit Workout</th>
<th># Ind.</th>
<th># Per.-Days</th>
<th>HealthKit Sleep</th>
<th># Ind.</th>
<th># Per.-Days</th>
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<tbody>
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<td>18,210</td>
<td>Strava</td>
<td>195</td>
<td>3,275</td>
<td>Apple Mobile Timer</td>
<td>636</td>
<td>14,523</td>
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<td>Lose It!</td>
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<td>Humancno</td>
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<td>294</td>
<td>Nikeplus Running</td>
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<td>Sleep++</td>
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<td>Strava</td>
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<td>Garmin Connect</td>
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<td>1,817</td>
<td>Neybox Pillow</td>
<td>184</td>
<td>3,088</td>
</tr>
</tbody>
</table>
User flow through baseline week of MHC study
Daily activity questionnaires

Daily check-in
Keeping your phone or device on you will help to better understand your daily activity, which will help the study.

In the last 24 hours, how often did you have your phone or wearable device with you?

- All the time
- Most of the time
- About half of the time

Next  Skip  Cancel

Daily check-in
Which activity did you do that may not have been recorded by your phone or wearable?

Walking
Jogging
Cycling
Tennis or other racquet sport

Next  Skip  Cancel

Daily check-in
Use the below scroll to indicate how long, in hours and minutes, you think you slept last night.

How many hours of sleep did you get last night?

- 4
- 5
- 6
- 7
- 8
- 9
- 10

0 min

Next  Skip  Cancel  Done

Stanford University
Automated six-minute walk test

Traditional

MyHeart Counts

User feedback

6-Minute Walk Test Comparison
You vs Others
820 yards
Automated six-minute walk test

Reference values for the six-minute walk test in healthy children and adolescents in Switzerland.

Ulrich S1, Hildenbrand FP, Treder U, Fischer M, Keusch S, Soeije R, Faenacht M.

Reference equations for the six-minute walk distance in healthy Korean adults, aged 22-59 years.


Health-related physical fitness measures: reference values and reference equations for use in clinical practice.

Eab BA Fun weg issuena m

Referece equations for the six-minute walk distance based on a Brazilian multicenter study.

Britto RR1, Probst VS2, de Andrade AE1, Samora GA1, Hernandes NA2, Marinho PF3, Karsten M4, Pitta F2, Parreira VF1.

Six-minute walk test-normal values of school children aged 7-12 y in India: a cross-sectional study.

D'Silva C1, Vejalsh K, Venkatesan P.

OBJECTIVE: To establish normal reference standards for six minute walk test of children aged between 7-12 y in India.

METHODS: Healthy children aged between 7 to 12 y were recruited randomly from the selected schools in India. 400 children were included.

RESULTS: 6 minute walk test (MWT) was performed according to standardized ATS guidelines. Distance walked in 6 min, Heart rate (HR), Blood pressure (BP), Oxygen saturation, anthropometric measurements and level of dyspnea were taken as outcome measures.

CONCLUSIONS: In this study, the mean distance covered in 6 min by boys was 670.74 ± 86.21 m and girls were 548.93 ± 44.78 m.
Automated six-minute walk test

Reference values for the six-minute walk test in healthy children and adolescents in Switzerland.
Ulrich S1, Hildenbrand FF, Treder U, Fischler M, Keusch S, Steiner R, Faesacht M.

Reference equations for the six-minute walk distance in healthy Korean adults, aged 22-59 years.

Health-related physical fitness measures: reference values and reference equations for use in clinical practice.

Reference values of the six-minute walk test in healthy Turkish children and adolescents between 11 and 18 years of age.

Reference equations for the six-minute walk distance based on a Brazilian multicenter study.
Brito RR1, Probst VS2, de Andrade AE1, Samora GA1, Hernandes NA2, Marinho PE3, Karsten M4, Pitta F2, Perreira VF1.

Six-minute walk test-normal values of school children aged 7-12 y in India: a cross-sectional study.
D’Silva C1, Vajishai K, Venkateshan P.

RESULTS: The study sample was 496 healthy children aged 7-12 years who were randomly selected from the selected schools in India. The study sample was divided into two groups: boys and girls. The sample included 259 boys and 237 girls. The mean age of the boys was 8.22 years (SD ± 1.23) and the mean age of the girls was 8.23 years (SD ± 1.18).

CONCLUSIONS: The mean distance walked in 6 min was 609 ± 166 m, with significant difference between boys and girls (p < 0.001). Boys covered more distance than girls. Heart rate increased from a baseline of 82.7 ± 1.63 to a maximum of 104.32 ± 3.11; heart rate recovery occurred at 5 min and 6 min in both the genders. SBP increased from baseline 109 ± 2.38 to maximum of 121.86 ± 1.75 at the end of the test, with no significant increase in DBP which was 68.51 ± 2.21 and 69 ± 2.78 at the end of the test. No significant change in oxygen saturation and dyspnea was observed during the test. Mean oxygen saturation was 97% at baseline, with an immediate drop of 96%.
Automated six-minute walk test

Reference equations for the six-minute walk distance

Health-related physical fitness measures: ref. practice.

A Reference values of the 6-minute walk test for the 11-18 years old adolescent.

A cross-sectional study.

d between 7-12 y in India.

Objective: To establish normal reference values for the 6-minute walk test.

Methods: Healthy children aged both boys and girls walked 6 min in a 48-foot corridor, with the distance walked recorded. Heart rate increased with distance walked.

Results: Children walked an average of 48 feet in 6 minutes. Heart rate increased with distance walked.

Conclusions: Normal reference values for the 6-minute walk test were established for healthy children aged 7-12 years.
Rich 6MWT data
Rich 6MWT data

Demo of LSE on walk data
Heart Age and Lifetime Risk Calculators

- **10-year risk**: How likely is an individual to suffer from a myocardial infarction within the next ten years, as compared to the general US adult population.

- **Heart age**: Age of an individual with the same 10-year-risk as our subject, but with optimal predictor values.

![Image](image-url)
Record-Breaking 40K Use App to Join Heart Study

Marcia Frellick
May 26, 2015

More than 40,000 people downloaded a smartphone app and joined an ongoing global research study to measure how activity affects heart health.

"Just to be clear, 2 months ago this didn't exist; there was nobody in this study," said Euan Ashley, MD, from Stanford University in California, who is one of the creators of the app. "Over the course of 2 weeks in March, 30,000 people signed up," he reported.

The response demonstrates that big data can be harnessed at minimal cost, which could help revolutionize the way research is done, Dr Ashley explained.

"We're really in a new era, and one we don't really understand," he said at the Big Data in Biomedicine Conference in Stanford.

Stanford researchers, in collaboration with the American Heart Association, designed the free smartphone app called MyHeart Counts. Anyone 18 or older with an iPhone 5s, 6, or 6 Plus can download the app, give consent to be included in the study, answer survey questions about risk factors, and then let sensors record their movements for 7 days. The app will ask users to
Figure 1 Proportion of daily users in the first five smartphone research apps developed using ResearchKit, March 9 to October 5, 2015.
We are Stanford’s 2nd most popular iOS app

<table>
<thead>
<tr>
<th>Name</th>
<th>Apple ID</th>
<th>App Units</th>
<th>Percentage of Total</th>
<th>Change</th>
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<tr>
<td>Stanford Mobile iOS</td>
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<td>731</td>
<td>47%</td>
<td>-3.4%</td>
</tr>
<tr>
<td>MyHeart Counts iOS</td>
<td>972189947</td>
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<td>24%</td>
<td>-8.3%</td>
</tr>
<tr>
<td>Stanford Magazine+ iOS</td>
<td>655174267</td>
<td>74</td>
<td>4.8%</td>
<td>-1.3%</td>
</tr>
<tr>
<td>STREAM-Stanford Migraine Study</td>
<td>1374032422</td>
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<td>4.7%</td>
<td>-1.4%</td>
</tr>
<tr>
<td>Hoover Institution iOS</td>
<td>964410905</td>
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<td>2.7%</td>
<td>-2.4%</td>
</tr>
</tbody>
</table>

Steady number of daily active users

Focus on bug fixes is reducing crashes

*Count is higher. Only users who opt-into apple analytics are counted; June bump due to email blast.
We are Stanford’s 2nd most popular iOS app (#1 for impressions)

Slight drop in number of daily active users

Focus on bug fixes is reducing crashes
Overview

● Motivation for the study
● MyHeart Counts platform
● Data portal
● Findings from observational study of physical activity in 50000 app users
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● Genomewide association study in collaboration with 23andMe
● Lessons learned
● Future directions
Feasibility of Obtaining Measures of Lifestyle From a Smartphone App
The MyHeart Counts Cardiovascular Health Study

Michael V. McConnell, MD, MSEE; Anna Shcherbina, MEng; Aleksandra Pavlovic, BS; et al.

Physical activity, sleep and cardiovascular health data for 50,000 individuals from the MyHeart Counts Study

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myheartcounts.stanford.edu
74% of onboarded participants choose to share broadly.

- Share broadly with qualified researchers: You can choose to share your coded study data with qualified researchers worldwide for use in this research and beyond. Coded study data are data that do not include personal information such as your name or email. Qualified researchers will need to meet certain criteria established by Stanford and agree to use the data in an ethical manner for research purposes.

- Share with Stanford researchers and its partners only: You can choose to share your study data only with Stanford and its partners. This means that your study data will not be made available to other researchers beyond Stanford and its research partners.

Diagram:
- Downloaded MHC app (n=112000)
  - Did not enroll (n=62161)
  - Provided consent (n=49839)
    - E-mail not verified (n=4195)
    - E-mail address verified (n=45644)
      - Withdrew from study (n=7923)
        - Opted to share broadly (n=34189)
        - Opted to share narrowly (n=11973)
1 - Accessing the MyHeart Counts data

The content available through this portal would not be possible without the generous participation of research participants and collaborating research investigators. The study utilizes a novel remote approach to enrollment in which participants self-guide through a visually engaging and robust informed consent process. As part of this process, participants specify if the data they donate to the study can also be used for secondary research purposes. Data described and made available here are derived exclusively from those participants who chose to make their data broadly available for secondary research. The requirements for accessing the study dataset incorporate elements to honor this engagement to sharing data. We are hopeful that the data generously donated by participants will encourage the formation of a broad, diverse, and collaborative community of researchers.

Steps for Access

Access to this data is granted only to qualified researchers who agree to specific Conditions for Use designed to protect the privacy of study participants. The MyHeart Counts data may not be redistributed.

To qualify for access to these data, follow the instructions below.

- **Step 1.** Register for a Synapse account (if you do not have one already)
- **Step 2.** Become a Certified Synapse user (if you are not already)
- **Step 3.** Have your user profile validated (if not done already)
- **Step 4.** Submit your Intended Data Use statement
- **Step 5.** Agree to the data-specific Conditions for Use
- **Step 6.** Download the data
Data is available to all “Qualified Researchers”

1. Register for a Synapse account (www.synapse.org)
2. Become a Synapse Certified User by passing a short quiz (www.synapse.org/#!Quiz:Certification)
3. Have Synapse User Profile validated by the Synapse Access and Compliance Team
4. Submit an Intended Data Use statement that is publicly posted
5. Agree to the data-specific Conditions for Use
Data is longitudinal over 6 months
Data is longitudinal over 6 months, but rarely continuous for a user.
Data is longitudinal over 6 months, but rarely continuous for a user.
Participants come from almost every state
Researchers come from all over the US & world

- China
- Qatar (2)
- Australia
Data use statements for using MyHeart Counts data

Researcher: Abhishek Pratap
Affilition: Sapi Bioswerorks

Extended Data Use Statement (accepted on 04/03/2019)

We hypothesize that the usage and user attributes in mobile apps could be associated with certain characteristics and the characteristics by use, we observed a correlation. Our team is interested in using the data for developing an understanding of what and what specific activities in applications people use often.

Researcher: Ali Ferdowsali Maleki
Affiliation: Texas A&M University at Qatar

Extended Data Use Statement (accepted on 06/06/2019)

We would like to analyze the MyHeart Counts data using machine learning approaches to investigate whether a medically meaningful but concise summary of a user’s health profile can be computed using their physical activity data. The ultimate aim is to investigate how accurately such machine learning algorithms can determine the health status of an individual using their lifestyle data that acquired through smart wearable devices such as a smartphone or a smart watch. We will use historical data to identify the relevant features as well as explore the conditional relationship strategies to improve the machine learning algorithms such as artificial neural network, deep learning, support vector machine, etc., for better performance. The performance of the developed algorithm will be evaluated using metrics including fold cross validation, accuracy, sensitivity, specificity, and area under the curve value.

Researcher: Brian But
Affiliation: Sapi Bioswerorks

Extended Data Use Statement (accepted on 04/16/2019)

I am interested in exploring these data to determine patterns of activity both within the My Heart Counts study as well as across digital health studies. Specifically, I am interested in investigation at different junctions of a remote digital health study.

Researcher: Xie Jiecheng
Affiliation: Biofouriers Pte Ltd

Extended Data Use Statement (accepted on 04/23/2019):

To investigate the feasibility of app-only healthcare monitoring and predictive analysis in iPhone

To investigate the correlation between cardiovascular disease and results of 6MWT

To analyze the walking pattern from 6MWT and validate algorithms on walking detection, walking distance and steps.

To analyze lifestyle pattern and validate algorithms on sleep detection

Researcher: Nirmal Netravali, MD
Affiliation: Massachusetts General Hospital

Extended Data Use Statement (accepted on 07/19/2019)

The purpose of this study is to describe a normal distribution of physical activity and hours of sleep among participants of the MyHeart Counts study, stratified by demographic information. Multiple studies, including the Framingham Heart Study, have established the importance of physical activity, fitness, and other lifestyle factors in contributing to normal cardiovascular health and in cardiometabolic disease risk. However, appropriate guidelines and evidence are still emerging. The MyHeart Counts Cardiovascular Health Study (Investigator’s Researcher: Nirmal Netravali, MD) will evaluate a broad range of cardiovascular health metrics in participants, including physical activity, fitness, and sleep patterns. Participants will be invited to their identified health data by qualified research associates. This study will be a descriptive analysis of the MyHeart Counts Cardiovascular Health Study data, the intent is to understand the normal distribution of physical activity, and sleep patterns among healthy study participants. The initial analysis will be performed using the R programming language on other similar statistical packages.

Researcher: Navid Shah
Affiliation: 2. Craig-Venter Institute

Extended Data Use Statement (accepted on 03/16/2019)

Several studies have shown that lifestyle factors such as fitness, body mass index, diet and sleep contribute to the risk for cardiovascular disease. Most of these studies use questionnaire, which is subjective, to quantify lifestyle factors at a given timepoints rather than continuous objective measurements using wearables. Our hypothesis is that continuous objective measurements, which allows identification of any abnormal fluctuation from an individual’s normal, is a better predictor of health risk. MyHeart Counts data is unique and offers potential to discover novel associations between lifestyle factors and health.

In this study, we will perform analysis to better understanding the impact of lifestyle factors on biological functioning of an individual measured by variables such as blood glucose, vital signs and the impact it has on cardiovascular health. We will explore relationships between measurements, including the subjective and objective measurements, that are captured using the wearables and surveys. We anticipate that this study will identify novel associations and risk factors for cardiovascular health and generate hypotheses for disease prevention recommendations. We will apply extended-state of-the-art AI approaches such as topological data analysis and reinforcement learning, in the process, we may also develop new AI tools.

Researcher: Tony Althoff
Affiliation: University of Washington

Extended Data Use Statement (accepted on 02/22/2019)

What do you want to do?

We want to discover insightful patterns in the rich behavioral data (e.g., physical activity, sleep) that are predictive of health outcomes (e.g., cardiovascular health).

Why are you doing it?

We are currently developing novel machine learning and data mining techniques that are able to learn useful representations for users in the study, and are able to surface actionable insights and health-relevant patterns.

How do you want to do it?

We will develop and apply machine learning and data mining techniques to the rich behavioral data (e.g., physical activity, sleep) that are predictive of health outcomes (e.g., cardiovascular health). In addition, we will apply causal inference methods to reduce the effect of confounding across multiple prediction tasks.

Researcher: Dr. Bingnan Xu
Affiliation: Department of Epidemiology and Preventive Medicine, School of Public Health and Preventive Medicine, Monash University, Australia

Extended Data Use Statement (accepted on 06/13/2019)

We aim to use this dataset to evaluate the impacts of air pollution (e.g., PM2.5, PM10, CO2 data and climatic data) and local humidity temperature on participants who provided the postcode of their address. Then, we will use a Cox model design with linear mixed effect models and aggregate the non-linear mixture to quantify the association between environmental exposure and indicators recorded by smartphone.

Researcher: Ross Tummers
Affiliation: Texas A&M University at Qatar

Extended Data Use Statement (accepted on 07/05/2019)

The objective is to study the MyHeart Counts data to create a machine-learning algorithms that can classify and predict potential health risks such as diabetes based on physical activity, fitness and sleep. This can be done by analyzing the data obtained through devices such as a smartphone or smartwatch and determining the correlation between an individual’s lifestyle and health status. Statistical analysis such as k-means and hierarchical clustering will be the method that employed to conduct the study.
Data use statements for using MyHeart Counts data

Researcher: Brian Bot
Affiliation: Sage Bio-networks
Intended Data Use Statement (accepted on 04/16/2019):
I am interested in exploring these data to determine patterns of activity both within the My Heart Counts study as well as across digital health studies. Specifically, I am interested in attrition rates at different junctions of a remote digital health study.

To investigate the feasibility of app-only healthcare monitoring and predictive analysis in iPhone
To investigate the correlation between cardiovascular disease and results of 6MWT
To analyze the walking pattern from 6MWT and validate algorithms on walking detection, walking distance and steps.
To analyze lifestyle pattern and validate algorithms on sleep detection.

Researcher: Nidhi Shukla
Affiliation: Z Jay Weisler Institute
Intended Data Use Statement (accepted on 04/20/2019):
Several recent studies have shown that lifestyle factors such as fitness, body mass index, diet and sleep contribute to the risk for cardiovascular disease. Most of these studies use questionnaires, which is subjective, to quantify lifestyle factors at a given time-point rather than continuous objective measurements using wearables. Our hypothesis is that continuous objective measurements, which allows identification of any abnormal fluctuation from an individual’s normal, is a better predictor of health risk. MyHeart Counts data is unique and offers potential to discover novel associations between lifestyle factors and health.
In this study, we will perform analysis to better understanding the impact of lifestyle factors on biological functioning of an individual measured by variables such as blood glucose, vital signs and the impact it has on cardiovascular health. We will explore relationships between measurements, including the subjective and objective measurements, that are captured using the wearable and surveys. We anticipate that this study will identify novel associations and risk factors for cardiovascular health and generation of hypothesis for disease prevention recommendations. We will apply extended state of the art AI approaches such as topological data analysis.
Data use statements for using MyHeart Counts data

Researcher: Naisha Shah  
Affiliation: J. Craig Venter Institute  
Intended Data Use Statement (accepted on 05/16/2019):

Several studies have shown that lifestyle factors such as fitness, body mass index, diet and sleep contribute to the risk for cardiovascular disease. Most of these studies use questionnaire, which is subjective, to quantify lifestyle factors at a given timepoint rather than continuous objective measurements using wearables. Our hypothesis is that continuous objective measurements, which allows identification of any abnormal fluctuation from an individual’s "normal", is a better predictor of health risk. MyHeart Counts data is unique and offers potential to discover novel associations between lifestyle factors and health.

In this study, we will perform analysis to better understanding the impact of lifestyle factors on biological functioning of an individual measured by variables such as blood glucose, vital signs and the impact it has on cardiovascular health. We will explore relationship between measurements, including the subjective and objective measurements, that are captured using the wearable and surveys. We anticipate that this study will identify novel associations and risk factors for cardiovascular health and generation of hypothesis for disease prevention recommendations. We will apply extended state-of-the-art AI approaches such as topological data analysis and reinforcement learning. In the process, we may also develop novel AI tools.
Data use statements for using MyHeart Counts data

Researcher: Wahid Fakih
Affiliation: Texas A&M University at Qatar
Intended Data Use Statement (accepted on 05/06/2019):

To analyze lifestyle patterns and validate algorithms on sleep detection.

Researcher: Ashima Pranav
Affiliation: Sapiens Bioworks
Intended Data Use Statement (accepted on 04/03/2019):

We hypothesize that the usage and user activity in mobile apps could be associated with certain characteristics of the users and activity types (e.g., monitored-based activity). Our team is interested in using the data for developing an understanding of what and what specific activities in application people use often.

Researcher: Nabiha Shul
Affiliation: 2. Craig Venter Institute
Intended Data Use Statement (accepted on 05/16/2019):

Several studies have shown that lifestyle factors such as fitness, body mass index, diet and sleep contribute to the risk for cardiovascular disease. Most of these studies use questionnaires, which is subjective, to quantify lifestyle factors at a given timepoint rather than continuous objective measurements using wearables. Our hypothesis is that continuous objective measurements, which allows identification of any abnormal fluctuation from an individual’s “norm,” is a better predictor of health risk. MyHeart Counts data is unique and offers potential to discover novel associations between lifestyle factors and health.

In this study, we will perform analysis to better understand the impact of lifestyle factors on biological function of an individual measured by variables such as blood glucose, vital signs and the impact it has on cardiovascular health. We will explore relationships between measurements, including the subjective and objective measurements, that are captured using the wearable and surveys. We anticipate that this study will identify novel associations and risk factors for cardiovascular and health and generation of hypotheses for disease prevention recommendations. We will apply extended state-of-the-art AI approaches such as topological data analysis and reinforcement learning. In the process, we may also develop novel AI tools.

Researcher: Dr. Rongbin Xu
Affiliation: Department of Epidemiology and Preventive Medicine, School of Public Health and Preventive Medicine, Monash University, Australia
Intended Data Use Statement (accepted on 05/13/2019):

We aim to use this dataset to evaluate the impacts of air pollution and climatic factors on participant’s sleep quality, physical activity, and heart health. We will link ambient air pollution (e.g., PM2.5, SO2, CO) data and climatic data (relative humidity, temperature) to participants who provided the postcode of their address. Then, we will use a panel study design, with linear mixed effect models and distributed lag non-linear models to quantify the association between environmental exposure and indicators recorded by smartphone.

Researcher: Nael Elhamamsy, MD
Affiliation: Mayhem Healthcare General Hospital
Intended Data Use Statement (accepted on 07/02/2019):

The purpose of this study is to describe a normal distribution of physical activity and hours of sleep among participants of the MyHeart Counts study, stratified by demographic information. Multiple studies, including the Preventing Heart Events Statistically (PHESS) study, have established the importance of physical activity, fitness, and other lifestyle factors in contributing to a reduced cardiovascular health and in cardiometabolic disease risk. However, a robust database such as on self-report or on an online period of active measurement, primarily due to the real-world challenges of data collection. With the advent of smartphones and wearable fitness monitors, observational data on real-world physical activity and sleep patterns are now available. The MyHeart Counts Cardiovascular Health Study (Mayhem) Research Toolkit for Tailored Study Enrollment and Data Collection on participants’ physical activity, sleep and self-reported health metrics. Participants consented to their de-identified data being used by qualified researchers worldwide. This study will be a descriptive analysis of the MyHeart Counts Cardiovascular Health Study data, used to better understand the distribution of physical activity and sleep patterns amongst healthy study participants, and evaluate the distribution is stratified by various demographic factors including age, sex, BMI, level of education and zip code. Statistical analyses will be performed using R programming language on other similar statistical packages.

Researcher: Nino Tumpek
Affiliation: Texas A&M University at Qatar
Intended Data Use Statement (accepted on 07/05/2019):

The objective is to study the MyHeart Counts data to create a machine-learning algorithms that can classify and predict potential health risks such as diabetes based on physical activity, fitness and sleep. This can be done by analyzing the data obtained through devices such as a smartphone or smartwatch and determining the correlation between an individual’s lifestyle and their health status. Statistical analysis such as k-means and hierarchical clustering will be the method that employed to conduct the study.
Overview

- Motivation for the study
- MyHeart Counts platform
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Scientific Data 6, Article number: 24 (2019) | Download Citation
50,000 users joined the MyHeart Counts study in the 6 months after launch.
Table 1. Participant Cardiovascular Health Diagnoses and Family History

<table>
<thead>
<tr>
<th>Demographic</th>
<th>No. of Participants</th>
<th>% Of Responders</th>
<th>% Of All Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Family History</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Father or brother with heart attack or coronary artery disease before age 65 y</td>
<td>3890</td>
<td>18.0</td>
<td>9.7</td>
</tr>
<tr>
<td>Mother or sister with heart attack or coronary artery disease before age 65 y</td>
<td>1600</td>
<td>7.4</td>
<td>4.0</td>
</tr>
<tr>
<td>None</td>
<td>16 144</td>
<td>74.6</td>
<td>40.3</td>
</tr>
<tr>
<td>No response</td>
<td>18 383</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Medications</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>To treat and lower cholesterol</td>
<td>2904</td>
<td>12.4</td>
<td>7.3</td>
</tr>
<tr>
<td>To treat hypertension and lower blood pressure</td>
<td>3385</td>
<td>14.5</td>
<td>8.5</td>
</tr>
<tr>
<td>To treat diabetes or prediabetes and lower blood glucose level</td>
<td>698</td>
<td>3.0</td>
<td>1.7</td>
</tr>
<tr>
<td>None</td>
<td>16 364</td>
<td>70.1</td>
<td>40.9</td>
</tr>
<tr>
<td>No response</td>
<td>16 666</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Heart Disease</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart attack or myocardial infarction</td>
<td>474</td>
<td>2.1</td>
<td>1.2</td>
</tr>
<tr>
<td>Heart bypass surgery</td>
<td>230</td>
<td>1.0</td>
<td>0.6</td>
</tr>
<tr>
<td>Coronary blockage or stenosis</td>
<td>370</td>
<td>1.6</td>
<td>0.9</td>
</tr>
<tr>
<td>Coronary stent or angioplasty</td>
<td>488</td>
<td>2.2</td>
<td>1.2</td>
</tr>
<tr>
<td>Angina, heart chest pains</td>
<td>448</td>
<td>2.0</td>
<td>1.1</td>
</tr>
<tr>
<td>High coronary calcium score</td>
<td>106</td>
<td>0.5</td>
<td>0.3</td>
</tr>
<tr>
<td>Heart failure or congestive heart failure</td>
<td>163</td>
<td>0.7</td>
<td>0.4</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>493</td>
<td>2.2</td>
<td>1.2</td>
</tr>
<tr>
<td>Congenital heart defect</td>
<td>413</td>
<td>1.8</td>
<td>1.0</td>
</tr>
<tr>
<td>None</td>
<td>19 272</td>
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<td>48.2</td>
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<tr>
<td><strong>Vascular Disease</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>158</td>
<td>0.7</td>
<td>0.4</td>
</tr>
<tr>
<td>Transient ischemic attack</td>
<td>152</td>
<td>0.7</td>
<td>0.4</td>
</tr>
<tr>
<td>Carotid artery blockage or stenosis</td>
<td>235</td>
<td>1.1</td>
<td>0.6</td>
</tr>
<tr>
<td>Carotid artery surgery or stent</td>
<td>322</td>
<td>1.5</td>
<td>0.8</td>
</tr>
<tr>
<td>Peripheral vascular disease, blockage or stenosis, surgery, or stent</td>
<td>254</td>
<td>1.2</td>
<td>0.6</td>
</tr>
<tr>
<td>Abdominal aortic aneurysm</td>
<td>77</td>
<td>0.4</td>
<td>0.2</td>
</tr>
<tr>
<td>None</td>
<td>20 269</td>
<td>94.4</td>
<td>50.7</td>
</tr>
<tr>
<td>No response</td>
<td>18 550</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>
K-means clustering used to assign participants to one of 10 activity groups.
Based on a week of baseline activity levels, participants assigned to one of five activity clusters.

A Clusters of recorded physical activity

B Probability for individuals in different activity clusters
State transitions are associated with health status independent of total activity.
MyHeart Counts app identified associations between sleep habits and self-reported happiness.
On average, predicted heart age in the MHC cohort is 6 years higher than biological age and was poorly predicted by users.
Overview

- Motivation for the study
- MyHeart Counts platform
- Data portal
- Findings from observational study of physical activity in 50000 app users
  - Randomized controlled trial of coaching strategies to increase user step count
- Genomewide association study in collaboration with 23andMe
- Lessons learned
- Future directions
MyHeart Counts digital RCT registered in ClinicalTrials.gov

Primary outcome:
Daily step count from HealthKit

Secondary outcomes:
- Sleep duration
- Sleep quality
- Self-reported mental wellbeing

N= 2783 consented (as of July 27, 2018)
Four interventions delivered via MHC app

- Passive education (American Heart Association)
- Personalized coaching based on activity cluster
- Daily mid-day 10,000 step prompt
- Continuous 1 hour sedentary trigger to stand and walk
Personalized coaching based on activity cluster derived from baseline week of monitoring.
Participants randomized to four interventions in cross-over design
Participants randomized to four interventions in cross-over design

Assign to one of five activity clusters (n=2783) → Enrolled in coaching study (n=2783)

1. Cluster-Specific Prompt (n=477)
2. 10K Daily Steps Prompt (n=453)
3. Read AHA Literature Prompt (n=453)
4. Hourly Stand Prompt (n=477)

7 day follow up period

Assign to one of five activity clusters (n=385)

1. Cluster-Specific Prompt (n=385)
2. 10K Daily Step Prompt (n=365)
3. Read AHA Literature Prompt (n=366)
4. Hourly Stand Prompt (n=384)

7 day follow up period

Assign to one of five activity clusters (n=322)

1. Cluster-Specific Prompt (n=322)
2. 10K Daily Step Prompt (n=326)
3. Read AHA Literature Prompt (n=304)
4. Hourly Stand Prompt (n=309)

7 day follow up period

Assign to one of five activity clusters (n=148)

1. Cluster-Specific Prompt (n=148)
2. 10K Daily Step Prompt (n=174)
3. Read AHA Literature Prompt (n=164)
4. Hourly Stand Prompt (n=162)

7 day follow up period
Participants randomized to four interventions in cross-over design

Assign to one of five activity clusters (n=2783)

Cluster-Specific Prompt (n=477)
10K Daily Steps Prompt (n=453)
Read AHA Literature Prompt (n=453)
Hourly Stand Prompt (n=477)

Enrolled in coaching study (n=2783)

7 day follow up period

Cluster-Specific Prompt (n=385)
10K Daily Step Prompt (n=365)
Read AHA Literature Prompt (n=356)
Hourly Stand Prompt (n=384)

Cluster-Specific Prompt (n=322)
10K Daily Step Prompt (n=326)
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Hourly Stand Prompt (n=309)

Cluster-Specific Prompt (n=148)
10K Daily Step Prompt (n=174)
Read AHA Literature Prompt (n=164)
Hourly Stand Prompt (n=162)

7 day follow up period
Participants randomized to four interventions in cross-over design
Participants randomized to four interventions in cross-over design
Participants randomized to four interventions in cross-over design

Assign to one of five activity clusters (n=2783)

Enrolled in coaching study (n=2783)

Cluster-Specific Prompt (n=477)

10K Daily Steps Prompt (n=453)

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Hourly Stand Prompt (n=477)

7 day follow up period

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10K Daily Step Prompt (n=326)

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Hourly Stand Prompt (n=309)

7 day follow up period

Cluster-Specific Prompt (n=148)

10K Daily Step Prompt (n=174)

Read AHA Literature Prompt (n=164)

Hourly Stand Prompt (n=162)

7 day follow up period
Participants randomized to four interventions in cross-over design.
Participants randomized to four interventions in cross-over design.
Participants randomized to four interventions in cross-over design

Baseline collected

Assign to one of five activity clusters (n=2783)

Enrolled in coaching study (n=2783)

Cluster-Specific Prompt (n=477)

10K Daily Steps Prompt (n=453)

Read AHA Literature Prompt (n=453)

Hourly Stand Prompt (n=477)

7 day follow up period

Cluster-Specific Prompt (n=385)

10K Daily Step Prompt (n=365)

Read AHA Literature Prompt (n=356)

Hourly Stand Prompt (n=384)

7 day follow up period

Cluster-Specific Prompt (n=322)

10K Daily Step Prompt (n=326)

Read AHA Literature Prompt (n=304)

Hourly Stand Prompt (n=309)

7 day follow up period

Cluster-Specific Prompt (n=148)

10K Daily Step Prompt (n=174)

Read AHA Literature Prompt (n=164)

Hourly Stand Prompt (n=162)

7 day follow up period

Final N ascertained

n= 868  n= 896  n= 853  n=879

Stanford University
Study demographics [n= 2783]

<table>
<thead>
<tr>
<th>Demographic</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart Disease</td>
<td>327</td>
<td>19.21%</td>
</tr>
<tr>
<td>Smoking status</td>
<td>24</td>
<td>2.72%</td>
</tr>
<tr>
<td>Family history of heart disease</td>
<td>477</td>
<td>28.4%</td>
</tr>
<tr>
<td>Hypertension (treated)</td>
<td>466</td>
<td>23.14%</td>
</tr>
<tr>
<td>High cholesterol (treated)</td>
<td>436</td>
<td>21.66%</td>
</tr>
<tr>
<td>Diabetes/prediabetes (treated)</td>
<td>88</td>
<td>4.37%</td>
</tr>
</tbody>
</table>

Number of Study Participants

Age distribution

Females (17.8%)

Males (82.2%)

Number of Individuals per County

Stanford University
Statistical analysis via linear mixed-effects model

- **Primary outcome:** Daily step count from phone accelerometry

- **Fixed effects:**
  - Treatment factor with five levels (baseline and four types of interventions)
  - Day index: Integer [1,35] indicating the day within the study cycle at which data was collected

- **Random effects:**
  - Participant

- **Outliers with daily step count > 25,000 excluded from analysis**
  - Sensor noise
<table>
<thead>
<tr>
<th>Effect Size (Steps)</th>
<th>P-value</th>
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<tr>
<td>185+/−78</td>
<td>1.77e−2</td>
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<td>1.77e-2</td>
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<td>237 +/- 77</td>
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All four interventions had a modest positive effect on primary outcome of daily step count

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<td>290+/-77</td>
<td>2.00e-4</td>
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- No intervention was more significant than the others.
Intervention effect size higher for Apple Watch users (as compared to users with only an iPhone)

- All p-values <0.01
Conclusions

- Feasibility of cross-over RCT conducted entirely in the digital domain
- All four examined interventions significantly increased the primary outcome of daily step count
- No intervention was found to be more statistically significant than the others
- No effect on secondary outcomes (sleep duration, sleep quality, mental wellbeing) was observed
- Behavioral coaching programs administered through smartphones can lead to short term increases in daily physical activity.
Overview

- Motivation for the study
- MyHeart Counts platform
- Data portal
- Findings from observational study of physical activity in 50000 app users
- Randomized controlled trial of coaching strategies to increase user step count
  - Genomewide association study in collaboration with 23andMe
- Lessons learned
- Future directions
Physical activity assessment via phone accelerometers

23andMe genetic data

Surveys about lifestyle factors and history of disease

Perform GWAS

Validate in other cohorts
23andMe Activity

Sign in with 23andMe

Email
Password

Forgot your password?
sign in
Sign up for free

Attention!
Your personal information is being requested. Please choose carefully.

RK Lifemap requests that you authorize its app to use the below information from your 23andMe account. 23andMe has not evaluated the app.

- The entire genome for all profiles in your account. This includes all SNP locations except those you haven’t opted into. If you grant access, a third party will

Congratulations
You have successfully signed up for 23andMe. MyHeart Counts will be able to access your data as soon as it’s available.
23andMe Activity
PCA analysis separates subjects by self-reported ancestry
57 MHC phenotypes for GWAS (40 continuous, 17 categorical)

**Features derived from accelerometry data**
- Minutes per day/ fraction of awake time spent stationary, running, walking, cycling, driving
- HealthKit daily step count and distance walked

**Self-reported medical history**
- Chest pain
- Dizziness
- Prescription drugs
- Heart disease
- Joint problems
- Diagnosed heart conditions
- Family history of heart disease

**Self-reported lifestyle**
- Weekly moderate/ vigorous activity
- Chronotype
- Diet (servings of fruit, vegetables, sugar)
- Mood (happy, depressed, anxious)
GWAS analysis

● Data pre-processing:
  ○ Mean value of each phenotype across subjects was calculated, and any outlier +/- 3 standard deviations away from the mean was truncated at this threshold.
  ○ Linear regression was then performed with phenotype as the continuous outcome
    ■ Covariates Age, Sex, PC1 - PC5
  ○ Residuals from the regression were quantile-normalized, and the resulting values were used as phenotypes for PLINK2 analysis.
  ○ Categorical phenotypes were converted to case/control values, with 1 indicating a control, and 2 indicating case.

● Total genotyping rate is 0.598551

● 1133211 variants and 1289 people pass filters and QC in PLINK
GWAS: Significant hits observed for five loci

<table>
<thead>
<tr>
<th>Phenotype</th>
<th>CHR</th>
<th>SNP</th>
<th>BP</th>
<th>P</th>
<th>Locus SNPs in GWAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minutes of running per week</td>
<td>2</td>
<td>rs113890238</td>
<td>114,029,767</td>
<td>3.28E-08</td>
<td>19</td>
</tr>
<tr>
<td>Minutes of moderate physical activity per week</td>
<td>17</td>
<td>rs2005705</td>
<td>36096300</td>
<td>2.92E-08</td>
<td>17</td>
</tr>
<tr>
<td>Daily HealthKit step count</td>
<td>3</td>
<td>rs536393866</td>
<td>186,894,677</td>
<td>4.02E-08</td>
<td>25</td>
</tr>
<tr>
<td>Familial history of heart disease (paternal)</td>
<td>1</td>
<td>rs575277</td>
<td>84,840,096</td>
<td>2.12E-08</td>
<td>42</td>
</tr>
<tr>
<td>HDL cholesterol levels</td>
<td>17</td>
<td>rs62076159</td>
<td>60,781,419</td>
<td>3.19E-08</td>
<td>16</td>
</tr>
</tbody>
</table>
Daily Step Count from HealthKit  \( N=997 \)

RPL39L intron

---

Stanford University
Minutes of Running per week  N=435
Minutes of moderate physical activity per week: Validation in the GWAS Catalog

N=1138

rs2005705 positively associated with BMI and risk of early-onset prostate cancer in the GWAS catalog

<table>
<thead>
<tr>
<th>Chromosome</th>
<th>Description</th>
<th>Reference</th>
<th>Year</th>
<th>Journal</th>
</tr>
</thead>
<tbody>
<tr>
<td>17</td>
<td>Chromosome 17q12 variants contribute to risk of early-onset prostate cancer.</td>
<td>Levin AM et al.</td>
<td>2008</td>
<td>Cancer research</td>
</tr>
<tr>
<td>11</td>
<td>Large-scale fine mapping of the HNF1B locus and prostate cancer risk.</td>
<td>Berndt SI et al.</td>
<td>2018</td>
<td>Human molecular genetics</td>
</tr>
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<td>Genome-wide association scan for variants associated with early-onset prostate cancer.</td>
<td>Lange EM et al.</td>
<td>2014</td>
<td>PloS one</td>
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● Lessons learned
● Future directions
Low barrier to entry allows rapid recruitment of large cohort

N=129

Testing the activitystat hypothesis: a randomised controlled trial

N=28

Increasing Recreational Physical Activity in Patients With Chronic Low Back Pain: A Pragmatic Controlled Clinical Trial.
Ben-Ami N, Chodick G, Mirovsky Y, Pincus T, Shapiro Y.

N=260

Fitness and health benefits of team handball training for young untrained women-A cross-disciplinary RCT on physiological adaptations and motivational aspects.

N=42

Exercise training in overweight and obese children: Recreational football and high-intensity interval training provide similar benefits to physical fitness.
Cvetković N, Stojanović E, Stojiljković N, Nikolić D, Scanlan AT, Milanović Z.

N=28
Long-term user engagement is one of the main challenges of wearable-based studies.
Improved strategies for longterm user engagement are needed.
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MHC Future Directions

Lab Studies
Several Years

Human Safety
Days or Weeks

Expanded Safety
Weeks or Months

Efficacy & Safety
Several Years

Preclinical
Phase I
Phase I/II
Phase III

Stages of Clinical Trials

Personal Risk Score

6.0

We’ve decided to take big data to the next level...

Humongous Data
MHC Future Directions

Lab Studies: Several Years
- Tens
- Preclinical
- Phase I

Human Safety: Days or Weeks
- Hundreds
- Phase II

Expanded Safety: Weeks or Months
- Thousands
- Phase III

Efficacy & Safety: Several Years

Stages of Clinical Trials

WE’VE DECIDED TO TAKE BIG DATA TO THE NEXT LEVEL...

Humongous Data

Stanford University
Heart Snapshot
Your phone’s camera can measure your heartbeat.
Learn how and why

Cover the flash and camera
Use your finger to cover the camera and flash on the back of your phone. Your finger nail should turn a little red once you cover the flash.

Sit down and relax
If you don’t feel relaxed, take a moment and breathe slowly before starting the measurement.
Tips for measuring resting heart rate

Heart Rate Recovery
Choose one of the tasks below. Each one is designed to raise your heart rate. Then we will measure how your heart recovers. The score is related to your VO2max.

3 Minute Stair Step
12 Minute Run or Walk
MHC Future Directions
HealthKit EMR Integration Today
MHC Future Directions
FDA’s MyStudies Application (App) example

https://www.fda.gov/Drugs/Science/Research/ucm624785.htm
Key MyStudies Attributes

- **Scalable**: Capability to simultaneously support multiple studies for a research organization
- **Modular**: Various modular components of the platform can be integrated with external/3rd party system of choice to create a tailored solution for your organization.
- **Secure**: Partitions all data and provides robust access controls
- **Compliant**: Can be deployed to comply with HIPAA, FISMA, and 21 CFR Part 11
- **Customizable**: All study content as seen in the app can be authored and updated via the WCP web application rather than through new software development per study or app
- **Tested**: FDA and PCORI sponsored clinical research demonstration projects
- **Open-source** and ready for research organizations to re-brand, publish, and use!
MyStudies Web Configuration Portal
MyStudies eConsent

Optional Eligibility Test

Overview
This study will ask about physical fitness. Your responses will not impact your healthcare and are only viewed by the study investigators. You must be at least 18 to participate in this study.

Data gathering
Data will be gathered weekly, and all questionnaires are optional.

Optional Comprehension Test

Review
Review the form below, and tap Agree if you're ready to continue.

Physical Activity
Overview
This study will ask about physical fitness. Your responses will not impact your healthcare and are only viewed by the study investigators. You must be at least 18 to participate in this study.

Data gathering
Data will be gathered weekly, and all questionnaires are optional.
MyStudies App Screens
Pattern.Health powering: ReBOOT Study of digital journaling post Transplant
ResearchKit Applications
MyHeart Counts Core Team
myheartcounts.stanford.edu

Euan Ashley
MB, ChB, DPhil
Principal Investigator

Abby King
PhD
Behavioral psychology

Steven Hershman
MS, MSE, PhD
Director of mHealth

Anna Shcherbina, MS, MEng
Graduate Student

Abhinav Sharma
MD, PhD(c)
Visiting Scholar

Michael V. McConnell
MD, MSEE
Study co-creator

Jack O'Sullivan, MBBS, DPhil
Visiting Scholar

Yas Moayedi
MD
Postdoctoral fellow
In CV medicine

Daniel Wu
BioX Intern

+ You? (Join the team!)