

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; Julian R. Homburger, BS; Rachel L. Goldfeder, MS; Daryl Waggot, MSc; Mildred K. Cho, PhD; Mary E. Rosenberger, PhD; William L. Haskell, PhD; Jonathan Myers, PhD; Mary Ann Champagne, RN, MS; Emmanuel Mignot, MD, PhD; Martin Landray, MB, ChB, PhD; Lionel Tarassenko, MA, DPhil; Robert A. Harrington, MD; Alan C. Yeung, MD; Euan A. Ashley, MB, ChB, DPhil

IMPORTANCE Studies have established the importance of physical activity and fitness, yet limited data exist on the associations between objective, real-world physical activity patterns, fitness, sleep, and cardiovascular health.

OBJECTIVES To assess the feasibility of obtaining measures of physical activity, fitness, and sleep from smartphones and to gain insights into activity patterns associated with life satisfaction and self-reported disease.

DESIGN, SETTING, AND PARTICIPANTS The MyHeart Counts smartphone app was made available in March 2015, and prospective participants downloaded the free app between March and October 2015. In this smartphone-based study of cardiovascular health, participants recorded physical activity, filled out health questionnaires, and completed a 6-minute walk test. The app was available to download within the United States.

MAIN OUTCOMES AND MEASURES The feasibility of consent and data collection entirely on a smartphone, the use of machine learning to cluster participants, and the associations between activity patterns, life satisfaction, and self-reported disease.

RESULTS From the launch to the time of the data freeze for this study (March to October 2015), the number of individuals (self-selected) who consented to participate was 48 968, representing all 50 states and the District of Columbia. Their median age was 36 years (interquartile range, 27-50 years), and 82.2% (30 338 male, 6556 female, 10 other, and 3115 unknown) were male. In total, 40 017 (81.7% of those who consented) uploaded data. Among those who consented, 20 345 individuals (41.5%) completed 4 of the 7 days of motion data collection, and 4552 individuals (9.3%) completed all 7 days. Among those who consented, 40 017 (81.7%) filled out some portion of the questionnaires, and 4990 (10.2%) completed the 6-minute walk test, made available only at the end of 7 days. The Heart Age Questionnaire, also available after 7 days, required entering lipid values and age 40 to 79 years (among 17 245 individuals, 43.1% of participants). Consequently, 1334 (2.7%) of those who consented completed all fields needed to compute heart age and a 10-year risk score. Physical activity was detected for a mean (SD) of 14.5% (8.0%) of individuals' total recorded time. Physical activity patterns were identified by cluster analysis. A pattern of lower overall activity but more frequent transitions between active and inactive states was associated with equivalent self-reported cardiovascular disease as a pattern of higher overall activity with fewer transitions. Individuals' perception of their activity and risk bore little relation to sensor-estimated activity or calculated cardiovascular risk.

CONCLUSIONS AND RELEVANCE A smartphone-based study of cardiovascular health is feasible, and improvements in participant diversity and engagement will maximize yield from consented participants. Large-scale, real-world assessment of physical activity, fitness, and sleep using mobile devices may be a useful addition to future population health studies.

JAMA Cardiol. 2017;2(1):67-76. doi:10.1001/jamacardio.2016.4395
Published online December 14, 2016.

← Invited Commentary page 76 and Editor's Note page 78

+ Author Audio Interview at jamacardiology.com

+ Supplemental content at jamacardiology.com

Author Affiliations: Author affiliations are listed at the end of this article.

Corresponding Author: Euan A. Ashley, MB, ChB, DPhil, Division of Cardiovascular Medicine, Department of Medicine, Stanford University, Falk Cardiovascular Research Bldg, 870 Quarry Rd, Stanford, CA 94305 (euan@stanford.edu).

Investigators have established the importance of physical activity, fitness, sleep, and diet in the maintenance of cardiovascular health. Low fitness is a key risk factor,^{1,2} while insufficient physical activity accounts for 5.3 million deaths per year and approximately 6% of the burden of coronary heart disease.³⁻⁵ Decrements in sleep quality through sleep fragmentation and obstructive sleep apnea also affect overall mortality.⁶

Most of these observations, particularly with respect to activity, have been achieved through individual efforts of research coordinators and have required in-person consent, interviews, exercise or sleep studies, and follow-up.^{7,8} Such methods rely on accurate post hoc participant recall. Survey-based physical activity estimation has been shown to systematically overestimate measured activity.^{9,10}

Mobile technology, in particular advances in smartphone sensors, offers a new approach to the study of cardiovascular health and fitness.¹¹⁻¹⁵ Direct measurement of activity through always-on, low-power motion chips provides a promising alternative to questionnaire-based approaches, as recognized by large-scale projects, such as the United Kingdom Biobank¹⁶ and the US Precision Medicine Initiative.¹⁶ Widespread ownership of smartphones worldwide could thus transform global clinical research.

In 2015, Apple Inc (Cupertino, California) introduced an open-source framework (ResearchKit¹⁷) to facilitate clinical research and standardization of data collection. Herein, we report the first findings from MyHeart Counts, one of the launch smartphone apps for the framework. MyHeart Counts is a cardiovascular health study administered entirely via smartphone, incorporating direct sensor-based measurements of physical activity and fitness, as well as questionnaire assessment of sleep, lifestyle factors, risk perception, and overall well-being.

Our objectives in this study were 2-fold. The first objective was to establish the feasibility of mobile consent and real-time gathering of sensor and survey data from a large ambulatory population. The second objective was to investigate the associations between patterns of physical activity, fitness, and self-reported well-being or medical history.

Methods

Data Acquisition

This study was approved by the Stanford University Institutional Review Board. The MyHeart Counts smartphone app was made available in March 2015, and prospective participants downloaded the free app from the Apple Inc app store between March and October 2015. The written informed consent process was developed specifically for the smartphone platform and incorporates unambiguous language in a “card” format optimized for reading and understanding on a telephone (eFigure 1 and eFigure 2 in the Supplement). After consent, a secondary screen seeks specific permission for sharing of each category of telephone data with researchers. At any time, the participant can withdraw a specific category of data or his or her entire participation directly from the telephone.

Consented participants were able to contribute data to a range of study components, including health surveys on diet,

Key Points

Question Can a smartphone approach enhance the study of cardiovascular health-related behavior by taking advantage of embedded security and sensor technology to optimize consent and facilitate data collection?

Findings In this smartphone cardiovascular health study, physical activity patterns were identified by cluster analysis and correlated with life satisfaction and self-reported disease. A pattern of lower overall activity but more frequent transitions between active and inactive states was associated with equivalent self-reported cardiovascular disease prevalence as a pattern of higher overall activity with fewer transitions.

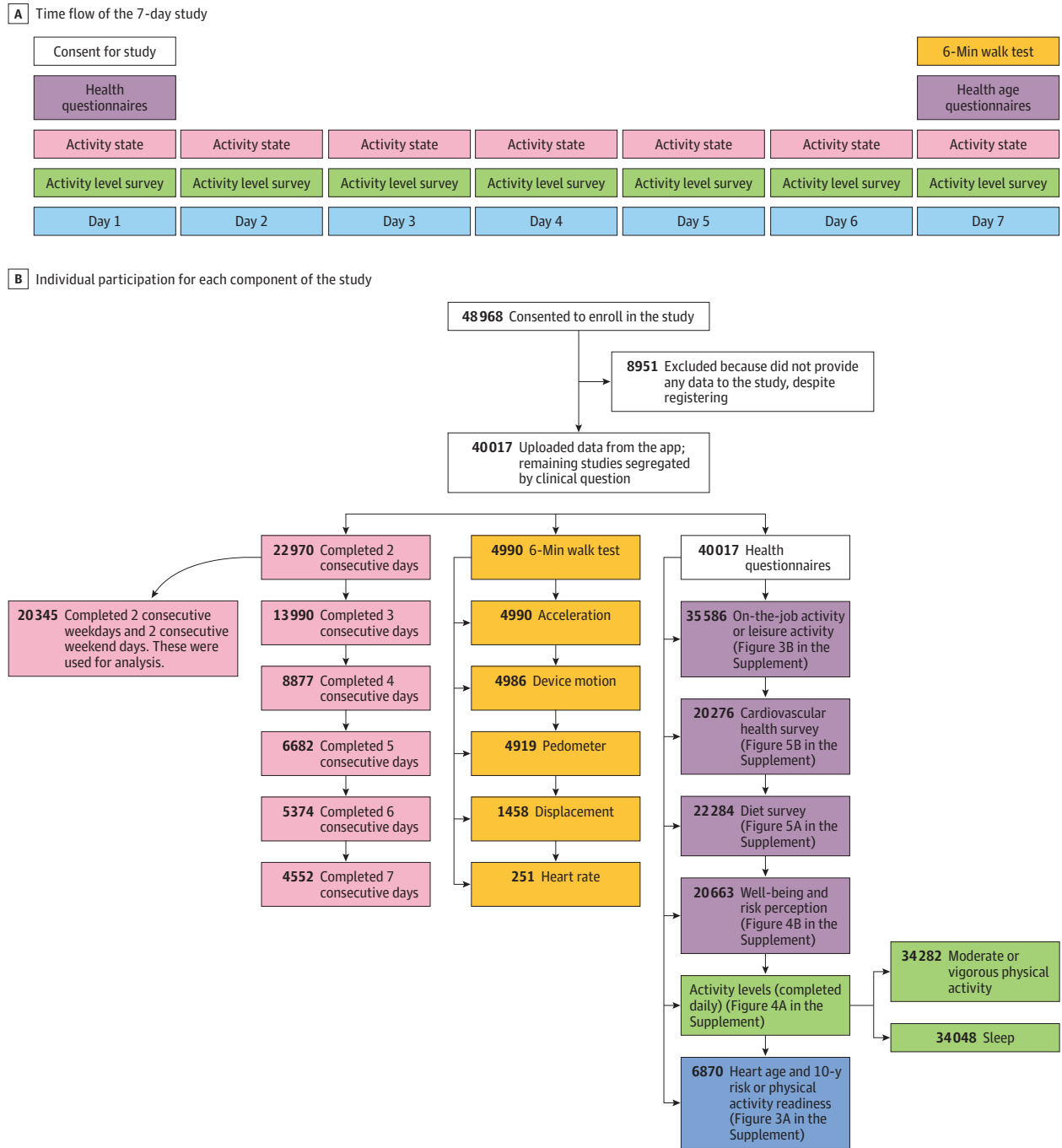
Meaning A smartphone-based study of cardiovascular health is feasible and allows rapid, large-scale, and detailed assessment of physical activity, fitness, and sleep.

well-being, risk perception, work-related and leisure-time physical activity, sleep, and cardiovascular health (Figure 1 and eFigures 3, 4, and 5 in the Supplement). Participants also self-reported demographic information, such as age, sex, and race/ethnicity. For reporting of race/ethnicity, they were given the opportunity to select multiple options (defined by the investigators) or none at all. During the initial 7-day monitoring period, the participant’s motion was recorded through the motion coprocessor chip of the telephone. The low-power motion chip integrates signals, including triaxial accelerometer, gyroscope, compass, and barometer, to estimate distance, as well as the presence and modality of movement, such as stationary, walking, running, cycling, or driving. On day 7, participants were requested to complete a self-administered 6-minute walk test that uses global positioning system-calibrated pedometer functionality built into the motion coprocessor chip. Reminders to complete surveys occur on a daily basis during the initial 7-day monitoring period.

Statistical Analysis

K-means and hierarchical clustering were applied to define groups with cohesive patterns of physical activity from the motion tracking data. Features for clustering included percentage of time spent stationary, percentage of time spent active, number of state changes between active and stationary, and the fraction of time spent on each activity (stationary, walking, running, cycling, driving, or unknown) (Figure 2A and eFigure 1A and eFigure 6 in the Supplement). Categorical comparison among multiple groups was performed using the χ^2 test. We tested for associations with life satisfaction using linear regression models with age and sex included as covariates. For the self-reported presence of disease, we tested the association using logistic models with age and sex as covariates. For both outcomes, stepwise selection of significant univariate associations was performed to build a multivariable model. When analyzing geographic differences in life satisfaction and activity, we developed a mixed-effects model with 3-digit zip code prefix modeled as a random effect and US census region modeled as a fixed effect. Detailed information on the statistical analysis and study findings is available in the eMethods and eResults in the Supplement.

Figure 1. Flowchart of Participants in MyHeart Counts Study



Data on downloads were derived from iTunes Connect (<http://itunesconnect.apple.com>), and data on participant consent numbers were derived from Sage Synapse (<http://www.synapse.org>). Study components are color coded, and matched colors are used to indicate correspondence between components in A and B.

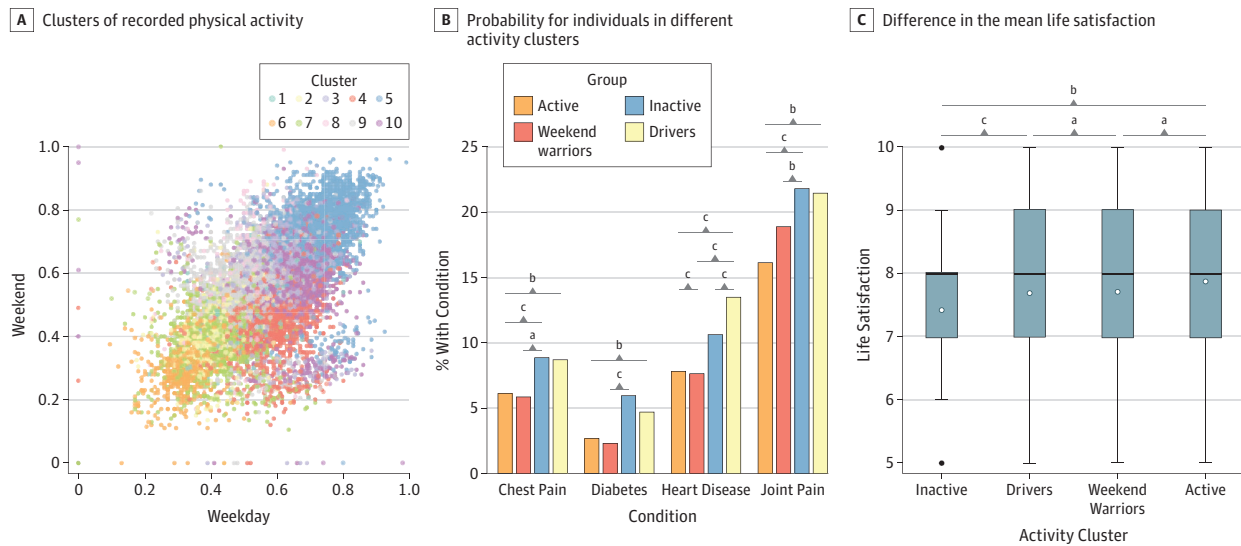
Results

Participation and Demographics

From the launch to the time of the data freeze for this study (March to October 2015), the number of individuals who consented to participate was 48 968 (Figure 1 and eTable 1 in the

Supplement). Participants were predominantly male (82.2% [30 338 male, 6556 female, 10 other, and 3115 unknown]), with a median age of 36 years (interquartile range, 27-50 years). Participants were from all 50 states and the District of Columbia, with the most participants from California (n = 4423) and the fewest participants from North Dakota (n = 35). Of 23 351 respondents, 6987 reported having a disease, while 3185

Figure 2. Patterns of Physical Activity and Model of Life Satisfaction



A, Based on proportion of time participants' smartphones indicated they were stationary during 2 weekdays and 2 weekend days. Two dimensions of clustering are illustrated for clarity from the original 4. In total, 20 345 individuals were included in the analysis. B, Chest pain ($P < .001$, $n = 17\ 062$, $\chi^2 = 34.16$, and Cramer $V = 0.0149$), type 2 diabetes ($P < .001$, $n = 17\ 062$, $\chi^2 = 23.07$, and Cramer $V = 0.0122$), heart disease ($P < .001$, $n = 17\ 062$, $\chi^2 = 22.68$, and Cramer $V = 0.0121$), and joint pain ($P = 3.42e-2$, $n = 17\ 062$, $\chi^2 = 34.16$, and Cramer $V = 0.0149$). In total, 17 062 individuals were included in the analysis. C, On a scale of 1 to 10, $P < .001$ and mean effect size of 0.383 points between individuals in recorded physical activity clusters (active,

weekend warriors, inactive, or drivers). Each white circle in C indicates the mean of the corresponding box plot. Analysis of variance tests were performed to check for significant associations of cluster membership with likelihood of having a particular health condition. Footnotes a, b, and c over a pair of bars indicate a significant difference between that pair of clusters and likelihood of the measured health condition. ^a $P < .05$. ^b $P < .01$. ^c $P < .001$.

(of 22 457 respondents) reported taking medication (Table 1). Participation dropped markedly during the initial 7-day monitoring period, and data for some measures are contributed only from several thousand individuals.

Quantity of Physical Activity

Among those who consented, 20 345 individuals (41.5%) completed 4 of the 7 days of motion data collection, and 4552 individuals (9.3%) completed all 7 days. Of the 20 345 individuals whose devices recorded physical activity, 13 896 (68.3%) were estimated by their smartphones to be stationary for more than 50% of the time for which data were recorded, spending a mean (SD) of 14.5% (8.0%) of their time active (10.9% of time walking and 3.5% of time on vigorous activity, such as running) (Table 2). On average, smartphones of male participants reported 3.8% more time active than smartphones of female participants ($P < .001$). A linear regression of sensor-measured active time onto age yields $P = .58$ (adjusted $R^2 < .001$). The linear regression of self-reported active time onto age yields $P < .001$, with a coefficient of interaction between age and activity equal to -0.49 (30 seconds). This result indicates no strong associations between active time and age.

Patterns of Physical Activity

K-means clusters of physical activity data are shown in Figure 2A. Clusters of activity levels were significantly correlated with self-reported cardiovascular health status, as determined by a χ^2 test for the presence or absence of chest pain,

type 2 diabetes, heart disease, and joint pain (Figure 2B and eTable 2 in the Supplement). Individuals in the least active cluster were found to have an elevated risk for all conditions listed above, with χ^2 standardized residuals ranging from 2.5 for hypertension to 6.3 for heart disease. Conversely, individuals in the “weekend warriors” cluster were at a significantly lower risk (standardized residuals below -2) for chest pain, diabetes, heart disease, and joint pain (Figure 2B and eTable 2 in the Supplement). Weekend warriors were defined as individuals who were more active during the weekend than during the weekdays. These individuals (Figure 2A) spent approximately 25% more time in the “active” state during the weekend.

The second analysis focused on the number of state changes from stationary to active and vice versa (eFigure 7 in the Supplement). Cluster analysis suggested that, although state changers were less active overall than weekend warriors, they experienced similarly better cardiovascular health status compared with those in inactive clusters.

Fitness

In total, 4990 individuals (10.2% of consented participants) completed the 6-minute walk test, made available only at the end of 7 days, with a mean (SD) step count of 693 (127) steps and a mean (SD) distance walked of 455 (520) m (Table 1). Participants who completed the 6-minute walk test were slightly older than the general study population (median age, 42 years and mean age, 43.2 years) and had a higher ratio of men to

Table 1. Participant Cardiovascular Health Diagnoses and Family History^a

Demographic	No. of Participants	% Of Responders	% Of All Participants
Family History		(n = 21 634)	(n = 40 017)
Father or brother with heart attack or coronary artery disease before age 55 y	3890	18.0	9.7
Mother or sister with heart attack or coronary artery disease before age 65 y	1600	7.4	4.0
None	16 144	74.6	40.3
No response	18 383	NA	NA
Medications		(n = 23 351)	(n = 40 017)
To treat and lower cholesterol	2904	12.4	7.3
To treat hypertension and lower blood pressure	3385	14.5	8.5
To treat diabetes or prediabetes and lower blood glucose level	698	3.0	1.7
None	16 364	70.1	40.9
No response	16 666	NA	NA
Heart Disease		(n = 22 457)	(n = 40 017)
Heart attack or myocardial infarction	474	2.1	1.2
Heart bypass surgery	230	1.0	0.6
Coronary blockage or stenosis	370	1.6	0.9
Coronary stent or angioplasty	488	2.2	1.2
Angina, heart chest pains	448	2.0	1.1
High coronary calcium score	106	0.5	0.3
Heart failure or congestive heart failure	163	0.7	0.4
Atrial fibrillation	493	2.2	1.2
Congenital heart defect	413	1.8	1.0
None	19 272	85.8	48.2
No response	17 560	NA	NA
Vascular Disease		(n = 21 467)	(n = 40 017)
Stroke	158	0.7	0.4
Transient ischemic attack	152	0.7	0.4
Carotid artery blockage or stenosis	235	1.1	0.6
Carotid artery surgery or stent	322	1.5	0.8
Peripheral vascular disease, blockage or stenosis, surgery, or stent	254	1.2	0.6
Abdominal aortic aneurysm	77	0.4	0.2
None	20 269	94.4	50.7
No response	18 550	NA	NA

Abbreviation: NA, not applicable.

^a In total, 20 323 participants provided responses to medical history questions.

women (5.6 vs 4.6 for the entire cohort). Sensor recordings indicated that the 6-minute walk test cohort was active during a mean (SD) of 15.1% (7.1%) of their total recorded time compared with a mean (SD) of 14.5% (8.0%) for the full cohort.

Sleep

Each participant self-reported the number of hours slept each night (Table 2). Overall, 34 048 participants (69.5% of those consented) reported a mean of 7.8 hours of sleep per night. Female respondents to the sleep survey (n = 5827) reported a mean of 0.3 hours more sleep than male respondents (n = 25 871) ($P < .001$).

We derived daily bedtimes for each participant based on the last time of movement recorded by the motion chip. We then compared the distributions of self-reported life satisfaction ratings (on a scale of 1-10) for participants with the earliest bedtimes (earliest tertile) with those for participants with the latest bedtimes (latest tertile) using the median bedtimes

for each participant (among 14 895 patients, 30.4% of those consented). Individuals with 2 or fewer bedtimes recorded or outliers (bedtimes before 7:30 PM or after 3:30 AM) were excluded. Participants who retired the earliest in the evening reported an overall higher life satisfaction rating (mean, 7.48) than participants who stayed awake the latest (mean, 6.80) ($P < .001$) (Figure 3B). Individuals who retired the earliest tended to be older (median, 44 years) than those who retired the latest (median, 33 years old). A linear model adjusted for age and sex (n = 14 179) found the median bedtime in hours to be a significant univariate predictor of life satisfaction ($\beta = -0.16$; 95% CI, -0.18 to -0.14 ; $P < .001$).

Models of Life Satisfaction and Self-reported Disease

In addition to associations with health conditions, activity levels were also found to correlate with participants' life satisfaction ($P < .001$) (Figure 2C). Individuals in the inactive cluster reported the lowest life satisfaction (mean, 6.82), while

Table 2. Exercise Activity, Time Active, and Sleep Information^a

Demographic	Mean (SD)					
	Self-reported Activity per Week, min (n = 31 749)	Sensor Measured		6-min Walk Test Step Count (n = 4919)	6-min Walk Test Distance, m (n = 1268)	Self-reported Sleep per Night, h (n = 34 048)
		Time Active/Time Walking/Time Vigorously Active, % (n = 18 683)	Time Active/Time Walking/Time Vigorously Active, min (n = 18 683)			
Overall	207 (227)	14.5 (6.9)/10.9 (5.4)/3.3 (2.9)	969 (460)/731 (359)/218 (193)	693 (127)	455 (520)	7.8 (1.2)
Sex						
Male (n = 30 338)	213 (231)	14.8 (6.9)/11.2 (5.4)/3.5 (3.0)	990 (460)/753 (360)/236 (199)	695 (120)	453 (521)	7.7 (1.1)
Female (n = 6556)	184 (205)	11.0 (6.2)/9.2 (5.1)/1.9 (2.1)	737 (412)/613 (338)/124 (138)	688 (148)	481 (521)	8.0 (1.2)
Age, y						
<30 (n = 12 181)	212 (240)	13.1 (17.5)/11.0 (5.4)/3.0 (2.7)	871 (1139)/738 (361)/201 (183)	682 (125)	427 (497)	7.9 (1.3)
30-39 (n = 9024)	203 (222)	14.7 (19.5)/11.0 (5.4)/3.3 (2.8)	985 (1307)/737 (359)/227 (187)	684 (137)	440 (517)	7.8 (1.2)
40-49 (n = 6328)	197 (210)	15.1 (20.4)/10.7 (5.4)/3.4 (3.1)	1005 (1367)/716 (359)/224 (205)	701 (121)	464 (538)	7.7 (1.1)
50-59 (n = 7068)	206 (219)	13.3 (18.9)/11.2 (5.3)/3.5 (3.0)	891 (1266)/752 (357)/236 (198)	703 (114)	448 (505)	7.7 (1.1)
60-69 (n = 1684)	229 (249)	20.4 (25.5)/9.9 (5.5)/3.4 (3.4)	1367 (1709)/664 (366)/224 (229)	716 (110)	494 (549)	7.6 (1.0)
≥70 (n = 519)	233 (215)	27.3 (29.4)/9.3 (5.0)/3.8 (4.1)	1829 (1970)/620 (336)/251 (272)	677 (121)	558 (548)	7.6 (1.0)

^a Exercise activity and sleep information was collected through questionnaires (n = 34 282), and time active was collected via motion tracker (n = 20 345). In total, 4990 individuals participated in the 6-min walk test.

individuals in the most active cluster reported the highest life satisfaction (mean, 7.48). Drivers and weekend warriors reported mean life satisfaction values of 7.14 and 7.36, respectively.

We tested the association of life satisfaction and self-reported disease status in our population with dietary, lifestyle, and other factors. Overall life satisfaction scores clustered around a mean of 7.12. Because many lifestyle predictors are correlated, we derived a multivariable linear model using stepwise selection on all significant univariate predictors, including age and sex as covariates. We found that fruit consumption, sugary drink intake, recorded activity, and minutes of self-reported vigorous activity remained significant predictors of life satisfaction (eTable 3 in the Supplement). For self-reported disease status, we used stepwise selection on significant predictors to derive a multivariable logistic regression model (with age and sex as covariates) that showed family history, whole grain consumption, and job activity as significant predictors (eTable 3 in the Supplement).

Geographic Diversity

We analyzed the pattern of behavior across the United States (Figure 3A) with a mixed-effects model containing 3-digit zip code prefix as a random effect and US census region as a fixed effect. Using analysis of variance, we found significant differences between US census regions in the measured activity levels (n = 14 406) ($P < .001$) and the reported life satisfaction (n = 14 391) ($P = .001$). The West had the highest mean activity proportion, while the Midwest, South, and Northeast had lower recorded activity levels (eTable 4 in the Supplement). Based on 16 hours of nonsleeping time a day, individuals in the West had on average an additional hour of

physical activity each week compared with individuals in the Northeast. The West also had the highest life satisfaction, and the Northeast had the lowest life satisfaction. The 0.2 difference in life satisfaction is equivalent to 15% of the entire range (6.9-8.2) seen between developed countries in previous results.¹⁸

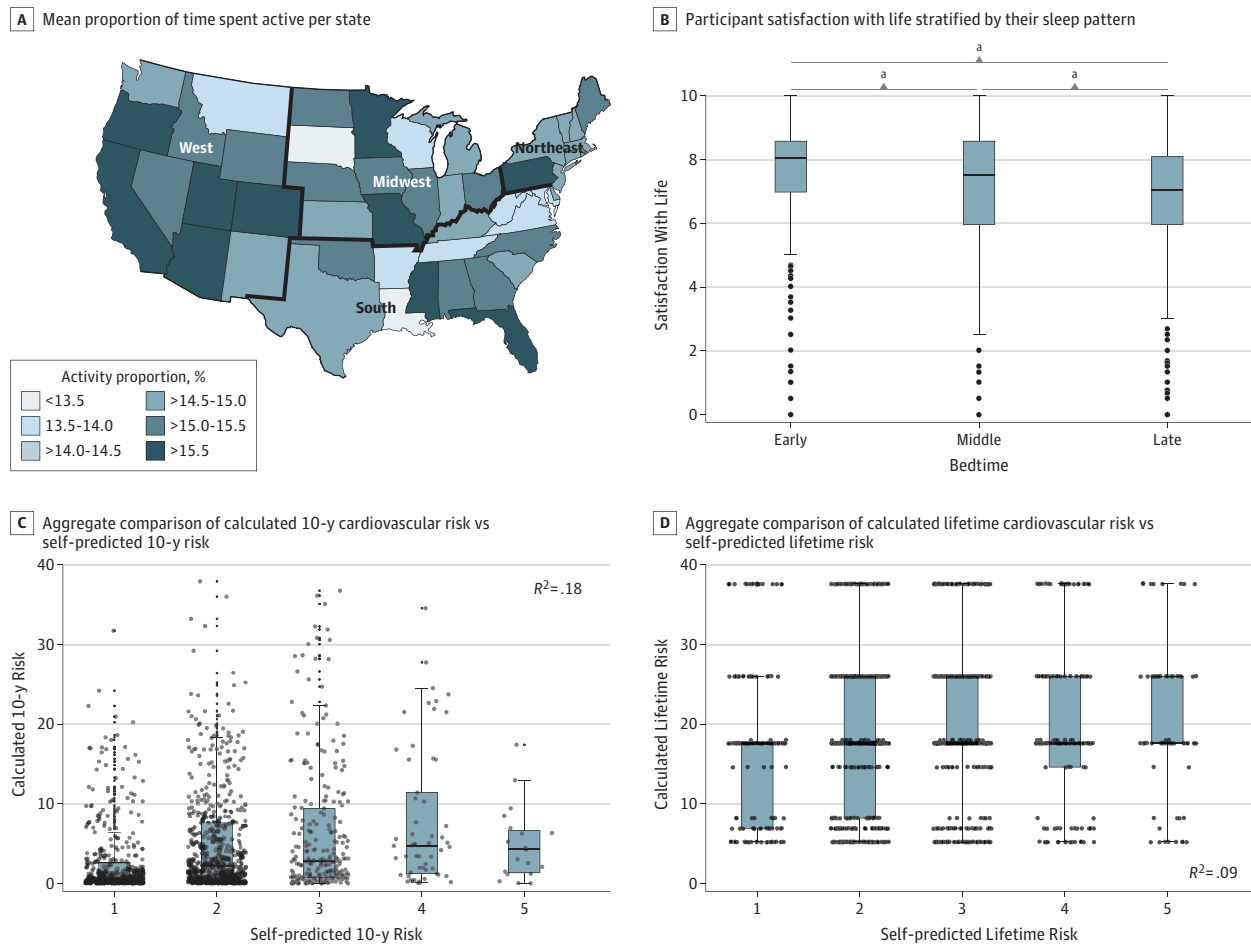
Perceived Activity and Actual Activity

At baseline, participants were asked to rate how active they were on a scale of 1 to 6 on the Leisure-Time Activity Survey (eFigure 4A in the Supplement). On the Moderate or Vigorous Physical Activity Questionnaire, participants were also asked to report the number of minutes of moderate and vigorous physical activity that they performed in a week. These values were compared with the total time participants spent in the walking, running, and cycling states, as determined by the motion tracker data. Despite the large number of participants in the study, we observed a significant association between the perceived and reported activity levels ($P < .001$), but the correlation between the perceived and reported levels was negligibly small ($R^2 < .001$).

Perceived Risk and Actual Risk

A participant's 10-year risk and lifetime risk of stroke and myocardial infarction¹⁹ were calculated according to the 2013 American College of Cardiology and American Heart Association atherosclerotic cardiovascular disease guidelines.²⁰ Predicted risk calculations were compared with individuals' self-reported perceptions of risk (eFigure 4B and eFigure 8 in the Supplement).²¹ A Pearson product moment correlation (R^2) of 0.18 was observed between individuals' perceived 10-year risk and the calculated 10-year

Figure 3. Geographic Diversity, Sleep Pattern, and Perceived Risk and Actual Risk



A, Time spent active is the sum of time walking, running, and cycling recorded by the smartphone app (n = 14 406). B, An individual with an early or late bedtime has a mean bedtime in the earliest or latest 33% of the cohort, respectively (n = 14 895). A pairwise analysis of variance was performed between the 3 groups (early, middle, late) and corresponding life satisfaction.

C and D, On a scale of 1 (not at all) to 5 (extremely).
^aP < .05.
^bP < .01.
^cP < .001.

risk (Figure 3C). The Heart Age Questionnaire, available only after 7 days, required entering lipid values and age 40 to 79 years (among 17 245 individuals, 43.1% of participants). Of the 1334 participants who completed all questions on the Heart Age Questionnaire, necessary to compute heart age and a 10-year risk score, 512 underestimated their 10-year risk (mean difference, 6.0%), while 817 overestimated their 10-year risk (mean difference, 1.2%). The remaining 5 individuals had predictions close to the actual value. Similarly, participants did poorly at predicting their lifetime risk: a Pearson product moment correlation of 0.09 was observed between individuals' perceived and calculated risk (Figure 3D). In total, 457 participants overestimated their lifetime risk by a mean of 12.7%, while 501 participants underestimated their lifetime risk by a mean of 12.0%, indicating that individuals predicted their personal risk with low accuracy.

Discussion

Seminal investigations established the importance of physical activity, fitness, sleep, and diet for cardiovascular health.^{4,22,23} Such studies were completed with time-consuming, in-person measurements with substantial reliance on participant recall. Mobile technology allows an alternative approach to such studies,^{10,24-26} with major challenges and opportunities.

Large-scale data afford approaches to analysis and insights that are not available from smaller-scale data.²⁷ Herein, we used an unsupervised clustering approach to define categories of individuals by their physical activity patterns. Such approaches²⁸ allow the data, rather than prior assumptions about the structure, to drive categorization. Despite decades of research, there is little certainty as to the optimal pattern

of physical activity to recommend for health. Indeed, advice from national organizations has changed significantly over time.²⁹ While causality requires randomization, we report herein correlative associations not just with overall activity but with a pattern of more frequent transition from inactive to active states. For example, our result that participants who changed their activity state frequently tended to be healthier aligns with prior findings that link prolonged periods of uninterrupted sedentary time with increased risk for metabolic syndrome and type 2 diabetes.^{22,30,31} Such observations support the randomized assessment of interventions aimed at augmenting activity state transitions during daily living.³¹

A major advantage of a smartphone-based study is that most people carry the device with them, allowing not only passive registration of motion but also active assessment of changing psychological states, such as life satisfaction and happiness. A major disadvantage is the inherent ascertainment bias. While such bias exists in all studies (eg, among the individuals who choose to contact a study coordinator or in the inclusion and exclusion criteria for a clinical trial), it is important to minimize this bias as much as possible. Of particular note, the bar for entry to this study was much lower than that for equivalent studies performed using in-person visits. This lowering has the demonstrated advantage that many people consented but has the notable disadvantage that those individuals are by definition less invested in the study and thus less likely to complete all portions. For some data points in this study, we have data for only several thousand individuals, while almost 50 000 consented. We believe that the low bar in fact represents an opportunity to engage this larger group who are interested enough to download the app and answer a few questions but not much more. Balancing engagement, data feedback, and study design remain areas for further research. We delayed the 6-minute walk test and heart age assessment until completion of all other portions of the study to minimize bias from this information, but that certainly contributed to the drop in participation in these tasks. An easy method to link lipid values directly from one's electronic health record would help. However, even in the Practice Innovation and Clinical Excellence (PINNACLE) electronic health record-based cardiovascular registry, data to calculate the 10-year risk score were available in less than 30% of patients.³² Future versions of MyHeart Counts will introduce more personalization and earlier participant feedback. Elements of gamification, exemplified by Pokémon Go (<http://www.pokemongo.com>), could also be introduced to maximize engagement.

We found a significant disconnect between an individual's perceived cardiovascular risk and his or her actual risk derived from the 2013 atherosclerotic cardiovascular disease pooled cohort equations. These findings are in line with those reported by Mazalin Protulipac et al,³³ who concluded that the actual presence of cardiovascular disease risk factors in participants did not appear to alter their perception of risk compared with participants without cardiovascular disease risk factors. Similarly, Ko and Boo³⁴ found that, among cardiovascular risk factors, dyslipidemia, obesity, smoking, and family history of cardiovascular disease did not affect self-perceived health. Imes and Lewis³⁵ observed that, even when individu-

als are aware of their cardiovascular disease risk, the association between health-related behavior change and perceived risk was inconsistent. For example, our results illustrate that self-reported minutes of moderate or vigorous physical activity and movement recorded by the smartphone do not agree, which suggests that participants were poor at predicting their levels of physical activity.³⁶ Such a disconnect between perceived and actual levels of physical activity and cardiovascular risk highlights the potential usefulness of smartphones as personalized informational tools to optimize healthy lifestyles. The MyHeart Counts app provides the user with feedback in the form of a heart age relative to ideal cardiovascular health status, an approach to personalizing and making more visceral the understanding of risk (eFigures 1 and 2 in the [Supplement](#)). In addition, we include feedback in the form of a plot showing where each individual falls in relation to the overall study distribution for the 6-minute walk test distance. The natural extension of such findings is toward tailored physical activity and lifestyle recommendations,³⁷ and indeed future versions of the app will introduce randomized studies of motivational strategies for improving activity, diet, and cardiovascular health measures.

Limitations

Our study has several important additional limitations. The demographics of the enrolled population reflect those of typical smartphone users.³⁸ For example, young male individuals are heavily overrepresented. We are testing engagement strategies that target other populations. Some individuals do not carry their smartphones with them at all times; therefore, physical activity measurements are a lower bound for actual physical activity. While daily questions were used to try to capture activity lost in this way, a stronger approach comes in the form of increasing users' adoption of wearable technology.³⁹ Furthermore, the motion trackers cannot distinguish the cause of periods of lack of motion. In addition, it is likely that (as in most studies of physical activity) participants may have been more active than usual during the first weeks of the study. Consequently, in a follow-up study, we will track individuals for multiple weeks to quantify the effect of different types of coaching strategies on modification of participant behavior. Validation of 6-minute walk test step counts reported by the smartphone (eFigure 9 in the [Supplement](#)) suggests that the step count algorithm needs improvement to achieve sufficient accuracy for clinical use.²⁵ Finally, the 2013 American College of Cardiology and American Heart Association atherosclerotic cardiovascular disease risk calculator has limitations. Specifically, the 10-year risk score was implemented for age 40 to 79 years and does not fully account for biogeographic ancestry and lifestyle factors.

Conclusions

Our study found 5 main results. First, we demonstrate the feasibility of consenting and engaging a large population across the United States using only smartphones. Second, we show that large-scale data can be gathered in real time

from mobile devices, stored securely, transferred, deidentified, and shared securely, including with participants. Third, we find that a data set for the 6-minute walk test larger than any previously collected could be generated in weeks. Fourth, we report that state transition patterns of activity, not just absolute activity, relate to the reported presence of disease. Fifth, we conclude that there is a poor association between perceived and recorded physical activity, as well as perceived and formally estimated risk. Most important, we

also present the major challenges and limitations of mobile health research, including the skewed age and sex of participants, plus the rapid drop-off in engagement over time, with the resulting loss of data collection for several measures. To realize the promise of this novel approach to population health research, participant engagement needs to be optimized to maximize full participation of those who have expressed at least enough interest to download the app and consent to join the study.

ARTICLE INFORMATION

Accepted for Publication: September 23, 2016.

Published Online: December 14, 2016.
doi:10.1001/jamacardio.2016.4395

Open Access: This article is published under *JAMA Cardiology's* open access model and is free to read on the day of publication.

Author Affiliations: Department of Medicine, Stanford University, Stanford, California (McConnell, Shcherbina, Pavlovic, Goldfeder, Waggot, Cho, Myers, Champagne, Harrington, Yeung, Ashley); Division of Cardiovascular Medicine, Department of Medicine, Stanford University, Stanford, California (McConnell, Shcherbina, Pavlovic, Goldfeder, Cho, Myers, Champagne, Harrington, Yeung, Ashley); Verily Life Sciences LLC, South San Francisco, California (McConnell); Department of Genetics, Stanford University, Stanford, California (Homburger, Ashley); Stanford Center for Cardiovascular Innovation, Stanford University, Stanford, California (Waggot, Yeung); Stanford Center for Biomedical Ethics, Stanford University, Stanford, California (Cho); Stanford Prevention Research Center, Stanford University, Stanford, California (Rosenberger, Haskell); Stanford Sleep Center, Stanford University, Palo Alto, California (Mignot); Big Data Institute, Nuffield Department of Population Health, University of Oxford, Oxford, England (Landray); Oxford Institute of Biomedical Engineering, Oxford, England (Tarassenko).

Author Contributions: Ms Shcherbina and Dr Ashley had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Dr McConnell and Ms Shcherbina contributed equally to this work.

Study concept and design: McConnell, Pavlovic, Waggot, Rosenberger, Myers, Champagne, Landray, Yeung, Ashley.

Acquisition, analysis, or interpretation of data: McConnell, Shcherbina, Homburger, Goldfeder, Waggot, Cho, Haskell, Myers, Mignot, Landray, Tarassenko, Harrington.

Drafting of the manuscript: McConnell, Shcherbina, Homburger, Goldfeder, Waggot, Myers, Ashley.
Critical revision of the manuscript for important intellectual content: McConnell, Pavlovic, Homburger, Goldfeder, Waggot, Cho, Rosenberger, Haskell, Myers, Champagne, Mignot, Landray, Tarassenko, Harrington, Yeung, Ashley.

Statistical analysis: Shcherbina, Homburger, Goldfeder, Waggot, Myers.

Administrative, technical, or material support: McConnell, Pavlovic, Myers, Harrington, Yeung, Ashley.

Study supervision: McConnell, Waggot, Myers, Yeung, Ashley.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr McConnell reported that he is on partial leave of absence from Stanford University and is an employee of Verily Life Sciences LLC. Dr Harrington reported being on the board of directors for Scanadu Inc (which is privately held) but reported receiving no consulting fees and reported having stock options with no current value. Dr Ashley reported that Samsung and Intel have provided small numbers of wearable devices for testing that were used for demonstration. No other disclosures were reported.

Funding/Support: The Division of Cardiovascular Medicine, Department of Medicine, Stanford University, received in-kind (software development) support from Apple Inc.

Role of the Funder/Sponsor: The funding source had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Additional Contributions: We thank Robert Tibshirani, PhD (Department of Statistics, Stanford University) for valuable statistical advice. No compensation was received.

REFERENCES

- Myers J, Prakash M, Froelicher V, Do D, Partington S, Atwood JE. Exercise capacity and mortality among men referred for exercise testing. *N Engl J Med*. 2002;346(11):793-801.
- Blair SN. Physical inactivity: the biggest public health problem of the 21st century. *Br J Sports Med*. 2009;43(1):1-2.
- Kohl HW III, Craig CL, Lambert EV, et al; Lancet Physical Activity Series Working Group. The pandemic of physical inactivity: global action for public health. *Lancet*. 2012;380(9838):294-305.
- Blair SN, Kohl HW III, Paffenbarger RS Jr, Clark DG, Cooper KH, Gibbons LW. Physical fitness and all-cause mortality: a prospective study of healthy men and women. *JAMA*. 1989;262(17):2395-2401.
- Lavie CJ, Arena R, Swift DL, et al. Exercise and the cardiovascular system: clinical science and cardiovascular outcomes. *Circ Res*. 2015;117(2):207-219.
- Jackowska M, Steptoe A. Sleep and future cardiovascular risk: prospective analysis from the English Longitudinal Study of Ageing. *Sleep Med*. 2015;16(6):768-774.
- Brocklebank LA, Falconer CL, Page AS, Perry R, Cooper AR. Accelerometer-measured sedentary time and cardiometabolic biomarkers: a systematic review. *Prev Med*. 2015;76:92-102.
- Martin A, Fitzsimons C, Jepson R, et al; EuroFIT Consortium. Interventions with potential to reduce sedentary time in adults: systematic review and meta-analysis. *Br J Sports Med*. 2015;49(16):1056-1063.
- Shephard RJ. Limits to the measurement of habitual physical activity by questionnaires. *Br J Sports Med*. 2003;37(3):197-206.
- Troiano RP, Berrigan D, Dodd KW, Mâsse LC, Tilert T, McDowell M. Physical activity in the United States measured by accelerometer. *Med Sci Sports Exerc*. 2008;40(1):181-188.
- Farmer A, Tarassenko L. Use of wearable monitoring devices to change health behavior. *JAMA*. 2015;313(18):1864-1865.
- Bassett DR Jr, Ainsworth BE, Swartz AM, Strath SJ, O'Brien WL, King GA. Validity of four motion sensors in measuring moderate intensity physical activity. *Med Sci Sports Exerc*. 2000;32(9)(suppl):S471-S480.
- Strath SJ, Kaminsky LA, Ainsworth BE, et al; American Heart Association Physical Activity Committee of the Council on Lifestyle and Cardiometabolic Health and Cardiovascular, Exercise, Cardiac Rehabilitation and Prevention Committee of the Council on Clinical Cardiology, and Council. Guide to the assessment of physical activity: clinical and research applications: a scientific statement from the American Heart Association. *Circulation*. 2013;128(20):2259-2279.
- Ozemek C, Cochran HL, Strath SJ, Byun W, Kaminsky LA. Estimating relative intensity using individualized accelerometer cutpoints: the importance of fitness level. *BMC Med Res Methodol*. 2013;13:53.
- Burke LE, Ma J, Azar KM, et al; American Heart Association Publications Committee of the Council on Epidemiology and Prevention, Behavior Change Committee of the Council on Cardiometabolic Health, Council on Cardiovascular and Stroke Nursing, Council on Functional Genomics and Translational Biology, Council on Quality of Care and Outcomes Research, and Stroke Council. Current science on consumer use of mobile health for cardiovascular disease prevention: a scientific statement from the American Heart Association [published correction appears in *Circulation*. 2015;132:e233]. *Circulation*. 2015;132(12):1157-1213.
- Ashley EA. The Precision Medicine Initiative: a new national effort. *JAMA*. 2015;313(21):2119-2120.
- Mohammadi D. ResearchKit: a clever tool to gather clinical data. *Pharm J*. 2015;7(May). doi:10.1211/pj.2015.20068358
- Abdallah S, Thompson S, Marks N. Estimating worldwide life satisfaction. *Ecol Econ*. 2008;65(1):35-47.

19. Lloyd-Jones DM, Leip EP, Larson MG, et al. Prediction of lifetime risk for cardiovascular disease by risk factor burden at 50 years of age. *Circulation*. 2006;113(6):791-798.
20. Goff DC Jr, Lloyd-Jones DM, Bennett G, et al; American College of Cardiology/American Heart Association Task Force on Practice Guidelines. 2013 ACC/AHA guideline on the assessment of cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines [published correction appears in *Circulation*. 2014;129(25)(suppl 2):S74-S75]. *Circulation*. 2014;129(25)(suppl 2):S49-S73.
21. Knowles JW, Assimes TL, Kiernan M, et al. Randomized trial of personal genomics for preventive cardiology: design and challenges. *Circ Cardiovasc Genet*. 2012;5(3):368-376.
22. Morris JN, Heady JA, Raffle PA, Roberts CG, Parks JW. Coronary heart-disease and physical activity of work. *Lancet*. 1953;265(6796):1111-1120.
23. Paffenbarger RS Jr, Hyde RT, Wing AL, Hsieh CC. Physical activity, all-cause mortality, and longevity of college alumni. *N Engl J Med*. 1986;314(10):605-613.
24. Bassett DR Jr, Wyatt HR, Thompson H, Peters JC, Hill JO. Pedometer-measured physical activity and health behaviors in U.S. adults. *Med Sci Sports Exerc*. 2010;42(10):1819-1825.
25. Brooks GC, Vittinghoff E, Iyer S, et al. Accuracy and usability of a self-administered 6-minute walk test smartphone application. *Circ Heart Fail*. 2015;8(5):905-913.
26. Rosenberger ME, Buman MP, Haskell WL, McConnell MV, Carstensen LL. Twenty-four hours of sleep, sedentary behavior, and physical activity with nine wearable devices. *Med Sci Sports Exerc*. 2016;48(3):457-465.
27. Halevy A, Norvig P, Pereira F. The unreasonable effectiveness of data. *IEEE Intell Syst*. 2009;(March/April):8-12.
28. Hastie T, Tibshirani R, Friedman J. *The Elements of Statistical Learning*. New York, NY: Springer; 2009:337-387.
29. Kohl HW, Gibbons LW, Gordon NF, Blair SN. An empirical evaluation of the ACSM guidelines for exercise testing. *Med Sci Sports Exerc*. 1990;22(4):533-539.
30. Healy GN, Matthews CE, Dunstan DW, Winkler EA, Owen N. Sedentary time and cardio-metabolic biomarkers in US adults: NHANES 2003-06. *Eur Heart J*. 2011;32(5):590-597.
31. Benatti FB, Ried-Larsen M. The effects of breaking up prolonged sitting time: a review of experimental studies. *Med Sci Sports Exerc*. 2015;47(10):2053-2061.
32. Hira RS, Kennedy K, Jneid H, et al. Frequency and practice-level variation in inappropriate and nonrecommended prasugrel prescribing: insights from the NCDR PINNACLE registry. *J Am Coll Cardiol*. 2014;63(25, pt A):2876-2877.
33. Mazalin Protulipac J, Sonicki Z, Reiner Ž. Cardiovascular disease (CVD) risk factors in older adults: perception and reality. *Arch Gerontol Geriatr*. 2015;61(1):88-92.
34. Ko Y, Boo S. Self-perceived health versus actual cardiovascular disease risks. *Jpn J Nurs Sci*. 2016;13(1):65-74.
35. Imes CC, Lewis FM. Family history of cardiovascular disease, perceived cardiovascular disease risk, and health-related behavior: a review of the literature. *J Cardiovasc Nurs*. 2014;29(2):108-129.
36. Prince SA, Adamo KB, Hamel ME, Hardt J, Connor Gorber S, Tremblay M. A comparison of direct versus self-report measures for assessing physical activity in adults: a systematic review. *Int J Behav Nutr Phys Act*. 2008;5:56.
37. Chow CK, Redfern J, Hillis GS, et al. Effect of lifestyle-focused text messaging on risk factor modification in patients with coronary heart disease: a randomized clinical trial. *JAMA*. 2015;314(12):1255-1263.
38. Smith A. *Smartphone Ownership 2013*. Washington, DC: Pew Research Center; 2013.
39. Case MA, Burwick HA, Volpp KG, Patel MS. Accuracy of smartphone applications and wearable devices for tracking physical activity data. *JAMA*. 2015;313(6):625-626.

Invited Commentary

First Steps Into the Brave New Transdiscipline of Mobile Health

Bonnie Spring, PhD; Angela Pfammatter, PhD; Nabil Alshurafa, PhD

Given substantial evidence that healthy lifestyle behaviors lessen the odds of cardiovascular disease, a guideline from the American Heart Association and American College of Cardiology¹ advises physicians to foster patients' physical activity. But how is the clinician to evaluate a patient's healthy lifestyle behaviors, let alone enhance them? Traditionally, patient self-reports supplied almost all behavioral data available to health professionals. However, whether given by free recall, structured questionnaire, or written logs, post hoc surveys inherently manifest forms of error well known to behavioral scientists. People forget. Many have no idea what moderate to vigorous activity feels like. Individuals also experience demands and motivations that distort what they report.

For a long while, not much could be done to increase confidence in the validity of behavioral assessments. Although one could observe peoples' behavior objectively in controlled labo-

ratory conditions or experimental tasks, legitimate questions arose about whether individuals would behave the same way in real life as they had in the laboratory. This state of affairs began to change in the 1980s, when acceleration signals from a worn sensor were first used to measure physical activity.²

Fast forward to the present, and sensors are everywhere, including the tiny accelerometer, gyroscope, ambient light detector, compass, and barometer inside smartphones. In this issue of *JAMA Cardiology*, McConnell and colleagues³ are to be congratulated for pioneering efforts to examine the physical activity, sleep, and fitness data from MyHeart Counts, a launch smartphone app developed by Apple Inc's ResearchKit. The team's first aim was to evaluate the feasibility of using a smartphone to consent a large representative sample of ambulatory adults and to gather real-time sensor and survey data from them. Their second aim was to analyze those data to gain insights about associations among physical activity, well-being, and physical health.

MyHeart Counts succeeded as a proof of concept, demonstrating the potential for personally owned mobile devices to accomplish real-world ambulatory assessment. McConnell and



Editor's Note page 78



Author Audio Interview at jamacardiology.com



Related article page 67