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Prediction using a randomized evaluation of data collection integrated through connected technologies (PREDICT): Design and rationale of a randomized trial of patients discharged from the hospital to home

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ABSTRACT

Background: Hospital readmission prediction models often perform poorly. A critical limitation is that they use data collected up until the time of discharge but do not leverage information on patient behaviors at home after discharge.

Methods: PREDICT is a two-arm, randomized trial comparing ways to use remotely-monitored patient activity levels after hospital discharge to improve hospital readmission prediction models. Patients are randomly assigned to use a wearable device or smartphone application to track physical activity data. The study collects also validated assessments on patient characteristics as well as disparate data on credit scores and medication adherence. Patients are followed for 6 months. We evaluate whether these data sources can improve prediction compared to standard modelling approaches.

Conclusion: The PREDICT Trial tests a novel method of remotely-monitoring patient behaviors after hospital discharge. Findings from the trial could inform new ways to improve the identification of patients at high-risk for hospital readmission.

Trial Registration: Clinicaltrials.gov Identifier: NCT02983812

1. Introduction

Nearly 1 in 5 patients discharged from the hospital are readmitted within 30 days. There has been significant study examining how to design prediction models to identify patients at high-risk of readmission. If these approaches were successful, then effective interventions could be targeted towards those patients. However, most of these models perform poorly [1–3]. A common limitation is that these models rely mostly on data from insurance claims and electronic health records up until the point of hospital discharge. They do not take into account other forms of data that measure patients' behaviors at home after they have left the hospital.

Our daily health behaviors contribute significantly to our longer-term health [4,5]. The use of mobile technologies such as wearable devices and smartphones is increasing and offers the ability to remotely-monitor activity levels within the everyday lives of patients [6,7]. Several pilot studies have demonstrated associations between activity levels and patients' outcomes including hospital readmission [8–10], but more rigorous randomized trials are lacking. Data from other sources could also provide insights into patient behaviors. For example, data on prescription refills could reveal medication adherence rates. Data on credit scores and other forms of financial information could indicate both socioeconomic status and also financial risk-taking behaviors that may influence health behaviors. Validated questionnaires could be used to understand other patient factors such as social support and risk preferences.

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The objective of PREDICT (Prediction using a Randomized Evaluation of Data collection Integrated through Connected Technologies) was to evaluate the effectiveness of hospital readmission prediction models that utilize novel data sources on daily patient behaviors such as activity levels, medication adherence, finances, and risk preferences. We will compare standard risk prediction models that rely on data up until the point of hospital discharge to models that incorporate information from these other data sources. We enrolled patients prior to hospital discharge and randomly assigned them to track activity levels at home using either a wearable device or smartphone and then compare how these methods for data collection differ in enhancing risk prediction models. The trial was conducted using a web-based platform at the University of Pennsylvania, called Way to Health [11], which facilitated patient enrollment, survey completion, automated study communications, and remote-monitoring of activity data.

2. Methods

2.1. Study design

PREDICT is a two-arm, randomized trial that remotely-monitored patient activity levels after hospital discharge for a 6-month period. The trial was conducted using Way to Health [11], a research technology platform at the University of Pennsylvania that has been used previously by our group for remotely-monitored activity tracking interventions [12–18]. All participants received $50 for enrolling in the trial and $50 for completing the 6-month period. Participants were randomly assigned to have their activity data collected remotely by either a wearable device or a smartphone application. The wearable device was provided free of charge and the smartphone application was available as a free download in the Google Play Store or Apple App Store. To improve recruitment rates and provide equal incentives among the arms, participants randomized to the smartphone application arm were still given a wearable device after the 6 month period ended. Our prior work has demonstrated that these types of devices accurately track physical activity [19]. Other elements of participant data were collected from a variety of sources and then aggregated to develop hospital readmission prediction. This study was approved by the University of Pennsylvania Institutional Review Board.

2.1.1. Participant recruitment

Patients admitted to two hospitals in Philadelphia (Hospital of the University of Pennsylvania and Penn Presbyterian Medical Center) were identified using a daily report from the electronic health record (EPIC) and then approached by a member of the research study team during their hospitalization between January 16, 2017 to December 5, 2018.

Patients were eligible for the trial if they were 18 years or older, had a smartphone compatible with the wearable device and smartphone application, had no current medical condition which prohibits them from ambulating or plan for a medical procedure over the next 6 months that would prohibit them from ambulating, planned to be discharged to home, able to speak and read English, and able to provide informed consent. Patients were excluded if they did not reside in the states of Pennsylvania or New Jersey, were currently participating in another physical activity study, or were pregnant.

2.1.2. Participant enrollment and data collection

Interested patients completed an initial screening questionnaire and if eligible then provided written informed consent. Patients then created an account on the Way to Health technology platform and selected whether to receive study communications by text message, email, interactive voice recording, or a combination. Patients were then directed to complete a series of assessments including surveys and validated questionnaires described in Table 1. These include collecting data on social support [20], risk preferences (DOSPERT) [21], personality type (Big Five) [22], and physical activity (IPAQ) [23]. During this process, patients provided consent for the study to obtain data on hospitalizations (Pennsylvania Health Care Cost Containment Council), credit scores (Experian), and medication dispensing and refills (CVS Health). Data on hospitalizations are provided as a binary indicator for each 30-day increment from the time of hospital discharge.

2.1.3. Randomization

After survey completion, patients were randomized electronically using block sizes of two and stratified by one of the following six conditions: acute myocardial infarction or coronary heart disease, chronic obstructive pulmonary disease, congestive heart failure, diabetes, pneumonia, or other condition.

2.1.4. Activity monitoring

Study coordinators helped patients to connect their activity tracking device to the Way to Health Platform and authorize it to access their data. Patients assigned to the wearable device arm were setup with the Withings Steel which was water resistant and had a battery that could last up to 8 months. Patients were asked to wear the device as much as possible including while sleeping and to sync it with the Withings Health Mate Smartphone application at least once a day. Patients assigned to the smartphone arm were setup with the Withings Health Mate application which used accelerometers in the smartphone to track activity. These patients were given the wearable device after their 6-month period completed. In both arms throughout the 6-month period, patients were sent a reminder to sync their device if data had not been transmitted for four consecutive days.

2.2. Outcome measures

The primary outcome is 30-day hospital readmission. The secondary outcomes include 90-day readmission, 6-month re-hospitalization and health care cost utilization within 6 months after discharge.

2.3. Statistical analysis

All analyses will be performed using intention-to-treat. Data from activity trackers is collected at the day level and is present if the participant used and synced their device. Data from electronic health records are collected up until the time of discharge with a 3 year look back for data not collected during the hospital admission. We will conduct preliminary descriptive analyses to compare univariate associations between the outcome variables (30-day readmission, 90-day readmission, and 6-month rehospitalization) and changes in data collected by the activity trackers (step counts, sleep duration, heart rate).

We will test the null hypothesis that the standard and enhanced model have similar predication for 30-day hospital readmission. For each arm, a standard model will be developed using electronic health record data up to the time of hospital discharge by fitting a multivariate logistic regression model to each of the binary dependent outcome variables using hospital and time fixed effects (month and year), and including independent variables for patient demographics, comorbidities, and length of stay in the hospital. The primary analysis will compare the standard model to an enhanced model that includes available data from the mobile devices (either wearable device or smartphone application) for predicting 30-day hospital readmission. Data from the activity trackers will be used to generate variables that represent monthly means for the measure (e.g. mean step counts during days 1–30, 31–60, etc) and proportion of missing day (e.g. 0.10 during day 1–30, 0.15 during days 31–60, etc). We will also generate variables to represent the change from each month to the next. We will use cross-validation by randomly splitting patients within each arm into several cohorts (e.g. 10 cohorts of 25 patients) and compare the cross-validated c-statistic between the standard and enhanced models using the replication method [24]. We will compare cross-validated c-statistics for the wearable device arm versus the smartphone arm to test if the

Table 1
Self-reported validated measures.

Measure	Survey questions	Description
The Medical Outcomes Study (MOS) Social Support Survey [20]	19	Social support across the dimensions of emotional/informational, tangible, affectionate, and positive social interaction for patients with chronic conditions
A Domain-Specific Risk-Taking (DOSPERT) Scale [21]	30	Risk taking in five domains: financial decisions, health/safety, recreational, ethical, and social decisions
Big Five Personality Test [22]	44	Personality across five traits: openness to experience, conscientiousness, extraversion, agreeableness, and neuroticism
International Physical Activity Questionnaire – Short Form (IPAQ) [23]	7	Physical activity duration and intensity

remote-monitoring data collection methods differ in enhancing the prediction model.

In secondary analyses, we will fit enhanced models that also include independent variables that represent data from the validated questionnaires, credit scores, and medication adherence rates. We will use the same cross-validation methods to evaluate the c-statistic to evaluate if these data elements significantly improve model prediction.

All hypothesis tests will be 2-sided and use a significance level of $P < .05$.

3. Results

3.1. Recruitment

Over a 2-year period, 500 patients were enrolled and randomized into the trial (Fig. 1). We approached 6916 patients of which 3467 were not interested and 2949 were not eligible. Main reasons for exclusion from the trial were not having a compatible smartphone ($N = 2292$), not being able to ambulate ($N = 450$) and not planned to be discharged to home ($N = 104$). Other reasons for exclusion from the trial were discharge before study enrollment was finished ($N = 39$), did not live in the state of Pennsylvania or New Jersey ($N = 35$), did not speak English ($N = 16$), other ($N = 7$), participating in another physical activity study ($N = 5$), and receiving chemotherapy (N = 1).

Self-reported validated measures are displayed in Table 1. Information on data sources including the electronic health record, mobile devices, and third-party vendors are displayed in Table 2. Differences in data collected between the wearable device and smartphone application are displayed in Table 3. The trial will conclude in May 2019 and analyses will be reported separately.

4. Discussion

The PREDICT Trial evaluates novel methods to improve the prediction of hospital readmissions by leveraging data from disparate systems to understand behaviors that occur at home. The trial will directly compare different methods of collecting physical activity data remotely either through a wearable device or smartphone application. This data was collected by using Way to Health [11], a research technology platform that facilitates the collection of remote-monitoring data without using more personal intensive approaches. It will also compare other forms of data on finances, medication adherence, and validated assessments of participant characteristics.

This study has several limitations. First, patients were enrolled while hospitalized which proved challenging at times and led to low enrollment rates (7.2%). Second, about one-third of patients approached were not eligible because they did not own a smartphone and findings may not be generalizable to those without this form of technology. Third, physical activity data was collected on step counts and did not include other forms of activity.

Daily behaviors play a significant role in individuals' longer-term health [4,5]. However, most readmission prediction models do not include data about these behaviors. Our trial has demonstrated that collecting these types of data is feasible. The use of wearable technology allowed for remote monitoring of patient generated physical activity data which provided reliable data, was easy to use, and scaled. The findings from this study will help to understand the ways in which these data sources can improve the identification of patients at high-risk of hospital readmission.

Conflict of interests disclosures

Dr. Patel is supported by career development awards from the Department of Veterans Affairs HSR&D and the Doris Duke Charitable Foundation. Dr. Patel is founder of Catalyst Health, a technology and behavior change consulting firm. Dr. Volpp is a principal at VAL Health, a behavioral economics consulting firm. Dr. Volpp also has received consulting income from CVS Caremark and research funding from Humana, CVS Caremark, Discovery (South Africa), Hawaii Medical Services Association, Oscar, and Merck, none of which are related to the work described in this manuscript.

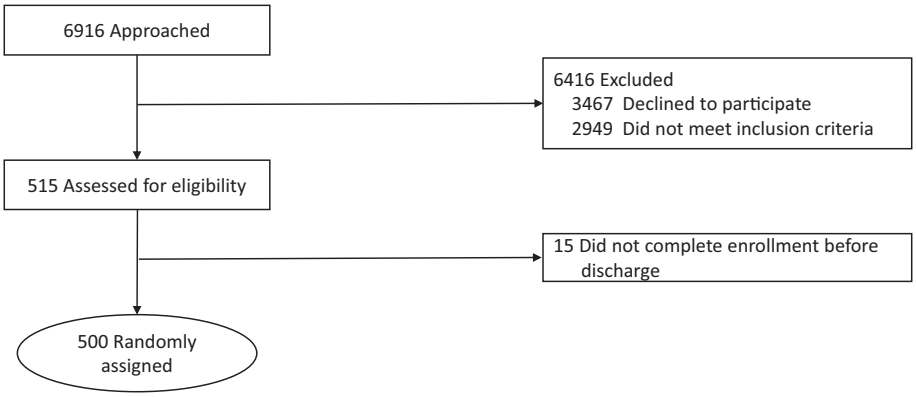

Fig. 1. Participant enrollment.

Table 2
Data types, sources, and timing.

Types of data	Source	Time period
In-hospital		
Participant characteristics	Electronic health record	At hospital discharge
Comorbidities	Electronic health record	At hospital discharge
Lab values	Electronic health record	At hospital discharge
Self-report data	Validated surveys	Upon enrollment
At-home		
Activity levels	Wearable (Withings Steel) or Smartphone App (Withings HealthMate)	6-month intervention period
Credit scores	Experian	Within 6 months of hospital discharge
Medication adherence data	CVS Health	6 months before and after hospital discharge
Hospitalization data	Pennsylvania Health Care Cost Containment Council (PHC4)	6-month intervention period

Table 3
Patient-generated physical activity data collected.

Data elements	Device	
Physical activity	Wearable (Withings Steel)	Smartphone App (Withings HealthMate)
Steps	X	X
Distance	X	X
Minutes of light activity	X	X
Minutes of moderate activity	X	X
Minutes of intense activity	X	X
Calories Burned		
Active calories burned	X	X
Total calories burned	X	X
Sleep		
Time initiated	X	
Time ended	X	
Minutes spent awake	X	
Minutes of light sleep	X	
Minutes of deep sleep	X	
Minutes of REM sleep	X	
Total minutes of sleep	X	
Seconds to fall asleep	X	
Seconds spent in bed after waking up	X	
Number of arousals	X	

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Role of the funder/sponsor

The funder 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.

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