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# Accuracy and Usability of a Self-Administered Six-Minute Walk Test Smartphone Application

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## Abstract

**Background—**The 6-minute walk test (6MWT) independently predicts congestive heart failure (CHF) severity, death and heart failure hospitalizations, but must be administered in clinic by qualified staff on a pre-measured course. As part of the Health eHeart Study we sought to develop and validate a self-administered 6MWT mobile application (SA-6MWTapp) for independent use at home by patients.

**Methods and Results—**We performed a validation study of a SA-6MWTapp in 103-participants. In phase one (n=52), we developed a distance estimation algorithm for the SA-6MWTapp by comparing step counts from an Actigraph and measured distance on a pre-measured 6MWT course to step counts and estimated distance obtained simultaneously from our SA-6MWTapp (best estimation algorithm, r = 0.89 [95% CI 0.78 – 0.99]). In phase two, 32 participants (including those with CHF and pHTN) used the SA-6MWTapp independently in clinic and the distance estimated by the SA-6MWTapp was compared to the measured distance (r = 0.83 [95% CI 0.79-0.92]). In phase three, 19 patients with CHF and pHTN consecutively enrolled from clinic, performed 3.2 ±1 SA-6MWTapp tests per week at home over 2 weeks. Distances estimated from the SA-6MWTapp during home 6MWTs were highly repeatable (coefficient of variation = 4.6%) and correlated with in-clinic measured distance (r = 0.88 [95% CI 0.87-0.89]). Usability surveys performed during the second (in-clinic) and third (at-home) phases demonstrated that the SA-6MWTapp was simple and easy to use independently.

**Conclusions—**A self-administered 6MWTapp is easy to use and yields accurate repeatable measurements in the clinic and at home.

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Disclosures

None.

### Keywords

disease management; exercise test; heart failure; hypertension; pulmonary; mobile applications; smartphone; telemedicine

Congestive heart failure (CHF) has an incidence in the United States of 875,000 cases a year, a prevalence of 5.1 million and accounts for over 1 million hospital admissions[1]. After discharge from the hospital, patients with CHF face a 10% mortality and 25% readmission rate within 30 days[2]. Considering the significant morbidity and mortality of CHF and its impact on the health system, strategies to predict and prevent CHF exacerbations are an imperative.

The 6-minute walk test (6MWT) independently predicts CHF severity, hospitalization, and death[3-5]. The primary outcome measurement of a 6MWT is the distance walked on a linear course defined by two cones set 30 meters apart. Despite its simplicity, the 6MWT currently requires administration by trained personnel in a clinical setting along a preset course.

The ubiquity of smartphones, with integrated accelerometers and GPS tracking, provide a unique opportunity to develop and implement an at-home, self-administered test to monitor changes in CHF severity. The Health eHeart Study is an ongoing remotely enrolled and followed cohort (with 21,143 participants at the time of the writing of this manuscript) that uses the internet, mobile technology and wearable sensors to collect data. As part of the Health eHeart Study, we sought to create a mobile application (app) that would allow a patient to self-administer a 6MWT anywhere, without the need for support personnel, estimate the distance walked (and other parameters described below), and transmit results wirelessly to a cloud server. We envision that a self-administered 6MWT application (SA-6MWTapp) could be used as a tool by clinicians and researchers to track the exertional capacity of patients longitudinally. In this study we report our initial experience with the accuracy and usability of a SA-6MWTApp.

## Methods

### 6MWTapp content

The SA-6MWTapp consists of: an instructional video; real-time, self-administration of the 6MWT according to the ATS protocol[6]; a record of step counts, heart rate, and estimated distance traveled; and wireless transmission of recorded data to a central database. Upon opening the SA-6MWTapp, the user first watches a short video describing the proper conduct of the SA-6MWT and contraindications to performing the test. It should be emphasized that the app does not require a pre-measured course, but simply instructs the user to identify a place (such as a hallway) that can be used for walking back and forth, with landmarks as pivot points on either end. The application prompts the user to enter their age, birth date, height and weight. Before each test, the user is asked about the presence of absolute contra-indications to performing a 6MWT (an MI within the last 30 days or symptoms consistent with unstable angina) and only continues if the participant denies the presence of either absolute contraindication. The application obtains the user's level of baseline dyspnea using a visual Borg dyspnea scale and records the pulse using

photoplethysmography from the user's finger placed over the phone's camera. During administration of the test, the SA-6MWTapp provides audible instructions that follow verbatim the ATS guideline script, delivered at appropriate times during the test, including coaching the patient if they stop walking prematurely (as part of the ATS script). At the end of 6 minutes, the user is instructed to stop walking, check their pulse, complete a second Borg dyspnea scale and report symptoms limiting their exertion. After two minutes of rest, a final pulse is measured and the test ends and all measurement are instantaneously transmitted wirelessly to a central database.

### Participant Recruitment and Characterization

In the algorithm development (phase 1) and in-clinic validation (phase 2), consecutive English-speaking patients over the age of 18 years were recruited from the UCSF Cardiology and Advanced Heart Failure/pHTN Clinics. In the home validation study (phase 3) we recruited consecutive English-speaking patients (age ≥ 18 year) over 7 days of Advanced Heart Failure/pHTN Clinic all of whom had a diagnosis of pHTN or CHF. Because the SA-6MWTapp is currently only available for iOS, only patients with iPhones were included in phase 3. In all three phases, we excluded participants with exercise limitations due to musculoskeletal conditions, New York Heart Association (NYHA) IV symptoms, those who had an MI within the preceding 30 days, those suffering from new or worsening angina and those refusing consent. Participant demographic and clinical characteristics were extracted by chart review. The study was approved by the UCSF institutional review board and all participants provided informed consent. (See Supplemental Figure 1).

### Algorithm Development (Phase 1)

In a preliminary step, we maximized the accuracy of the SA-6MWTapp for step counting in 32 participants (not included in the overall 103 counted in the study). Participants underwent an inclinic, staff-administered 6MWT wearing two iPhone 4s devices — one phone placed in a holster and the other phone placed in their front pants pocket. A research-grade accelerometer (ActiGraph GT3X) was worn on the hip and used as a reference standard for step counts and analyzed using ActiLife 6 software (ActiGraph, LLC)[7]. The initial step-counting algorithm in the SA-6MWTapp was inaccurate at low step counts (Supplemental Figure 2). The raw data from the iPhone accelerometer was compared to accelerometer data from the ActiGraph, and the sensitivity threshold and algorithm for translating accelerometer signals to step counts were adjusted in the SA-6MWTapp. Upon retesting in an additional 14 participants, the adjusted SA-6MWTapp algorithm was shown to have an excellent correlation ($r = 0.94$) with the Actigraph step count data.

We then turned our attention to development of the SA-6MWTapp distance estimation algorithm. In a separate cohort (Phase 1), 52 participants navigated the SA-6MWTapp independently. A 6MWT was conducted via the SA-6MWTapp along a pre-measured, marked clinical 6MWT course with one iPhone placed in a holster and a second iPhone running a separate SA-6MWTapp in the front pants pocket. The observed measured distance walked and SA-6MWTapp estimated distances were then compared. An unadjusted univariate model of step counts predicting distance demonstrated an overestimation of

distance at low step-counts and an underestimation of distance at high step-counts (Supplemental Figure 3). We recalculated distance adjusting steps by stride using the standard formula of 0.414 x height (in meters) to estimate stride length[8] and found that this formula was inaccurate in participants with symptomatic CHF or pHTN (r = 0.68). We explored other linear models of distance estimation from step counts using participant height, steps and interaction of steps and height. The best performing model was selected and incorporated into the SA-6MWTapp based on two criteria: the lowest root mean square error (RMSE) and percentage of time the SA-6MWTapp estimated distance was within 15% of the observed measured distance. The later boundary was chosen *a priori* based on prior studies of 6MWTs in CHF patients showing that a 10-30% change in distance is associated with changes in NYHA class[9, 10].

### In-Clinic Validation (Phase 2)

The in-clinic validation cohort (n=32) used the SA-6MWTapp to perform a 6MWT in clinic along a pre-measured 6WMT course using an iPhone 4s placed in their pants pocket, and a second iPhone 4s in a hip holster. The distance estimated by the SA-6MWTapp placed in the pocket was compared to the measured distance walked on the marked 6MWT course. In order to determine differences between phone locations, estimated distances and step counts between hip and pocket were compared.

### Home Validation (Phase 3)

A separate cohort (n=19) of participants with pHTN or CHF was asked to download the SA-6MWTapp and perform at least 3 SA-6MWTs independently at home each week for 2 weeks. The video and instructions embedded in the App served as the only source of guidance on how to use the SA-6MWTapp. Participants received 3 text messages a week reminding them to conduct the 6MWT. An in-clinic walk was conducted immediately preceding (n=5) or immediately following (n=11) the two weeks of home walks (3 refused to come in for followup 6MWT). The in-clinic, staff-administered 6MWT measured distance was compared to the mean home walk SA-6MWTapp estimated distance. An in-clinic walk could only precede home walks in participants who had already had a 6MWT within the last 6 months. The variability of at-home SA-6MWTapp estimated distances was also determined.

### Application Usability

A usability survey was conducted during the development phase (Phase 1), using the Post-Study Systems Usability Questionnaire, which has been used to assess the a home CHF monitoring tool[11] and assesses: 1) ease of learning; 2) overall ease of use; 3) simplicity; 4) effectiveness; and 5) user experience. The usability of the final version of the SA-6MWTapp was assessed during the home validation (Phase 3), using the widely validated System's Usability Scale (SUS)[12]. Additionally, we contacted all participants to assess the incidence of adverse events including: falls, hospitalization, chest-pain, shortness of breath or need for rescue medication such as nitroglycerin, or extra doses of diuretics.

### Statistical Analysis

Baseline characteristics were compared between participants with or without diagnoses of CHF or pHTN in the algorithm development (Phase 1), in-clinic (Phase 2), and at-home (Phase 3) validation phases using *t*- and fisher exact tests as appropriate. The distribution of in-clinic measured distance and SA-6MWTapp estimated distances were analyzed using quantile-quantile plots and found to be normally distributed. Methods of distance measurements were compared using *t*-tests. Means are expressed as mean ± standard deviation (SD).

The interaction of iPhone body position compared to the Actigraph step counts was explored and was found to be negligible. The possibility of a non-linear relationship between step counts and in-clinic, staff-administered 6MWT measured distance was explored by modeling 3-knot restricted cubic splines and was ruled out. An unadjusted univariate model found a relationship of 0.66 meters/step (95% CI of 0.63-0.68).

For distance estimation model selection, we used 10-fold cross-validation to estimate the optimism-corrected root mean squared error (RMSE) of candidate models. Summary results for all models are shown in Supplemental Table 1. The best performing model (Model #4), including height, steps, their interaction, and excluded the intercept, was then incorporated into the SA-6MWTapp.

Bootstrapping with 500 repetitions was used to obtain the 95% confidence intervals for the correlation between the SA-6MWTapp estimated distances and in-clinic staff-administered measured distances in the in-clinic (Phase 2) and at-home (Phase 3) validation phases. The intra-class correlation coefficient (ICC) between the SA-6MWTapp estimated distance and measured distances were calculated for each of the 3 phases of the study. For the home walk phase, the first home-walk measurement was excluded in participants who had never had a prior 6MWT, given the well-known learning effect of the 6MWT. The interaction of the timing of the in-clinic walk (pre or post home walks) and the association of SA-6MWTapp-estimated distance with in-clinic measured distance was also explored. To assess repeatability of SA-6MWTs, the coefficient of variation (CV) of home walk distances was estimated. In a sensitivity analysis, the correlation, ICC and CV calculations were repeated including the first home walk performed in 6MWT naïve participants.

## Results

### Step Counting Algorithm

The initial step count algorithm refinement (n= 32 not included in subsequent phases), which occurred prior to Phase 1, yielded a correlation with Actigraph step counts of 0.71 in the holster and 0.66 in the pocket position (Supplemental Figure 2). The correlation was worse for elderly and symptomatic participants. After adjusting the step counting algorithm to increase the sensitivity threshold and algorithm for translating accelerometer signal to step counts, the correlation with Actigraph step counts improved to 0.94 and 0.89 in the holster and pocket position (Figure 1).

## Participant Characteristics

One hundred and three participants were included in the development (Phase 1, n=52), in-clinic validation (Phase 2, n=32) and home validation (Phase 3, n=19) phases (Table 1, Supplemental Figure 1). In the home validation phase (Phase 3), 87 participants were approached of which, 62 were excluded (20 lacked an iPhone, 16 had musculoskeletal limitations, 2 did not have pHTN or CHF, 2 did not speak English, 2 had Class IV symptoms). No eligible patient refused consent. Six consented but did not download the app. Three participants in the home validation study did not have an in-clinic walk (because they would not return for the test) and were only included in analysis of variability. In the development (Phase 1), in-clinic (Phase 2) and home validation (Phase 3) phases, 50%, 58% and 100% of the participants had a diagnosis of pHTN or CHF, respectively. There was a trend towards increased weight in those with history of pHTN or CHF and a trend towards shorter distance walked with increasing grade of NYHA symptoms (see Table 2).

## Measures of App Accuracy and Repeatability

**Algorithm Development (Phase 1)—**The best performing model demonstrated a correlation between in-clinic, staff-administered 6MWT measured distance, and SA-6MWTapp estimated distance of r = 0.89 (95% CI 0.78 – 0.99, $p < 0.001$) overall and r = 0.75 (95% CI 0.55 – 0.96, $p < 0.001$) in participants with pHTN or CHF. iPhone position did not influence the estimation of measured distance in any of the models considered during the model selection phase ($p = 0.7$) and step counts recorded in the two positions were highly correlated r= 0.98 (Figure 2). The mean difference ± standard deviation (SD) between in-clinic, staff-administered 6MWT measured, distance and SA-6MWTapp-estimated distance in the development validation cohort was 1 ± 45 meters ($p = 0.9$). The SA-6MWTapp distance was within the pre-specified accuracy of 15% for 86% of the participants. The variation in measured walk distances between participants was far greater than the difference between SA-6MWTapp-estimated and in-clinic measured distances (ICC: 0.85 [95% CI 0.77-0.93]), independent of distance walked (Table 3, Figure 3A,B).

**In-Clinic Validation (Phase 2)—**Distance estimated by the SA-6MWTapp had a correlation to in-clinic, staff-administered 6MWT measured distance of r = 0.83 (95% CI 0.73 – 0.92) overall and r = 0.70 (95% CI 0.20 – 0.99) in those with pHTN or CHF. The mean difference ± SD between SA-6MWTapp estimated and in-clinic, staff-administered 6MWT measured distance, was 0.0 ± 47 meters ($p = 0.9$) and the SA-6MWTapp estimated distance was within the pre-specified accuracy of 15% for 91% of the participants. The variation in walk distances between participants was far greater than the difference between SA-6MWTapp estimated and in-clinic, staff-administered 6MWT measured distance, ICC: 0.84 (95% CI 0.74 – 0.94), independent of distance walked (Table 3, Figure 3C,D). The position of the iPhone did not influence step counts in a subset of this study population (Supplemental Figure 4).

**Home Validation (Phase 3)—**Participants performed a mean ± SD of 3.2 ± 1.0 walks per week and a median of 3 (Supplemental Figure 5). The correlation between SA-6MWTapp estimated and in-clinic, staff-administered 6MWT measured distance along a pre-measured course, in the home validation group was r = 0.88 (95% CI 0.87 – 0.86). The mean

difference ± SD between SA-6MWTapp estimated and in-clinic, staff-administered 6MWT measured distance was 7.6 ± 26 meters (p = 0.3). The SA-6MWTapp accuracy was within the pre-specified accuracy of 15% for 100% of the participants. The difference between SA-6MWTapp estimated and in-clinic, staff-administered 6MWT measured distance was much smaller than variability between participants walk distances (ICC: 0.89 [95% CI 0.79-0.99]), independent of distance walked (Table 3, Figure 3E,F).

Within each participant, the variation in home walk distances was small (Table 3, Figure 3F) when compared to their mean home walk distance (CV= 4.6%). The interaction between the timing of the in-clinic, staff-administered 6MWT and the association between SA-6MWTapp estimated and the in-clinic, staff-administered 6MWT measured distance was not significant (p=0.94). When the first home walk was included for 6MWT naïve participants, the measures of accuracy, and CV and ICC did not change significantly (Table 3).

### Analysis of Usability and Safety

During the development phase, a total of 25 participants completed the exploratory usability survey (27 opted out due to time constraints). The majority of participants scored the SA-6MWTapp favorably in all 5 areas, including ease of use and willingness to use if prescribed (Figure 4, Supplemental Table 2).

At the conclusion of the home validation phase, a total of 12 participants completed the usability survey, results of which are shown in Figure 5 and detailed in Supplemental Table 3. Completion of the survey was not associated with the timing of in-clinic tests, NYHA class symptoms, or walk distance. Most participants thought the SA-6MWTapp was easy to use independently. All participants were contacted for interviews and assessment of adverse events. There were no incidence of falls, hospitalization, chest-pain, new onset shortness of breath or any need for rescue medication such as nitroglycerin, or diuretics during the two-week testing phase.

## Discussion

We have demonstrated that a mobile SA-6MWTapp accurately estimates 6MWT distance in the clinic and in the home over a broad range of walk distances and across a spectrum of patients with CHF and pHTN. Participants independently performed multiple 6MWTs in their home, without prior in-person training and with a high degree of repeatability. Participants using the SA-6MWTapp reported that they could use the SA-6MWTapp confidently, independently and would perform the test at home if recommended by their physician. This demonstrates the feasibility of a novel SA-6MWTapp to remotely monitor the functional capacity of heart failure and pulmonary hypertension patients.

The 6MWT is a clinically accepted and well characterized tool for monitoring congestive CHF, pHTN, COPD, peripheral vascular disease and other chronic disease states; however, as of yet this test has been restricted to a clinical point of care test. In an attempt to directly recapitulate the clinical 6MWT for home use, Du *et al* tested the accuracy of walking around lengths of rope in healthy volunteers in a controlled clinical environment (correlation

coefficient of r = 0.81)[13]. Despite this promising start, this technique was not developed further and is limited by the lack of prompts and reproducibility that results from delivering a scripted test. By using the smartphone, our SA-6MWTapp has multiple advantages. The SA-6MWTapp senses motion, delivers scripted prompts at the appropriate time and allows interactivity, creating the ability to more faithfully replicate the ATS-guideline 6MWT.

Prior investigators have demonstrated that measures of ambulatory physical activity using wearable sensors can predict CHF hospital readmission[10, 14]. This prior work is based on *ad hoc* and retrospectively reviewed activity, rather than the prospective performance of a reproducible test, such as a 6MWT. By contrast the SA-6MWTapp allows for on-demand testing, instantaneous result transmission, and emulation of a clinical test in ways that other activity monitors can't. The SA-6MWTapp administers BORG score surveys and heart rate monitoring, which are key clinical measurements recorded during 6MWTs[15]. The SA-6MWTapp can also be coupled with a system of automated or manual alerts to remind patients to perform the test, as is already built into the Health eHeart Study platform and utilized in this study.

The development of a home-based 6MWT in the form of a smartphone application has use beyond CHF management. Six-minute walk testing yields important prognostic information in diseases such as coronary disease, chronic obstructive pulmonary disease (COPD), dementia and morbid obesity to name a few[16-20]. In a cohort of 556 outpatients with stable Coronary Artery Disease, Beatty *et al* found those in the lowest quartile of 6MWT distance (<419 meters) had a > 4 fold increased hazard for major cardiovascular events as compared to those with in the highest quartile (>544 meters) [16]. Six-minute walk test distance is also an important endpoint in the assessment of the efficacy of drugs and devices[21]. Remote assessment using the SA-6MWTapp could increase the frequency of assessments, decrease the need for in clinic assessment and could represent a novel way to reduce overall costs in longitudinal studies.

In this preliminary study of the usability and accuracy of the SA-6MWTapp, the strengths are the inclusion of 103 participants over the course of the development, validation, and home validation phases with a wide range of walk test distances, ages and disease severity. Participants in the home validation study were allowed to choose their own test course (identified hallways or other spaces independently that allowed them to perform a “back and forth” walk), as detailed in the in-app instructions. Remarkably, the SA-6MWTapp estimated distances performed at home were highly correlated with measured distances on in-clinic, staff-administered tests along a traditional pre-measured 6MWT course. While difference between measured and estimated distances did not conclusively vary with increasing distance walked, visual examination of BA plots suggest that the SA-6MWTapp may under estimate distance at higher walk distances. The sample size in our study may be too small to detect this definitively, and crucially, distances above 550 meters are likely to be of little clinical consequence. Additionally, the standard deviation (SD) for the difference between the SA-6MWTapp and in-clinic, staff-administered 6MWT measured distance was 45 and 47 meters in the algorithm development and in-clinic validation, representing ~10% of the mean walk distance in these groups. In the home validation (Phase 3), the SD was 26 meters (only 5% of the mean distance) and the mean home tests were within 15% accuracy in all

participants. This suggests that the SA-6MWT is clinically useful, especially when multiple tests are considered as occurred in the home walk validation phase.

There were no adverse events during home walk testing, suggesting that unmonitored home testing is safe. This finding is not surprising given the lack of published reports of an increased hazard of adverse events at or around the time of the conduct of the six-minute walk tests despite the extensive use of the 6MWT in CHF and pHTN populations. The performance of home-based app self-administered 6MWT is novel; however prescription of home-based exertion in CHF is not. The ACTION-HF trial tested a graded clinical then home-based exercise training in 2,331 participants after in clinic assessments and monitored exercise training and found no significant increase in hospitalizations, death, ICD- firing, fractures, strokes/TIAs or myocardial infarctions[22]. Our experience in this report of home monitoring of SA-6MWTs is limited to those with NYHA III or less severe symptoms. Larger studies of the safety and accuracy of self-administered 6MWTs with the SA-6MWTapp are required. Until such time as these studies are completed one might consider an assessment in clinic for people with unstable symptoms, or significantly impaired physical activity (such as class 3b CHF symptoms). Frailty and physical disability limit this technology from being applicable in all patients.

### Conclusions

A SA-6MWTapp can accurately and repeatable deliver a six-minute walk test and accurately estimate distance in participants with a broad range of exercise capacity (as determined by 6MWT distance) in both normal individuals and those with varying severity of CHF or pHTN in the clinic or remotely. Users found the SA-6MWTapp simple, easy to use and would use the SA-6MWTapp at home if prescribed.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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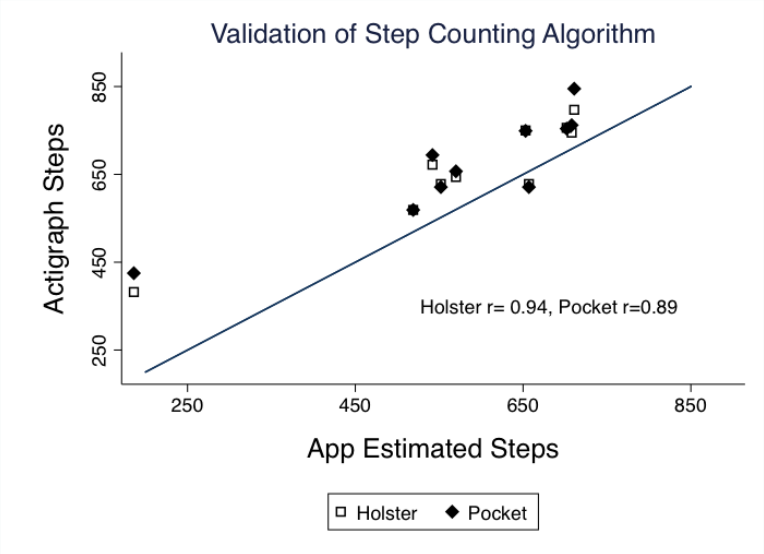



**Figure 1.**
Correlation between Actigraph and SA-6MWTapp estimated steps in the step counting algorithm development.

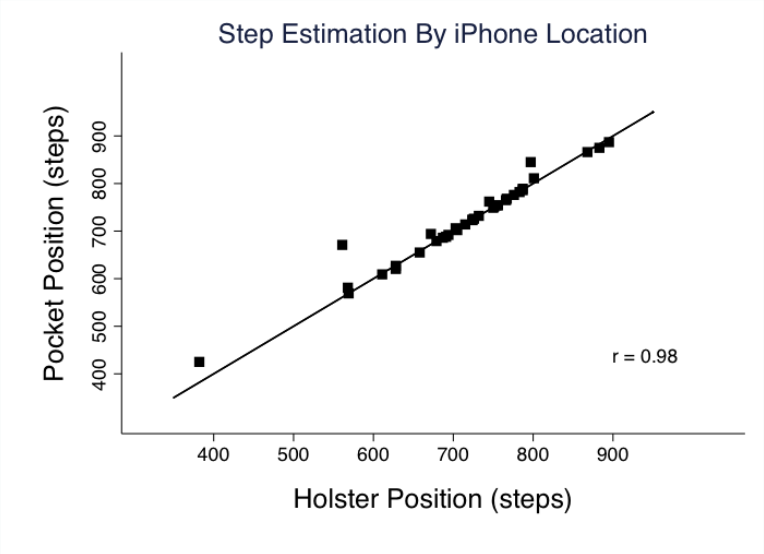
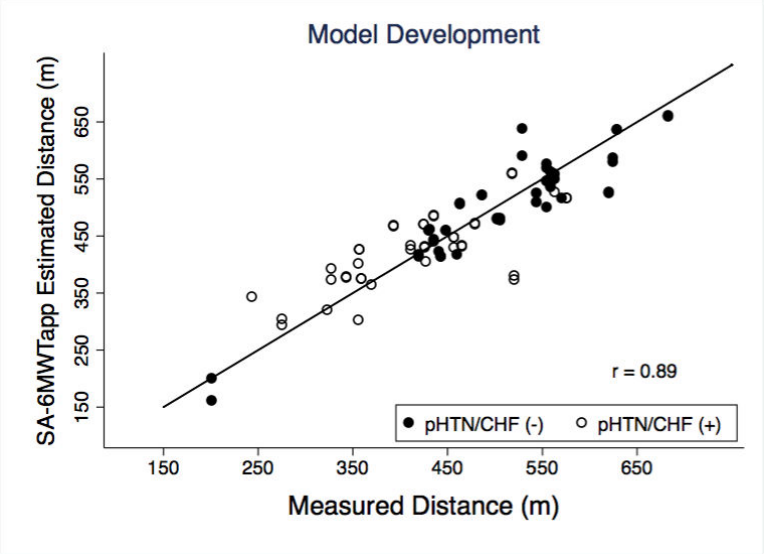
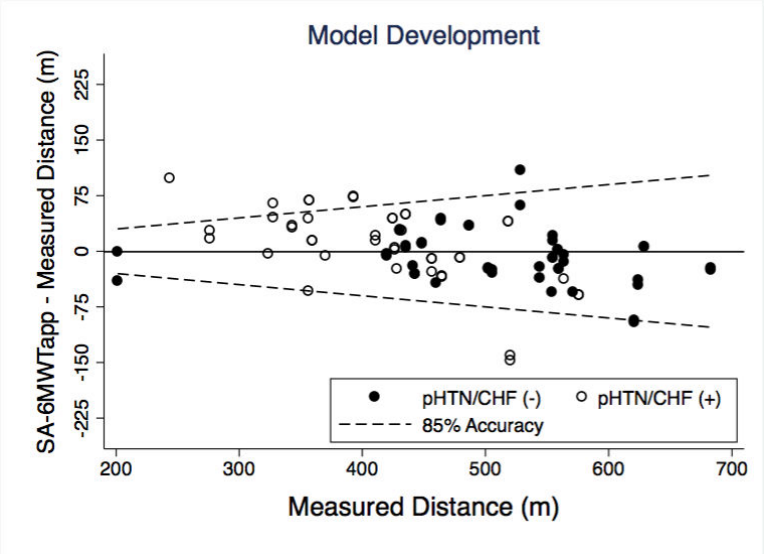
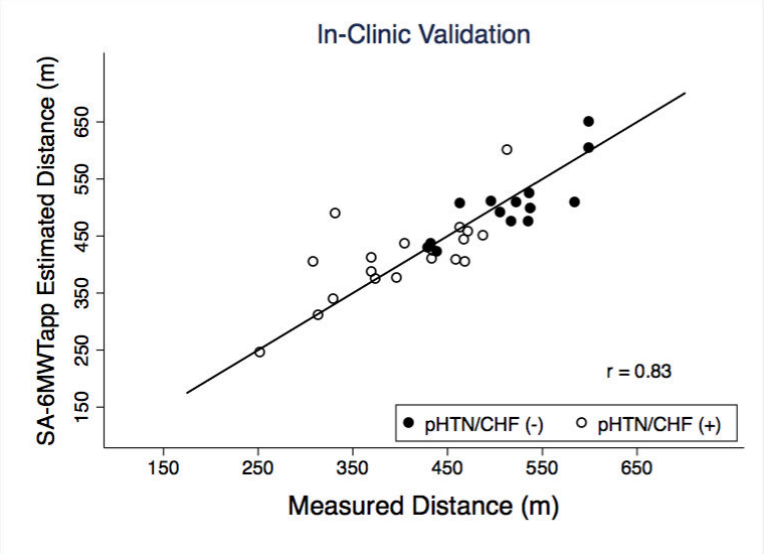
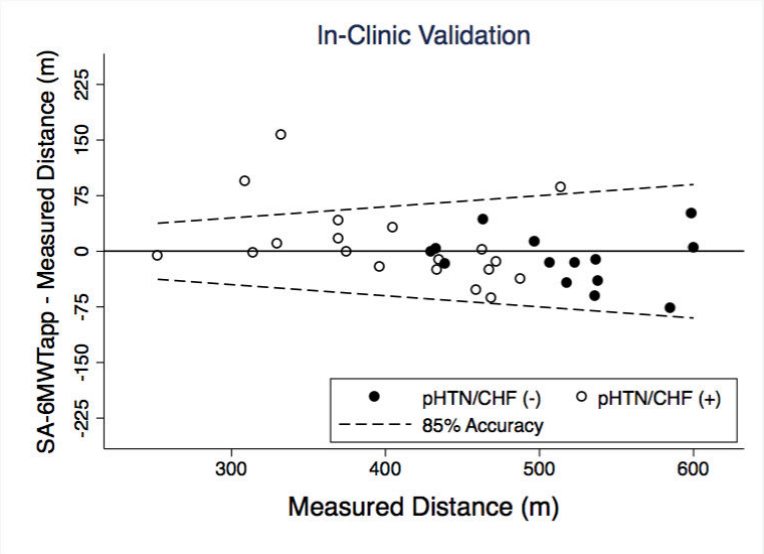



**Figure 2.**
Correlation between SA-6MWTapp estimated steps when the iPhone is placed in the holster versus when the iPhone is placed in the front pocket.





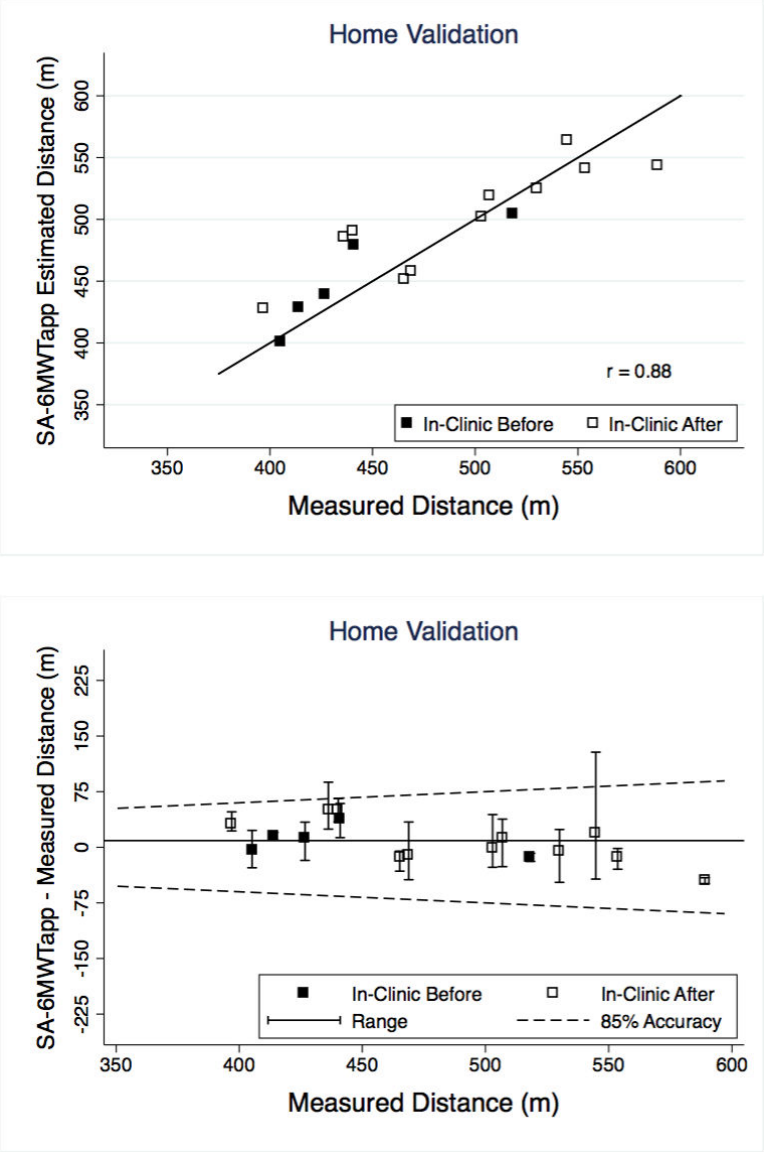



**Figure 3.**

Correlation between SA-6MWTapp estimated and in-clinic, staff-administered 6MWT measured distance in the (A) Model Development (Phase 1), (C) In-Clinic Validation (Phase 2) and (E) Home Validation (Phase 3). Difference between SA-6MWTapp Estimated and in-clinic, staff-administered 6MWT measured distance plotted against in-clinic, staff-administered 6MWT measured distance in the (B) Model Development (Phase 1), (D) In-Clinic Validation (Phase 2) and (F) Home Validation (Phase 3). Participants with pHTN or CHF are denoted with (○) and those without by (●). Participants in the Home Validation (all of whom have pHTN or CHF ) are denoted by (■) if the in-clinic 6MWT walk preceded and (□) if the in-clinic 6MWT walk followed home walks. Minimum and maximum SA-6MWTapp home walk distances for each of the participants are denoted by whiskers in (F). A dashed line (---) denotes the limits of a 15% difference between SA-6MWTapp estimated and in-clinic, staff administered measured distance (B,D,F).

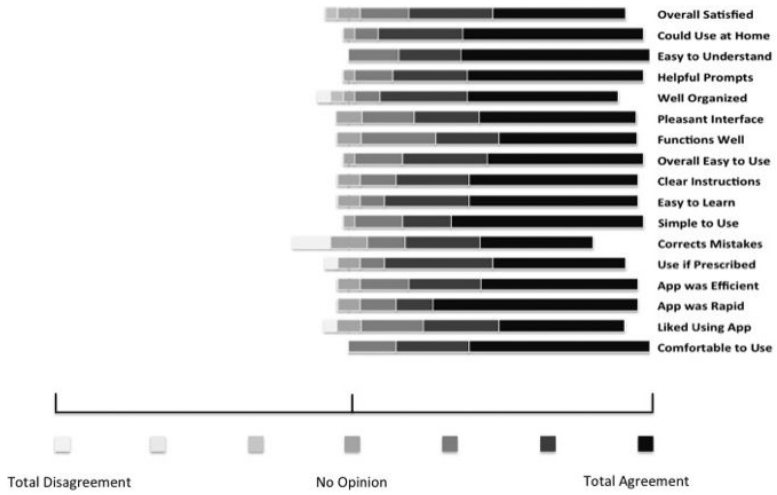



**Figure 4.**

Cumulative results to exploratory usability survey statements (listed in the column on the right) are demonstrated. The cumulative response on the 7-point Likert scale of agreement or disagreement with the survey statements is demonstrated by gradations of shades of black to white. The grey scale values for total agreement or total disagreement and no opinion are labeled.

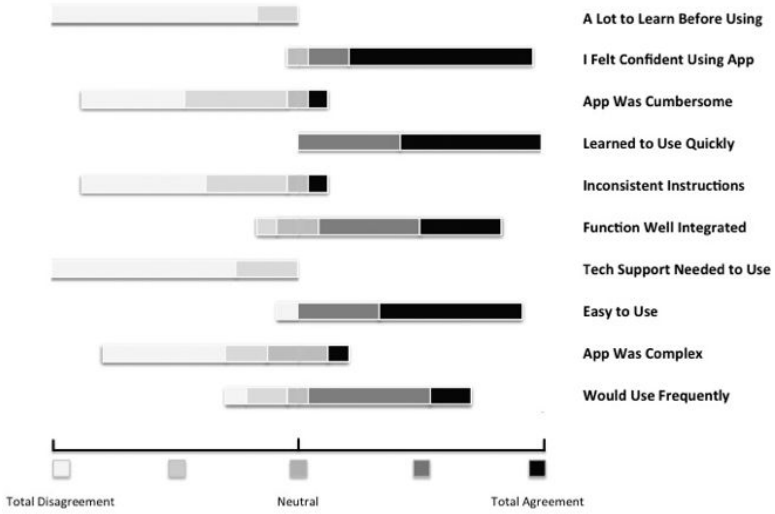



**Figure 5.**

Cumulative results to the final usability survey for the Home Validation cohort. Abbreviated statements are listed in the column on the right. The cumulative responses on the 5-point Likert scale of agreement or disagreement with the survey statements are demonstrated by gradations of shades of black to white. The grey scale values for total agreement or total disagreement and no opinion are labeled.

## Table 1

Participant characteristics in the three cohorts of the SA-6MWTapp validation study

| | Model Development (Phase 1) | | In-Clinic Validation (Phase 2) | | Home Validation (Phase 3) |
|---|---|---|---|---|---|
| | **No CHF/pHTN (26)** | **CHF or pHTN (26)** | **No CHF/pHTN (13)** | **CHF or pHTN (19)** | **CHF or pHTN (19)** |
| Male | 13 | 6 | 5 | 5 | 6 |
| Race | | | | | |
| White | 16 | 18 | 9 | 13 | 13 |
| African American | 1 | 3 | | | 1 |
| Asian | 9 | 3 | 5 | 4 | 2 |
| Native Hawaiian or Pacific Islander | 0 | 1 | 0 | 0 | 0 |
| Hispanic/Latino | 0 | 1 | 0 | 2 | 0 |
| NYHA Class | | | | | |
| I | -- | 9 | -- | 5 | 7 |
| II | -- | 11 | -- | 8 | 10 |
| III | -- | 6 | -- | 6 | 5 |
| CAD | 3 | 1 | 0 | 0 | 2 |
| Atrial Fibrillation | 0 | 1 | 1 | 0 | 5 |
| Age, years (max-min) | 46 ± 18 (23-82) | 52 ± 15 (24-81) | 38 ± 18 (22-67) | 47 ± 14 (25-76) | 54 ± 19 (25-76) |
| Height (in cm) | 168 ± 10 | 167 ± 10 | 170 ± 10 | 168 ±10 | 170 ± 10 |
| Weight (kg) | 67± 13 | 75 ± 21 | 80 ± 24 | 81 ± 15 | 74 ± 20 |
| Distance Walked, m (max-min) * | 511 ± 98 (201-683) | 414 ± 81 (244-576) | 514 ± 58 (430-600) | 402 ± 72 (252-514) | 477 ± 59 (397-589) |

* Distance walked, as measured on a marked course, was significantly shorter for participants with a diagnosis of pHTN or CHF vs. those without in both Model Development and In-Clinic Validation cohorts $p < 0.01$.

**Table 2**

Participant mean distance walked in meters as measured on a marked course (Measured Distance) or SA-6MWTapp (App Estimated) and the mean of the differences between measures within participants in Model Development, In-Clinic and Home Validation cohorts

| | Model Development (Phase 1) | | | | In-Clinic Validation (Phase 2) | | | | Home Validation (Phase 3) | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **n** | **Measured Distance mean (sd)** | **App Estimated mean (sd)** | **Difference mean (sd)** | **n** | **Measured Distance mean (sd)** | **App Estimated mean (sd)** | **Difference mean (sd)** | **n** | **Measured Distance mean (sd)** | **App Estimated mean (sd)** | **Difference mean (sd)** |
| All Participants | 52 | 467 ± 101 | 466 ± 92 | 1 ± 45 | 33 | 450 ± 86 | 451 ± 81 | 0 ± 47 | 16 | 477 ± 59 | 485 ± 47 | 8 ±26 |
| pHTN/CHF | 26 | 417 ± 81 | 425 ± 64 | −8 ± 52 | 19 | 402 ± 73 | 412 ± 73 | −9 ± 54 | 16 | 477 ± 59 | 485 ± 47 | 8 ±26 |
| pHTN/CHF - | 26 | 512± 98 * | 503 ± 97 * | 9 ± 37 | 13 | 514 ± 58 ≠ | 502 ± 62 * | 12 ± 36 | | -- | -- | -- |
| NYHA Class | | | | | | | | | | | | |
| I | 9 | 445 ± 66 | 446 ± 62 | 0 ± 27 | 5 | 449 ± 78 | 454 ± 103 | −5 ± 49 | 6 | 513 ± 41 | 521 ± 27 | 8 ±26 |
| II | 11 | 409 ± 87 | 412 ± 68 | −3 ± 67 | 8 | 401 ± 52 | 404 ± 18 | −3 ±53 | 7 | 461 ±70 | 463 ± 50 | 3 ± 32 |
| III | 6 | 362 ± 76 | 408 ±52 | −45 ± 40 | 6 | 366 ± 32 | 387 ± 36 | −21 ± 66 | 3 | 446 ± 12 | 458 ± 11 | 13 ±24 |

In the Home Validation cohort, only those participants who returned to the clinic for the in-clinic walk are included. Difference in distance walked between those with and those without pHTN or CHF

* p <.001

≠ p <0.0001.

## Table 3

Accuracy and repeatability measures of the SA-6MWTapp in the Development, In-Clinic validation and Home Walk cohorts

| | Algorithm Development (Phase 1) (n=52) | In-Clinic Validation (Phase 2) (n=32) | Home Validation (Phase 3) (n=19) | |
|---|---|---|---|---|
| | | | All Walks | First Walk Excluded in Naive |
| ICC SA-6MWTapp versus In-Clinic Distance (95% CI) | 0.85 (0.77-0.93) | 0.84 (0.74 - 0.94) | 0.88 (0.77-98) | 0.89 (0.79-0.99) |
| Correlation SA-6MWTapp versus In-Clinic Distance (95% CI) | 0.89 (0.78-0.99) | 0.83 (0.73 - 0.92) | 0.86 (0.85-0.87) | 0.88 (0.87-0.89) |
| SA-6MWTapp within Pre-specified 15% Accuracy | 86% | 91% | 100% | 100% |
| Overall Coefficient of Variation | -- | -- | 4.7% | 4.6% |
| CV – NYHA I (n=7) | -- | -- | 5.6% | 5.8% |
| CV – NYHA II (n=10) | -- | -- | 3.7% | 3.4% |
| CV – NYHA III (n=5) | -- | -- | 3.2% | 3.0% |

Home walk cohorts are analyzed with and without with the elimination of the first walk in those participants who had never had a 6MWT before (Naive). ICC= Intra-class correlation coefficient. CV= Coefficient of variation.