



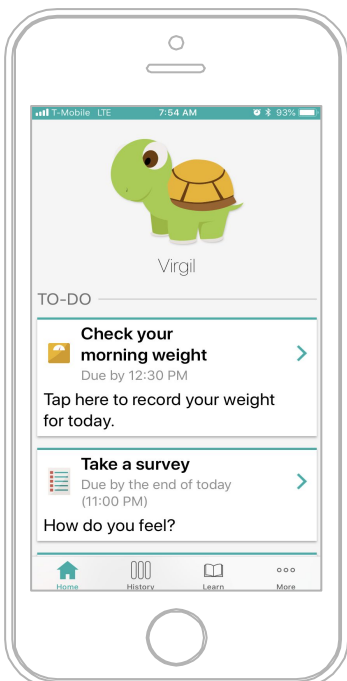
Behavior Design in Heart Failure Pilot Study

Will patients act on instructions provided by an app?

EXECUTIVE SUMMARY

Over a 6 month period, Pattern Health in collaboration with Medtronic and Duke's Center for Advanced Hindsight (CAH) conducted a pilot study of 26 congestive heart failure patients (CHF) using the HealthStar app by Pattern Health. The primary aim of the pilot was to understand if CHF patients would act on instructions provided by a mobile app. Additionally, there was a desire to determine if an app could impact the unmet psychological needs of CHF patients. Therefore, the secondary aims of improving patient agency and control, mastery and confidence, and mood and well-being were also studied.

Medtronic
Further, Together



During a 6 month study of congestive heart failure patients using the HealthStar app, the following results were observed:

- Most users remained active on HealthStar after the first week and used the app consistently throughout the 6 month duration of the study
- When patients set a specific implementation intention (II), as prompted by the app for their evening weight task, they were far more likely to follow through
- Users of the HealthStar app actively engaged in the study's mood intervention (pleasant activities) and reported liking of the intervention. Furthermore, completing pleasant activities was related to a decrease in irritability and increase in contentment

Overall the study was a successful pilot and valuable information was learned about how heart failure patients respond to instructions given by an app. Most importantly, we learned that **when patients set an implementation intention (II) they completed their task 70% of the time compared to only 36% of the time when they failed to set an II.** In addition, response to the HealthStar app was very positive, indicating that app acceptability among a typical heart failure population is good.

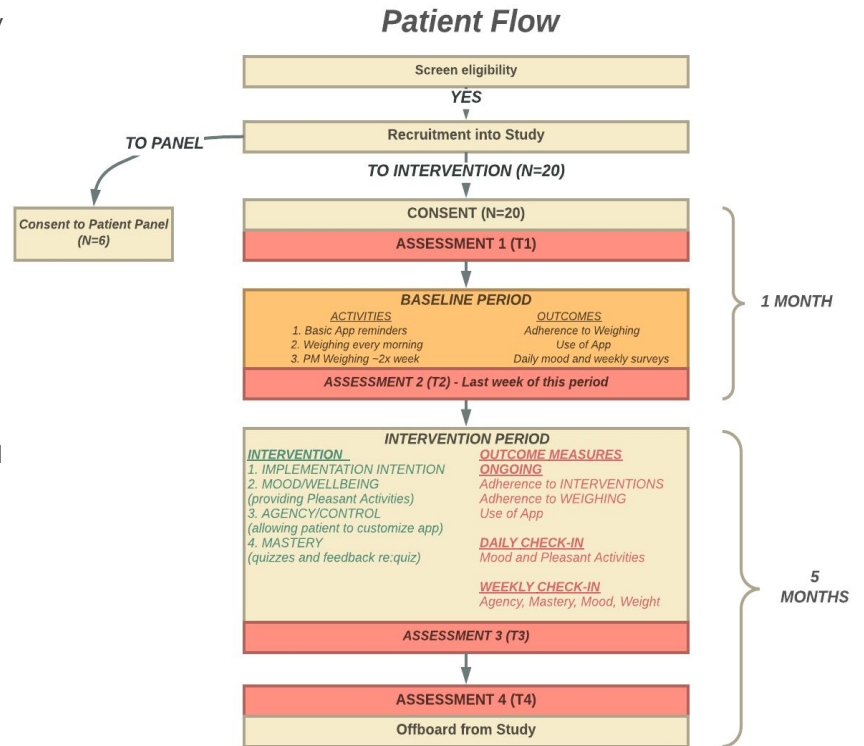
METHODS

26 patients with heart failure were recruited from 2 Duke Health Cardiology Clinics in Durham, North Carolina. 6 of these patients participated in a patient panel which met in person over a period of several months to give qualitative feedback about the app. This feedback was gathered during focus groups and used to make modifications to the app and recruitment.

20 patients participated in the primary study which lasted a total of 6 months. The first month of the study served as a baseline period where patients received only basic app reminders to take daily AM weight and random PM weight (~2x / week). Following this, the intervention period of the study lasted for 5 months, for a total duration of 6 months on study. During the intervention phase of the study, patients were asked to do the following:

- Take a morning weight measurement daily and a PM weight measurement ~2x per week when prompted
- Set an Implementation Intention (II) when prompted for PM weight. Patients were asked to indicate when (e.g. before dinner, after dinner, before brushing teeth, etc.) they will take their weight- no further reminders were given
- Select and complete curated Pleasant Activities to improve mood and well-being (behavioral activation therapy)
- Complete simple health quizzes to increase CHF literacy and boost feelings of mastery
- Customize the app to create patient agency

Figure 1.0 - Patient Flow



Patients were reimbursed for their participation in this study, payments occurred following longer survey completion

Figure 2.0 Patient Patterns

Condition 1:

	Frequency	Time to Complete
Check Weight	Daily	AM
Check Weight	Every 3 days	PM*
Weekly Check In	Every Wednesday	1 day
Mood Survey	Daily	1 day
Pleasant Activities	Daily	20 days
Complete Survey	Various	Various

* PM weight used implementation intentions

Condition 2:

	Frequency	Time to Complete
Check Weight	Daily	AM
Check Weight	Every 3 days	PM*
Take Health Quiz	Every Mon and Thurs	7 days
Weekly Check In	Every Wednesday	1 day
Mood Survey	Daily	1 day
Pleasant Activities	Daily	20 days
Complete Surveys	Various	Various

PATIENT DEMOGRAPHICS

In total, 138 people were pre-screened via EHR and 90 of those pre-screened were eligible. Of those approached, the most common reason for patient ineligibility (63%) was not owning a smartphone or access to the internet. The other reasons included severe mental illness, being a non-English speaker, and cognitive impairment.

The following summarized the study participant demographics.

Figure 3.0 Patient Demographics

	Panel (N=6)	Study (N=20)
Age	60 yrs	57 yrs
Gender (% Female)	16.7%	42%
Annual Income		
<\$15,000	50%	40%
\$15,000-35,000	33.3%	13.3%
\$36,000-50,000		6.7%
\$51,000-75,000		13.3%
\$76,000-100,000		20%
>\$100,000	16.7%	6.7%
Race		
African American	50%	60%
Caucasian	50%	40%
Marital Status (% married)	40%	40%
Education Level		
Grade school	16.7%	
High school	16.7%	47%
Some college		20%
Undergraduate degree	33.3%	20%
Graduate degree	33.3%	13%



14

Android Users



6

iPhone Users

Average BMI = 36.2
Average daily medications: 10

The demographic characteristics of the sample in this study were wide ranging. There was a bimodal distribution of income with 40% of people making less than than \$15,000 a year while 26.7% made >\$76,000. In addition, the sample was balanced in terms of race, gender, and education level. Interestingly, there were no significant differences in app acceptance or usage by income, age, gender, race, or education level. People completed the tasks, pleasant events, and surveys at similar rates. Furthermore, there were no significant differences in Mastery, Agency, or Mood by demographic variables. This may be due to the small sample size, but it may also suggest that apps are not only beneficial for those with a higher income or education level (as is often thought). In fact, this assertion is supported by feedback from the patient panel where a patient with a grade school education level stated that they used the app daily and found it incredibly beneficial.

RECRUITMENT CHALLENGES

There were a number of difficulties faced in recruitment for this study, resulting in a much longer recruitment period than was anticipated. Several main issues were identified and addressed. Many of the issues had to do with beliefs and behavior of the primary study coordinator about who would be a good candidate for an app study. It became clear in this study (and similar studies that we are working on) that those recruiting patients often have beliefs that only younger, more tech savvy patients are good candidates for app studies. Thus, older patients were initially not approached at the same rate as younger patients. Furthermore, the study coordinator was not as comfortable using or explaining technology as we would have liked. Thus, retraining and debiasing information was provided to the coordinator. In addition, other recruiters were utilized to overcome these barriers. These challenges did illustrate the need for very thorough training of those recruiting and assisting patients in using apps as well as making the onboarding flow as simple as possible.

BEHAVIORAL INTERVENTION DESIGN

General Approach to Behavior Design

There are several main steps to undertake when designing successful behavioral interventions. First, map out the behavior of interest with all contributing personal, contextual, and structural factors to an extremely high level of detail to identify possible levers and barriers. A comprehensive review of the academic literature is completed to provide an overview of the prior findings about the behavior as well as conceptually related behaviors and interventions in similar populations. Analysis of practical constraints is also conducted to allow for a narrowing down of the levers and pathways that are available as interventions based on cost, patient access, patient characteristics, and so forth. Finally, this is combined with existing experience and knowledge of theory and human behavior change to identify which behavioral interventions are the most appropriate and have the greatest chance for success in the care pathway.

Process in the Current Study

On this project, the behavior of interest for Medtronic whether patients would take a medication when prompted by an app (not a habitual daily medication). However, given the clear pragmatic barriers to addressing that directly in this pilot study, a proxy was selected. In collaboration with Medtronic, it was determined that asking patients to take an afternoon weight when prompted by an app would serve as a good proxy behavior in this pilot study. Thus, patients were asked to take morning weight daily (just as they might take daily morning medications) along with a randomly requested PM weight (just as they might be asked if using a certain device).

Identification of Important Factors

Why Mastery, Agency/Control, and Mood/Well-being?

Within the field, it is often discussed that patients' lack of adherence may be tied to lack of empowerment, not feeling in control or knowledgeable about their illness, and interference by affective states such as mood. For example, feelings about the controllability of illness is often discussed as a possible barrier or motivator for medication adherence. However, it is rarely a target of intervention and is typically analyzed as a predictor. The same is generally true for Mastery and Mood. Most often, mood (depression in particular) is seen as a factor that decreases adherence but is not used as a means through which improvement and change can occur. Thus, in this study we sought to extend the prior research by not just measuring these variables as possible predictors of adherence, but by manipulating them in an effort to improve adherence.

Why Implementation Intentions?

It is difficult for people to translate goals into action for a variety of reasons (forgetting, unable to initiate, bad habits interfering, etc.) People rely on automatic processes to guide their behavior which can be problematic when their automatic processes are not in line with their goals. However, by setting Implementation Intentions, we can alter people's automatic processes to make the "correct" behavior the automatic behavior. Implementation Intentions set up a conditional "If X situation happens, then I will Y" which allows the goal-directed behavior to be automatically elicited when the correct situation happens thereby removing many of the barriers to action.

Implementation Intentions are simple to implement, extremely low cost, and highly effective across a range of behaviors. For example, In a study with coronary heart disease patients, researchers found that participants who learned about the importance of exercise were more likely to set intentions to exercise but not likely to actually carry them out. In contrast, only the participants who received information on exercise AND were prompted to write when and where they planned to exercise showed increases in weekly exercise. In addition, setting an Implementation Intention has been found to predict: higher rates of exercise behavior, vaccination, increased fruit and vegetable intake, decreased fat intake, and increased screening for cancer. Given the practical benefits as well as documented efficacy for similar types of behaviors, it was determined that Implementation Intentions would be a successful intervention for PM weight taking in this population.

WEIGHT ADHERENCE

Morning weight taking was relatively stable throughout the study (65% completion). However, PM weight taking was more variable. When patients set an implementation intention for their evening weight they followed through 70.7% of the time compared to 36% when they did not set an implementation intention.

It is important to note that PM weight taking in the baseline period (when there were no implementation intentions) did not correlate with implementation intention setting in the intervention period. This suggests that it is not simply that more adherent people were setting implementation intentions.

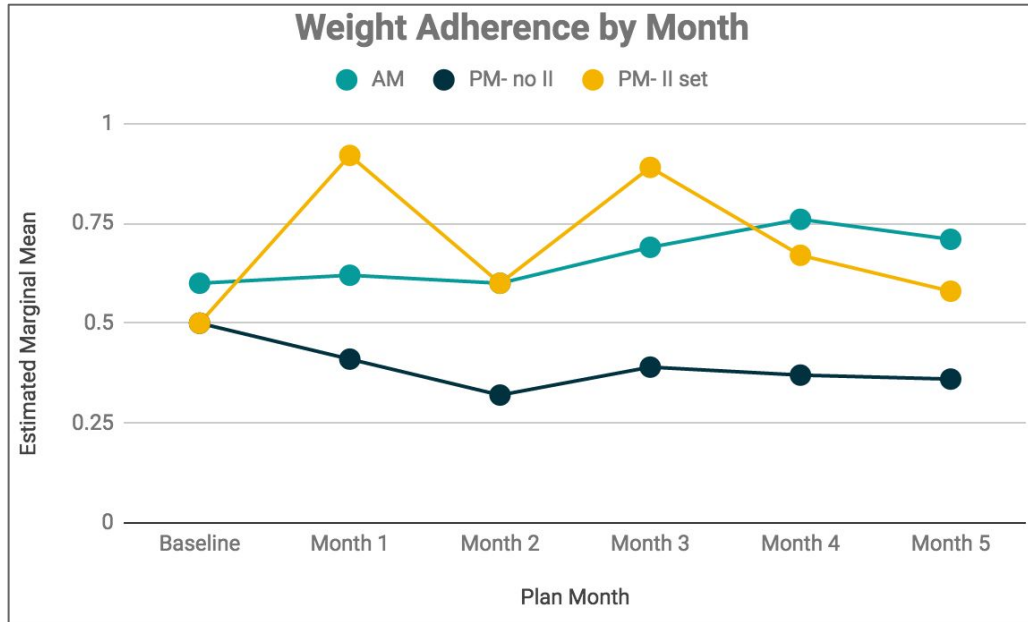


Figure 4.0 - Weight Adherence by Month

70.7% of PM weight completed when implementation intention was set compared to 36% when implementation intention was not set

The industry average for in-app survey completions is around 13% ([Apptentive](#)).

In the HealthStar app, survey completion was high for the Baseline Survey and the Pleasant Events surveys. While the rest of the surveys fell below the desired survey completion rate, all were well above the in-app average. In addition, given that many of these surveys were given daily or weekly over a period of 6 months, the rates of completion were very good.

Figure 8.0 - Survey Adherence

	Frequency	# taken	# offered	Completion rate
Baseline surveys	1x	19*	19*	100%
Pleasant Events Survey	With every event completed	372	421	88%
Health Quizzes (C2 only)	Daily	347	453	77%
Mood Surveys	Daily	1585	2816	56%
Weekly Checks [^]	Weekly	218	423	52%
Midpoint 1	1x	13	19	68%
Midpoint 2	1x	9	19	47%
Offboarding surveys	1x	11	19	58%

* exclude deceased

FEATURES AND MASTERY

Quantitative

As part of the final off-boarding survey, patients were asked to rate the app features on a scale of 1 to 7 based on how much they found each feature to be motivating. Patients rating the challenges as most motivating followed by Reminders and the Virtual Pet.

Figure 5.0 - Feature Rating

Feature	Average Rating
Challenges	5.3
Reminders set by the HealthStar app	5.2
virtual pet	5.1
Messages from the app	5.1
Information in the app	5
Health quizzes	5
Ability to customize reminders	4.7
Setting goals	4.4
Mood tracking	4.3

Mastery was found to be positively correlated with weight taking in both AM and PM. It was also related to feelings of Agency and positive mood reports.

The intervention designed to increase mastery did not impact results. This could have been due to the sample size or that the mastery scores were already fairly high so there was not a wide margin for improvement.

Qualitative

Patients participating in the panel were asked to provide feedback on the app features. Overall, the patients enjoyed the app and wanted to continue using it past the baseline period.

Panel participants often felt strongly about the pet. Some enjoyed the virtual pet and believed it was motivating when it was sad or upset while others were put off by the pet. Participants also appreciated the ability to easily monitor their weight and receive educational content via the quizzes. The main feature panel participants felt the app was lacking was medication tracking.

Figure 6.0 - Mastery Score and Adherence

		AM Weight	PM Weight	Agency	Mastery	Mood
AM Weight	Pearson Correlation	1	.689**	.507**	.450**	.363**
	Sig. (2-tailed)		.000	.000	.000	.000
	N	278	278	278	278	278
PM Weight	Pearson Correlation	.689**	1	.598**	.432**	.337**
	Sig. (2-tailed)	.000		.000	.000	.000
	N	278	278	278	278	278
Agency	Pearson Correlation	.507**	.598**	1	.577**	.520**
	Sig. (2-tailed)	.000	.000		.000	.000
	N	278	278	278	278	278
Mastery	Pearson Correlation	.450**	.432**	.577**	1	.510**
	Sig. (2-tailed)	.000	.000	.000		.000
	N	278	278	278	278	278
Mood	Pearson Correlation	.363**	.337**	.520**	.510**	1
	Sig. (2-tailed)	.000	.000	.000	.000	
	N	278	278	278	278	278

** Correlation is significant at the 0.01 level (2-tailed).

Figure 7.0 - Mood and Choosing Pleasant Events

		Progress	Happy	Irritable	Anxious	Content	Tired
Progress	Pearson Correlation	1	.119	-.223**	-.056	.214**	-.013
	Sig. (2-tailed)		.060	.000	.380	.001	.836
	N	687	250	250	250	250	250
Happy	Pearson Correlation	.119	1	-.570**	.051	.838**	-.721**
	Sig. (2-tailed)	.060		.000	.426	.000	.000
	N	250	250	250	250	250	250
Irritable	Pearson Correlation	-.223**	-.570**	1	.013	-.577**	.441**
	Sig. (2-tailed)	.000	.000		.832	.000	.000
	N	250	250	250	250	250	250
Anxious	Pearson Correlation	-.056	.051	.013	1	-.006	-.083
	Sig. (2-tailed)	.380	.426	.832		.931	.194
	N	250	250	250	250	250	250
Content	Pearson Correlation	.214**	.838**	-.577**	-.006	1	-.596**
	Sig. (2-tailed)	.001	.000	.000	.931		.000
	N	250	250	250	250	250	250
Tired	Pearson Correlation	-.013	-.721**	.441**	-.083	-.596**	1
	Sig. (2-tailed)	.836	.000	.000	.194	.000	
	N	250	250	250	250	250	250

** Correlation is significant at the 0.01 level (2-tailed).

* Correlation is significant at the 0.05 level (2-tailed).

a. Cannot be computed because at least one of the variables is constant.

PLEASANT ACTIVITIES DATA

Patients completed 91% of pleasant activities which resulted in decreased irritability and increased contentment

Every day, patients were given the opportunity to select and complete a pleasant activity from a curated list. This intervention was based on validated therapy for mood called behavioral activation.

Overall pleasant activities were completed 91% of the time. Additionally, it was found that completing pleasant activities was related to decreased irritability ($r = -.22^{**}$) and increased contentment ($r = .21^{**}$) $**p < .01$.

Of the pleasant activities selected, remembering a loved one was the most selected and the most popular pleasant activity category was relaxing followed by contemplating and being effective.

Top Pleasant Events

1. Remember a loved one
2. Have peace and quiet
3. Think about an interesting question
4. Cook
5. Listen to music
6. Laugh
7. Clean your house
8. Help someone
9. Exercise
10. Pray

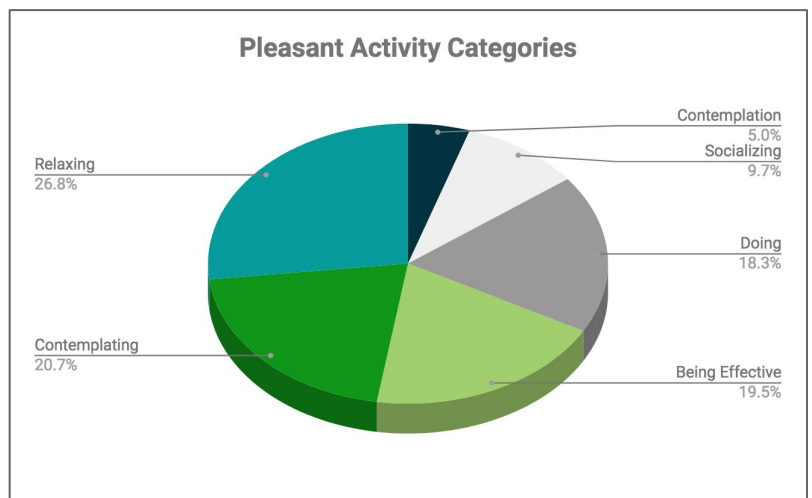


Figure 8.0 - Pleasant Activity Categories

ENGAGEMENT

Most engagement drop off occurred during the first week (30% drop off - 70% retention). According to Localytics, 21% of users only open a mobile application once and on average mobiles apps see a 38% retention rate. The HealthStar app saw a 75% retention rate at month 1, 60% retention at month 3 and 50% at 6 months (*Figure 2.0*).

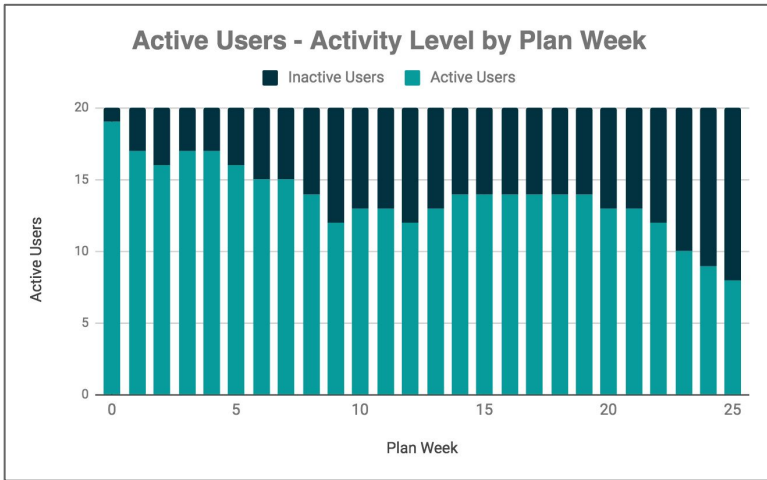


Figure 9.0 - Active User Activity by Plan Week

The average active users opened the app 5.65 days per week

ENGAGEMENT, CONT.

Patients who were engaged past week 1 of the plan remained faithfully active throughout the study. The average active user opened the app 5.65 days per week (*Figure 10.0*). A survey from Flurry from August of 2017, found that most health and fitness apps used their apps at least 2 times per week.

According to Firebase Analytics, the average active Android user completed 1 task per session and the daily engagement time was 3 minutes 35 seconds. Active users spend approximately 1 minute 17 seconds on a single screen.

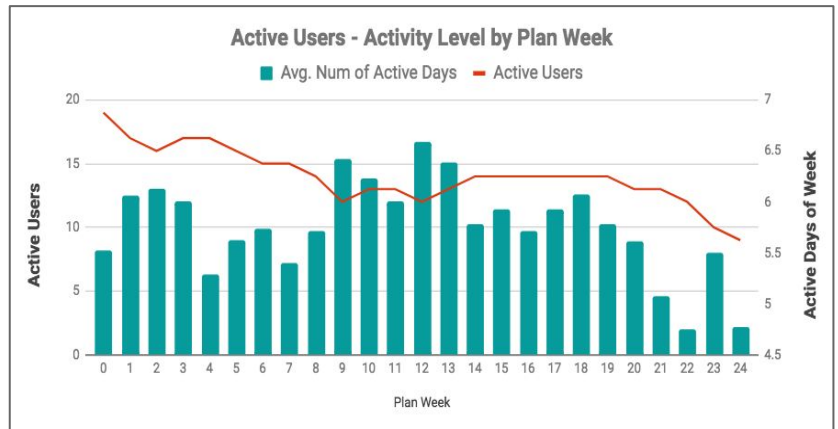


Figure 10.0 - Active User Activity by Plan Week

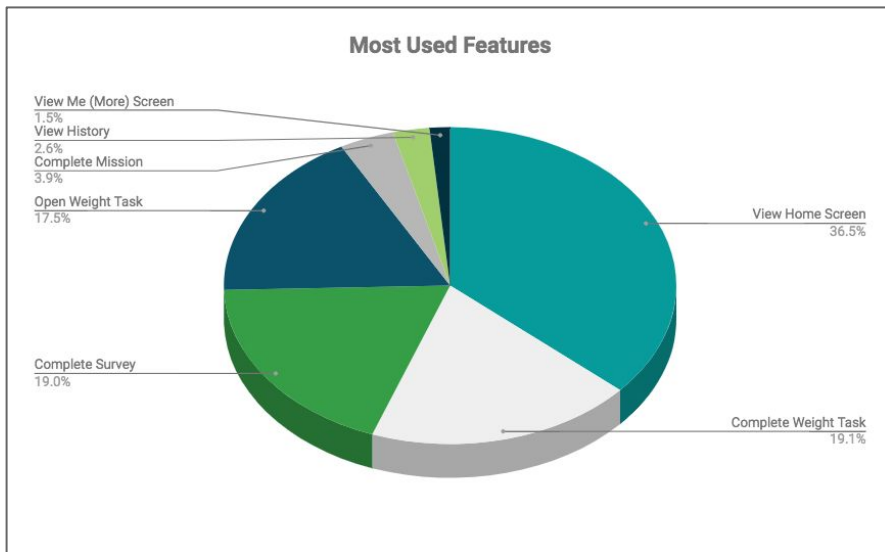


Figure 11.0 - Most Used Features

iOS does not provide this level of reporting detail. However, a majority of users (70%) used Android devices and the data would likely be similar across devices.

Not surprisingly, the Home screen was the most used feature in the app followed next by completing the weight task.

Note that there is a difference between opening the weight task and completing the weight task. This is due to users stepping on the scale and recording their weight via bluetooth (therefore not opening the app).

"Health has a lot to do with behavior. If we can improve our health-related behaviors, we can also improve our health. Through randomized controlled trials and field studies we are trying to figure out the secret formula of using human motivation for better health."

- Dan Ariely (Principal, Center for Advanced Hindsight)

RESULTS, RETURN ON INVESTMENT, AND FUTURE PLANS

The ability to help patients better pattern their behavior to proven care plans is a critical part of improving health outcomes and bending the cost curve. As the shift towards value based care accelerates in the United States and globally, a proven ability to impact behavior will drive huge ROI and become an important competitive advantage for large organizations participating in risk based care arrangements.

The key takeaways from the pilot study were:

- Implementation Intentions are an effective way to increase the likelihood of a patient following through on instructions from a mobile app (70.7% compliance to PM weight checks with Implementation Intention compared to 36% without)
- Patients were very engaged with Pleasant Activities and completed them 91% of the time. Additionally, completing the Pleasant Activity was related to decreased irritability ($r=-.22$, $p<.01$) and increased contentment ($r=.21^{**}$, $p<.01$)
- Patients who stay engaged past week 1 are very active (5.76 active days/wk)
- Additional features and personalization are required to engage more users
- The patient onboarding experience is important and impacts engagement

This research study shows the promise a continued collaboration between Medtronic and Pattern Health can bring to Medtronic. Continuing to focus on behavior design, user engagement and experience, and workflow efficiencies through new and larger research and direct clinical engagements across a spectrum of care specialities will provide tangible benefits to Medtronic in the future.

Pattern Health looks forward to taking the key learnings from this research and patient panel feedback, implementing enhancements, and continuing to partner with Medtronic on cutting edge behavior design innovation.

TRUSTED PARTNERS



Ed Barber, CEO & Co-founder
Pattern Health
ebarber@pattern.health
919-308-1402

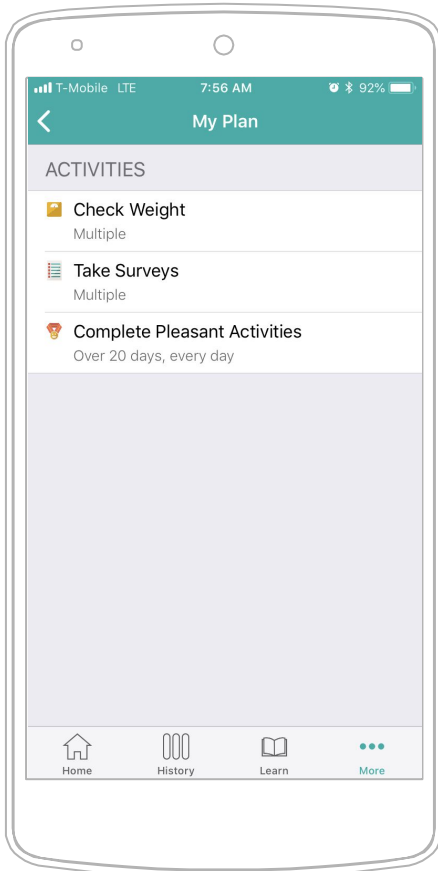


APPENDIX

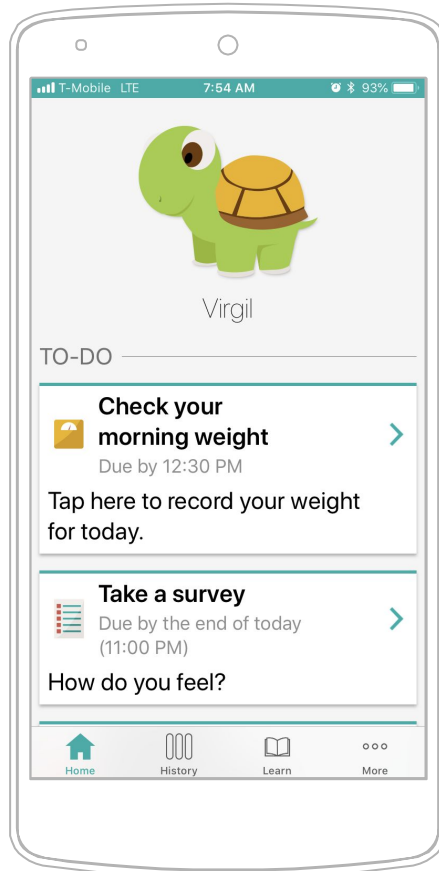
APPENDIX

The following materials are provided to give additional insight in to the patient experience and activities.

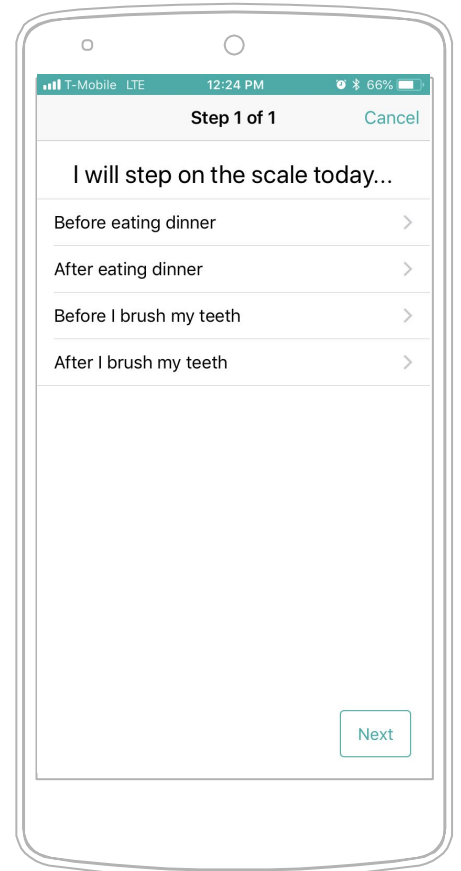
Plan Overview



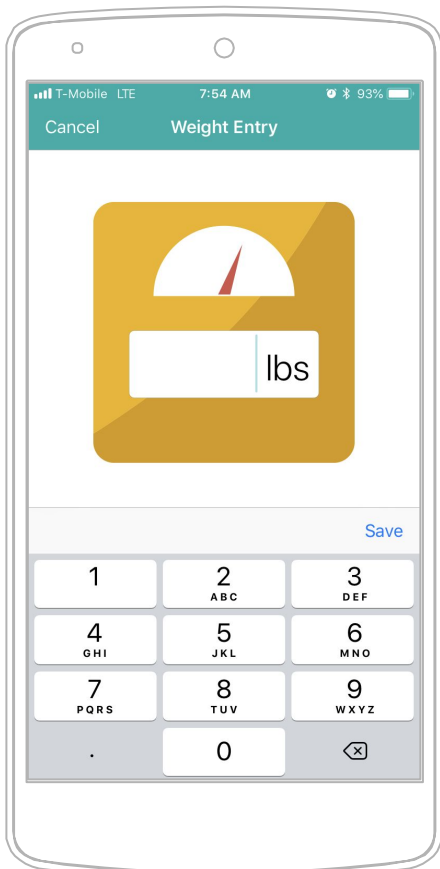
Home Screen



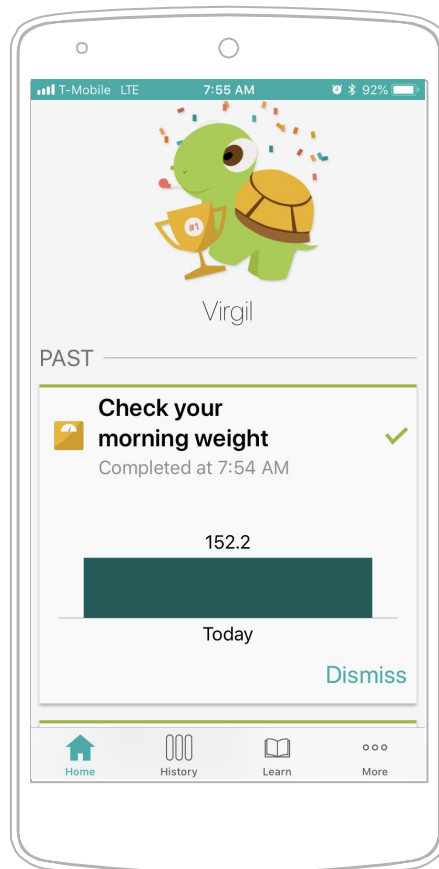
Implementation Intention



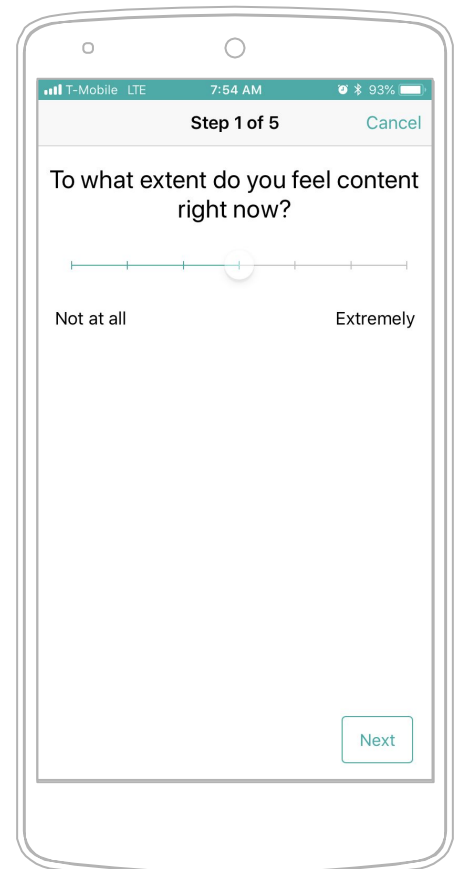
Weight Entry



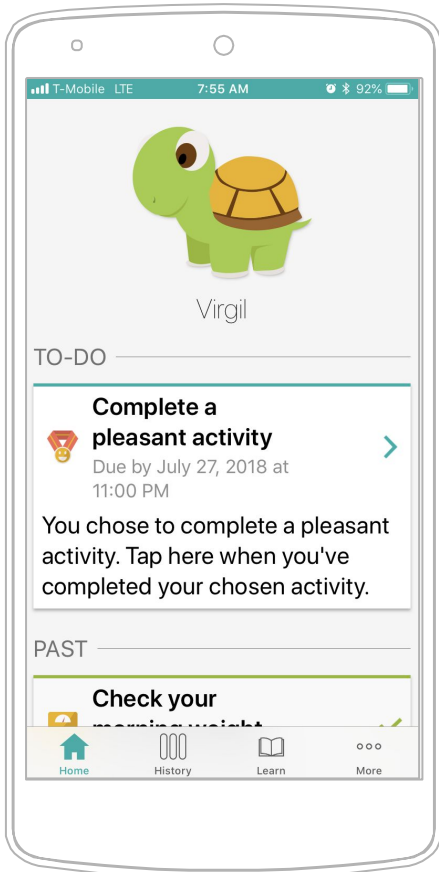
Weight Completion



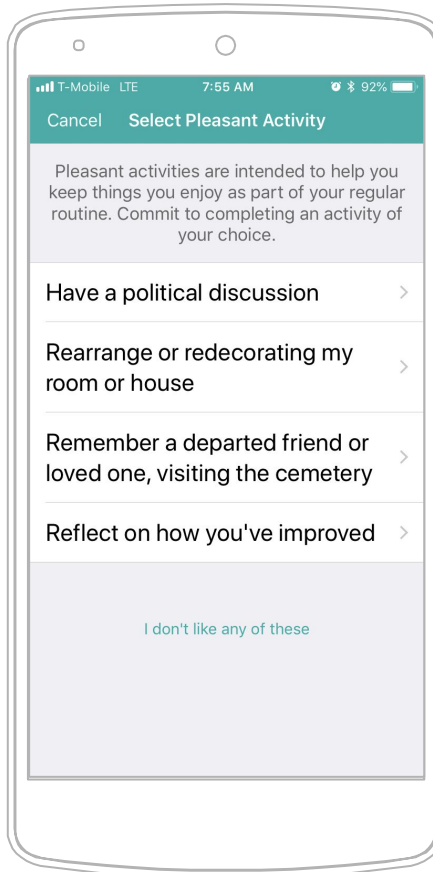
Surveys / Quizzes



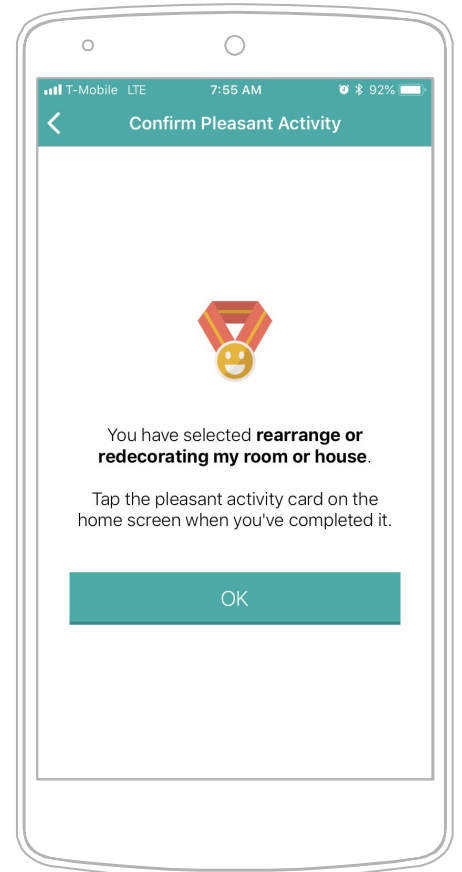
Pleasant Activity



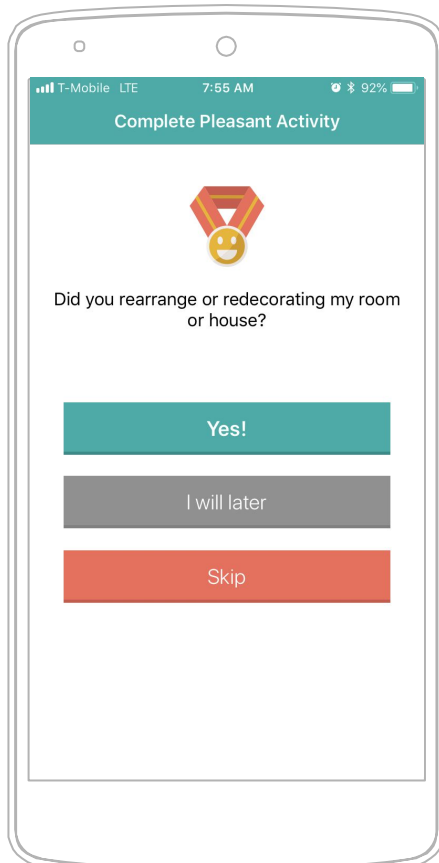
Select Activity



Confirm Activity



Complete Activity



Activity Feedback

