Using Wearable Technology to Increase Daily Activity:

A Weight and Wellness Program Initiative

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Abstract

Purpose: To assess study participants behavioral responses and perception of effectiveness of an activity tracking device to increase physical activity. Obesity is an endemic health issue in the U.S. and continues to gain concern for increasing morbidity and mortality rates. Benefits of physical activity are firmly established across healthcare disciplines to combat and prevent obesity, yet sedentary behaviors continue to be on the rise. The use of wearable technology, that provides real-time feedback of activity, has been identified as a promising tool for increasing physical activity.
Methods: Analysis of a subset of questions from a larger survey was used to evaluate wearable device attitudes and behavior changes over time. Convenience sample (n=10), ages >18, required enrollment in a clinic-based weight and wellness program (WWP) to participate. The survey questions assessed effectiveness of wearable device on a 0-10 motivation scale to increase physical activity and a self- assessment of behavioral changes at specific intervals over a 6-month period. Descriptive statistics and non-parametric, two-tailed tests will be used to analyze the data. Due to the necessity of detecting minute differences with the small sample size, the significance level will be tested at the $p<0.10$.
Results: Participants >18 years of age, enrolled in a WWP (n=10) included 20% male and 80% female. Although a 12.3% increase in the mean score was found from week-1 to 6-months, the results were not statistically conclusive to the effectiveness of self-motivation to increase activity by participants wearing an activity tracking device; however, results are statistically significant for participants to increase activity with behavior changes based on device dashboard.
Conclusions: It is recommended for primary care providers to encourage the use of an activity tracking wearable device for behavior change to increase activity.

Keywords: *activity tracking; effectiveness; health improvement; motivation; physical activity; primary care; sedentary lifestyle; tracking device; wearable devices; weight loss*

Wearable Technology Application to Increase Daily Activity

Obesity continues to be a mounting health issue in the United States (U.S.), causing great concern for higher morbidity and mortality rates. Due to this undeniable widespread problem, on-going research surrounding the complexity of obesity and prevention interventions, including the benefits of physical activity, is accomplished. Although a surplus of information is readily available regarding the benefits of regular exercise, the American Heart Association (2016) states any amount of physical activity is better than succumbing to a sedentary lifestyle. Sedentary behavior, defined as low physical activity with primary behaviors as sitting or lying for extended periods of time during waking hours, has shown significant increase in health-related issues such as diabetes, cardiovascular disease and depression (Chau et.al., 2013). Although there is a significant amount of evidence to support the necessity of regular physical activity, obesity and the numerous issues associated continue to be on the rise. The adaptation of wearable activity tracking devices to improve motivation and behavior change toward increased physical activity is promising for implementation in the primary care setting.

Introduction

Support for a healthy lifestyle, which typically includes balanced diet high in whole foods and a regular physical activity, is a prominent provider-patient topic in the primary care setting. Several medical associations and colleges have consistently concluded the first line treatment for numerous initial diagnosis of common ailments (e.g. obesity, diabetes, hypertension) is the recommendation of lifestyle changes to improve diagnosis (Fihn et.al., 2012). Sedentary lifestyle, due to a range of factors (e.g. office work, commuting, TV binge-watching) has unfortunately become more of the daily norm than an active lifestyle, significantly increasing chronic health risks. For instance, Chau et.al. (2013) identified that total sitting time, >4-8

hours/day and > 8 hours per day, increased all-cause mortality (per 1-hour increment, 2% and 8% respectively). According to Owen et.al. (2010), 25% of the population spend 70% of their time sitting during waking hours.

Additionally, there is a linear progression of total sitting time and higher mortality risk. Increased cardiovascular disease is associated with sitting for more than 10 hours/day, compared to five hours per day with women and obese persons being at a higher risk (Same, et.al., 2015). In one study, participants were asked to remain in bed for an extended period (~23 hours per day) for five days. With no weight gain noted, results showed a significant elevation of total cholesterol, plasma triglycerides and glucose, as well as insulin resistance (Tremblay, et.al., 2010).

Just as there are numerous factors that keep people from being active, there are several dynamics to increasing activity level, including self-motivation. Wearable technology that provides personal feedback related to activity status has shown promise for increasing physical activity through knowledge, motivation and engagement (Batsis et.al., 2016; Lee, et.al., 2016; Park, Kim & Kwon, 2015; Patel et.al., 2016). In fact, research has shown those persons who track activity have a higher propensity to lose weight, be more engaged in healthier behaviors and increase activity (Batsis et.al., 2016; Gao, Li, & Luo, 2015; Lee, et.al., 2016; Pourzanjani, Quisel & Foschini, 2016). The purpose of this project is to assess physical activity motivation attitudes and behavior changes through the introduction of wearable technology and real-time dashboard feedback.

Evidence Search and Synthesis

An exhaustive evidence search and literature review includes a comprehensive database search strategy including several key search terms and phrases. Proquest and PubMed were

primary search databases. Boolean search terms in all databases include; *activity tracking; effectiveness; health improvement; motivation; physical activity; primary care; sedentary lifestyle; tracking device; wearable devices; and weight loss.*

Subsequent results were filtered to include peer-reviewed scholarly journals, as well as dates from 2007 through 2017. The results applying *weight loss* AND activity yielded over 800,000 results, so a more focused search on *weight loss* AND *activity tracking device* AND *motivation* yielded 41,308 results, *wearable devices* AND *health improvement* yielded 13,680 results. Adding *motivation* yield manageable results of 3,723 studies.

ProQuest and PubMed both yielded large numbers of peer-reviewed articles for the time period of 2007 through 2017 using the same search terms. RefWorks as a database was used to manage selected article duplications from all database searches, with a final 52 chosen articles. A critical assessment commenced for content related to interventional or outcome focus aspects of the using an activity tracking device to increase motivation and behavior changes, including supportive background data. Out of those studies, 16 have been selected for inclusion in this project, including background and significance evidence. Those articles excluded require further analysis to identify the pertinence to the current research questions. The selected articles include applied interventions, outcomes and the correlation of the wearable tracking activity device on improving sedentary behaviors.

The inclusion of seven studies specific to interventions was accomplished through rapid critical appraisal technique (Melnyk, 2005). Most of the research portray a deliberate use of statistical measurement, including analysis of interventions. The levels of evidence demonstrate the following: Level I (n=2, randomized, well-controlled trials); Level II (n=2, well-designed non-RCT); Level III (n=2, non-experimental descriptive studies) and Level IV (n=1, cohort and

well-designed case-controlled studies) evidence. Wearable technology provides personal feedback related to activity and has shown promise for increasing physical activity through knowledge, motivation and engagement. In fact, research demonstrates that those persons who track activity have a higher propensity to lose weight, be more engaged in healthier behaviors and increase activity. Three articles describe acceptance of wearable technology as promising for health-related behavior change and all articles describe at least some level of health improvement evidence.

Review of Literature

The definition of a wearable device is an "…electronic device that provide(s) the functions of a computer system and are able to be attached to or worn on the body" (Park, 2015). Research has been accomplished to address various wearable device effectiveness topics, including the validity and reliability of data, behavior changes, self-efficacy, and self-perception of motivation, to name a few. The studies indicating the actual efficacy of the device, such as whether there is accurate data provided to the participant, will not be addressed in this report. Rather the evidence contemplated in this report is focused on the attitudes and behaviors of the participants wearing these devices.

Wearable device technology has shown weight-related positive results, indicating that mobile technology with real-time participant feedback offers an opportunity to promote weight loss and improve health (Pellegrini, 2012; Pourzanjani, 2016). The intentional use of wearable tracking devices correlates positively with perceived control of health information, interactivity and action, leading to behavior changes and increased motivation to improve physical activity (Park, 2015). In one empirical study, the acceptance of wearable technology was positively associated with: perceived ease of use and opinions of usefulness for increased technology

adaptation; high-level of influence based on social construct to adapt to wearable health technology; and the self-perception of improved health benefits though real-time feedback to the user (Gao et.al., 2015). There are some concerns surrounding privacy of personal health information, however, Gao and colleagues (2015) identified this is a personal risk-benefit analysis and may be influenced by the fluctuating media coverage in response to technology and privacy.

In the "quantifiable self" theory, users of wearable health tracking devices are gaining more knowledge about self, in turn self- identifying and acting on those behavioral changes that need to be adjusted per self-motivation and objectives (Patel, 2015). According to Patel (2015), there is a high potential to have sustainable behavioral changes for increased activity through the use of wearable technology; however, he identified this is best if used in conjunction with other engaging lifestyle change theories and programs . Sustainability of the long-term effectiveness requires further research studies to be accomplished; however, there is promising early data that both motivation and behavior changes to increase activity is more effective with wearable device and real-time feedback technology implementation and could be a lifelong application (Lee, 2016; Tosato, 2017). The use of wearable technology has a significant place in the primary care setting and offers the primary care provider an evidence-based discussion point to assist patients with lifestyle change to increase physical activity (Cadmus-Bertran, 2017; Montoya, 2017).

Health Behavioral Theory and Implementation Framework

Pender's Health Promotion Model describes the relationship between a person's health beliefs or attitude and potential behaviors and appears to be a core framework throughout the research articles. The Health Promotion Model evaluates three core realms, including: individual experiences and characteristics; behavior specific affect and reasoning; and outcomes of

behavior (Srof, 2006). Application of the Health Promotion Model to the use of wearable activity trackers follows along the path of pre-intervention behavior, perceptions of the intervention and commitment to changed behavior. These core realms provide guidance to the primary care provider starting with the initial conversation regarding lifestyle changes and certainly provide a basis for assessment and understanding of patients' initial motivating influences.

The Ottawa Model of Research Use offers the fundamental methodology of implementing evidence-based interventions through a multiphase approach (Appendix C). This simple three-step model provides a basis for knowledge translation of the wearable device intervention and evaluation through: the assessment of supportive systems and potential barriers of the intervention; monitoring of the wearable device effectiveness: and the degree of use and evaluation of effectiveness and behavior outcomes (National Collaborating Centre for Methods and Tools, 2010). In addition, the Ottawa model provides specific guidance to achieve the steps necessary for assessment, monitoring and evaluation. The use of this model for implementing a wearable device review and replicative intervention provides the foundational guide by thoroughly instructing on the attainment of necessary actions for successful research implementation and outcomes.

Methods

As part of a larger grant-funded study between ASU Biodesign Institute and the Mayo Clinic Weight and Wellness Solution Program, this analysis focuses primary on the potential motivation and behavior changes of participants enrolled in a weight and wellness center who were given an activity tracking device with training for real-time self-assessment of activity (e.g. number of steps taken by participant over time). Data was collected at five different intervals, including an initial 1-week, 3-week; 6-week, 12-week and 6-months assessments. Institutional

Review Boards (IRB) from both The Mayo Clinic (Appendix D) and Arizona State University (Appendix E) approved the project in separate IRB approval letters. Human rights protection were in place as all subjects were given an anonymous identification number, and data was gathered in aggregate form.

Population and Evaluation Questions

The population is a subset of adult participants in a Weight and Wellness Solution Program (WWSP) with a BMI>25 who agreed to wear a tracking device and receive follow-up visits at timed intervals to assess outcomes. The inclusion criteria required participants to not have worn a physical activity tracking device within the previous 3-months prior to study. The questions attained for the project is a subset of a >100-question comprehensive instrument used on all WWSP participants prior to starting the program. The instrument, called *4291 Partenheimer Obesity Registry, Mayo WWSP*, is a survey created by The Mayo Clinic to effectively assess their specific population and includes basic demographic questions: gender, living status, current employment questions, as well as nutritional, behavioral, mental status and activity related questions. The subset of questions, a 16-question evaluation survey, is selected for the wearable device intervention project and entails activity-related information to assess participants' perceived level of physical activity prior to implementing the wearable device intervention. The evaluation subset questions selected provide baseline information regarding level of activity and use of a wearable device or smartphone application for health prior to the intervention of a wearable device (Appendix A). This is valuable information to assess self-reported baseline activity levels and provide foundational support toward the implementation of a wearable device to improve activity.

Outcome Measurement

The instrument used to evaluate the outcomes of the intervention is part of a larger data collection tool for those participants agreeing to wear an activity tracker and review an activity dashboard application associated with the tracking device. There are two primary motivation and behavior change questions selected from this original questionnaire for the purposes of outcome analysis (Appendix B). The outcome instrument is the *Mayo360 Personalized Support System: Patient-Driven Lifestyle Solutions for Weight and Wellness (Mayo360PSP),* which consists of a 22-mix-mode questionnaire, used by the health coach during follow-up video visits. This specific tool was created by the research team for WWSP participants wearing a Fitbit Charge2© device. The health coach visits are scheduled at specific intervals of initial, 3-week, 6-week, 12-week and 6-months and address the questions within the *Mayo360PSP* instrument. The two questions chosen for outcome measurement are key to understanding the effectiveness of the intervention, namely the self-reported motivation scale and open-question behavior changes related to wearing an activity tracking device (Appendix B). According to Pourzanjani (2016), adherence to activity tracking shows a predictability in weight loss presumably due to engagement with the wearable device/application. The reliability and validity of the specific questions has not been tested, however, the use of short item surveys including rating scale and open-ended questions, are well-studied for qualitative data gathering (Gogal et.al., 2014). Evaluation of wearable device/application intervention through pre-device activity and post- device motivational questions in the WWSP population provides constructive information for sustainability of the device intervention.

Results

Descriptive statistics, frequency analysis and non-parametric tests were used to analyze the data. This project is similar to an exploratory pilot study to generate a hypothesis. For the purposes of this study, due to the importance of detecting small to moderate differences with a small sample size (p values >0.05 but <0.10 are referred to as trend); therefore, significance was tested at the p <0.10 (Fugate Woods Lentz, Mitchell, Heitkemper & Shaver, 1997).

Descriptive Analysis

The majority of the sample (N=10) were female 8(80%). Living status revealed 30% (3) lived alone and 70% (7) do not live alone, with 50% (5) married with children. Participants employed full-time were 90% (9), with one participant currently not working full-time. Eighty percent of the participants go to their workplace, with the remaining 20% (2) working remotely. The number of participants who work day shift, Monday - Friday is 9 (90%), 10% (1) working other than day shift and Monday-Friday. Seven (70%) participants stated they have not participated in regular activity over the past 6-months, 3(30%) stated they have participated in regular activity in the last 6-months.

Table 1. Previous use of an activity device.

		Frequency	Percent	Valid Percent	Total Percent
I have used an activity tracking device.	yes	2	20.0	20.0	20.0
	no	8	80.0	80.0	80.0
	Total	10	100.0	100.0	100.00

Table 2. Current use of an activity device.

		Frequency	Percent	Valid Percent	Total Percent
I am currently using an activity tracking device.	yes	7	70.0	70.0	70.0
	no	3	30.0	30.0	30.0
	Total	10	100.0	100.0	100.00

Table 3. Previous use of technology-based health application.

		Frequency	Percent	Valid Percent	Total Percent
I have used an activity tracking application.	yes	5	50.0	50.0	50.0
	no	5	50.0	50.0	50.0
	Total	10	100.0	100.0	100.0

Table 4. Current use of technology-based heath application.

		Frequency	Percent	Valid Percent	Total Percent
I am currently using an activity application.	yes	3	30.0	30.0	30.0
	no	7	70.0	70.0	70.0
	Total	10	100.0	100.0	100.0

Additionally, participants' pre-intervention, initial assessment identified that 70% (7) responded to watching 6-20+ hours per week of television; 60% (6) spend > 20 hours per week on a technology-based device (e.g. smartphone or tablet); 70% (7) either sit all day while at work or only get up for a few minutes each hour while working.

According to the mean average score measuring the effectiveness of motivation to increase physical activity, there was a 12.3% increase in mean score from initial to end of 6-months.

Table 5. Mean score of participant response scale of 0-10 at assigned intervals.

Question	N	Minimum	Maximum	Mean	Std. Deviation
Initial Post Effectiveness	10	3.00	10.00	7.6000	2.71621
Week 3 Post Effectiveness	10	4.00	10.00	8.1000	2.02485
Week 6 Post Effectiveness	10	5.00	10.00	8.4000	1.89737
Week12 Post Effectiveness	10	7.00	10.00	8.3000	1.33749
Week 24 Post Effectiveness	10	6.00	10.00	8.6000	1.42984

Statistical analysis of the participants responses over time for the "How would you rate the effectiveness of the Fitbit on motivation to increase exercise?" was accomplished. A non-parametric Friedman test was conducted comparing the effectiveness inclusive of the initial, 3-week, 6-week, 12-week and 6-month time intervals, rendering a Chi-square value of 1.91. No significant difference was found ($\chi2(4) = .896$, $p > 0.10$). The use of a wearable device did not significantly affect motivation of the participants to increase exercise over 6-months.

Statistical analysis of the participants reported behavior changes, which were based on the real-time feedback of the wearable device or dashboard, was accomplished. A non-parametric Freidman test was conducted comparing responses of behavior change over time, including the initial, 3-week, 6week, 12-week and 6-month time intervals, rendering a Chi-Square of 9.252. A significant difference was found ($\chi2(4) = .05$, $p < 0.1$). The use of a wearable device with real-time feedback significantly affects behavior change to increase activity.

Discussion

Knowledge that physical activity is beneficial in preventative health objectives has been identified for several decades. However, even with this long-time acknowledgement, there remains only one in five adults that engage in regular physical activity per CDC guidelines (Sullivan & Lachman, 2017). Research has identified that both motivation and behavior changes require various strategies for long-term sustainability (Montoya, 2017; Patel, 2015). The use of

wearable technology to enhance motivation and behavior change has been proven, both in research and portrayed with this project, as a promising adjunct to primary care provider discussions about lifestyle changes. One potential way to promote lifestyle change, and specifically exercise goals, is through early and often discussion of motivating factors which influence behavior (Sullivan, 2017). If personal tracking and data is identified by individuals as a potential motivating influence to increase exercise, the wearable technology platform provides an economical and proven method for providers to discuss. Additionally, providers or other key healthcare professionals working with individuals to improve physical activity, have the option of incorporating accountability through logs similar to blood pressure and glucose readings (Cadmus-Bertram, 2017).

Limitations and Future Research

This project has several limitations. First, the pre and post questions were not wholly based on tools identified as valid and reliable. The qualitative post-intervention survey provided the perceptions of the participant over time, however, there was no significance for the Likert rating probably attributed to the timing of the initial contact. The participants were provided the wearable device, then were asked the initial questions within a week, allowing time to be engaged with the device. This has the potential to skew results of overall significance for the effectiveness of motivation. It is anticipated that had the question(s) been asked *prior to* receiving the device, the results would have been statistically significant (e.g. participant presumption of effectiveness of device).

Future studies should ask the same two questions *prior to* the participant receiving the wearable activity tracking device, in addition to the demographic and pre-behavior questions. There is a possibility the ratings would have changed enough for significance. Second, the pre-

post questions were complimentary; however, future studies should present the pre and post survey with identical questions to have a comparative analysis. As described by Golfashani (2003), reliability and validity of the instruments in qualitative research is imperative but may not be defined as stringently as necessary with quantitative studies. Additionally, the small sample size would ideally be higher, as well as the participant expansion to the primary care setting. Adding quantitative data points (e.g. weight, cholesterol, blood pressure) would be beneficial for monitoring in both practice and research. Measurable data will not only provide progress to the provider and patient, but also substantiate the use of the tracking device for actual outcomes and not rely solely on participant perceptions.

In conclusion, using a wearable activity device to increase daily activity remains a viable option for patients requiring lifestyle changes which include boosting routine physical activity. Primary care providers, through motivational interviewing and shared decision-making, can identify with their patients' if an activity tracker with real-time feedback is an appropriate option. In addition, to align with sustainability potential, the primary care provider should suggest the patient using an activity tracking device provide a log, or printout, of activities and bring to the office to review during routine follow-ups and track progress. This information will assist both the patient and provider with better understanding of their health prevention habits, as well as provide a basis for provider decision-making on initiating medications. Ideally, dissemination of the wearable device research will infiltrate organizations focused on preventive health too either continue sustainability studies, or include in guideline recommendations the inclusion of a wearable tracking device with real-time data review.

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APPENDIX A

Table 1. WWSP Pre-Program Participant Questions

Survey Question
Q08 How would you describe activity at your job? Q53 How many hours do you watch TV in a week? Q54 How many hours are you using a computer or mobile device in a week? Q55 How many hours of sleep do you typically average per night?
Q61 On average, how many days per week do you engage in MODERATE intensity exercise? (Examples of MODERATE intensity exercise: Brisk exercise, biking less than 10 mph, general gardening (weeding), golfing (no cart)) Q62 How Many Minutes per day do you engage in exercise at the MODERATE intensity level? Q63 On average how many days per week do you engage in exercise at the VIGOROUS intensity level? (Examples of VIGOROUS intensity exercise: Jogging, running, biking more than 10 mph, heavy gardening (digging)) Q64 How Many Minutes per Day do you engage in exercise at the VIGOROUS intensity level?
Q65 I am CURRENTLY physically active (at least 30 minutes per week). Q66 I intend to become MORE physically active in the next 6 months. Q67 I CURRENTLY engage in REGULAR physical activity (150 minutes of moderate physical activity per week, or 75 minutes of vigorous physical activity per week, or a combination of moderate and vigorous physical activity per week). Q68 I have been REGULARLY physically active for the past 6 months.
Q69 I have used an activity tracking device. Q70 I am currently using an activity tracking device. Q71 I have used a diet, or diet/activity tracking app. Q72 I am currently using a diet, or diet/activity tracking app.

Note: Questions abstracted from instrument 4291 PARTENHEIMER Obesity Registry, Mayo Clinic WWSP.

APPENDIX B

Table 2. Evaluation Questions Wearable Device and Activity

Survey Question
Since your last follow-up (health coach) visit, on a scale of 0-10, how would you rate the effectiveness of wearing the Fitbit for motivation to increase exercise? 0=no motivation 5= some motivation 10= significantly more motivation
Since your last (health coach) visit, did you make any health-related changes based on the information from your Fitbit dashboard (or device)?

Note: Questions abstracted from instrument Mayo 360 Personalized Support System: Patient -Driven Lifestyle Solutions for Weight and Wellness

APPENDIX C

Ottowa Model of Research Use

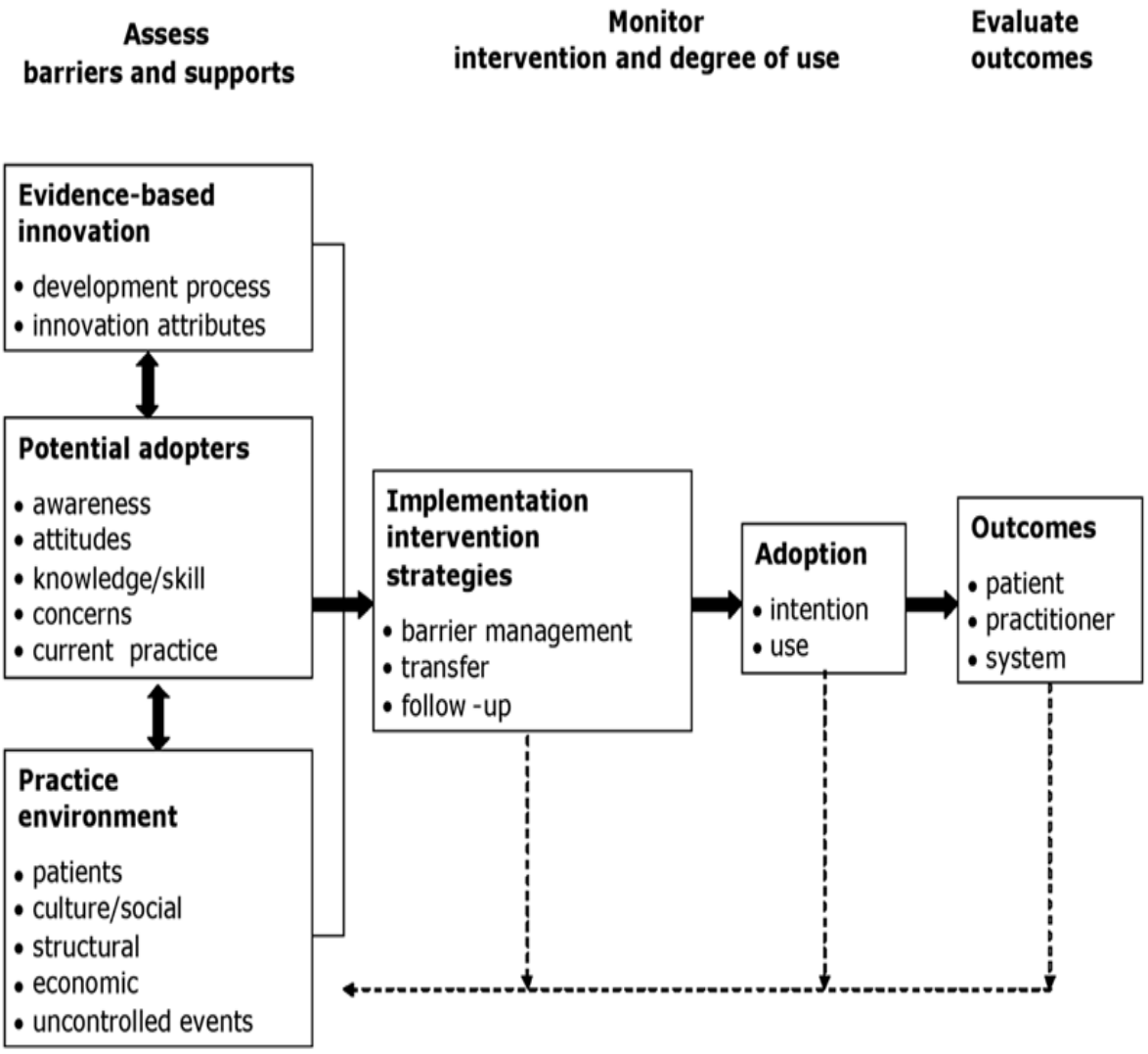

Image copied at: http://ktdrr.org/ktlibrary/articles_pubs/ncddrwork/focus/focus18/figure2.html

APPENDIX D

MAYO CLINIC

Principal Investigator Notification:

From: Mayo Clinic IRB
To: Amy Foxx-Orenstein
CC: Allison Adams
Tanya Carroccio
Amy Foxx-Orenstein
Michaele Menghini
Nichole Plouffe
Lisa Stewart
Andre Watkins
Amy Woof

Re: **IRB Application #:** 17-008269
Title: Using Wearable Technology to Increase Daily Activity: A Weight and Wellness Program Initiative

IRBe Protocol Version: 0.01
IRBe Version Date: 11/10/2017 6:38 AM

IRB Approval Date: 11/10/2017
IRB Expiration Date: 11/9/2018

The above referenced application is approved by expedited review procedures (45 CFR 46.110, item 5). This approval is valid for a period of 3 years. The Reviewer conducted a risk-benefit analysis, and determined the study constitutes minimal risk research. The Reviewer determined that this research satisfies the requirements of 45 CFR 46.111.

The Reviewer approved waiver of the requirement to obtain informed consent in accordance with 45 CFR 46.116 as justified by the Investigator, and waiver of HIPAA authorization in accordance with applicable HIPAA regulations.

The Reviewer approved the accrual of 27 subjects and to review data that exist from August 31, 2016 through November 7, 2017.

The investigator is reminded to contact Legal Contract Administration regarding appropriate agreement(s).

AS THE PRINCIPAL INVESTIGATOR OF THIS PROJECT, YOU ARE RESPONSIBLE FOR THE FOLLOWING RELATING TO THIS STUDY:
1) When applicable, use only IRB approved materials which are located under the documents tab of the IRBe workspace. Materials include consent forms, HIPAA, questionnaires, contact letters, advertisements, etc.
2) Submission to the IRB of any modifications to approved research along with any supporting documents for review and approval prior to initiation of the changes.

3) Submission to the IRB of all Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO) and major protocol violations/deviations within 5 working days of becoming aware of the occurrence.
4) Compliance with applicable regulations for the protection of human subjects and with Mayo Clinic Institutional Policies.

Mayo Clinic Institutional Reviewer

APPENDIX E

Knowledge Enterprise Development

APPROVAL: EXPEDITED REVIEW

Diane Nunez
CONHI - DNP
602/496-0751
DIANE.NUNEZ@asu.edu

Dear Diane Nunez:

On 8/6/2017 the ASU IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	Using Wearable Technology to Increase Daily Activity: A Weight and Wellness Program Initiative
Investigator:	Diane Nunez
IRB ID:	STUDY00006638
Category of review:	(4) Noninvasive procedures, (5) Data, documents, records, or specimens, (7)(a) Behavioral research
Funding:	None
Grant Title:	None
Grant ID:	None
Documents Reviewed:	• WTI.IRB_Signed Letter of Support.pdf, Category: Off-site authorizations (school permission, other IRB approvals, Tribal permission etc); • Carroccio_CV.pdf, Category: Vitaes/resumes of study team; • eIRB WWSP Honeybee.pdf, Category: Off-site authorizations (school permission, other IRB approvals, Tribal permission etc); • Carroccio_citiCompletionReport5963777.pdf, Category: Non-ASU human subjects training (if taken within last 3 years to grandfather in); • IRB_ Instruments WWSP_Carroccio.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • ASU.IRB_Carroccio_Wearable Devices.pdf, Category: IRB Protocol; • Nunez_2014_citiCompletionReport2224391.pdf,

	Category: Non-ASU human subjects training (if taken within last 3 years to grandfather in); • eIRB WWSP Honeybee2.pdf, Category: Off-site authorizations (school permission, other IRB approvals, Tribal permission etc); • Mayo Clinic Permission for Data abstraction.pdf, Category: Other (to reflect anything not captured above);

The IRB approved the protocol from 8/6/2017 to 8/5/2018 inclusive. Three weeks before 8/5/2018 you are to submit a completed Continuing Review application and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 8/5/2018 approval of this protocol expires on that date. When consent is appropriate, you must use final, watermarked versions available under the "Documents" tab in ERA-IRB.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator

cc: Tanya Carroccio
Tanya Carroccio