MONITORING PHYSICAL ACTIVITY IN PERSONS LIVING WITH FIBROMYALGIA: A HEALTHCARE DELIVERY INNOVATIONS PROJECT

by

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DEDICATION

For my family and friends who supported me, believed in me, encouraged me and kept me sane during this long journey. I could not have done this without you.

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GLOSSARY

ADL- Activities of daily living
FM- Fibromyalgia
FIQR- Revised Fibromyalgia Impact Questionnaire
IADL- Instrumental activities of daily living
PA- Physical Activity
SWBS- Smart, wearable body sensor

ABSTRACT

Physical activity is an important component of symptom management in patients with fibromyalgia. A means to aid fibromyalgia patients in developing, monitoring and achieving physical activity goals may be useful in fostering resilience. The aim of the project was to explore the feasibility and acceptability of using a smart, wearable body sensor - the Fitbit One - to monitor physical activity in persons living with fibromyalgia. This project also explores use of the Fitbit One to examine the relationship between number of steps per week and fibromyalgia symptom impact. This healthcare delivery innovations project utilized a feasibility study design, where participants were asked to wear a Fitbit One for four consecutive weeks while performing their usual routines. Each week participants filled out the Revised Fibromyalgia Impact Questionnaire (FIQR), and at the end of the four-week period, the researcher interviewed participants about their experience wearing the Fitbit One. Participants (n=8) all identified as white females and had a previous diagnosis of fibromyalgia. Content analysis revealed three qualitative themes: 1) Device usability; a majority (n=7) felt the Fitbit One was easy to use 2) personal awareness; a majority (n=7) stated that the device increased their exercise awareness and 3) device feedback; most (n=6) participants felt that device feedback lead to physical activity goal setting. No participant felt that the device impacted pain. 7 of 8 participants' FIQR scores indicated decreased or unchanged symptom impact in daily living. Steps vs. FIQR graphs showed that for 6/8 participants the number of steps either increased or stayed the same, while self-reported fibromyalgia impact stayed the same or improved throughout the study. Findings suggest that Fitbit One use and wear are acceptable to individuals with fibromyalgia. Most participants cited increased awareness of physical activity as a benefit. Graphical analysis of steps compared to fibromyalgia impact suggests that increased steps may indicate decreased symptom impact. Given participants responses to usefulness and acceptability of the device, it seems that integration of smart, wearable body sensors into healthcare may be effective as another means to enable fibromyalgia self care.

REASONING AND OVERVIEW

Background

Problem Statement

Fibromyalgia syndrome (FM) is a chronic disease that is highly disabling and affects 2-8% of the U. S. population (Vincent et al., 2013). Onset often occurs in the 3rd or 4th decade of life, primarily affects women, and is characterized by central nervous system sensitivity that leads to disturbed sleep patterns, chronic-widespread pain, environmental sensitivity and low energy levels (Wolfe, 2010). These symptoms significantly impact physical activity, including basic activities of daily living (ADL) and instrumental activities of daily living (ADL) and overall quality of life (Clauw, 2014; Craft et al., 2015). FM is primarily diagnosed and treated in primary care but is minimally responsive to pharmacologic therapies (Woolf, 2011). A growing body of evidence, however, suggests that engaging in regular exercise programs can be as effective as pharmacologic treatment in reducing FM symptom impact (Segura-Jiménez et al., 2015; Clauw, 2014; Busch, Barber, Overend, Peloso, & Schachter, 2007). A recent phenomenological study indicates that the most resilient patients in Montana focus on staying active, engaging in activities of a social nature, maintaining a balanced view of life, and appreciating their body (Torma, 2015). The resilient individuals interviewed in the phenomenological study managed to live an active lifestyle despite symptoms of FM that can limit physical activity (PA) and the ability to achieve PA goals (Torma, 2015; Craft et 2015). Thus a means to aid those patients considered less resilient in developing,

monitoring and achieving PA goals may also be useful in helping them become more resilient.

Current recommendations for the management of FM include a gradual increase in daily PA (Häuser et al., 2010). Providers are encouraged to recommend adding PA slowly, beginning at or just below the level of activity in which the patient currently participates with a goal of at least 30 minutes of low intensity walking at least 3 days a week (Häuser et al., 2010; Goldenberg, 2015). Light to moderate PA in this population may be as minimal as vacuuming the house or walking to their job. This is a recommendation that needs to be managed by the patient, making it difficult for providers to prescribe specific doses of physical activity. Without a means of measuring daily PA, patients with FM are left to guess how much walking or other light to moderate PA they have performed in a day.

Walking is a readily available, low-impact form of exercise that can reduce FM impact. A recent study of persons living with FM (N=199) revealed that for every 1,000 incremental steps per day, scores for physical function and pain-related interference were significantly improved (Kaleth, Slaven, Ang, 2014, p.1890). It was also notable that pain ratings did not worsen with activity but actually improved. However, these changes were not statistically significant. The findings suggest that step count is an important PA metric to monitor when treating FM patients in the primary care setting.

Accelerometers are sensors that detect motion along a plane related to acceleration from activity, such as walking. These devices have historically been used to collect reliable and valid measures of PA. Until recently, the technology of

accelerometers has been expensive and limited availability for use in research. With the invention of consumer-grade, smart, wearable body sensors (SWBS), this technology has been made more affordable, typically costing $50-100 per device. The technology has now been on the market long enough that there is evidence of reliability and validity for these devices as well (Nelson, Kaminsky, Dickin, & Montoye, 2016; Huang, Xu, Yu, & Shull, 2016; Singh et al., 2016; Diaz et al., 2015; Fergusen, Rowland, Olds, & Maher, 2015; Takacs et al., 2014; Noah, Spierer, Gu, & Bronner, 2013). In addition to steps, the SWBS can also monitor energy expenditure and sleep quality, providing a more holistic picture of a user's physical activity habits. Instant feedback is provided to users when PA goals are met, which can engage a user's involvement in his/her care (Lobelo et al., 2016; Hopia, Punna, Laitinen, & Latvala, 2015; Jelin, Granum, & Hilde, 2011). SWBS are potentially effective tools in the primary care setting as a means of monitoring and supporting self-management of a PA program.

Purpose of the Project

The specific aim of this project was to explore the feasibility and acceptability of using a SWBS to monitor PA in persons living with FM. A secondary aim is to explore methods that can be used to examine the relationship between number of steps per week and FM impact. The general aim of this healthcare delivery innovations project is to improve the process of monitoring PA in persons living with FM who are receiving care in a primary care clinic. The monitoring process begins when the patient initiates care in the primary clinic, continues through the treatment phase, and ends upon discharge from the service.

It was important to study the relationship between SWBS and FM impact now because FM is a highly disabling chronic condition that affects 2-8% of the US population (Vincent et al., 2013). Treatment of this chronic condition focuses on healthcare maintenance, rather than cure – specifically, on reducing FM impact on physical function, symptoms, and overall quality of life. Physical activity is an excellent metric to monitor FM impact in this population of patients. Physical activity also protects health in persons living with chronic illnesses (Ablin et al., 2013; Busch et al., 2007; Clauw, 2014; Häuser , 2010; Jones, 2006). PA measures that are valid, reliable, and acceptable to patients are needed to monitor the impact of disease as well as effectiveness of treatment (Arnold, Clauw, Dunegan & Turk, 2012). Acceptability of device wear is particularly important since any outside stimulus can cause increased physical pain to individuals suffering from chronic, widespread pain. Objective PA measures offer benefits beyond better health and self-management by patients. Integrating measures that can be used to demonstrate treatment effectiveness in the primary clinic will enhance clinic reimbursement in the current pay-for-performance healthcare reimbursement environment.

BUILDING TOPIC UNDERSTANDING

Literature Review

Articles and guidelines published after 2010, were located using Google Scholar, MEDLINE on Web of Science, PubMed, CINAHL, Guidelines Clearinghouse and UpToDate. Search terms included FM, PA, activity monitor, smart wearable body sensors, accelerometer, motivation, symptom management, barriers and FIQ-R. The Montana State University research librarian was consulted when difficulty finding pertinent content was experienced. Articles included for use were those pertaining to the pathophysiology of FM, effective treatments for the disease, gaps in care associated with increasing PA in the FM population, and smart, wearable body sensors as a tool for motivating and monitoring PA. Citations within these articles were also examined and articles were retrieved and reviewed when appropriate. This literature review, while not exhaustive, represents a comprehensive sample of the literature available on these topics. This section begins with a description of the theoretical framework guiding the development of this project, a review of the epidemiology of FM (definition, pathophysiology, diagnosis, treatment, self-management), and a review of research related to SWBS.

Project Theory

Nola J. Pender's Health Promotion Model (HPM) guided the development of this project. The HPM was designed to shift health delivery from treating preventable illness, to preventing worsening of these illnesses. The HPM accomplished this through the use

of positive motivation and understanding of factors that can influence motivation (Pender, 2011b). Specifically applicable to this project was an understanding that "people are biopsychosocial beings that react to and shape their surrounding environment in order to express their full potential" (Pender, 2011a, p. 3). Healthcare providers are part of this environment and can also influence a patient's reactions (Pender, 2011a).

Fibromyalgia

Fibromyalgia is a rheumatic disorder characterized by chronic, widespread pain, fatigue, and mood and sleep disorders (Wolfe et al., 2010). The symptoms of fibromyalgia can begin at any age and the disease affects females more than males at a ratio of 2:1 (Vincent et al., 2013). Treating this disorder often focuses on managing pain with medications, but meaningful symptom improvement is difficult to achieve without also including other pharmacologic and self-management practices that influence exercise and sleep (Clauw, 2014).

Pathophysiology

The symptoms of fibromyalgia are related to altered central nervous system processing. The brain of patients with fibromyalgia demonstrates a greater than normal sensitization to painful and non-painful stimuli (Maestu et al., 2012). Altered chemical processes in the pain control centers of the brain likely mediate this. These alterations include a decrease in μ-opioid receptor binding potential, an increased level of substance P in the cerebrospinal fluid (CSF) and a deficiency of serotonin norepinephrine and dopamine (Harris et al., 2007; Russell et al., 1994; Russel, Vaeroy, Javors & Nyberg, 1992). The μ-opioid receptors provide an analgesic effect when bound

with endogenous opioids such as endorphins and enkalephins (Salemi et al., 2007). Many pain treatments utilize the exogenous opioid receptor agonists to mimic an analgesic effect. In patients with fibromyalgia, μ-opioid receptors do not bind as readily to opioids as they would in a healthy brain, thus leading to a blunted analgesic effect (Harris et al., 2007). Substance P is a neuropeptide that is responsible for transmission of pain from the periphery to the brain (Russell et al., 1994). It is noted in patients with chronic pain and fibromyalgia (Russel et al., 1994). The presence of substance P in patients with fibromyalgia is a key-differentiating factor from chronic fatigue syndrome (Evengard et al., 1997). Norepinephrine, serotonin and dopamine are thought to decrease pain perception through interference with pain signal transmission (Russel, Vaeroy, Javors & Nyberg, 1992). The norepinephrine, serotonin and dopamine neurotransmitters are not as prevalent in individuals with fibromyalgia compared to controls. (Russel, Vaeroy, Javors & Nyberg, 1992). This leads to an inability to inhibit pain responses, especially for repeated stimuli (Julien, Goffaux, Arsenault, & Marcharnd, 2005; Montoya et al., 2006). In short, patients suffering from fibromyalgia require fewer stimuli to feel pain, and when they do feel pain, it lasts longer and is triggered with less provocation.

Factors influencing the concomitant symptoms of fibromyalgia, including sleep and mood disorders and low energy level are less understood. Triggers may include the same things that provoke fibromyalgia onset, including physical or emotional trauma or an episode of acute pain that would not usually last more than one month (Lyon, Cohen, & Quintner, 2011; Clauw, 2014). Physiologic causes for fibromyalgia can negatively impact sleep, mood and energy level as a patient struggles to deal with the chronic

widespread pain. Studies have revealed an abnormal sleep cycle and hyper-arousal in fibromyalgia patients. Some hypothesize that these abnormalities may also contribute to fibromyalgia pain onset and flare-ups. (Roehrs et al., 2013; Moldofsky, 2009).

Diagnosis. As a somatic disorder, fibromyalgia is difficult to diagnose. The 1990 American College of Rheumatology (ACR) has established a guideline for classifying fibromyalgia that includes widespread pain present for ≥ three months. Widespread pain is classified as pain present in both sides of the body, pain above and below the waist and pain in the axial skeleton. Additionally, pain must be present in 11 of 18 pre-determined tender points (Wolfe et al., 1990). Wolfe et al. readdressed this in 2010 in a study that added cognitive and somatic symptom consideration through the use of a symptom severity scale (SS) and the widespread pain index (WPI). This new criteria may also identify more men who have not have been diagnosed using the previous criteria, which included evidence of tender points (Wolfe et al., 2010). In 2011, a survey criteria intended for epidemiological use was developed (Clauw, 2014). The 2011 criteria consist of a single page that is filled out by the patient and addresses pain locations, sleep, mood, and other somatic symptoms. The 2011 diagnostic criteria have a specificity of 67.2% and a sensitivity of 83.5% of patients (Bennett et al., 2014). Bennett et al. (2014) proposed a modification to the 2011 criteria that seems to show greater specificity, but needs to be tested independently (Henderson, 2014). With all of these criteria in use, reaching a diagnosis of fibromyalgia can be confusing, but clinicians should suspect the disorder when patients complain of multifocal pain not explained by injury or inflammation (Clauw, 2014).

Treatment. The treatment of fibromyalgia includes pharmacological and non-pharmacological approaches (Ablin et al., 2013). Because opioid receptors are down-regulated in this population, opioids are minimally effective and should be avoided (Harris, 2007). Pharmacologic recommendations should instead focus on pain-mediating neurotransmitters such as inhibiting glutamate, and potentiating norepinephrine and serotonin (Clauw, 2014). There is strong evidence to support the use of gabapentanoids, serotonin norepinephrine reuptake inhibitors, γ-hydroxybutyrate and tricyclic compounds in the treatment of fibromyalgia (Clauw, 2014). Some studies hypothesize that topical medications may be effective related to a higher number of μ-opioid receptors in the skin of some patients with fibromyalgia (Salemi et al., 2007). However, pharmacologic therapies show only modest improvement and current guidelines in the United States and abroad recommend that aerobic exercise and cognitive behavioral therapy is included in the treatment plan (Ablin et al., 2013).

Aerobic exercise is an effective means of increasing physical function and decreasing fibromyalgia symptom impact (Busch, Barber, Overend, Pelso, & Schachter, 2007). Any aerobic exercise program in this population should start at a level below the patient's current fitness and gradually increase duration and intensity to reach 20 to 30 minutes, 3 days per week at a pace in which the patient is able to speak fluently (Häuser et al., 2010). If the exercise plan intensity is too high, patient symptom improvement is not as noticeable and patients are more likely to quit the planned program (Jones et al., 2006). It is important to monitor the dose of exercise to reduce the risk of inducing a flare in FM symptoms.

Self-management. Patients with a diagnosis of fibromyalgia are often significantly less physically active than their healthy counterparts (McLoughlin, Colbert Stegner, & Cook, 2010). A cycle of pain can reduce motivation to physical activity, so they become sedentary and gain weight, which in turn makes physical activity more difficult (Craft et al., 2015). Successful means of increasing physical activity levels include individual exercise instruction and self-management programs (Jordan, Holden, Mason & Foster, 2010). By involving chronically ill patients in the management of their own care, health outcomes can be improved (Free et al., 2013).

Mobile devices are a feasible and effective means of involving patients in symptom monitoring (Vanderboom, Vincent, Luedtke, Rhudy, & Bowles, 2012). Participants with chronic musculoskeletal pain cite mobile interventions as an effective way to obtain feedback that allows them to reflect on their current symptoms and motivate them to stay active (Jelin, Granum, & Hilde, 2011). Mobile applications paired with smart, wearable body sensors, have the added benefit of providing the patient and primary care provider a way to gather objective data about a patient's physical activity levels. Preliminary evidence suggesting a negative correlation between steps per day and measures of FM impact and pain interference make this a potentially valuable monitoring tool (Kaleth, Slaven, & Ang, 2014). This data offers the provider an opportunity to help fibromyalgia patients better manage their care and evaluate the response to treatment.

Smart wearable body sensors (SWBS)

The use of smart, wearable body sensors in the home environment can be an effective method to track PA that is well-tolerated by patients (Bassett & John, 2010). Devices like Fitbit, Nintendo Wii, and other similar wearable devices are being used in clinical trials to track physical activity (Paton, 2012; Appleboom, 2014). Wellness organizations, such as the Montana University Systems Wellness program, also use these devices, which are purchased in large quantities at a discount and offered as incentives for participants that reach beginning health goals. These devices can also be synced with the wellness system programming to help participants earn points as they work towards achieving their wellness goals (Montana University System Wellness Incentive Program, n.d.).

PROJECT SETUP

Methods

Design

This healthcare delivery innovations project was guided by Nola J. Pender's Health Promotion Model (Pender, 2011). Ethical approval was obtained from the Montana State University Institutional Review Board. This project took place in Belgrade and Livingston, Montana, Bend and Medford, Oregon, Murray, Utah, and Sacramento, California. Each participant wore the Fitbit One for four consecutive weeks at some time between March 4, 2016 and May 30, 2016. All participants were recruited though fliers posted in the community, online advertisements, and by word of mouth. Any person interested in participating was welcomed as long as they a) had a diagnosis of FM consistent with the ACR modified 2010 FM diagnostic criteria (Wolfe et al., 2010) and b) owned or had access to a computer or smart phone.

Before beginning to wear the Fitbit One, all participants received a short, one-on-one instruction session provided by the Doctor of Nursing Practice (DNP) candidate either in person or by phone. The session was used to introduce and provide a rationale for the project, answer participant's questions, assure them that participation was voluntary and let them know that they could withdraw at any time. Additionally, participants received the following information:

1. Basic physical activity recommendations similar to what would be provided during an office visit i.e., walking as a recommended form of PA with gradual increase in intensity and duration.
2. Instructions on how to use the SWBS, their Fit Bit One (wear it at all times, except during water activities; pair the device with mobile phone or computer, linking the device with researcher's account).

Participants were also told that they could keep the Fitbit One at the end of the project as a token of appreciation for participation.

Data Collection and Management

Persons who expressed interest in the study were mailed a questionnaire to determine eligibility for participation in the project, along with an information sheet and consent form. The questionnaire was used to gather contact information, demographic information and to determine if the person met the ACR modified 2010 FM diagnostic criteria. If the initial questionnaire and consent to participate were returned, additional data was collected weekly throughout the project. Additional data included FIQR scores, steps per day, hours weekly that the device was not worn and subjective experience of device use.

FM impact was measured using the revised Fibromyalgia Impact Questionnaire (FIQR). FIQR is a 21-item questionnaire that asks participants to rate symptom impact on a 10-point Likert scale. A higher score indicates greater symptom impact. The FIQR has substantial evidence of reliability and validity in all ages of fibromyalgia patients (Bennet et al., 2009). The FIQR questionnaire was administered at the end of each week

during the project. A link to the online version of the FIQR was emailed and texted to participants each week. SurveyMonkey® (SurveyMonkey®, 2015), a free online software tool used to build surveys was used to collect weekly FIQR responses. Researchers then downloaded responses to an Excel worksheet for further interpretation.

Number of steps per day was collected using the Fitbit One^{tm} device. The Fitbit One, a consumer-level SWBS, costs approximately $100 USD per unit; it is widely available, and has evidence of validity and reliability in healthy populations (Nelson, Kaminsky, Dickin, & Montoye, 2016; Huang, Xu, Yu, & Shull, 2016; Singh et al., 2016; Diaz et al., 2015; Fergusen, Rowland, Olds, & Maher, 2015; Takacs et al., 2014; Noah, Spierer, Gu, & Bronner). The Fitbit One was chosen because it is a valid and reliable SWBS that is widely available to the population of interest. The Fitbit One's ease of use and affordable cost make this an ideal SWBS for use in daily PA monitoring. The Fitbit One^{tm} is a wearable fitness monitor that was released by the company Fitbit in late 2012 (Wollman, 2012). The device is a SWBS with a display that shows, time, steps, distance and other fitness statistics for the day. Goal tracking is made easy since the device syncs wirelessly with personal phones and computers. Fitbit One can be worn as a clip that attaches to belts, bras and pockets or as a wristband (Fitbit, 2015). Step count from this device was monitored and recorded by the DNP student by way of the proprietary Fitbit interactive software available online. This software allowed each device to be linked to another for monitoring. Metrics available in this manner include steps per day and daily activity intensity. As these metrics were reported, they were collected and entered by the

DNP student into an Excel document on a weekly basis. A wristband and hip clip was included with the Fitbit One to allow options for wear.

During the first week, all participants were called or sent a text message daily to investigate problems with their device, and as a reminder to wear the device. For the next 3 weeks all participants were sent a weekly text or email reminding them to upload Fitbit data to the mobile application and complete the weekly survey. If the participant failed to upload data or complete the survey, the DNP student called or texted the participant once in the evening of the missed day, and once the following morning.

Subjective experience of device use by participants was collected in the form of a one-on-one exit interview with the DNP student. The interview was guided by two multi-part, structured, open-ended questions exploring the acceptability and the subjective experience of wearing the fit bit device (Appendix A). Interviews took place over the phone at a time set by the participant. Perceived utility, acceptability and ease of use were explored. Interviews were recorded using a digital recorder to ensure that content and meaning were not lost. All interviews lasted between seven and 16 minutes. Interviews were transcribed verbatim by the DNP student prior to analysis. Initial major themes were developed by grouping the responses according to questions. Dependability was ensured through careful explanation of the process used to obtain answers and through thorough evaluation of conclusions regarding question themes. Dependability was further supported as one interviewer conducted all interviews, ensuring consistency. Confirmability was achieved through supporting the themes mentioned using research

that has been published regarding fibromyalgia management and the lived experience of these individuals.

Prior to content analysis the researcher examined her beliefs and biases in order to identify and then bracket preconceived ideas. The pertinent beliefs and biases identified were a) that the experience of pain is influenced by psychosocial factors, b) given the right support and tools pain can become less disabling, c) the integration of technology into medicine is helpful to practitioner and patient. Transferability was not addressed as this is not a formal study that intends to make claims about this population, but is rather an examination of the need for further research regarding this project's findings.

Recruitment was originally planned to take place in western Montana via fliers in pain clinics, neurology clinics, community members and individuals who had participated in a previous study examining fibromyalgia (Torma, 2015). Due to a very low response rate, an IRB amendment was submitted which allowed for recruitment to take place via flier postings throughout Bend, Redmond, and Madras, Oregon and through online ads on Facebook. This resulted in responses from individuals in Oregon, California, Montana and Utah. The geographic variability of respondents required a change in initial meeting and final interview processes from the planned, in-person meetings to allow for over-the-phone communications. Additional IRB amendments included allowing the study to continue into July 2016 to permit more time for recruitment.

During the study few changes to planned procedure were made with the exception of device malfunction and one hospitalization. There were several instances of Fitbit One malfunction, which included one user being unable to unplug the device from the

charger, concern from four users that the device was not properly tracking steps, and inability to charge and sync the device. During these instances the DNP student communicated with the participants more than once daily, even visiting the home of one participant, in an attempt to help trouble-shoot the device. Fitbit customer support was contacted two times for help with these issues and a new charger was sent to one participant. Communications between the DNP student and participants occurred mostly via text message and email, but also occurred over the phone for one participant. With the exception of one device that stopped working after the study was done, issues were largely resolved during the first week of participation. In regards to hospitalization, the individual indicated interest in continuing the study so the researcher counted her first week of data and let her resume the study (week two) 16 days later, after she had recovered. This was acceptable since the first week is considered the baseline data gathering for this project.

PROJECT FINDINGS

Data/Results

All participants completed the study (n = 8); however, one participant did not fill out the week 2 FIQR survey, and another participant took a 1.5-week break between study week 1 and 2 related to a hospitalization for a bowel obstruction. Participants mean age was 41.5, with ages ranging from 26 to 66. The mean Widespread Pain Index (WPI) score was 11.625±5.012, with a range of 16 and mean Symptom Severity (SS) score was 6.375±2.722, with a range of 9. FIQR scores are described below in the quantitative data analysis section. WPI is a measure of extent of pain (Wolfe et al., 2010). Per the ACR modified 2010 FM diagnostic criteria, fibromyalgia diagnostic criteria are satisfied with a Widespread Pain Index (WPI) ≥ 7 and Symptom Severity (SS) scale score ≥ 5 or a WPI 3 – 6 and a SS scale score ≥ 9. One participant had an SS scale score below 5, but was included related to a long standing diagnosis of fibromyalgia, which had allowed years of learning effectively manage fibromyalgia symptom impact.

Table 1. Participant Characteristics

Demographics	Mean ± SD	Range
BMI	21.33±4.145	11.95
Years diagnosed with FM	14.4±7.46	22
Widespread Pain Index	11.625±5.012	16
Symptom Severity	6.375±2.722	9
Baseline		
FIQR total*	39.38±18.42	39.67
FIQR symptoms*	21.875±8.353	26.5
FIQR difficulty w/ function*	9±5.514	11.67
FIQR overall impact*	8.5±6.32	16
Steps weekly	57524±21021	71704
Steps Daily	8218±4055[T]	20167[T]

FM= Fibromyalgia Syndrome; BMI= Body Mass Index; FIQR= Revised Fibromyalgia Impact Questionnaire; *=Higher score indicates worse symptoms; [T]= Includes one very low score related to not wearing the device all day

Quantitative Data Analysis

The results of this small pilot study, while not generalizable, highlight some interesting outcomes. It is not surprising to see some variability in steps and FIQR from week to week, since it is well known that the pain associated with fibromyalgia is unpredictable from one moment to the next. Despite this variability, five of the eight participants had decreased FIQR scores and 2 had unchanged FIQR scores over the length of the study, indicating decreased or unchanged symptom impact in daily living. Week one and four FIQR results for each participant are reported in table 2.

Table 2. Individual FIQR Scores

Participant	FIQR total		FIQR symptoms		FIQR difficulty with function		FIQR overall impact	
	Week 1	Week 4	Week 1	Week 4	Week 1	Week 4	Week 1	Week 4
1	15.5	43.967	15.5	35.3	0	0.667	0	8
2	46.5	35.667	24.5	16	11	9.667	11	10
3	55.167	22.333	30.5	17	10.667	1.333	14	4
4	46.833	32	21.5	19	11.333	11	14	2
5	52.667	50.667	33	28	11.667	13.667	8	9
6	7.167	7.667	6.5	6	0.667	0.667	0	1
7	54.5	50.333	23.5	24	15	12.333	16	14
8	36.667	36.667	20	18	11.667	12.667	5	6
Week 1= Baseline; FIQR= Revised Fibromyalgia Impact Questionnaire								

Over the course of the four-week project, the participant's daily steps were recorded. The average number of steps taken each day was then calculated by week (table 3). For six of the eight participants, average daily steps increased or remained unchanged over the four-week period. For participant 1 and 8 average daily steps decreased. These same participants also showed decreased total steps over the week. Reasons believed to contribute to this are discussed later, but may be related to a hospitalization and forgetting to wear the device. In regards to time that the device was not worn, data was gathered weekly as a self-reported time in hours over the previous week. Participant 5 mentioned in the interview that remembering to wear the device was not a problem, and wore it even during sleep. Participant number 8 mentioned also that she had little difficulty remembering the device. This may be the reason that they did not report time not worn.

Table 3. Average Daily Steps and Hours Device Not Worn by Individual

	Average Daily Steps				Weekly Time (Hours) Device Not Worn			
Participant	Week 1	Week 2	Week 3	Week 4	Week 1	Week 2	Week 3	Week 4
1	7825	9916	6232	5741	1	6	8	*
2	13775	13953	15684	15017	0	2	4	2
3	6085	10907	8332	10282	12	6	8	6
4	8032	8583	7134	10013	20	0	4	0
5	7640	8579	10665	9572	NR	NR	NR	NR
6	9446	7739	11231	11484	0	0	5	0
7	3531	4425	3065	3432	1	2	10	2
8	9947	9455	7969	8126	2	NR	NR	NR

NR= Not Reported; *=Number not given, answered "Difficulty the last week remembering to wear it"

Table 3. The average number of steps that each participant took daily in the given week and the self-reported hours that the Fitbit One was not worn. Time not worn does not include time that the device was off for sleeping and water activities.

In regards to total FIQR scores versus total number of steps taken during the week, the results of this study show that for five out of eight participants the number of steps increased from the end of week one to the end of week four, while the FIQR scores for the same individuals decreased or remained unchanged in the same time period (table 4).

Table 4. Trend of Steps and FIQR from Week 1 to 4

Participant	Steps	FIQR total
1	↓	↑
2	↑	↓
3	↑	↓
4	↑	↓
5	↑	↓
6	↑	←→(↑)
7	←→(↓)	↓
8	↓	←→

Table 4. This table shows the trend of each participant's FIQR total and the total number of weekly steps over the course of the study. Arrows pointing up mean that the value increased from week one to week four. Arrows pointing left and right indicate no or minimal change. An increased FIQR indicates greater symptom impact on daily life. For the majority of the sample increasing steps did not increase fibromyalgia symptoms impact on daily life.

FIQR difficulty of function is one part of the total FIQR score reported above and contains nine questions intended to measure the amount of difficulty that a responder has performing activities of daily living (ADLs) over the previous seven days. As this score decreases, it indicates decreasing difficulty in carrying out ADLs. The majority of participants (n=5) reported a decreased difficulty score as their number of steps increased over the study period (figure 1). This indicates that as the steps increased, difficulty of performing ADLs decreased for those participants.

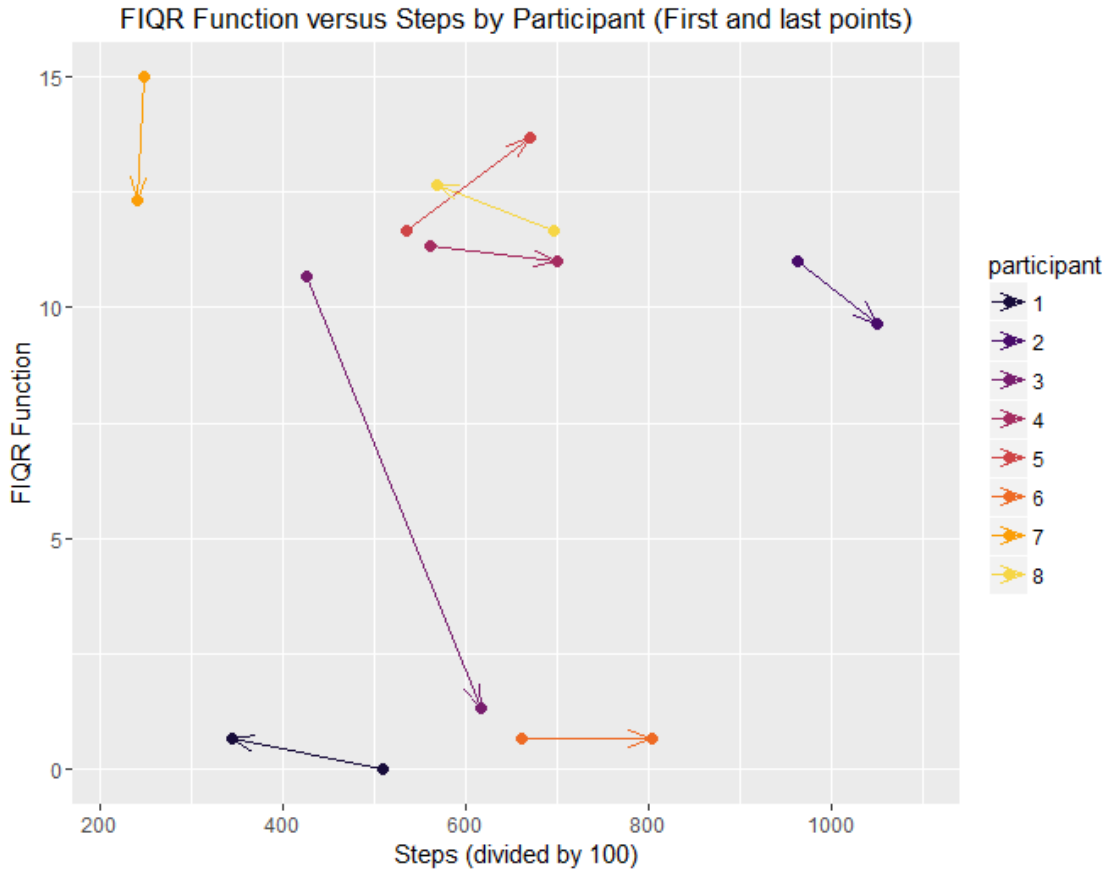

Figure 1. The x-axis corresponds to the number of steps (divided by 100). The y-axis corresponds to FIQR function scores. Different colored points and lines correspond to the different participants. For each participant, lines connect the points corresponding to week one with an arrow pointing to the final week for that participant.

FIQR overall is another section that makes up the FIQR total score reported above. This section contains two questions that ask about how much the symptoms of fibromyalgia overwhelmed the responder and impacted a responder's goal accomplishment over the previous seven days. For half (n=4) of the participants in this study, FIQR overall decreased as the participant's number of steps increased; this means that these participants reported being less overwhelmed by their symptoms as steps increased. This was true throughout the duration of the study. Figure 2 illustrates this relationship.

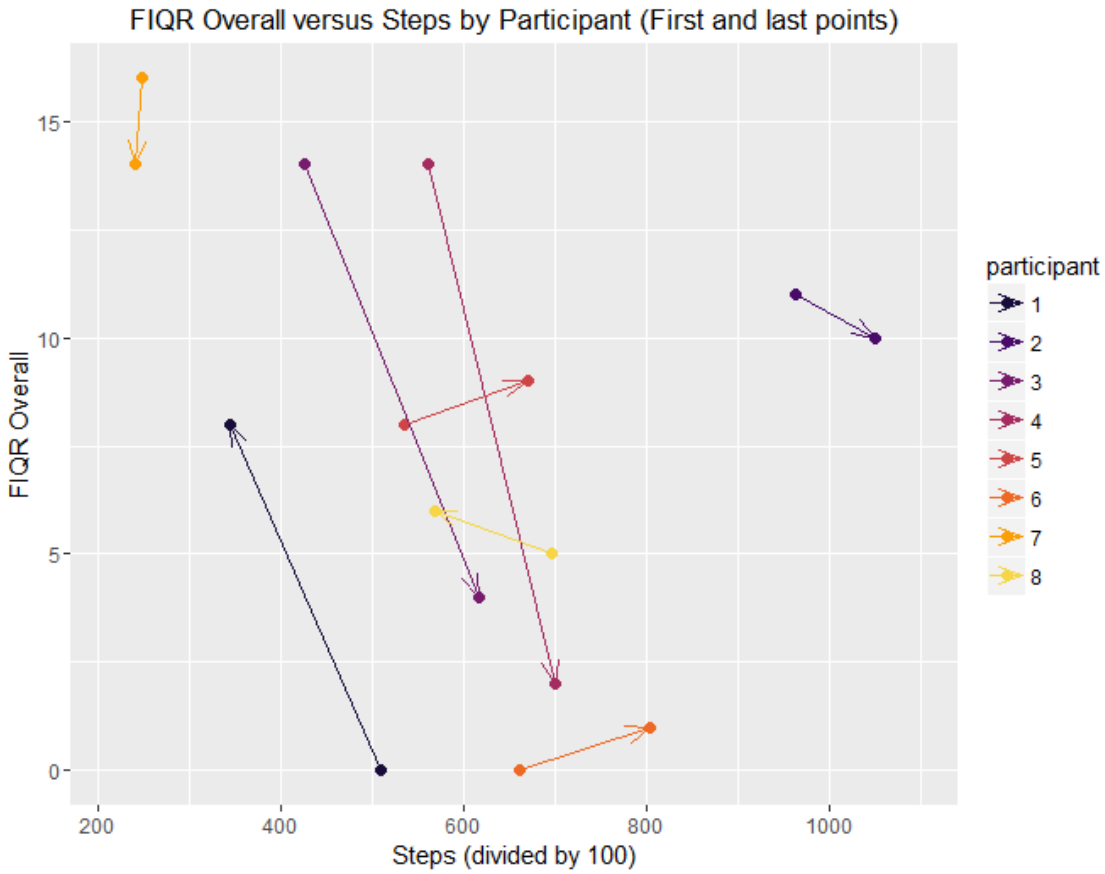

Figure 2. The x-axis corresponds to the number of steps (divided by 100). The y-axis corresponds to FIQR overall scores. Different colored points and lines correspond to the different participants. For each participant, lines connect the points corresponding to week one with an arrow pointing to the final week for that participant.

Finally, all FIQR symptom scores were reportedly decreased by the majority of participants (n=6) over the course of the study (figure 3). The symptoms section of the FIQR measures the intensity with which the responder experienced common fibromyalgia symptoms over the preceding week. A lower score indicates less symptoms or a lower intensity of symptoms.

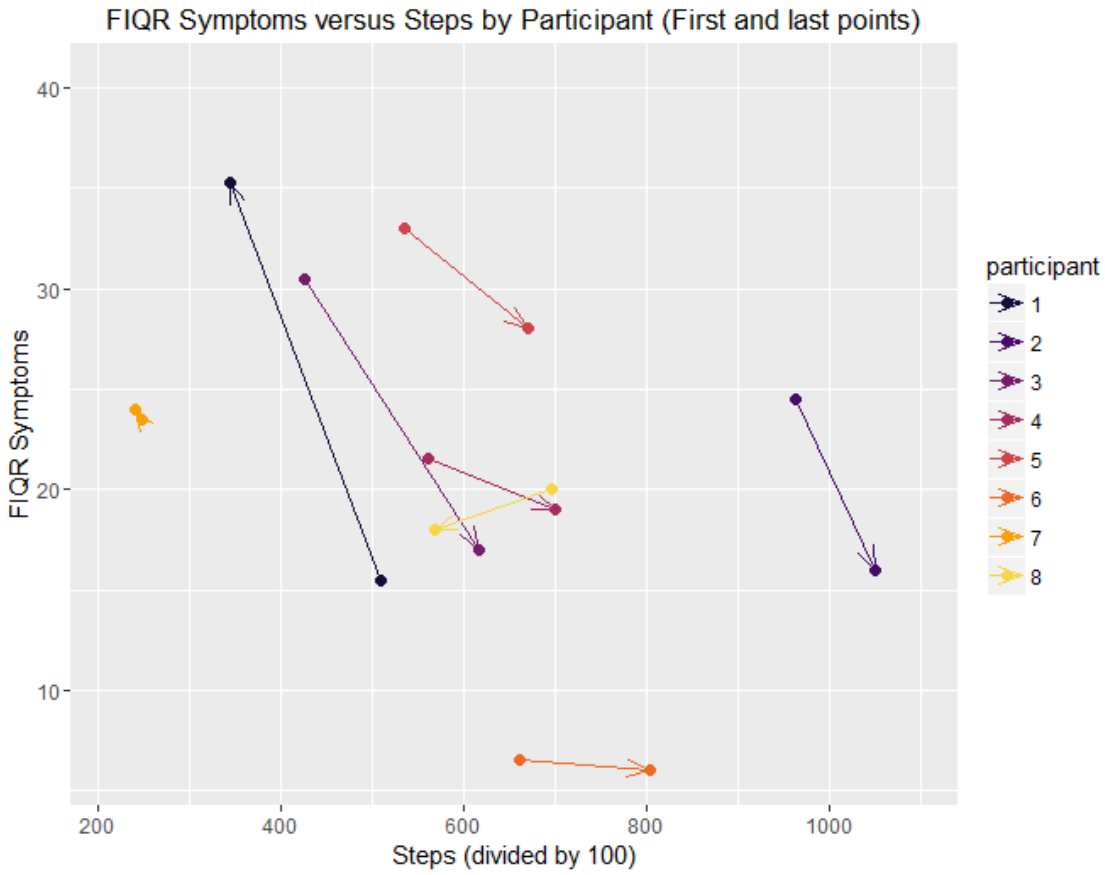

Figure 3. The x-axis corresponds to the number of steps (divided by 100). The y-axis corresponds to FIQR symptom scores. Different colored points and lines correspond to the different participants. For each participant, lines connect the points corresponding to week one with an arrow pointing to the final week for that participant.

Improvement in FM symptom impact was reported by all but two participants. In one instance this was directly related to a hospitalization and in the second a self-reported difficulty remembering to wear the device for the last week related to high stress level. The years of diagnosis for one was slightly above the mean and within one standard deviation while the other was below the mean and also within one standard deviation. These participants fell in the middle and low middle of initial WPI and SS scores, so this was not considered as a factor.

Qualitative Data Analysis

Using content analysis for the qualitative data, saturation emerged after the eighth interview analysis. When considering the initial question regarding acceptability of wear and use of the Fitbit device, three themes arose. These themes and sub themes were 1) device usability: function and wear, 2) personal awareness: level of activity and activity versus symptoms and 3) device feedback.

Device Usability - Function. The majority of participants (n=7) felt that the device was easy to use. The most often-cited positive feature was the syncing with mobile devices. Most frequently cited frustrations included inaccurate step count, difficulty using the sleep timer at appropriate times and lack of physical instructions included in device packaging. On device function, one participant said:

> "…on more than a few occasions I would check it or watch it as I was walking and it wouldn't be tracking steps or it would be not, like I could let it just sit there and not even put it on my wrist and it would say that I got up and actually was doing things during sleep, or shutting it off and it wouldn't record the shut off time correctly, things like that."

Device Usability - Wear. Participants were able to wear the device at all times except during water activity, sleep, and when forgotten. Reason cited most for forgetting the device was removal of the device for any reason, including device charging, water activity and sleep. Participants did not experience pain or discomforts with device wear except during sleep when the silicone wristband became uncomfortable. Two participants tried the wristband briefly and did not like the texture or look so took the device out of the wrist band and wore the device in their pocket for the remainder of the 4 weeks. Of the participants that used the wristband for the duration of the study (n=4), 2 felt that the wristband securement was too large for small wrists and that the clasp mechanism was unsecure and too difficult to operate.

Personal Awareness - Level of Activity. All participants mentioned an increased awareness of their level of activity as a result of wearing the device. Many (n=7) stated that the device feedback was an eye opener to how much or how little they were already doing. Additionally, the number of steps that are involved in everyday tasks surprised many. When asked how the device feedback affected them, one participant said:

> "…it was really motivating… I feel better about myself again because, like I say you don't realize how many steps you take, um feeding the chickens, taking care of the dogs, even something as miniscule as picking up the poop in the yard is way more steps than you realize you're taking…"

Personal Awareness - Activity versus Symptoms. All participants stated that the act of wearing the Fitbit One did not increase or decrease their pain. This is important since even small stimuli can cause physical pain to individuals suffering from

fibromyalgia. One participant felt that the device encouraged higher levels of PA, and could have been what caused an increase in physical pain. Another participant mentioned that her increased flare-ups were likely related to a new workout program she had started prior to wearing the Fitbit One. Two participants mentioned that the device reaffirmed that they feel better when they are moving more. Over half (n=5) of participants did not notice a change in their emotions as a result of wearing the device. Reasons cited for positive emotional effects were attributed to meeting goals and realizing they were more active than previously thought. Negative emotional effects were cited as being reminded of how fibromyalgia had forced a more sedentary lifestyle than desired. Many users mentioned linking the steps reported for the day with their level of pain or emotional state. One quote given about noticing steps in relation to symptoms was:

> "…on the days that my pain level was higher absolutely [I noticed a change in the number of steps I was taking]. I walked dramatically less um, and I could visually see that using the Fitbit."

Device Feedback. Most participants (n=6) felt that wearing the device did not lead to increased steps. However, most participants (n=6) also reported activity goal setting related to device feedback. These goals included reaching a set number of steps daily, completing Fitbit challenges with friends, and attending their usual fitness classes when they may have otherwise not. When asked if the device influenced activity patterns, one participant said:

> "I was aware like, ok I need to go to yoga even though I don't wear it while I'm in hot yoga, because of all the sweat, but um, like, ok cool, I'm gonna do this and yeah, it kept me on schedule."

Feedback from the Fitbit was cited as inspiring and motivating.

PULLING IT ALL TOGETHER

Discussion

The project specific aims were to explore the feasibility and acceptability of using a smart, wearable body sensors to monitor physical activity in persons living with fibromyalgia. A secondary aim was to explore methods that can be used to examine the relationship between number of steps per week and FM impact. The findings of this project suggest that the Fitbit One device may be acceptable to use to monitor physical activity in persons with fibromyalgia. Well-supported reliability and validity of the device (Nelson, Kaminsky, Dickin, & Montoye, 2016; Huang, Xu, Yu, & Shull, 2016; Singh et al., 2016; Diaz et al., 2015; Fergusen, Rowland, Olds, & Maher, 2015; Takacs et al., 2014; Noah, Spierer, Gu, & Bronner, 2013) ensure that step counts were accurate, and this project indicates that the devices were not viewed as painful or cumbersome to users with fibromyalgia. The technical difficulties experienced by some users indicate a need for an initial instruction session on device use, provision of a hard copy of instructions with the device, or providing a phone number and e-mail address to an agent that would be responsive to individuals in need of technical support.

Two large studies recently performed indicate that there is a correlation between increased steps, and decreased fibromyalgia impact (Segura-Jiménez et al., 2015; Kaleth, Slaven, Ang, 2014). While unable to support or refute this association related to the small sample size of this project, the trends observed suggest that this was true for more than half of the participants. Given participants' responses to usefulness and

acceptability of the device, it seems that integration of SWBS into healthcare may be effective as another means to manage FM symptoms. The findings from this pilot project supports recommendations that encourage integration of eHealth monitoring into electronic medical records in order to empower patient self-care and connection to practitioners (Lobelo et al., 2016; Hopia, Punna, Laitinen & Latvala, 2015).

Strengths and Limitations

The strengths of this project include the wide geographic range of participants, the large amount of steps data collected for each user, and the candid nature of each user's interview at the end of the four-week project period. Participants for this project were all white females, but the homogeneity is expected given the region of recruitment and the higher number of women than men diagnosed with this disease (Wolfe, 2010). The small sample size, potentially considered a weakness, was acceptable since the aim of this study was to establish feasibility for a larger study. Sample size was not expanded since data saturation was reached in regards to acceptability of device use. Finally, these participants all claimed to have an established physical activity pattern, and thus may represent a more active group of the fibromyalgia population. This may be related to the wording of the recruitment flier, which mentioned the project as one monitoring physical activity.

Implications for Nursing Education, Practice and Research

SWBS devices are widely available and often easily accessible to persons with fibromyalgia. This project indicates that wearing these devices is acceptable among

individuals with fibromyalgia. Given the association between steps and fibromyalgia impact, step count may be useful as an objective measure of symptom impact and therapeutic effect of interventions. This may also translate into awareness of the amount of physical activity possible to perform before the physical activity begins to be the cause of pain and increased symptom impact. In this manner, SWBS put persons with fibromyalgia in control of moderating or increasing physical activity in a productive manner.

As the relationship between physical activity and fibromyalgia symptom impact becomes better understood, study of the SWBS as a means to decrease fibromyalgia symptom impact may be indicated. The absence in this project of a more sedentary group, and thus those likely to receive the most benefit from physical activity, may be an area for future study. Studies in different climates, with particular attention to variety of profession would be helpful in gathering data from a wider range of activity levels and potentially establishing causal relationships. The additions of a control group and assigned interventions may be helpful in gathering data from a wider range of activity levels and in establishing a causal relationship. The additions of a control group may also be useful in examining effect of the SWBS on activity levels.

Conclusion

Findings from the interviews suggest that SWBS (Fitbit One) are acceptable to use and wear for individuals with FM. Participants indicated that the devices increased their awareness of both their activity level and their FM impact. In most cases this increased awareness was cited as a benefit to wearing the device. Objective measurement

of steps, when compared to self-reported FM impact, indicate a potential relationship, as observed in previous studies.

This is one of the first studies done investigating the use of SWBS as a means of objectively monitoring fibromyalgia symptom impact. This feasibility study indicates that further research regarding SWBS as a reliable tool to objectively monitor fibromyalgia symptom impact may be beneficial to both persons with fibromyalgia and the clinicians that manage this disease. These preliminary findings can inform nursing practice and education as to the potential benefits of SWBS in objectively monitoring physical activity patterns as it relates to fibromyalgia symptom impact. On a larger scale, this project raises awareness that mobile health technology may offer previously unrealized benefits to clinical populations.

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APPENDIX A

QUESTIONS ASKED TO EACH PARTICIPANT DURING THE EXIT INTERVIEW

Exit Interview Questions

1. Tell me about your experience with wearing the Fitbit One during all activity.
    a. Was it easy to use? What was easy about it and were there any things about wearing it that were difficult?
    b. Were you able to wear it at all times? Can you tell me about the times that you were not able to wear it – were there things that you did to make wearing it possible? What things were you able to do that made wearing the device more acceptable?
    c. Did it work as directed? Can you tell me about a time when the device did not work as directed? What did you do?
    d. Tell me what it was like to wear this Fitbit One.
    e. In regards to your pain, can you describe any differences as a result of wearing the fitbit?
    f. Did you notice any change in your emotion as a result of wearing the fitbit and can you describe those changes?
    g. Did you notice a change in the number of steps you were taking? Can you describe what you think happened in regards to this change?
2. Please describe for me how the feedback from the Fitbit One (steps, goals, etc) influenced you.
    a. Did you take more steps? How many more and why
    b. Did you find yourself setting goals? What were those goals?