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Kristen Howell Date

Fitbit® Feasibility, Acceptability, and Utility for Research among Pediatric Cancer Survivors

By

Kristen Howell

Master of Public Health

Epidemiology

Ann Mertens, PhD

Committee Chair

Jordan Gilleland Marchak, PhD ABPP

Committee Member

Rebecca Lewis, MPH

Committee Member

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Kristen Howell

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Faculty Thesis Advisor: Ann Mertens, PhD

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ABSTRACT

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By Kristen Howell

Pediatric cancer survival rates are increasing. The growing survivor population is at an increased risk of death due not only to cancer-related causes but also to chronic conditions such as diabetes or cardiovascular disease. Physicians and parents are likely to not emphasize the importance of physical activity due to potential treatment-related cardiac damage; however, regular physical activity is important for a long, healthy life. Physical activity tends to be expensive and time consuming to monitor, but novel technology such as wearable fitness trackers might be the solution to monitoring activity in this survivor population.

This study used Fitbit® Flex™ devices and online questionnaires through a six-month study on a cohort of teenage childhood cancer survivors (n=30) from the Aflac Cancer Survivor Program based out of Atlanta, GA. The aims of this study were to assess the feasibility, acceptability, and utility of using a wearable fitness tracker to conduct research among childhood cancer survivors.

The Fitbit® devices were used for 22.7% of the study period. Three types of Fitbit® users were identified – habitual, occasional, and initial. We did not observe a significant difference between the three types in the average number of steps taken per day or the average number of active minutes performed per day. We found that pediatric cancer survivors with a lower initial BMI z-score were 7.1 times likely to use their Fitbit® habitually compared to those with a higher initial BMI z-score ($p<0.05$). We also found that habitual users found the Fitbit® to be more helpful in monitoring their exercise habits and to lead a more active lifestyle than those who were not habitual users. Additionally, we found a weak positive correlation between patient-reported physical activity and Fitbit®-captured activity.

Overall, teenage childhood cancer survivors are not likely to use the Fitbit® consistently enough to gather quality physical activity data. Those that used the devices habitually had lower BMIs compared to those who did not use the devices habitually. In future studies, it will be necessary to cultivate more participant engagement to ensure more accurate physical activity records.

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BACKGROUND

Cancer has consistently been one of the top leading causes of death in the United States for the past 40 years (1). Among children in the United States, cancer is the leading cause of diseased-related death (2). In 2018, it is estimated that there will be 10,590 new cancer diagnoses and 1,180 deaths due to cancer among children under the age of 15 in the United States (3). Fortunately, survival rates for pediatric cancers are generally favorable due to the improvement of treatment and supportive care. The five-year survival rate has been increasing over the last several decades – from 50% in 1975 to 83% in 2013 (3-6). Additionally, Armstrong et al. observed a reduction in 15-year mortality for all causes among a large cohort of childhood cancer survivors (12.4% to 6.0% $p<0.001$) (5).

Although childhood cancer survival rates are becoming more favorable, research has shown that this growing population of childhood cancer survivors will face additional health risks from late-effects of the treatment received (7-13). Pediatric cancer survivors are at an increased risk of death due not only to cancer-related causes, such as recurrence and secondary malignancies, but also to chronic conditions, such as hypertension, diabetes, or cardiovascular disease (10, 12-14). In a large retrospective cohort study of childhood cancer survivors and siblings, Oeffinger et al. observed an adjusted relative risk of a chronic condition in a survivor was 3.3 (95% CI: 3.0, 3.5) and for a severe or life-threatening condition, the risk was 8.2 (95% CI: 6.9, 9.7) compared to siblings of survivors (13). In a study of over 200 childhood cancer survivors, Lipshultz et al. observed that even survivors who did not receive cardiotoxic therapy are at risk of cardiovascular abnormalities and all childhood cancer survivors should be screened for premature cardiovascular disease (15).

Additionally, it been observed that childhood cancer survivors have significantly decreased physical activity and increased obesity compared to the general population (9, 16, 17). In a qualitative study regarding the experience of parents of cancer survivors, Van Dongen-Melman et al. observed that parents are less likely to encourage their children to engage in physical activity to prevent possible harm or simply for fear of upsetting their child (18). However, the American Cancer Society recommends at least 60 minutes of moderate to vigorous physical activity per day and other healthy behaviors to both adult and childhood cancer survivors and these recommendations have a significant positive impact on health-related quality of life (HRQoL) (19). It has also been observed that in the general population parent participation is effective in physical activity interventions for children, especially when the parent is responsible for implementation (20).

Physical activity has been shown to improve metabolic control and the overall quality of life (QoL) of both childhood and adult cancer survivors, such as decreasing anxiety and fatigue while increasing body image and self-esteem (21-25). Efforts by research teams to measure physical activity have previously been conducted in person, but such monitoring can be time consuming and expensive to maintain (26, 27). Researchers have also used activity logs or questionnaires where subjects report their physical activity, but these can be unreliable and they may also introduce bias (23-25, 27, 28).

Social scientists have recently begun using innovative data collection technologies, such as smartphones and wearable activity tracking devices, creating novel opportunities to monitor behavior over time. The adoption of portable technology has become more ubiquitous over the last decade. As of 2018, for example, 95% of Americans own a smartphone (29). As Americans become more comfortable with the idea of owning such devices, they may become increasingly useful to improving the validity of longitudinal data collection on behavior. Using wearable activity trackers, such as the Fitbit®, may also help reduce costs and increase the possible longevity of a study.

Released in 2008, the Fitbit ® is a flexible wristband that tracks activity data, such as the wearer's daily steps taken, calories burned, distance travelled, physical activity, and sleep. The data can then be synced to a smart device, such as a cellphone, tablet, or iPod, which allows for automatic feedback to the user and data collection for the researcher. These wearable devices paired with a smart phone provide the opportunity to monitor and manage physical activity at a relatively low cost (30).

Researchers have found a significant positive correlation (intraclass correlation coefficient [ICC]>0.75) between the Fitbit® Flex™ and the gold standard of step counting (31-33). A study among adults found that the Fitbit® Flex™ tends to slightly underreport steps with a mean difference that ranged from -3.1 to -0.3 steps; however, they also observed a reliability for step count of 0.99 (34). In a study comparing the Fitbit® Flex™ to a waist-worn ActiGraph (an accelerometer commonly used in research), they found a good to excellent significant positive correlation between step counts from the two devices (ICC=0.85); however, in contrast to the previous study, the Fitbit® Flex™ overestimated steps compared to the ActiGraph ($p<0.01$) (35). The researchers concluded that due to the fact that the Fitbit® Flex™ is worn on the wrist, it might wrongly classify certain arm movements as steps (35).

In a study of 20 adult women regarding Fitbit® Flex™ feasibility, Arigo et al. found that the Fitbit® adherence was high with participants wearing their devices for 97% of the days (36). Arigo et al. also assessed the acceptability of the device in her cohort and found that acceptability was high and there were little to no suggestions to improve the study regarding the device (36). In another study of 292 hospital employees, Losina et al. reported that 63% of the cohort wore the device for more than 4 days per week with 52% meeting their personal weekly goal or CDC's recommended guidelines for at least 12 out of 24 weeks (37). These subjects also reported high acceptability, with 79% saying that they would agree to participate in the study again (37).

While we are gaining a solid understanding of how fitness trackers like the Fitbit® can be used to monitor activity patterns among adults, very few studies have examined their usefulness for studying children's activity. The purpose of this study is to assess the feasibility, acceptability, and utility of using wearable devices (specifically the Fitbit® Flex™) to collect data on teenage childhood cancer survivors. This study will also examine factors that predict the usage patterns of Fitbit® trackers by children as well as the correlation between self-reported physical activity and Fitbit®-captured physical activity. Ultimately, the results of this study can be used to help promote healthy lifestyle behaviors, such as physical activity, during adolescence to help prevent chronic health outcomes for childhood cancer survivors later in life. We hypothesize that the Fitbit® Flex™ will be both feasible and acceptable in a population of teenage childhood cancer survivors. In addition, we hypothesize that factors such as sex, age, BMI, and parent's self-reported physical activity will predict the usage patterns of the Fitbit® Flex™. Lastly, we hypothesize a positive correlation between self-reported physical activity and Fitbit®-captured activity.

METHODS

Recruitment and Eligibility

Participants were recruited from the Aflac Cancer Survivor Program (CSP) at Children's Healthcare of Atlanta (CHOA) during their outpatient clinic visit. Participants were considered eligible if they were between the ages of 13 and 18, spoke English, had been without treatment for two or more years, had medical clearance to be physically active, lived within an hour of a metro Atlanta Young Men Christian's Association (YMCA), and the child or their parent/guardian owned a smart device with Bluetooth technology. Patients were excluded if they had significant cognitive delays that would impair the ability to participate or if they had a BMI lower than the 25^{th} percentile. Upon consent, the participants were given a Fitbit® Flex™, instructions for its use, and a 24-week family membership to the YMCAs in the Atlanta Metropolitan area. This study solely focuses on Fitbit® and survey data. Future studies will explore the YMCA data. The participants also received written educational material on the importance of physical activity to stay healthy that included a recommendation of 60 active minutes per day. All participants completed informed consent. This study was approved by Emory University Institutional Review Board (IRB) and Children's Healthcare of Atlanta IRB.

Instruments

The teens and one of their parents were asked to complete a baseline survey and a six-month follow-up survey online. These responses were collected and managed using REDCap electronic data capture tools hosted at CHOA (38). REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing an intuitive interface for validated data entry, audit trails for tracking data manipulation and export procedures, automated export procedures for seamless data downloads to common statistical packages, and procedures for importing data from external sources. The initial survey included questions regarding demographics and physical activity. The follow-up survey addressed the teen's and parent's opinions on a number of statements regarding their Fitbit® experience on a five-point Likert-type scale (Strongly Agree to Strongly Disagree). For example, two of the statements for the teenagers were as follows: "Wearing a Fitbit® helped me self-monitor my exercise habits," and "Wearing a Fitbit® encouraged me to lead a more active lifestyle." The participants received a $20 gift card when both the teen and parent completed the survey at each time point.

Godin Leisure-Time Exercise Questionnaire

Each survey used the Godin Leisure-Time Exercise Questionnaire (GLTEQ), which asks about the number of times per week that the teens and parents typically perform at least 15 minutes of strenuous, moderate, and mild exercise activities. For example, "During a typical seven-day period, how many times on the average do you do the following kinds of exercise for more than 15 minutes during your free time? Strenuous exercise – running, jogging, hockey, football, etc. Moderate exercise – fast walking, tennis, bicycling, etc. Mild exercise – easy walking, yoga, fishing, bowling, etc." (39). A weekly activity leisure score is computed by multiplying each weekly frequency of strenuous, moderate, and light activities by nine, five, and three respectively then taking the sum of the three components (39). This questionnaire also asks a more general question about how often (often, sometimes, or never/rarely) you do regular activity to work up a sweat in a typical seven-day period (39).

Medical Record Extraction

The height and weight of each teen were recorded during their annual clinic visits at Aflac CSP. These measurements were used to calculate each participant's body mass index (BMI) z-scores and percentiles for baseline and 12 months. The BMI percentiles and z-scores are adjusted for sex and age according to the guidelines laid out by the Centers for Disease Control and Prevention (CDC). CDC guidelines state that less than the fifth percentile indicates underweight, fifth to 85th percentile indicates normal weight, 85th to 95th percentile indicates overweight, and equal to or greater than the 95th percentile indicates obese (40).

Information regarding the patient's treatment was also extracted from their medical records in order to assess the intensity of their treatment. The intensity of treatment for pediatric cancers differs based on the diagnosis, staging, risk group, and whether the disease is an initial diagnosis or a relapse (41). The "Intensity of Treatment Rating" scale (ITR) is a valid and reliable mean for classifying the intensity of the treatment received. On this scale, there are four levels of intensity ranging from least intensive (Level 1) to most intensive (Level 4). The patients' medical charts were consulted to designate an ITR score for each participant. The psychologist and medical director from Aflac CSP confirmed the ITR scores.

Fitbit® Flex™

The Fitbit® Flex™ is a flexible wristband that tracks activity, such as the wearer's steps, calories burned, distance traveled, and sleep. It uses an accelerometer to designate an activity level – "Lightly Active", "Fairly Active" or "Very Active" – based on how fast the wearer is moving. The Fitbit® syncs all its data to a smart device where users can view their own statistics on a regular basis. On the day of recruitment, each participant was provided a Fitbit® Flex™ along with all of its packaging and instructions. A member of the research team assisted in creating each participant's Fitbit® account and answering any initial questions.

CHOA built a web application programming interface (API) registered with Fitbit® and participants granted authorization to download and store data from Fitbit® servers onto servers owned by CHOA. This study only uses the first six months of data downloaded from Fitbit®. For some participants, there were errors initiating participant access to the CHOA Fitbit® API. We excluded participants with more than 10 days of missing data from the initiation of this study because we would not know how to classify their Fitbit® usage.

Statistical Analysis

Feasibility

All data were analyzed using SAS 9.4 with an alpha of 0.05. To assess the feasibility of the Fitbit® tracker, we evaluated the usage by separating the teens into three categories – initial, occasional, and habitual users. The Fitbit® was considered used if any data were recorded (steps and/or active minutes) on a given day. The initial users only used their Fitbit® during the first 34 days. The occasional users continued to use their Fitbit® after day 34, but fewer than 85 days throughout the study period. The habitual users were participants who consistently used their Fitbit® for at least 85 days (45%) of the study period. In order to see the feasibility of the Fitbit® for the overall sample, we calculated percent of days that the device was worn. First, the number of possible days that the device could have been worn was calculated by multiplying the number of participants by 183 (number of days in six months) and subtracting the number of days with missing data due to the error mentioned previously. The number of total days of recorded data was then divided by the number of possible days the device could have been worn.

Next, we assessed how the participant's usage differed among the three usage classification groups. We analyzed the number of days used, steps per day of the days the Fitbit® was used, the average number of "very" active minutes per day of the days the Fitbit® was used, and total (all "lightly", "fairly", and "very" active minutes combined) active minutes per day of the days the Fitbit® was used. We compared these means across the usage groups using an analysis of variance (ANOVA) table.

Additionally, we analyzed factors that might predict each participant's Fitbit® usage. A Fisher's exact test was used to examine the categorical variables – sex, BMI classification, race/ethnicity, household income, intensity of treatment rating, and parent self-reported physical activity (retrieved from the GLTEQ). Logistic regression models were tested to examine the effect of the continuous independent variables – age at baseline, BMI z-score at baseline, and number of years since treatment – on Fitbit® usage category. For these models, we used a dichotomized version of the ordinal outcome – habitual user vs. other. We also reported the means and standard deviations of these continuous variables to demonstrate the similarities and differences between the two Fitbit® usage groups.

Acceptability

The acceptability of the Fitbit® tracker was measured by collecting evaluation scores from the participants and parents six months after program initiation. We asked the subjects the extent to which they agreed with two statements: “Wearing a Fitbit® helped me self-monitor my exercise habits,” and “Wearing a Fitbit® encouraged me to lead a more active lifestyle.” The response sets for the statements were a five-point Likert-type scale, assessing to what extent they agreed with the statements (‘Strongly Agree’ to ‘Strongly Disagree’). A Fisher’s exact test was used to assess the difference between the positive responses (Strongly agree or Somewhat Agree) and the neutral or negative responses (‘Neither Agree or Disagree’, ‘Somewhat Disagree’, ‘and Strongly Disagree’) among the three usage groups for both parents and teenagers.

Utility

We were also interested in the relationship between the patient-reported physical activity, which was reported in the baseline survey via the GLTEQ, and the Fitbit®-captured physical activity. We assessed the correlation between the leisure activity score and the first seven days of overall active minutes recorded from the Fitbit® as well as the participants’ self-reported strenuous activity with Fitbit®-captured very active minutes for the first seven days. There was an outlier from the GLTEQ who was more than one standard deviation away from the mean. The same analysis was repeated excluding the outlier to assess the difference in correlation.

Sub-Analysis

Additionally, we examined the mean BMI z-score change within each of the three groups from baseline (day of consent) to 12 months after baseline. The means for each group were compared using paired t-tests. We also tested the difference in means across the groups using an ANOVA table.

RESULTS

Participant Demographic Characteristics

There were 42 teenagers originally enrolled in the study; however, due to the errors in initiating participant access to the CHOA Fitbit® API, 12 participants were excluded from the study because they had more than ten days of missing physical activity data at the beginning of the study (Figure 1). The participants in this study consisted of 30 childhood cancer survivors. There were 15 who completed the six-month follow-up survey and 15 who did not. Of those who completed the follow-up survey, ten attended their 12-month follow-up visit at the Aflac CSP and five did not. Of those who did not complete their follow-up survey, eight attended their 12-month follow-up visit at the Aflac CSP and seven did not (Figure 1).

Participant demographic characteristics are presented in Table 1. The average age of the participants was 14.7, 60% were female, 37% were classified as overweight or obese, and 37% were minorities. Participant cancer diagnosis included the following: 46.7% leukemia (acute lymphoblastic leukemia and acute myeloid leukemia), 16.7% solid tumors (e.g. neuroblastoma, retinoblastoma), 16.7% sarcoma (osteosarcoma, rhabdomysarcoma), 13.3% lymphoma (e.g. Burkitt's lymphoma, Hodgkin's lymphoma), and the other 6.7% included Wilms tumor and aplastic anemia. Nearly half (46.7%) of the participants were diagnosed before age 5 and half had a level 2 ITR score. On average, the participants had been without treatment for 6.76 years.

Feasibility

Overall, the Fitbits® had recorded data for 1,238 days out of 5,459 days that the participants had them in possession (22.7%). Some participants quit using their Fitbit® in the first week (23%). The device was worn for an average of 41 days (of a possible 183 days) throughout the study period with an average of 5,847 steps per day and 13 "very" active minutes per day of the days that the device was worn (Table 2). There were six habitual users, 11 occasional users, and 13 initial users.

The mean number of days that the participant used the Fitbit® was significantly different across the usage classification groups ($p<0.01$), which is expected due to the usage classification definitions (Table 2). On average, habitual users used their Fitbit® 118 days, occasional users used their Fitbit® 39 days, and initial users used their Fitbit® seven days throughout the 183-day study period. The three groups did not differ significantly in steps per day ($p=0.09$), very active minutes per day ($p=0.74$), or total active minutes per day ($p=0.18$). Overall, the participants began to neglect to wear their Fitbit® as the study moved forward. Even the habitual users, who used their Fitbit® 5-7 days per week on average at initiation, only used their device for three days per week towards the end of the study (Figure 2).

Next, factors that might predict variability in the use of the Fitbit® were assessed. Categorical variables were analyzed using Fisher's exact test (Table 3). Sex, race/ethnicity, household income, and parent self-reported physical activity were all found not statistically significant ($p=0.40$, 0.48, 0.41, and 0.59 respectively). BMI category and intensity of treatment rating were both approaching significance ($p=0.09$ and 0.10 respectively). Continuous variables were analyzed using an ordinal logistic regression model with the

Fitbit® usage dichotomized into habitual or less than habitual users, grouping occasional and initial users together (Table 4). Baseline age and number of years since treatment were both found not statistically significant (p=0.89 and 0.32 respectively); however, baseline BMI z-score was found statistically significant with an OR of 0.14 (p=0.04), suggesting that teenagers with a higher initial BMI were less likely to use their Fitbit® habitually compared to those with a lower initial BMI.

Acceptability

To assess the acceptability of the Fitbits®, the teenagers and parents were asked on their six-month follow-up survey to rank their opinions of statements regarding their Fitbit® experience on a five-point Likert-type scale from "Strongly Agree" to "Strongly Disagree." Only 15 teenagers and 16 parents provided responses to these statements. The first statement was "Wearing a Fitbit® helped me/my child self-monitor my/their exercise habits" (Figure 3). All of the habitual teenagers (n=5), 60% of the occasional teenagers (n=5), and 60% of the initial teenagers (n=5) agreed with the statement (p=0.45). All of the habitual users' parents (n=5), 80% of the occasional users' parents (n=5) and 50% of the initial users' parents (n=6) agreed with the statement (p=0.30). The next statement was "Wearing a Fitbit® encouraged me/my child to lead a more active lifestyle" (Figure 4). All of the habitual teenagers, 40% of the occasional teenagers, and 40% of the initial teenagers agreed with the statement (p=0.13). As for the parents, 80% of the habitual users' parents, 80% of the occasional users' parents, and 33% of the initial users' parents agreed with this statement (p=0.23).

Utility

Finally, we were interested in the relationship between the participants' self-reported activity compared to the data provided by the Fitbit®. There were four participants that did not provide complete answers to the baseline GLTEQ. One participant completely skipped the question, while three others did not provide an answer to one of the three activity categories (mild, moderate, or strenuous), leaving them with an incomplete leisure-time score. The average leisure-time score, which combines their self-reported physical activity in a typical week, was 60.9 (Range: 8-340, n=26). There was a weak positive correlation between the participants' Godin Leisure-Time score and their overall active minutes in their first seven days (r=0.28, p=0.17; n=26) (Figure 5). There was a strong positive correlation between the self-reported strenuous exercise in a typical week and total very active minutes in the first seven days (r=0.72, p<0.01; n=28) (Figure 6).

There was one male participant who submitted self-reported activity that was more than one standard deviation away from the sample mean. When he was removed from the analysis, both correlations were weaker. The correlation between the participants' Godin Leisure-Time score and their overall active minutes in their first seven days was 0.07 (p=0.73; n=25) (Figure 7). The correlation between the self-reported strenuous exercise in a typical week and total very active minutes in the first seven days was 0.47 (p=0.01; n=27) (Figure 8).

Sub-Analysis

Last, we analyzed the mean difference of the BMI z-scores using ANOVA tests and paired t-tests (Table 5). BMI data were available for 20 participants because the other ten participants either missed their annual (12 month) appointment or 12 months had not yet passed when the analysis was completed. There was a significant difference between the means of the three classification groups at baseline and at one year ($p= 0.04$ for both time points). The habitual users had an average BMI closer to the mean of the general population, while initial users had an average BMI that was more than one standard deviation from the mean of the general population. This mirrors the results found in Table 4. There was no statistically significant mean change in BMI z-score in any of the usage categories over time. Overall, the average change in BMI z-score for the participants was a gain of 0.05 ($p=0.45$). Habitual users had a gain of 0.02 ($p=0.75$; $n=4$), occasional users had a gain of 0.03 ($p=0.73$; $n=7$), and initial users had a gain of 0.08 ($p=0.56$; $n=9$).

DISCUSSION

Pediatric cancer survivors are at an increased risk of death due to non-cancer related chronic conditions such as cardiovascular disease, hypertension, and diabetes (10-12, 14). Physical activity is recommended to decrease the risk of future cardiovascular disease and increase the quality of life of childhood cancer survivors (22, 24, 25). However, childhood cancer survivors have significantly low physical activity compared to the general population (12, 23, 27, 28). Physical activity has often been captured via observation or activity logs but these can be expensive or lead to bias (22-25, 27, 28). Novel technology like wearable fitness trackers can provide a more cost effective and reliable means of measuring patient physical activity compared to observation or self-report (31-35). The aims of this study were to assess the feasibility, acceptability, and utility of a Fitbit® Flex™ tracker in a cohort of pediatric cancer survivors in order to improve future research on pediatric cancer survivors. A strength of this study is that Fitbit® devices are relatively cost effective and less time consuming than gathering activity logs or face-to-face monitoring of activity. Another strength of this study is that the population is exclusively pediatric cancer survivors. There is limited literature regarding this cohort and using wearable physical activity trackers so this study can lead the way for innovative research among this population.

In this six-month observational study of 30 pediatric cancer survivors, few participants used their Fitbit® throughout the entire study period. The majority of participants quit wearing their Fitbit® by the fourth week. In previous Fitbit® exposure studies, researchers used a smaller study period with more face-to-face contact and follow-up to ensure that the participant remains engaged in the study and these studies did not experience an attrition issue (36, 42-44). In a study using a different Fitbit® device (Fitbit® One™, a clip-on device) on young adults, it was observed that participants were likely to abandon use of the Fitbit® because they did not trust its accuracy (45). Interviews from this study revealed that users discovered inaccuracies especially when using workout machines, such as the StairMaster or treadmill, at the gym. The inability to adjust the inaccuracies on their devices frustrated them and led to abandonment (45). In future studies, it would be interesting to see if the teenagers from our study experienced the same problem when attending the YMCA.

We did not observe a significant difference in the number of daily steps taken or the amount of active minutes performed among the four usage classifications. On the days that the participants were wearing their Fitbit®, they were likely to get the same amount of steps and active minutes regardless of their usage classification group. This is comparable to other studies where it has been observed that when wearing the Fitbit®, one is more aware of their physical activity and more likely to engage in activity (36, 42, 43). The device reminds you to move which helps to bring attention back to the user's physical activity.

Sex, BMI classification, race/ethnicity, household income, intensity of treatment, history of parent physical activity, age, and number of years since treatment were all found to be independent of Fitbit® usage ($p>0.05$). However, when examining BMI as a continuous variable, pediatric cancer survivors with a low BMI were 7.1 times more likely to be a habitual Fitbit® user compared to those with a high BMI ($p=0.04$). This finding is of importance because when conducting physical activity studies in the future using wearable activity monitors, the participants with high BMI (more than one standard deviation above the mean of the general population) are more likely to stop using their device. There were also possible trends with categorical BMI (healthy vs. overweight/obese) and intensity of treatment rating. These results were approaching significance and might be different with a larger sample size. In future studies, it might be necessary to reach out to these subjects with a higher BMI and those who received a more intense treatment more frequently in order to get accurate physical activity. If they do not use their device, they would most likely be excluded from the study and results would be biased towards subjects with lower BMI and less intense treatment.

As for acceptability, the subjects that found the device to be more helpful for monitoring their exercise habits and leading a more active lifestyle were the habitual users and their parents ($p>0.05$ for both teens and parents). Although these results were statistically insignificant, it is still important to note that if the user is having a good experience and finding the device helpful then they are more likely to continue using it.

Additionally, we observed a significant positive correlation between self-reported strenuous activity and "very active" minutes captured by the Fitbit® in the first seven days of the study. However, there was an outlier who self-reported high activity on all levels which slightly skewed the results. After removing the outlier, the correlation was nearly halved. It is unclear whether the weak correlation is due to inaccurate patient-reported activity or inaccurate Fitbit®-captured activity. Previous studies have examined the validity of the Fitbit® Flex™ among adults, but there have been mixed results. Diaz et al. found that the device underestimated steps, while Chu et al. found that it overestimated steps (34, 35). The Fitbit® data might also be incomplete for this analysis if the user did not wear their device for the full seven days. The user might have correctly reported their activity, but it was not captured by the device if it was not worn. In future studies, it is important to decide how to classify the use of the device a priori. For example, if a Fitbit® records less than 200 steps on a particular day, did the user have a sedentary day or did they only wear the device for a couple of hours? This is a major limitation to using wearable physical activity trackers. We are unable to know if sedentary minutes recorded by the device are truly sedentary.

Patient-reported physical activity could also be inaccurate. It has been observed in the past that the correlation between self-reporting and direct measuring is generally low to moderate (46). Further research needs to be done to understand the relationship between self-reporting via GLTEQ and Fitbit®-captured data. Additionally, since we observed a relationship between BMI and usage, future research could also assess the relationship between BMI and acceptability. Those with a low BMI might like their device more than those with a high BMI. Further, it has been observed that strenuous activity is more accurately recorded by the Fitbit® (34). Therefore, future research should also address the relationship between physical activity and acceptability. Those with higher physical activity might find the device more accurate and helpful for monitoring their activity.

Lastly, we observed a significant difference between the mean BMIs among usage groups at both baseline and one year ($p=0.04$ for both time points). This suggests that those with a lower BMI are more likely to use their Fitbit® habitually, which matches with our previous results. However, we did not observe a significant annual change in BMI in any of the usage classifications. This was expected as this was not an intervention study.

There are a few limitations to this study. First, eligibility was dependent on several factors which might introduce a bias. For example, they needed access to a smart device.

This might have left out several teens from low income housing and make our sample not generalizable to the population. Along that note, all participants were recruited from the Aflac Cancer Survivor Program based out of Atlanta, GA which might not be generalizable to the overall childhood cancer survivor cohort. Additionally, many participants did not complete the online questionnaires which left gaps in our data. Further, although this is a six-month study, the survivors only attend the clinic once per year so we were limited to annual BMI data instead of biannual data.

Overall, the Fitbit® is a more cost effective and accurate mean of gathering physical activity data (31-35). However, this study shows that childhood cancer survivors are not likely to use their Fitbit® consistently enough to gather quality data. Over one-quarter of the participants discontinued use during the first ten days of the study. Further, those with a high BMI (more than one standard deviation above the mean of the general population) are even less likely to use their Fitbit® consistently. If future studies intend to use wearable fitness trackers, consistent follow-up is necessary to make sure all of the participants consistently wear their devices. This could be done using follow-up telephone calls and social media to ensure that participants are charging their devices and staying engaged with the program.

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TABLES

Table 1 – Demographics and characteristics of study participants

	n=30
Age at baseline Mean (SD)	14.7 (1.4)
Sex n (%)	
Male	12 (40%)
Female	18 (60%)
BMI percentile at baseline n (%)	
Normal/Healthy	19 (63.3%)
Overweight	6 (20%)
Obese	5 (16.7%)
Race/Ethnicity n (%)	
African American	7 (23.3%)
Asian	0
White	19 (63.3%)
Hispanic	2 (6.7%)
Native American	0
Other	1 (3.3%)
Missing	1 (3.3%)
Household Income n (%)	
$10,000-$24,999	2 (6.7%)
$25,000-$49,000	7 (23.3%)
$50,000-$74,999	5 (16.7%)
$75,000-$99,999	2 (6.7%)

$100,000-$124,999	5 (16.7)
$125,000-$149,000	2 (6.7%)
Above $150,000	5 (16.7%)
Missing	2 (6.7%)
Cancer Diagnosis n (%)	
Leukemia	14 (46.7%)
Lymphoma	4 (13.3%)
Sarcomas	5 (16.7%)
Solid Tumors	5 (16.7%)
Other	2 (6.7%)
Age at Diagnosis n (%)	
<5	14 (46.7%)
5-10	12 (40%)
<10	4 (13.3%)
Intensity of Treatment Rating (ITR-2) n (%)	
1 – Least Intensive	1 (3.3%)
2 – Moderately Intensive	15 (50%)
3 – Very Intensive	8 (26.7%)
4 – Most Intensive	6 (20%)
Years Since Treatment Completion Mean (SD)	6.76 (3.4)

Table 2 – Six-month physical activity summaries by Fitbit® usage classification

	Overall n=30	**Habitual Users n=6**	**Occasional Users n=11**	**Initial Users n=13**	**p***
Number of days used Mean (SD) Min, Max	41 (46) 1, 180	119 (38) 85, 180	39 (14) 22, 68	7 (6) 1, 19	<0.01
Steps/day Mean (SD) Min, Max	5847 (2715) 193, 11284	7548 (3028) 3672, 11284	6248 (2491) 3822, 11244	4723 (2422) 193, 8095	0.09
Very active minutes/day Mean (SD) Min, Max	13 (23) 0, 120	19 (20) 2, 53	10 (7) 2, 25	14 (32) 0, 120	0.74
Total active minutes/ day Mean (SD) Min, Max	188 (71) 21, 313	231 (64) 120, 300	191 (66) 108, 313	166 (72) 21, 274	0.18

*ANOVA table was used to determine the significance of the difference between the means across the usage groups.

Table 3 – Categorical potential predictors of Fitbit® usage classification

	Habitual Users n=6	**Occasional Users** n=11	**Initial Users** n=13	**p***
Sex				0.40
Male	1 (8%)	6 (50%)	5 (42%)	
Female	5 (28%)	5 (28%)	8 (44%)	
Baseline BMI Categories				0.09
Normal	6 (32%)	7 (37%)	6 (32%)	
Overweight/Obese	0	4 (36%)	7 (64%)	
Race/Ethnicity				0.48
White	4 (21%)	8 (42%)	7 (37%)	
Other	2 (20%)	2 (20%)	6 (60%)	
Missing		1		
Household Income				0.41
Under $100,000	2 (13%)	8 (50%)	6 (37%)	
Above $100,000	3 (25%)	3 (25%)	6 (50%)	
Missing	1	1	2	
ITR				0.10
1-2	3 (19%)	5 (31%)	8 (50%)	
3	2 (25%)	3 (38%)	3 (38%)	
4	1 (17%)	3 (50%)	2 (33%)	
Parent Physically Active				0.59
Often	2 (33%)	2 (33%)	2 (33%)	
Sometimes	2 (12%)	7 (44%)	7 (44%)	
Rarely	2 (25%)	2 (25%)	4 (50%)	

*Fisher’s exact test determined significance between the usage groups and potential predictive factors

Table 4 – Univariate analysis of continuous potential predictors comparing habitual users to occasional and initial users

Model	Exposure	OR	95% CI		p*	Habitual Mean (SD) n=6	Other Mean (SD) n=24
1	Baseline Age	0.95	0.49	1.87	0.89	14.7 (1.03)	14.8 (1.45)
2	Baseline BMI Z-Score	0.14	0.02	0.91	0.04	0.14 (0.64)	1.05 (0.82)
3	Years Since Treatment	1.15	0.87	1.51	0.32	8.00 (2.10)	6.46 (3.64)

*Univariate logistic regression

Table 5 – Change in BMI percentile from baseline to 12 months

	Overall n=20*	Habitual Users n=4	Occasional Users n=7	Initial Users n=9	p†
BMI Z-Score Mean (SD)					
Baseline	0.97 (0.90)	0.04 (0.77)	0.99 (0.69)	1.37 (0.87)	0.04
12 months	1.02 (0.94)	0.06 (0.74)	1.02 (0.75)	1.45 (0.90)	0.04
Difference	+0.05	+0.02	+0.03	+0.08	
p‡	0.45	0.75	0.73	0.56	

*Includes only those who have both baseline and 1-year data.

†ANOVA table used to compare means across usage groups

‡ Paired t-tests used to compare BMI mean change for each group

FIGURES

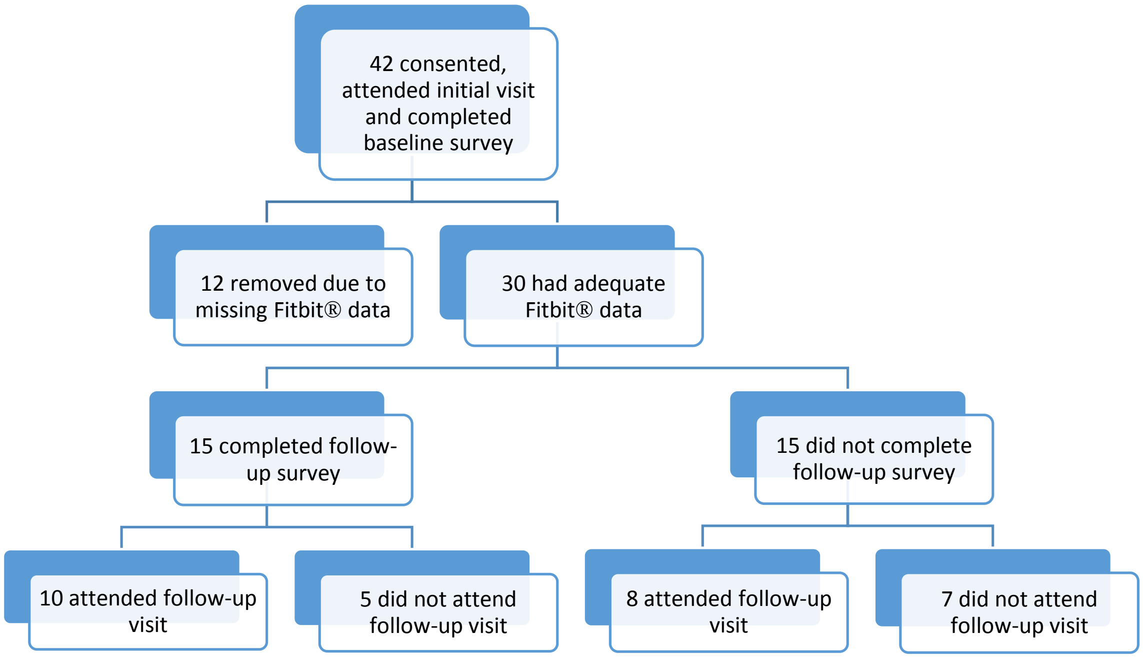

Figure 1 – Flow chart of study participation. The initial visit and baseline survey were completed at the start of the study. The follow-up survey was to be completed at 6 months after baseline. The follow-up visit was to be attended at 12 months after baseline.

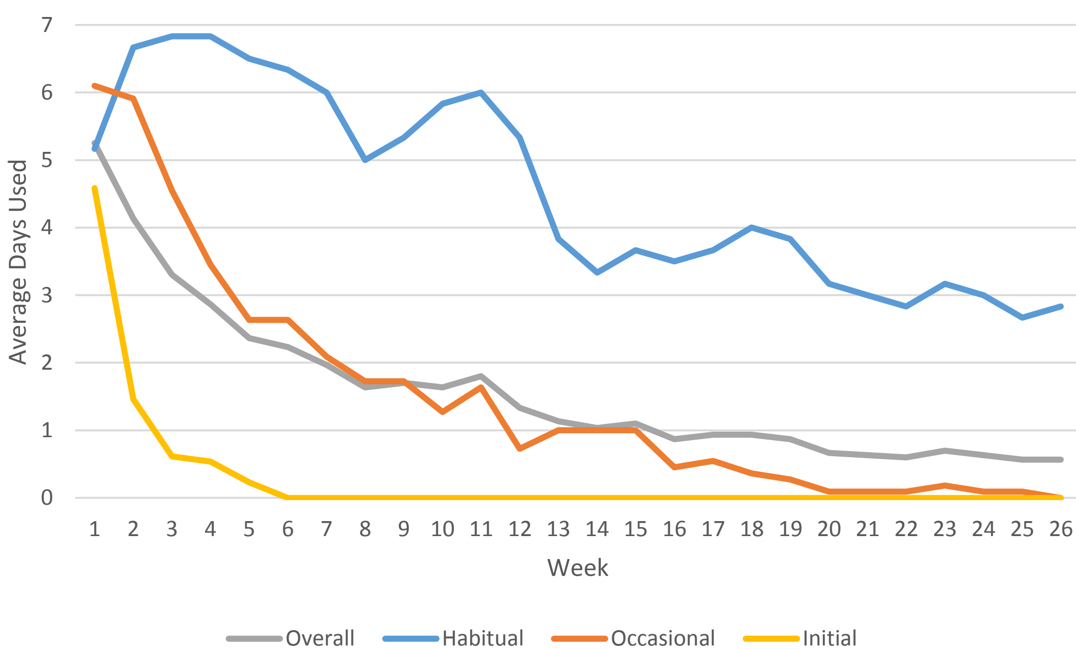

Figure 2 – Average number of days the Fitbit® was used per week by Fitbit® usage classifications (n=30).

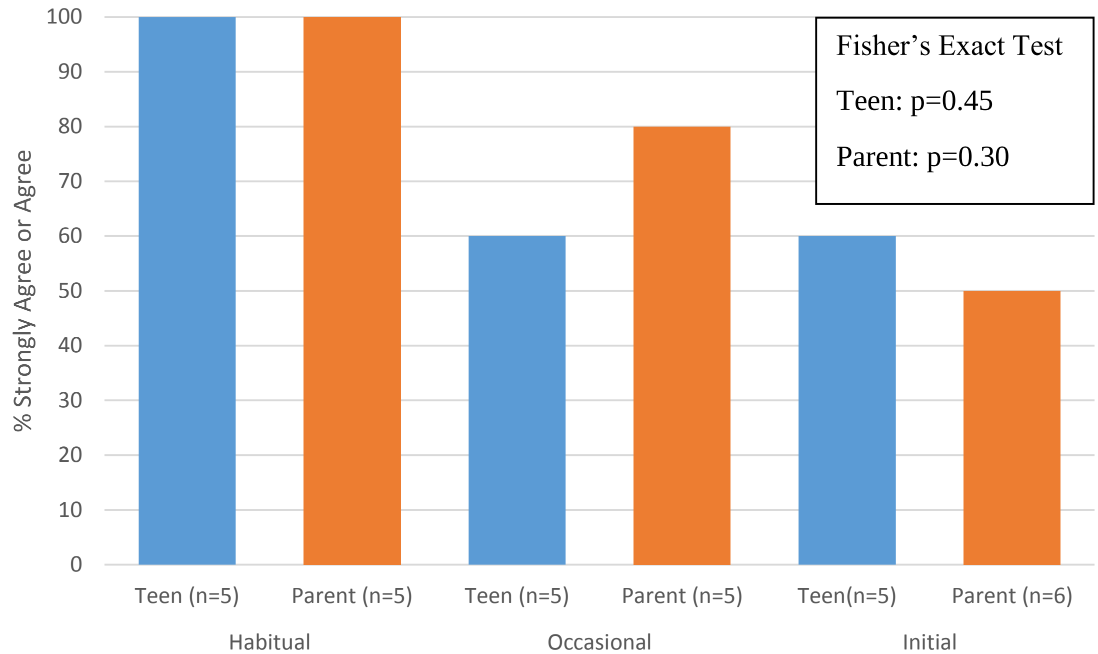

Figure 3 – Percent of teens and parents who indicated 'Strongly Agree' or 'Somewhat Agree' to the following statement: "Wearing a Fitbit® helped me/my child self-monitor my/their exercise habits."

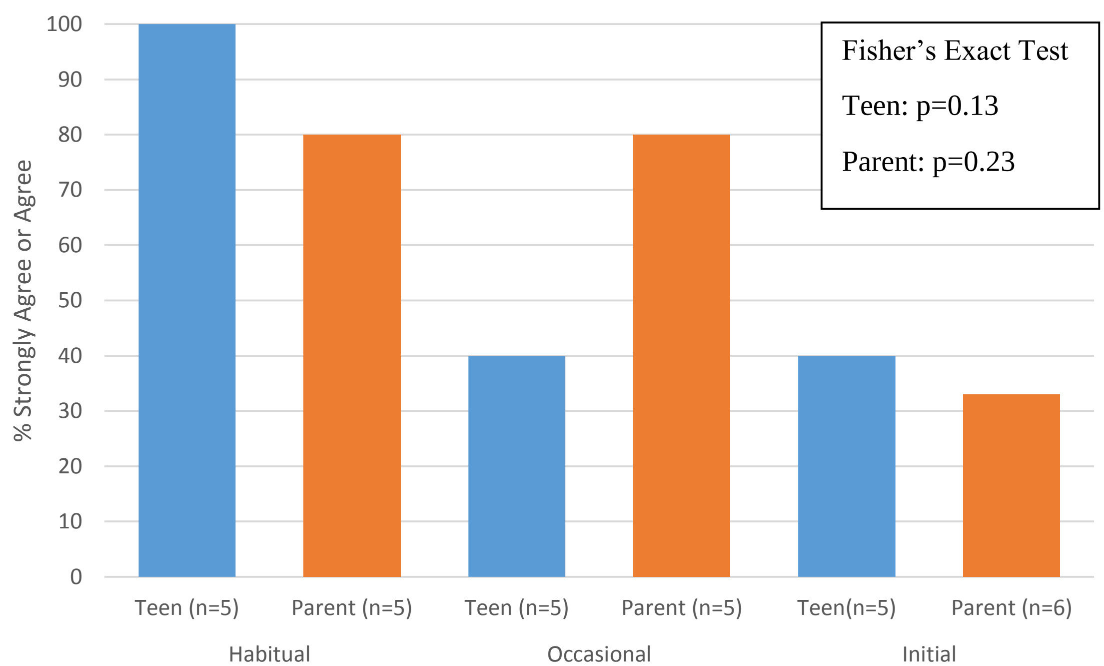

Figure 4- Percent of teens and parents who indicated 'Strongly Agree' or 'Somewhat Agree' to the following statement: "Wearing a Fitbit® encouraged me/my child to lead a more active lifestyle."

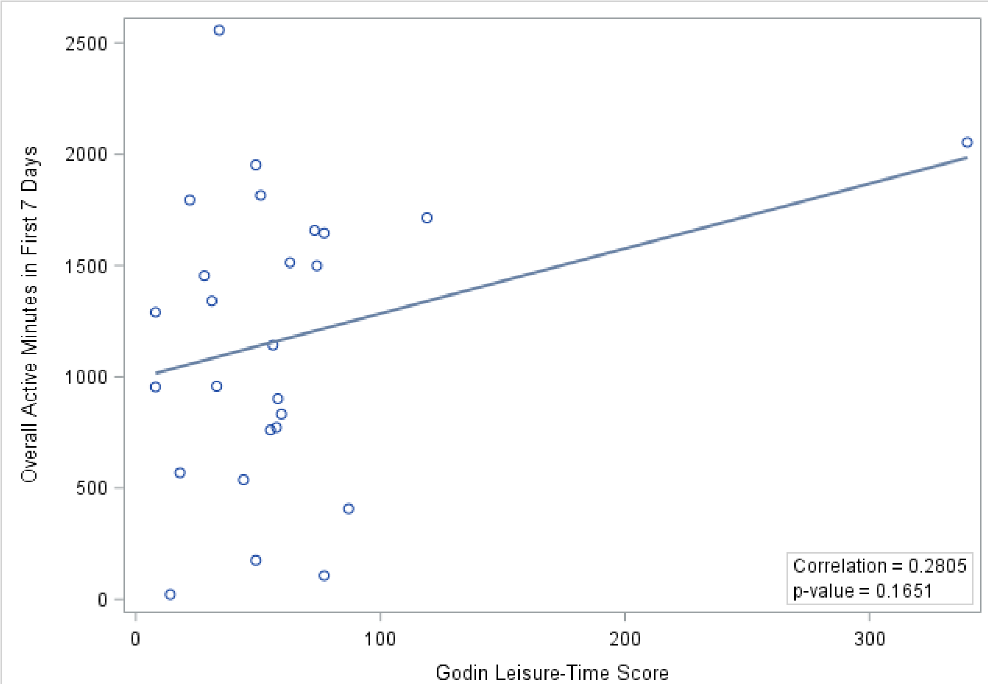

Figure 5 – Correlation between Godin Leisure-Time Score from self-reported activity and overall active minutes in the first 7 days of recorded Fitbit® data (n=26).

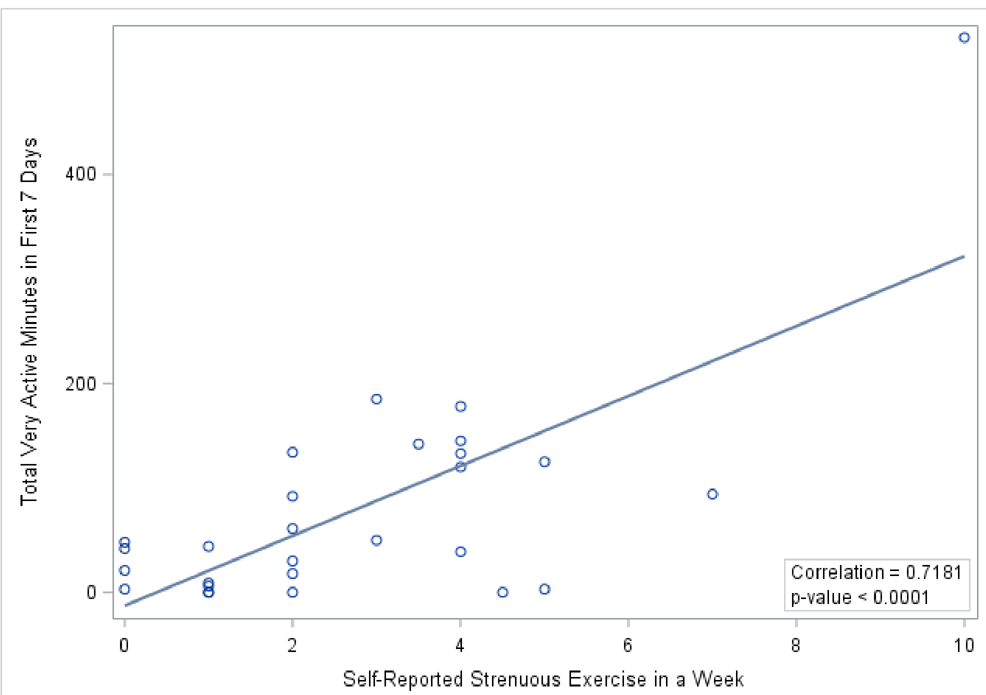

Figure 6 – Correlation between self-reported strenuous exercise and Fitbit®-captured very active minutes in first 7 days of recorded data (n=28).

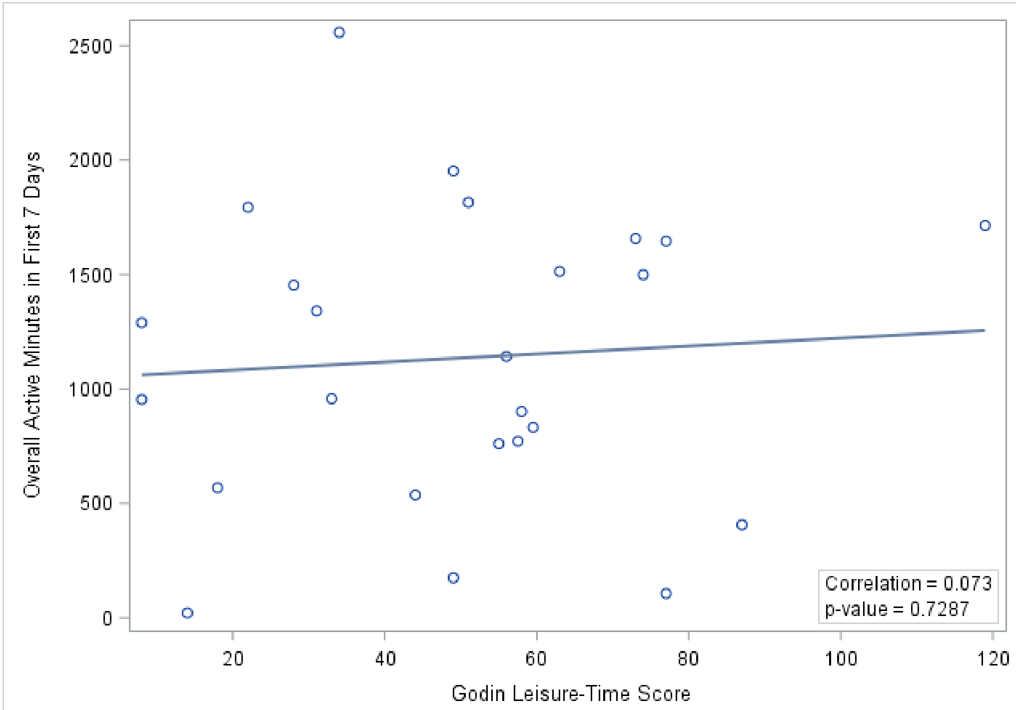

Figure 7 – Correlation between Godin Leisure-Time Score from self-reported activity and overall active minutes in the first 7 days of recorded Fitbit® data without the outlier (n=25).

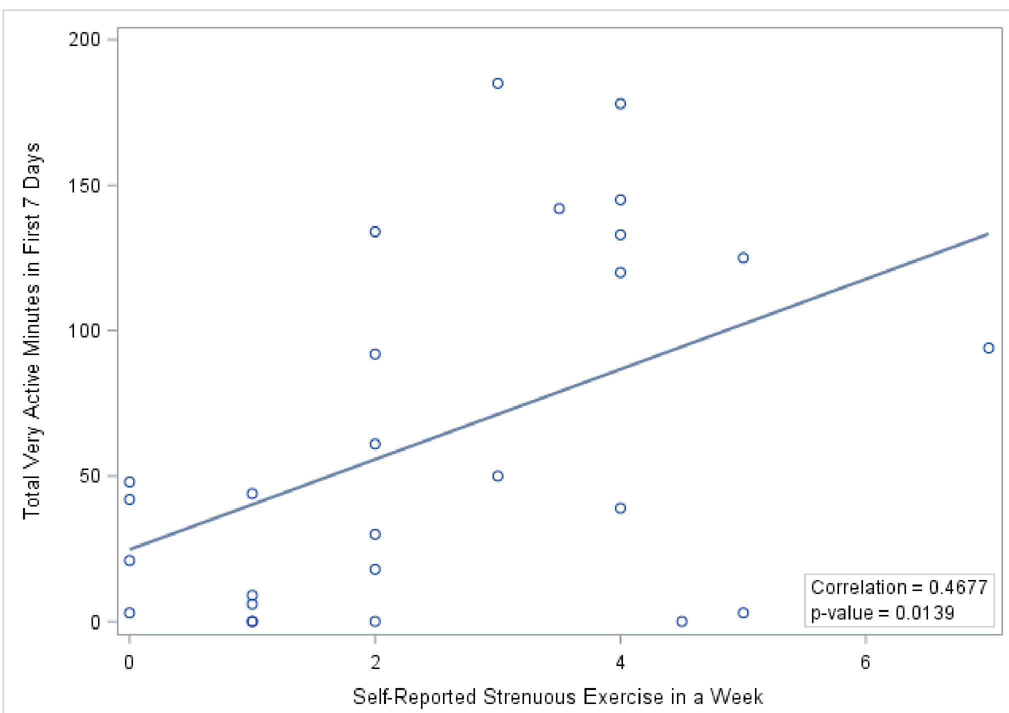

Figure 8 – Correlation between self-reported strenuous exercise and Fitbit®-captured very active minutes in first 7 days of recorded data without the outlier (n=27).