COMPARISON OF THE FITBIT ZIP TO THE ACTICAL ACCELEROMETER IN CHILDREN AND ADULTS

by

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ABSTRACT

Portable fitness-tracking devices are part of a broader category of wearable technological devices. The wearable device industry is poised to explode and research firms such as Juniper and IMS predict wearable devices to be a multi-billion dollar industry by 2016. Newly released portable fitness-tracking devices claim to measure various physical activity related variables including energy expenditure and total activity time. With growing concern for obesity prevention, the availability and affordability of these devices could allow children and adults to monitor their physical activity to ensure they meet published guidelines related to physical activity. This study proposed using the Actical accelerometer to validate the accuracy of the FitBit Zip measurements. Participants included healthy children between the ages of 8 and 14 years and healthy adults between the ages of 18 and 40 years. Each participant was fitted with an ActiCal accelerometer and FitBit Zip device and each participant performed a physical activity protocol consisting of sedentary, light, moderate, and vigorous intensities. Laboratory accelerometers, such as the ActiCal accelerometer, are a valid tool in measuring the physical activity in children and adults whereas research is lacking in providing documented validity of the FitBit Zip.

Chapter 1

INTRODUCTION

For children between 6 and 17 years old, the Centers for Disease Control and Prevention recommends 60 minutes of moderate-to-vigorous physical activity per day at least 3 times a week, as well as muscle strengthening and bone strengthening activities 3 times a week (CDC, 2011). CDC recommendations for adults include 150 minutes per week of moderate-to-vigorous physical activity as well as muscle strengthening activities that target all major muscle groups 2 or more days a week (CDC, 2011). Despite these recommendations, it is estimated that more than 50 percent of adults and 10 percent adolescents do not meet the guidelines for physical activity (CDC, 2013). To help address compliance with physical activity guidelines, a new "wearable technology" industry is emerging with gadgets that can quantify individuals' physical activity in an effort to increase compliance. These gadgets include electronic wristbands and small pod-like devices with sensors such as pedometers, accelerometers, gyroscopes, and GPS that collect data on an individual's physical activity levels. Some of the more popular devices that have emerged over the last two years include the Nike+ FuelBand, Jawbone Up, Bodybugg, and the FitBit Zip. Many of these devices offer similar functionality but vary in terms of price, build quality, and components. However, the concept of physical activity trackers is not a new phenomenon; accelerometers capable of quantifying physical activity variables have been used in lab settings dating back to 2003. The purpose of this study was to assess the FitBit Zip's ability to measure physical activity by comparing it to measurements from the Actical accelerometer. The FitBit Zip makes an interesting comparison to laboratory accelerometer because it offers a unique approach to physical activity tracking due to its ease of use, relative low price, and advanced data collection capabilities but lacks validity research.

The Actical is an acceptable tool for comparison because the device has been validated in multiple peer-reviewed publications (Philips, 2013). However, the Actical and other similar professional accelerometers are not intuitive for the user outside of the laboratory environment. The FitBit Zip, compared to professional laboratory accelerometers, is designed with ease of use in mind. Unlike the ActiCal accelerometer, the Zip has a screen indicator that displays basic data such as calories burned, steps taken, and distance traveled. In order to access similar data on the Actical the user would have to dock the device, extract the data, and then open the energy expenditure application. The Zip also supports a docking feature which allows the user to see a more detailed analysis of physical activity levels. A USB receiver allows the Zip to be docked wirelessly and if the receiver is left plugged into the computer, the Zip will dock wirelessly whenever the device is within 20 feet of the computer. To dock the Actical accelerometer, the device must be connected to a USB docking station which also requires an additional power source. The Actical must also be positioned in a specific manner on the docking station otherwise the computer will not be able to communicate with the device and extract the data. The intricacies of docking the Actical results in a tedious process whereas the Zip's wireless technology results in automated data transmission. Finally, the Zip does not require any specialized computer software or hardware to analyze and display physical activity data. Data is analyzed via web-based software that can be utilized wherever an internet connection exists. If an internet connection is not available, the Zip can also sync to an iOS or Android smartphone and display the data via the free FitBit mobile application. Ultimately, the FitBit Zip is a physical activity tracker designed for the consumer population with minimal technical knowledge needed to set up and operate the device.

The FitBit Zip is also a physical activity tracker that is competitively priced for the consumer market. Devices such as the Nike+ FuelBand, Jawbone Up, and the Bodybugg cost $149, $130, and $100 respectively whereas the Zip costs $60 (Duffy 2013). Although the Zip is the cheapest physical activity tracker in the consumer market, all of the previously mentioned devices are significantly less expensive that the Actical accelerometer. The latest Actical accelerometer alone costs upwards of $700. In addition to the cost of the accelerometer, the software and docking hub combined can total almost $2000 (Philips, 2013). The cost difference between consumer physical activity trackers and the Actical reflect the differences in design and sophistication between the devices. For example, the Actical can easily be used to collect data at specific times whereas the consumer physical activity trackers are in a "constantly-on" mode. Furthermore, consumer physical activity trackers do not easily transfer from one individual to the other because set up usually requires registration via email address and mobile device pairing (FitBit, 2013). When researchers are measuring basic physical activity variables, consumer physical activity trackers have the potential to replace sophisticated expensive accelerometers. The trade-off of financial savings at the expense of software and hardware sophistication is a factor researchers must weigh in choosing the appropriate device for a particular study.

The FitBit Zip is unique among inexpensive physical activity trackers in that it is capable of measuring multiple variables. Basic variables the device measures includes step count, distance traveled, and calories burned. The Zip also measures minutes spent in light, moderate, and vigorous physical activity levels. In addition to the previously mentioned variables, the free software allows the user to track food and weight activity. The Zip is capable of measuring these variables because the device contains a micro electro-mechanical accelerometer instead of the typical pedometer components. The accelerometer measures acceleration on three axes whereas typical pedometer components are only capable of counting the number of steps via a pendulum sensor. Measuring acceleration on three axes and incorporating software to analyze accelerometer data provides a more accurate way of tracking the user's physical activity. The Actical device also uses accelerometers and software to analyze physical activity levels, and the software allows the researcher to apply different algorithms depending on the population and activity being performed. The FitBit Zip software utilized to analyze accelerometer data is proprietary and the Zip does not allow the user to access the raw data collected by the device.

The purpose of this study is to compare the FitBit Zip to the Actical and establish that the FitBit Zip is a valid tool for measuring physical activity levels. In order to validate the device, participants will engage in a bout of physical activity while wearing the FitBit Zip and the Actical accelerometer. The Actical accelerometer has been validated in multiple populations, therefore physical activity data will be extracted and compared from both devices in order to determine if the FitBit Zip is as accurate as the Actical. If the FitBit Zip can accurately track physical activity levels, the device will appeal to researchers as a cheaper and simpler alternative to the costly Actical accelerometers. A validated physical activity tracker will also appeal to the general public as a way to track whether they are achieving healthy levels of physical activity throughout the day. FitBit does not make any validity studies publically accessible, therefore this study aims to establish some form of external validity to inform both researchers and consumers.

Chapter 2

LITERATURE REVIEW

Within the United States, over 10 percent of children and 50 percent of adults do not meet the recommended guidelines for daily physical activity (CDC, 2013). Furthermore, low physical activity levels are a determinant of future health complications as research has shown that physical inactivity is a risk factor for cardiovascular disease, cancer, and osteoporosis later in life (WHO, 2013). The future health implications of low physical activity levels suggest a significant need to increase compliance with recommended guidelines. One way to increase compliance is to provide children and adults with tools to assess physical activity levels (Zhao, 2013). Typical tools consist of self-report surveys for adults and proxy-report surveys filled out by parents for their children. These reports, however, overestimate physical activity levels (Vanhelst, 2012) and justify the need for an objective monitor capable of measuring physical activity levels. The FitBit Zip has positioned itself as a physical activity monitor capable of measuring physical activity levels and is available at a more accessible cost than other methods used to measure physical activity.

Physical activity can be defined as all bodily movement that engages skeletal muscle and increases energy expenditure above basal level. Furthermore, physical activity in an individual is an observable behavior that is easily identified as either being physical active or being sedentary. Although the presence of physical activity in an individual is an important metric, objectively measuring physical activity proves to be a complex task requiring sophisticated tools. Basic tools for measuring physical activity include questionnaires, pedometers and heart rate monitors. Questionnaires are typically self-report surveys that rely on an individual's memory or perception of physical activity. Pedometers and heart rate monitors objectively measure physical activity by tallying the total number of steps the user takes and by measuring changes in heart beats per minute, respectively. Although these variables are objective observations of physical activity, the unidimensional nature of these variables leaves much to be desired when researching physical activity. More advanced methods of measuring physical activity consist of direct/indirect calorimetry, direct observation, and the doubly labeled water method. Although these methods yield highly accurate and meaningful data, the complexity and sophistication of the equipment used in these methods result in an expensive endeavor for any facility. In between basic and complex gold-standard methods of physical activity monitoring, we have technological methods that utilize physical activity trackers or accelerometers. The purpose of this review will be to describe the advantages and disadvantages of various forms of physical activity monitoring.

2.1 Gold-standard Methods

Direct observation, direct/indirect calorimetry, and the doubly labeled water method are three methods widely considered to be the gold standard of physical activity assessment. These methods are often used as tools to validate newer approaches to physical activity assessment.

2.1.1 Direct Observation

One of the earliest methods of physical activity assessment is direct observation. Generally speaking, direct observation entails an observer classifying physical activity behaviors into distinct categories that can later be quantified and analyzed. Despite being one of the earliest methods of assessing physical activity, current research still shows that direct observation can be a valid tool in measuring physical activity intensities (Lyden, 2013). The reliance on observers to accurately identify and quantify physical activity does however increase the probability of error. In order to maximize the accuracy of direct observation, observers should be trained to a critical level of reliability before the observation study commences and observers should also be tested for reliability throughout the observation period (McKenzie, 2006). However the process of training observers as well as testing observers throughout the study can prove to be an arduous task (McKenzie, 2000). The main strength of direct observation is the ability to record detailed contextual information whereas energy expenditure and activity intensity are difficult to determine and do not always correspond to other measurement methods (Saint-Maurice, 2011). Despite the subjective nature of direct observation, concurrent validity with accelerometry, heart rate monitoring, and indirect calorimetry has established at least 8 observation methods that can be useful to researchers (McKenzie, 2002).

2.1.2 Direct/Indirect Calorimetry

Direct and indirect calorimetry use the laws of thermodynamics to assume that all energy expended by an individual results in heat production. The heat produced via energy expenditure is indicative of chemical energy liberated by metabolic processes. Indirect calorimetry quantifies energy expenditure by measuring the rate of oxygen consumption and carbon dioxide production (da Rocha, 2006). This method typically consists of either open-circuit or closed-circuit systems where the difference between these two systems relates to how the expired respiratory gases are collected. Indirect calorimetry has become popular in physical activity assessment because of lower costs compared to direct calorimetry as well as the ability to estimate the relative contribution of macronutrients in total energy expenditure (Murgatroyd, 1993) Measuring gas exchange is not problematic and easily done with available modern equipment, whereas translating gas exchange to thermal equivalents of macronutrient metabolism still relies on assumptions that are easily violated (Walsberg, 2006). On the other hand, direct calorimetry is a highly accurate method in measuring energy expenditure through heat loss (Rao, 1995) but the instruments are extremely expensive to build, maintain and operate. These instruments primarily consist of an isothermal heat sink or convection system that can work independently or conjunction with each other to measure radiative, convective, and evaporative heat loss (Levine, 2005). A key advantage to direct calorimetry is the ability to measure heat loss, and thus energy expenditure, in both metabolically normal and abnormal states without relying on assumptions used in indirect calorimetry (Kaiyala, 2011).

2.1.3 Doubly Labeled Water

The doubly labeled water method uses water in which the hydrogen and oxygen elements have been replaced with respective isotopes that can be traced. The earliest use of doubly labeled water dates back to 1955 where DLW was administered to 15 mice allowing oxygen consumption and carbon dioxide production to be calculated by establishing isotope elimination curves derived from blood samples (Lifson, 1955). This method is unique because it allows for energy expenditure research to be conducted without the construction of an expensive calorimetry chamber. It took about 25 years of method and equipment refinement before DLW was used to estimate energy demands in humans (Schoeller, 1982). Since then, DLW has been used to measure energy demands and energy expenditure of various typical and atypical human populations (Speakman, 1998).

2.2 Basic Methods

Pedometers, heart rate monitors, and physical activity questionnaires are examples of three basic instruments used in physical activity research. These instruments are relatively low-cost, time efficient, and easily applied to larger population studies. However, trade-offs exist in the types of variables that can be measured as well as the validity and reliability of these instruments.

2.2.1 Pedometers

Pedometers are devices worn at the hip that count the number of steps and individual takes. The devices contain a mechanical, electrical, or electromechanical pendulum-like sensor that identifies when the individual takes a step by the motion of the pendulum arm. Newer devices contain microelectromechanical inertial sensors and utilize special software to provide a more accurate measurement of step counts. Internal mechanism differences between pedometers plays a role in determining the device’s cost as well as the device’s sensitivity and device placement can affect the validity of the pedometer measurements (Schneider 2004, De Cocker 2012). On the other hand, the simplicity of pedometer design allows the devices to be reliable measurement tools across a wide array of populations (Strycker 2007, Maher 2013). Furthermore, the nature of the internal mechanism makes pedometers most accurate for assessing steps, less accurate for assessing distance, and even less accurate for assessing kilocalories (Crouter, 2003). An up-and-coming area of research utilizes pedometers as a way to increase physical activity levels, but a lack of evidence exists among the age groups that may benefit from pedometer interventions as well as the types of goals that are achievable through pedometer interventions (Lubans 2009, Tudor-Locke 2009). In general, pedometers provide a basic measurement of physical activity but this measurement is only a small variable in the grand scheme of what defines physical activity.

2.2.2 Heart Rate Monitors

Heart rate monitors are devices that measure heart rate and report the rate either in real time or record the rates for use at a later time. Most heart rate monitors consist of a chest strap and wireless receiver, but newer devices can be strapless or have integrated fabric sensors that are less obtrusive than the typical chest strap. Furthermore, heart rate monitors have been validated for use in children and adults when compared to heart rate measurements recorded via electrocardiogram (Gamelin 2006, 2008). Another advantage of heart rate monitors is that monitors are not as sensitive to placement as pedometers (Brage, 2006). Brage et al showed that heart rate monitors can be accurate when placed on different body segments during walking, running, and free-living conditions. These monitors a valuable tool in the research setting due to its ease of measurement, its ability to record values over time, and its reflection of the relative stress placed on the cardiopulmonary system due to physical activity (Welsman, 1992). Although pedometers and heart rate monitors both report basic numerical values associated with physical activity, the physiological relationship between heart rate, physical activity intensity, and energy expenditure allows the heart rate monitor to report more clinically relevant data than pedometers or questionnaires. Achten et al's review was able to show that heart rate monitoring can provide valuable data in regards to energy expenditure, but this method only provides a satisfactory estimate of energy expenditure on a group level. On an individual level, heart rate monitoring is not as accurate for predicting energy expenditure because the relationship between HR and energy expenditure is influenced by multiple factors including hydration and ambient temperature (Achten, 2003).

2.2.3 Questionnaires

Although physical activity questionnaires are subjective and inherently limited, these self-report surveys offer a low cost method to gather physical activity data across multiple age ranges and demographics. Some common examples of physical activity questionnaires include the Global Physical Activity Questionnaire (GPAQ, World Health Organization), International Physical Activity Questionnaire (IPAQ), and the Physical Activity Questionnaire (PAQ, Kowalski 2004). These questionnaires are an important tool when assessing physical activity in a large-scale study, but the reliability and validity of physical activity questionnaires is difficult to verify.

2.2.3.1 Validity

In order for physical activity questionnaires to be useful, the surveys need to be able to assess the variables researchers are interested in studying. Unfortunately, the validity correlation coefficients from the vast majority of existing and newly developed PAQs were considered poor to moderate (Helmerhorst, 2012). Furthermore, self-report measures can validly rank physical activity behavior but they are unable to adequately quantify physical activity (Masse, 2012). In children, the lack of validity present in physical activity questionnaires may be due to multiple factors. Some of these factors include the inability to think abstractly and perform physical activity recall as well as variable physical activity patterns when compared to other age groups (Sallis 1991, Baquet 2007). Although challenges exist when using physical activity questionnaires in youths, interviewer assistance may enhance the accuracy of recall and reporting among children and adolescents (Kohl, 2000). Adults may be the most appropriate audience for physical activity questionnaires, however validity does vary in accordance with cultural and socioeconomic factors (Craig, 2003). Generally speaking, physical activity research should use more advanced methods in order to quantify associated variables.

2.2.3.2 Reliability

Although reliable methods such as doubly labeled water and calorimetry exist to measure physical activity levels, using these methods on a large scale study would be time-consuming and costly. Despite discrepancies in validity, physical activity questionnaires do contain an element of reliability (Phillippaerts, 1998). It is important to note that long-term studies will have reduced reliability when compared to short-term studies using physical activity questionnaires (Bonnefoy, 2001). Of the many physical activity questionnaires available, the most extensively reviewed questionnaire is the International Physical Activity Questionnaire. This survey has been shown to be reliable amongst adults in various settings and languages, but research is currently lacking in reliability of questionnaires in children and adolescents (Arvidsson, 2005). A limiting factor in determining validity and reliability of physical activity questionnaire use in children and adolescents is that most questionnaires are given to the parents or guardians and suffer bias from the observer (Oliver, 2007).

2.3 Technological Methods

Technological methods fall between basic methods and gold-standard methods in terms of complexity and measurements. These methods typically consist of devices outfitted with multiple sensors such as GPS, gyroscope, altimeter, and accelerometer components. For the purpose of this review, we will focus on stand-alone accelerometers used in physical activity research.

2.3.1 Accelerometers

For any researcher, it is important to know if physical activity trackers or accelerometers are valid tools to use in the target population. Whether the target population consists of children, adults, or those with disabilities, data collected from the physical activity tracker would be useless if the device is capable of accurately measuring physical activity in the target population. Physical activity accelerometers typically are only available to researchers and typically rely on sophisticated software to analyze the data on the device.

2.3.1.1 Children

Accelerometers are becoming a widely accepted tool for measuring physical activity levels. Although many devices have been validated for use in children, the definition of childhood can be divided into many subcategories that span multiple ages. The importance of validating the use of accelerometers in childhood age subgroups is highlighted by the difference in physical activity patterns and the difference in anthropometric variables (Stone, 2007). One of the youngest subgroup of children consists of toddlers, who range from 1 year old to 3 years old. A recent study aimed to address the lack of research regarding the use of accelerometry-based physical activity measurement in toddlers. Criterion validity was established and accelerometers were able to differentiate between sedentary and non-sedentary behaviors but were unable to differentiate between light physical activity and moderate-to-vigorous physical activity (Van Cauwenberghe, 2011). Another subgroup of children consists of preschoolers who range from 3 years old to 6 years old. One of the most recent studies regarding validity of accelerometry use in preschoolers found that accelerometers were capable of objectively capturing postural and physical activity data in preschool aged children. Validity was established by comparing second-to-second direct observation of posture and physical activity with accelerometer data and accelerometry was also identified as having practical utility and reliability (Davies, 2011). Additional subgroups of childhood ages consist of middle childhood and pre-adolescence where age spans have not been universally established. However, accelerometers have been shown to be valid and reliable for ages 8 to 14 years old (Ekblom 2012, Trost 1998)

2.3.1.2 Adolescents

As mentioned earlier in this text, accelerometers measure activity in regards to the mass the device is attached to therefore physiological differences between users could affect validity and reliability. It is important to assess accelerometer validity and reliability in separate age groups because children and adolescents differ in body size, body composition, and motor skills (Berk, 2012). Although physiological differences exist among age groups, accelerometer use has been shown to be valid in females between 15 and 18 years old (Dowd, 2012) and in as well as adolescents between 10 and 16 years old (Vanhelst, 2010). In conclusion, ample evidence is available validating the use of accelerometers in measuring physical activity in all age ranges from childhood through adolescence.

2.3.1.3 Adults

In scientific literature, the term adulthood can range from as young as 18 years old to over 65 years old. Therefore it is necessary to validate the use of accelerometers in different stages of adulthood much like research has validated accelerometer use in various stages of childhood. The relative validity of multiple accelerometers has been established in young adults (Wetten 2013), but it is important to note that older adults differ from young adults in both the type and intensity of physical activity. In older adults, physical activity measurements obtained from accelerometry has been validated against indirect calorimetry and doubly labeled water techniques (Ekelund 2002, Plasqui 2007). Specifically, the Actical accelerometer has been validated for use in middle-aged and older adults (Hooker, 2011) . Although accelerometer can provide objective measurements of physical activity levels in older adults, aging effects of physical and cognitive health may limit older adults' compliance with accelerometer protocol (Garatachea, 2010).

2.3.1.4 Cut-points

Although evidence supports the use of accelerometers across most age groups, accurate assessment of physical activity via accelerometry is enhanced when age-specific cut-points are utilized. Cut-points are constants, measured in counts per minute, that are used to classify the user's physical activity into sedentary, light, moderate, and vigorous levels. Physical activity levels have corresponding cut-points that act as thresholds when analyzing accelerometer activity counts for a given time. Accelerometer cut-points are typically established via calibration techniques but these techniques are often methodologically diverse and produce a wide range of variation among cut-points, even when using the same accelerometer make and model (Matthew 2005). The most common accelerometers found in a research setting include the Actigraph (Actigraph, Pensacola, FL), the Actical (Mini Mitter – Respironics, Bend, OR), and the RT3 (Stayhealthy Inc., Monrovia, CA) and each accelerometer has a unique set of cut-points for physical activity levels as well as population-based cut-points. For the Actical, current research supports the use of the decision-boundary method for determining cut points. This method uses sensitivity and specificity analysis to identify the most appropriate cut-points for light, moderate, and vigorous physical activity intensity in adults and children (Colley 2011, Jago 2007).

2.3.1.5 Activity Type

Although the notion of physical activity monitoring implies ambulatory motions, physical activity research is also interested in sedentary behaviors. Earlier accelerometer models were not capable of monitoring postural activities such as lying, sitting, or standing. Newer models consist of different electromechanical sensors capable of measuring gravitational forces associated with posture (Plasqui, 2013). With more advanced sensors, accelerometers can now be used in a wide array of physical activities ranging from static postural activities to ambulatory movements. Various algorithms have been derived to not only classify the type of static or ambulatory activity but to also identify the transition from one state of activity to the other (Bonomi 2009, Yang 2010). Furthermore, using more than one accelerometer to monitor physical activity greatly enhances the ability to identify and classify various forms of physical activity (Zhang, 2003). The ability is identify and classify physical activity via accelerometry has the potential to provide more accurate assessment of energy expenditure. Using activity classification may offer a better alternative to energy expenditure assessment than relying on accelerometer activity counts (Bonomi, 2009). Much like determining cut-point thresholds, it is the researchers' responsibility to identify the algorithms that most appropriately target the population being studied.

Selecting the appropriate physical activity classification algorithm enhances the accuracy and relevancy of data collected via accelerometry.

2.4 Conclusion

In order to increase compliance with recommended guidelines for physical activity, children and adults need access to tools capable of quantifying their physical activity levels. Basic methods such as self-reports, heart rate monitors, and pedometers lack the sophistication necessary to validly quantify physical activity levels with regards to recommended guidelines. Gold-standard methods, although highly accurate, are too complex for the average user and consist of expensive equipment not available to the average consumer. A relatively new monitoring method consists of using accelerometers to capture quantitative physical activity data. Accelerometers are more complex than basic methods, but not as resource-intensive as the gold-standard methods and offer researchers and consumers a less expensive way to obtain objective measures of physical activity. With the recent advances in consumer electronics, accelerometers are now being offered as personal devices that individuals can record and track their own physical activity. The FitBit Zip is marketed as a physical activity tracker that the general public can easily use to determine similar objective measures that would be achieved via professional accelerometers like the Actical. For this reason, we will attempt to determine the validity of the FitBit Zip in both children and adults.

Chapter 3
METHODOLOGY

3.1 General Methodology

This study consisted of two groups divided between children and adults. Initial recruitment set the age range 8 years old to 14 years old and 18 years old to 40 years old for children and adults, respectively. Inclusion criteria consisted on healthy children and adults within the aforementioned age ranges with a body mass index below 30. Exclusion criteria consisted of any physical or psychological limitation that would prevent the successful completion of the treadmill portion of the physical activity protocol. Each subject participated in a twenty-minute bout of physical activity that spanned sedentary, light, moderate, and vigorous intensities. Subjects wore the Actical and FitBit Zip devices while performing the physical activity protocol. Time spent in each physical activity intensity was 5 minutes. Sedentary physical activity consisted of seated video watching where the participants watched an informative video about the FitBit Zip. Light physical activity consisted of treadmill walking at 1.2mph for children and 1.5mph for adults. Moderate physical activity consisted of treadmill walking at 2.5mph and 3.0mph for children and adults, respectively. And vigorous treadmill activity consisted of treadmill running at 4.5mph and 5.0mph for children and adults, respectively. All treadmill bouts were performed at a 0% incline. Participants were given a self-determined recovery time between treadmill bouts as well as the opportunity to rehydrate if necessary. During the treadmill protocol, each physical activity intensity session was video recorded to assess the total number of steps taken.

3.2 Participants

Subjects were recruited by announcements made via email list distribution as well as flyers posted on University of Delaware' s campus. Inclusion criteria consisted of healthy children between the ages of 8 and 14 years old and healthy adults between the ages of 18 and 40 years old. Healthy children were defined as having a body mass index below 30. A minimum age of 8 years was selected due to the nature of the equipment and exercise protocol, and a maximum of age of 14 years was selected to ensure that all participants could be classified as "children" according to an accelerometer review by Freedson et al.. The adult age range was selected to represent individuals post-pubescent but before signature age-related changes in physiology and biomechanics. Prior experience using a treadmill was not necessary. Exclusion criteria consisted of any physical or psychological limitation that would prevent the successful completion of the treadmill portion of the physical activity protocol. Physical or psychological limitations include, but are not limited to, arthritis, ACL rupture, or severe mental illness. Fifteen children and twenty adults were recruited to participate in this study (Table 1). Subjects were to arrive at the Human Performance Lab wearing comfortable clothes conducive to physical activity (athletic shoes, shorts, etc.).

Table 1: Demographic data of study participants.

	N (Female)	**N (Male)**	**Mean Age (years)**	**Mean Weight (lbs)**	**Mean Height (in)**
Children	6	9	10.7 ± 1.87	80.5 ± 15.9	57.9 ± 4.76
Adults	6	14	23.8 ± 5.14	175 ± 39.6	68.5 ± 3.85

3.3 Protocol

Eligible participants were scheduled to arrive at the Human Performance Lab wearing clothes conducive to treadmill activity (running shoes, athletic shorts, t-shirt, etc.). Upon arrival, participants were oriented to the study and equipment and were given an opportunity to express questions or concerns. Adult participants read and signed an Informed Consent form. Children participating in the study were read a Child Assent form and were instructed to sign the Child Assent form. Parents or legal guardians of each child also read and signed Informed Consent forms for each child. In order to calibrate the Actical accelerometer and FitBit Zip to each participant, the participant's height, weight, age, and sex were entered into each device's calibration setup on a computer. Before beginning the physical activity protocol, each participant donned a belt that contained the Actical and FitBitThe sedentary activity portion of this study required each participant to watch a five-minute video clip describing the FitBit Zip. After the sedentary activity portion of the protocol, participants proceeded to perform three treadmill activities. A video recording device was positioned at floor level to capture the total number of steps taken during each treadmill bout. Light treadmill activity consisted of walking for five-minutes at 1.2mph for children and 1.5mph for adults, respectively. Moderate treadmill activity consisted of walking for five-minutes at 2.5mph and 3.0mph for children and adults, respectively. Vigorous treadmill activity consisted of running for five-minutes at 4.5mph and 5.0mph for children and adults, respectively (Table 2).

Table 2: Four stages of the physical activity protocol.

Intensity	Activity	Duration (min)	Speed (mph) (child)	Speed (mph) (adult)
Sedentary	Movie watching	5	N/A	N/A
Light	Treadmill walking	5	1.2	1.5
Moderate	Treadmill walking	5	2.5	3.0
Vigorous	Treadmill running	5	4.5	5.0

Treadmill speeds for children were selected in reference to the Compendium of Energy Expenditures for Youth (Ridley 2008). Treadmill speeds for adults were selected in reference to the Compendium of Physical Activities: an Update of Activity Codes and MET Intensities (Ainsworth 2000) and the five-minute time limit was selected from similar accelerometer validity studies (Adam Noah 2013, Nichols 1999). At the beginning and end of the sedentary, light, moderate, and vigorous physical activity bouts, participants were instructed to press the indicator button on the Actical accelerometer while the researcher synced and recorded data obtained from the FitBit Zip. By design, the FitBit Zip tracks physical activity on a continuous basis and does not have an indicator button. Without the ability to use an indicator button on the FitBit Zip, the difference between data recorded at end-bout and beginning-bout served as a way to calculate energy expenditure data for each five-minute bout of physical activity.

3.4 Equipment

Equipment included the Actical accelerometer (Phillips Respironics, Bend, OR) and FitBit Zip (FitBit Inc., San Francisco, CA) with all corresponding software and hardware. The Actical accelerometer and FitBit Zip are devices with sensors capable of measuring physical activity variables such as energy expenditure, intensity, and step counts. Prior to collecting data, all Actical accelerometers were factory calibrated. The corresponding software and hardware for these devices enable the devices to be synced to a computer or mobile device where the data is extracted and analyzed. The Actical software presented physical activity data as total minutes spent in sedentary, light, moderate, and vigorous intensities. Although the Energy Expenditure function in the Actical software sets the epoch length at 1 minute, epoch length was set at 15 seconds and the activity counts within the shorter epochs were added resulting in no loss of activity counts for each 1-minute period. The FitBit software presented physical activity data as total number of steps and total minutes spent in sedentary, light, moderate, and vigorous intensities. Participants wore the Actical and the FitBit Zip on a neoprene belt that was secured around the waist such that both devices were on the participant's left hip. A mobile device (Apple Inc., Cupertino, CA) was used to video record each treadmill bout. Physical activity bouts were performed on the GE T2100 treadmill (GE Healthcare, Mickleton, NJ).

3.5 Statistical Analysis

Dependent measures included the number of minutes of physical activity in sedentary, light, moderate, and vigorous intensities and the number of steps taken in light, moderate, and vigorous intensities. The number of minutes of physical activity was measured by the Actical accelerometer and the FitBit Zip device, and the number of steps was measured by manual counts and the FitBit Zip device. The independent measure in this study was physical activity intensity. Physical activity intensity included four levels, physical activity performed at sedentary, light, moderate, and vigorous intensities.

A two-way repeated measures ANOVA was used to determine if a significant difference exists between the number of minutes in each physical activity measured by the Actical and FitBit Zip across intensities. In addition, a two-way repeated measures ANOVA with correction adjustment was used to determine if a significant difference exists between manual step-counts and FitBit's pedometer function across conditions. Alpha was set at the .05 level a priori, and all post-hoc comparisons used a Bonferroni correction. This correction divides alpha by the total number of comparisons to ensure that the cumulative error does not surpass the .05 level. This analysis was performed on the entire sample, and then separately for adults and children.

Chapter 4

VALIDITY OF THE FITBIT ZIP FOR USE IN CHILDREN AND ADULTS

4.1 Introduction

For individuals between the ages of 6 and 17 years, the CDC recommends 60 minutes of moderate-to-vigorous physical activity per day at least 3 times a week, as well as muscle strengthening and bone strengthening activities 3 times a week. For adults, the CDC recommends 150 minutes per week of moderate-to-vigorous physical activity as well as muscle strengthening activities that target all major muscle groups 2 or more days a week. It is estimated that 52 percent of adults and 14 percent of adolescents do not meet these guidelines for physical activity (CDC, 2013). A major hurdle for compliance with CDC recommendations is the ability to track physical activity levels among individuals. Various methods, such as questionnaires and pedometers, exist for individuals to track physical activity, but methods vary in accuracy and validity. Physical activity tracking is difficult for individuals because subjective measurements like self-reporting have been shown to overestimate compliance with physical activity guidelines when compared to objective measurements like accelerometry (Tucker, 2011). Before the recent growth in the mobile device industry, objective physical activity tracking was typically performed in a laboratory setting using sophisticated sensors and equipment. Individuals can now utilize standalone physical activity trackers or trackers that pair with their smartphone to measure physical activity levels similar to the way researchers measure physical activity. Although these new devices report similar measurements obtained from laboratory accelerometers, consumers are presented with carefully designed advertisements instead of validity and reliability information on these devices. The influx of new tools able to measure physical activity leads to the ultimate question of whether these new devices are capable of accurately assessing physical activity levels.

This influx of new tools to measure physical activity has made many devices commercially available to a wide audience. The FitBit Zip (FitBit Inc., San Francisco, CA) is a relatively low-cost physical activity tracker designed to measure daily physical activity variables. Physical activity measurements include time spent in different activity intensity levels (light, moderate, vigorous) as well as daily caloric energy expenditure, steps counts, and distance traveled. These measurements are similar to measurements taken by more advanced devices such as the Actical accelerometer (Phillips Respironics, Bend, OR) but do not require the same financial and technical investment. Accelerometer sensors are typically piezoelectric or electromechanical in design and function by measuring a mass's acceleration in three dimensions. Acceleration in a plane produces deformational changes within the sensor, which generated a voltage related to the intensity of that acceleration. For an accelerometer to accurately detect the movements of a smaller relative mass, such as a child's mass compared to an adult's mass, the accelerometer must have the sensitivity to detect those changes in acceleration. Therefore the purpose of this study was to assess the validity of the FitBit Zip physical activity monitor in children and adults by comparing it to the Actical accelerometer when both devices are worn during a physical activity protocol. The Actical was chosen as a comparable device because of published validity studies in children and adults (Heil 2006, Puyau 2004, Hooker 2011). Hypothesis one aimed to identify if differences exist between Actical and FitBit measurements of physical activity in children and hypothesis two aimed to identify if differences exist between Actical and FitBit measurements of physical activity in adults.

4.2 Methods

Fifteen participants between the ages of 8 and 14 years (mean age: 10.7 years, SD ± 1.87) and twenty adult participants between the ages of 18 and 40 years (mean age: 23.8 years, SD ± 5.14) were recruited via email distribution requests and informative flyers posted in public areas. Inclusion criteria consisted on healthy children and adults within the aforementioned age ranges with a body mass index below 30. Exclusion criteria consisted of any physical or psychological limitation that would prevent the successful completion of the treadmill portion of the physical activity protocol. Participants were not given any financial incentive for data collection. This study was approved by University of Delaware's Institutional Review Board and written informed consent, child assent, and informed parental consent forms were obtained.

Participants arrived at the Human Performance Lab and were oriented to the study and to the equipment. Height, weight, age, and sex of each participant was recorded. These values were used to calibrate the Actical accelerometer and the FitBit Zip using their respective software interfaces. Before beginning the physical activity protocol, participants were given a chance to express concerns or ask questions regarding the procedure or equipment. The physical activity protocol consisted of four stages with physical activity performed at sedentary, light, moderate, and vigorous levels (Table 3).

Table 3: Four stages of the physical activity protocol.

Intensity	**Activity**	**Duration (min)**	**Speed (mph) (child)**	**Speed (mph) (adult)**
Sedentary	Movie watching	5	N/A	N/A
Light	Treadmill walking	5	1.2	1.5
Moderate	Treadmill walking	5	2.5	3.0
Vigorous	Treadmill running	5	4.5	5.0

Participants were instructed to wear a belt with the Actical and FitBit Zip clipped on to the left side of the belt. Treadmill speeds and duration were selected in accordance with previous accelerometer validity studies and published physical activity compendiums (Adam 2013, Nichols 1999, Ainsworth 1993, Ridley 2008).

Dependent measures include the number of minutes of physical activity in sedentary, light, moderate, and vigorous intensities and the number of steps taken in light, moderate, and vigorous intensities. The independent measure in this study is physical activity intensity. Physical activity intensity included four levels, physical activity performed at sedentary, light, moderate, and vigorous intensities. The number of minutes of physical activity was measured by the Actical accelerometer and the FitBit Zip device, and the number of steps was measured by manual counts and the FitBit Zip device.

A two-way repeated measures ANOVA was used to determine if a significant difference exists between number of minutes of physical activity measured by the Actical and FitBit Zip across intensities. A two-way repeated measures ANOVA with correction adjustment was also used to determine if a significant difference exists between manual step-counts and FitBit's pedometer function across conditions. Alpha was set at the .05 level a priori, and all post-hoc comparisons used a Bonferroni correction. This analysis was performed on the entire sample, and then separately for children and adults.

4.3 Results

4.3.1 Accelerometer Function in Entire Sample

There was a significant main effect of physical activity intensity, F(2.14, 72.9) = 331, p<.001, partial eta squared=.907. There was also a significant interaction effect between which device was used and the recorded minutes of physical activity at specified intensities, F(2.58, 87.8) = 540, p<.001, partial eta squared=.941 (Table 4).

Table 4: Accelerometer function ANOVA table for the entire sample.

Source	SS	df	Mean square	F	Sig.	Partial eta squared
PA intensity	277.5	2.14	129.4	331	<.001	.907
Device	325.7	1.0	325	1635	<.001	.980
Interaction	337.3	2.58	130.5	540	<.001	.941

At sedentary PA, there was a significant difference of .257 minutes between Actical and FitBit measurements, p=.002. At light PA, there was a significant difference of 4.51 minutes between Actical and FitBit measurements, p<.001. At moderate PA, there was a significant different of 4.17 minutes between Actical and FitBit measurements, $p<.001$. At vigorous PA, there was a significant difference of .20 minutes between Actical and FitBit measurements.

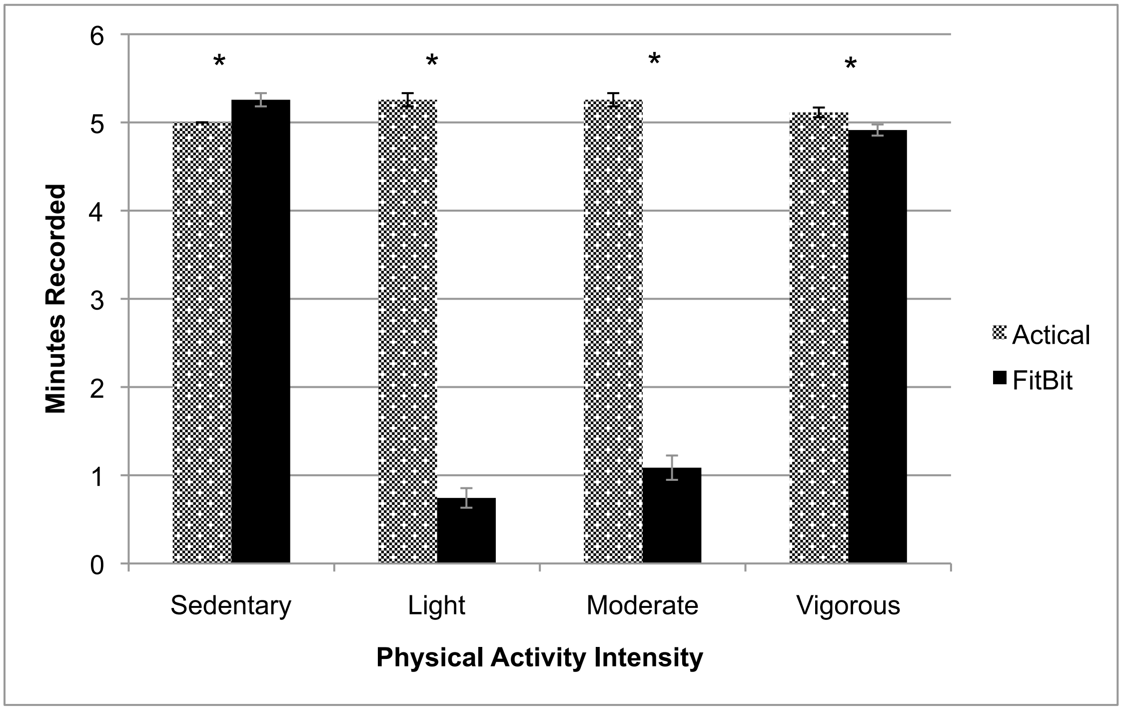

Figure 1: Actical and FitBit measurements during the physical activity protocol for entire sample.

The designation of physical activity minutes by the FitBit as compared to the Actical is shown in Table 5. As the Actical recorded 5 minutes of light physical activity, the FitBit recorded .69 minutes of light physical activity. As the Actical recorded 5 minutes of moderate physical activity, the FitBit recorded 1.11 minutes of moderate physical activity.

Table 5: The minutes recorded at different intensities by the FitBit as compared to the Actical in the entire sample.

	FitBit Zip			
Actical	Sedentary	Light	Moderate	Vigorous
Light	1.29	.69	3.11	.2
Moderate	.029	.343	1.11	3.71

4.3.2 Accelerometer Function in Children

There was a significant main effect of physical activity intensity, $F(1.97, 27.5) = 190$, $p<.001$, partial eta squared=.931. There was also a significant interaction effect between which device was used and the recorded minutes of physical activity at specified intensities, $F(2.18, 30.5) = 233.6$, $p<.001$, partial eta squared=.943 (Table 6).

Table 6: Accelerometer function ANOVA table for children.

Source	SS	df	Mean square	F	Sig.	Partial eta squared
PA intensity	131	1.97	66.6	189.7	<.001	.931
Device	156.4	1.0	156.4	738.1	<.001	.981
Interaction	153.0	2.18	70.2	233.6	<.001	.943

At sedentary PA, there was no significant difference between Actical and FitBit measurements, $p=.082$. At light PA, there was a significant difference of 4.67 minutes between Actical and Fitbit measurements, $p<.001$. At moderate PA levels, there was a significant difference of 4.40 minutes between Actical and FitBit measurements, $p<.001$. At vigorous PA levels, there was a significant difference of .276 minutes between Actical and FitBit measurements, $p=.041$.

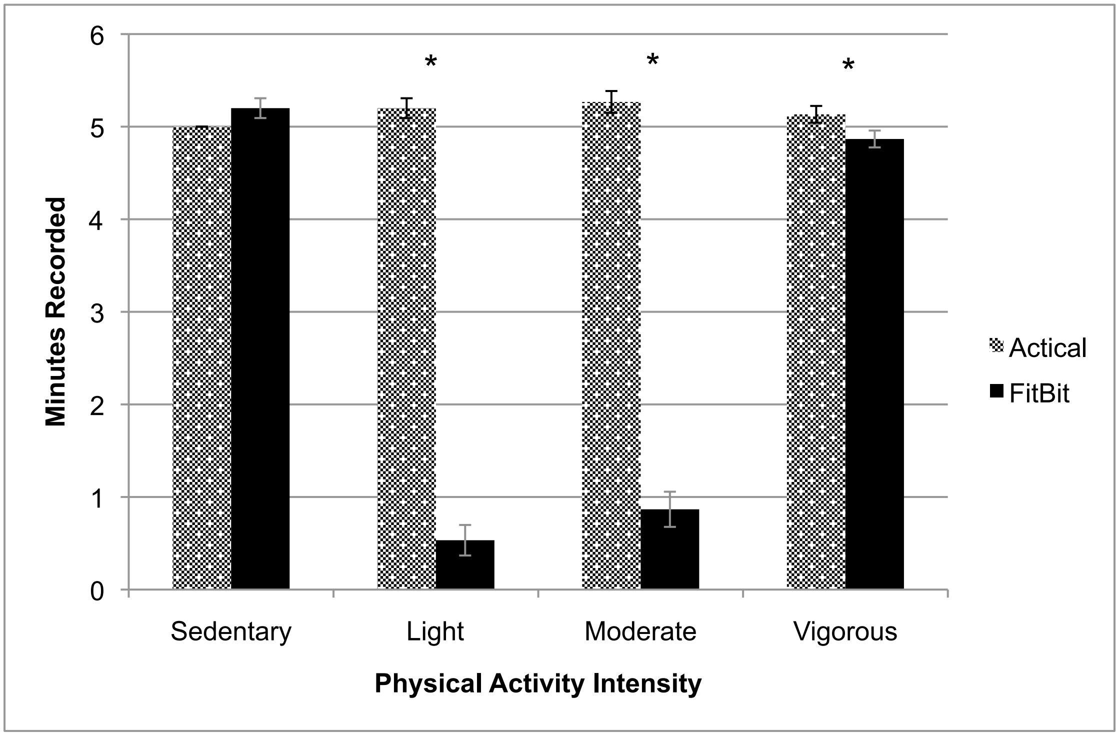

Figure 2: Actical and FitBit measurements during the physical activity protocol in children.

The designation of physical activity minutes by the FitBit as compared to the Actical is shown in Table 7. As the Actical recorded 5 minutes of light physical activity, the FitBit recorded .53 minutes of light physical activity. As the Actical recorded 5 minutes of moderate physical activity, the FitBit recorded .87 minutes of moderate physical activity.

Table 7: The minutes recorded at different intensities by the FitBit as compared to the Actical in children.

	FitBit Zip			
Actical	Sedentary	Light	Moderate	Vigorous
Light	1.53	.53	2.67	.47
Moderate	0	.4	.87	3.87

4.3.3 Accelerometer Function in Adults

There was a significant main effect of physical activity intensity, F(2.06, 39.1) = 153, p<.001, partial eta squared=.889. There was also a significant interaction effect between which device was used and the recorded minutes of physical activity at specified intensities, F(2.49, 47.2) = 297.0, p<.001, partial eta squared =.940 (Table 8).

Table 8: Accelerometer function ANOVA table for adults.

Source	SS	df	Mean square	F	Sig.	Partial eta squared
PA intensity	147.1	2.06	71.5	152.6	<.001	.889
Device	170.2	1.0	170.2	1089	<.001	.983
Interaction	184.6	2.49	74.3	297.0	<.001	.940

At sedentary PA, there was no significant difference between Actical and FitBit measurements, p=.010. At light PA, there was a significant difference of 4.40 minutes between Actical and FitBit recorded measurements, p<.001. At moderate PA levels, there was a significant difference of 4.00 minutes between Actical and FitBit measurements, p<.001. At vigorous PA, there was no significant difference between Actical and FitBit measurements, p=.267.

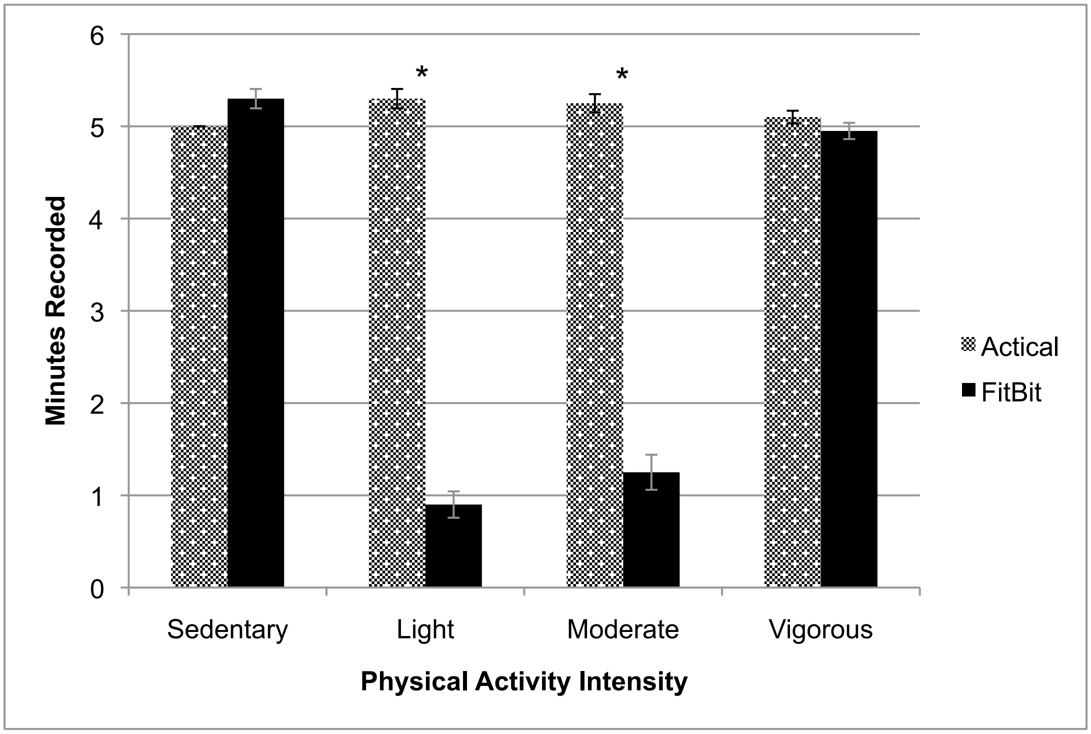

Figure 3: Actical and FitBit measurements during the physical activity protocol in adults.

The designation of physical activity minutes by the FitBit as compared to the Actical is shown in Table 9. As the Actical recorded 5 minutes of light physical activity, the FitBit recorded .80 minutes of light physical activity. As the Actical recorded 5 minutes of moderate physical activity, the FitBit recorded 1.30 minutes of moderate physical activity.

Table 9: The minutes recorded at different intensities by the FitBit as compared to the Actical in adults.

	FitBit Zip			
Actical	Sedentary	Light	Moderate	Vigorous
Light	1.10	.80	3.45	0
Moderate	.05	.30	1.30	3.60

4.3.4 Step Count Function in Entire Sample

There was a significant main effect of physical activity intensity, $F(1.38, 46.8) = 426$, $p<.001$, partial eta squared=.926. There was also significant interaction effect between manual counting and the Fitbit when comparing the number of steps taken during each intensity level, $F(1.19, 40.3) = 8.05$, $p=.005$, partial eta squared = .191.

At light PA, there was a significant difference of 54.8 steps between manual counts and FitBit counts, $p=.006$. At moderate PA, there was no significant difference between manual counts and FitBit counts, $p=.451$. At vigorous PA, there was no significant difference between manual counts and FitBit counts, $p=.778$.

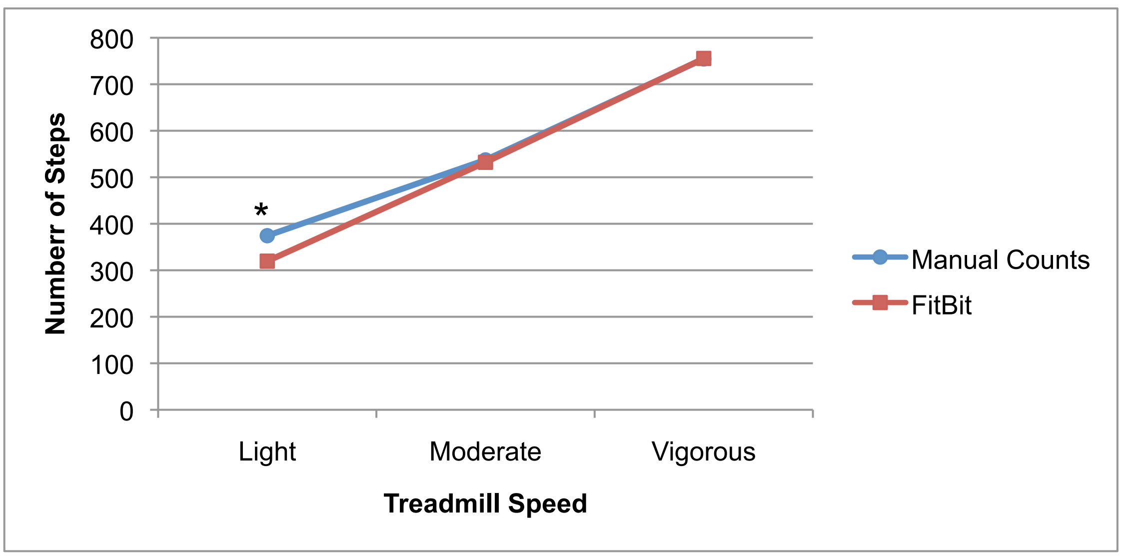

Figure 4: Step count differences between manual counts and FitBit for the entire sample during the physical activity protocol.

4.3.5 Step Count Function in Children

There was also a significant main effect of physical activity intensity, $F(1.22, 17.1) = 240$, $p<.001$, partial eta squared=.945. There was also significant interaction effect between manual counting and the FitBit when comparing the number of steps taken during each intensity level, $F(1.28, 17.8) = 4.26$, $p=.046$, partial eta squared $=.233$.

At light PA, there was no significant difference of steps between manual counts and FitBit counts, $p=.072$. At moderate PA, there was also no significant different of steps between manual counts and FitBit counts, $p=.534$. At vigorous PA, there was no significant difference of steps between manual counts and FitBit counts, $p=.092$.

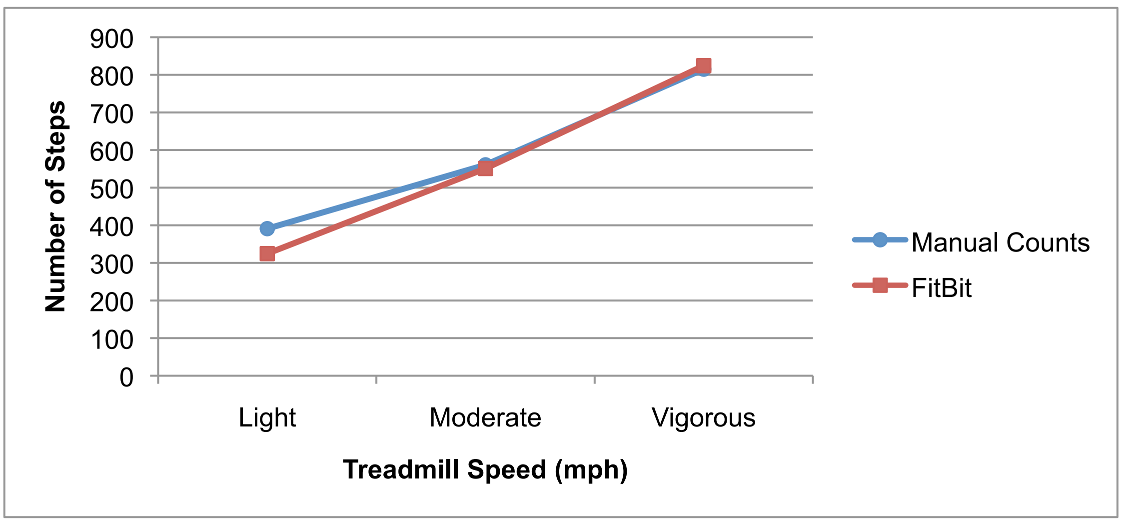

Figure 5: Step count differences between manual counts and FitBit for children during the physical activity protocol.

4.3.5 Step Count Function in Adults

There was no significant interaction effect between manual counting and the FitBit when comparing number of steps taken during each intensity level, $F(1.05, 19.9) = 3.90$, $p=.061$, partial eta squared $=.170$. There was also a significant main effect of physical activity intensity, F(1.46, 27.7) = 267, p<..05, partial eta squared=.934.

At light PA, there was a significant difference of 46.1 steps between manual counts and FitBit counts, p=.041. At moderate PA, there was no significant different between manual counts and FitBit counts, p=.633. At vigorous PA, there was no significant difference between manual counts and FitBit counts, p=.245.

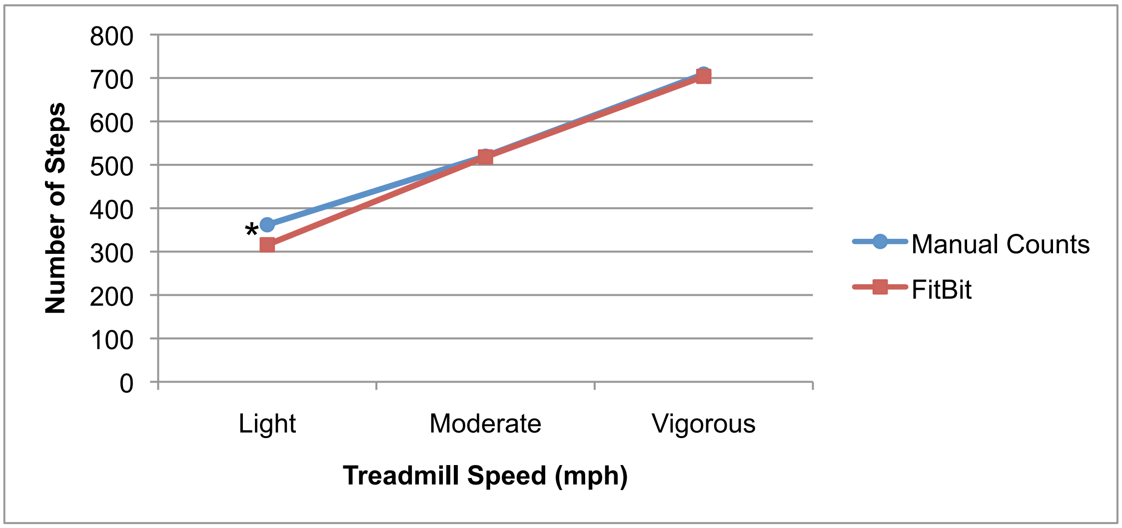

Figure 6: Step count differences between manual counts and FitBit for adults during the physical activity protocol

4.4 Discussion

4.4.1 Accelerometer Function

In the entire sample, a significant interaction effect between device and recorded minutes of physical activity supports the hypothesis that significant differences exist between FitBit measurements of physical activity and Actical measurements of physical activity. The FitBit overestimated the amount of time spent in sedentary physical activity and underestimated the time spent in light, moderate, and vigorous physical activity. Across the entire sample at sedentary and vigorous physical activity levels, the discrepancy between Actical and FitBit measurements was minimal such that the difference was less than 20 seconds. At light and moderate physical activity levels, the FitBit grossly underestimated the amount of time spent in each level. When compared to the Actical accelerometer for the entire sample, the FitBit Zip is not able to accurately measure physical activity levels.

In children, a significant interaction effect between device and recorded minutes of physical activity supports the hypothesis that significant different exist between FitBit measurements of physical activity and Actical measurements of physical activity. The FitBit was able to accurately measure the amount of time spent in sedentary physical activity, but underestimated the amount of time spent in light, moderate, and vigorous physical activity. Although the discrepancy between Actical and FitBit measurements of vigorous physical activity was less than 20 seconds, the FitBit grossly underestimated the amount of time spent in light and moderate physical activity. Therefore, the FitBit Zip is able to identify if children are sedentary or active but unable to differentiate between levels of being physically active.

In adults, a significant interaction effect between device and recorded minutes of physical activity supports the hypothesis that significant different exist between FitBit measurements of physical activity and Actical measurements of physical activity. At sedentary and vigorous physical activity levels, the FitBit was able to accurately measure the amount of time spent in each activity level. However, the FitBit was unable to accurately measure the amount of time spent in light and moderate. Therefore the FitBit Zip is able to identify if adults are sedentary or vigorously active, but unable to determine the amount of time lightly or moderately active.

In all three samples, the FitBit misclassified light and moderate physical activity level measurements. This misclassification may be due to accelerometer components, accelerometer sensitivity or software analysis. A recent study by Danneker et al. was able to manually classify physical activity measurements by the FitBit, albeit a time-consuming technical process. When manually classified, FitBit measurements of energy expenditure did not differ significantly from room calorimetry (Danneker, 2013). This finding lends credence to the notion that the FitBit software analysis or accelerometer sensitivity requires recalibration. As seen in previous literature, accelerometer calibration is unique to the target population and physical activity (Freedson 2005, Matthew 2005) and specific calibration is necessary to accurately measure physical activity.

Occasionally, the Actical accelerometer reported time spent in physical activity intensity as greater than five minutes. This discrepancy can be attributed to the time delay of individuals' transition from the treadmill platform to a position of comfort on the safety rails and pressing the indicator button.

To this date, only two searchable publication assessing the FitBit Zip's ability to quantify physical activity levels was found. When compared to room calorimetry, FitBit measurements of energy expenditure were significantly different (Danneker, 2013). This study supports the findings of Danneker et al. in that the FitBit is not a valid device in measuring physical activity. Additionally, Stahl and Insana used the FitBit to measure weekly energy expenditure compared to a valid and reliable self-report method among older adults. Again, the FitBit underestimated weekly energy expenditure in the target population. (Stahl, 2013). As an accelerometer, the FitBit Zip does not represent a device capable of replacing the Actical accelerometer in a laboratory setting. Clinicians also should not utilize the FitBit Zip as a standalone device to measure their patients' physical activity levels.

4.4.2 Step Count Function

In the entire sample, a significant interaction effect between manual counting and the Fitbit supports the hypothesis that significant differences exist between the FitBit Zip and the true value. At light physical activity levels, the FitBit underestimated the total amount of steps when compared to manual counts. At moderate and vigorous physical activity levels, however, the FitBit was able to accurately estimate the total amount of steps when compared to manual counts.

In children, a significant interaction effect between manual counting and the FitBit supports the hypothesis that significant differences exist between the FitBit Zip and the true value. Although a significant interaction effect exists, there are no significant differences between FitBit measurements and manual counts in light, moderate, and vigorous physical activity levels. Therefore the FitBit Zip is able to accurately assess the number of steps taken during light, moderate, and vigorous activity levels in children.

In adults, a significant interaction effect between manual counting and the FitBit supports the hypothesis that significant differences exist between the FitBit Zip and the true value. The FitBit underestimated the amount of steps taken at light physical activity levels, but accurately estimated the amount of steps taken in moderate and vigorous physical activity levels.

As of this date, only one searchable publication was found assessing the step count function of the FitBit. However, the publication utilized the FitBit Ultra whereas this study utilized the FitBit Zip. The difference between the two FitBit models is the ability of the FitBit Ultra to track sleep patterns as well as physical activity data, although both models utilize the same sensors (FitBit 2013). Fulk et al determined the FB may be a low cost alternative to measure the stepping activity on level, predictable environments of people with stroke and TBI who can walk at speeds greater than 1.3mph. However, the sample used in Fulk et al's study was not comparable to the normative sample of this study and the conclusions should not be seen as analogous.

4.4.3 Conclusion

In an effort to meet CDC physical activity recommendations, individuals can utilize physical activity monitors as an objective tool to ensure compliance with the recommendations. These physical activity monitors, however, must be validated against current laboratory methods so that individuals can accurately compare their physical activity levels to those recommended by the CDC. The FitBit Zip is a physical activity tracker capable of determining whether children and adults are sedentary or physical active, but the device lacks the ability to accurately quantify light and moderate physical activity levels. On the other hand, the FitBit Zip is an appropriate device to use for tracking step counts in children and adults

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Appendix A

INSTITUTIONAL REVIEW BOARD APPROVAL

UNIVERSITY OF DELAWARE

RESEARCH OFFICE

210 Hullihen Hall
University of Delaware
Newark, Delaware 19716-1551
Ph: 302/831-2136
Fax: 302/831-2828

DATE:	April 4, 2013
TO:	Andrew Giannini
FROM:	University of Delaware IRB
STUDY TITLE:	[441751-2] Validity of FitBit Zip physical activity monitor.
SUBMISSION TYPE:	Amendment/Modification
ACTION:	APPROVED
APPROVAL DATE:	April 4, 2013
EXPIRATION DATE:	March 15, 2014
REVIEW TYPE:	Expedited Review
REVIEW CATEGORY:	Expedited review category # 4

Thank you for your submission of Amendment/Modification materials for this research study. The University of Delaware IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.

Appendix B

INFORMED CONSENT

University of Delaware
Informed Consent Form

Title of Project: Validity of the FitBit Zip physical activity monitor.

Adviser Investigator: Dr. Nancy Getchell
Student Investigator: Andrew Giannini

Other Investigators:

You are being asked to participate in a research study. This form tells you about the study including its purpose, what you will do if you decide to participate, and any risks and benefits of being in the study. Please read the information below and ask the research team questions about anything we have not made clear before you decide whether to participate. Your participation is voluntary and you can refuse to participate or withdraw at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to participate, you will be asked to sign this form and a copy will be given to you to keep for your reference.

1. PURPOSE/DESCRIPTION OF THE RESEARCH

You are being asked to participate in a research project at the University of Delaware. The purpose is to determine if the FitBit Zip physical activity monitor can validly measure physical activity levels in adults.

Previous studies have been conducted to measure validity and reliability of laboratory-grade physical activity monitors in adults. This study will use similar procedures to assess the validity of a personal physical activity monitor that is more commercially available to the general public.

You have been chosen for this study because you are between the ages of 18 and 40 years old. You will be one of at least 20 adult participants in this research study. There will also be 20 child participants in this research study.

The total length of your participation will not exceed 60 minutes. Full participation will require one visit to the Human Performance Laboratory at the University of Delaware. Your height, weight, and age will be recorded through the use of a scale and tape measure.

You will first be asked to watch a video clip describing the FitBit Zip and then you will be asked to walk on a treadmill at three different speeds while wearing the FitBit Zip physical activity monitor and the ActiCal accelerometer on a neoprene belt. You will walk for 5 minutes in each speed interval for a total length of 15 minutes of treadmill activity. The treadmill speed intervals will be set at 1.5mph (slow), 3.0mph (medium), and 5.0mph (fast). A videocamera will record your feet only to count the total number of steps taken.

2. CONDITIONS OF SUBJECT PARTICIPATION

Information about you obtained from this study will be kept strictly confidential. You will not be individually identified, except by a subject number that is known only to the researchers. Video record will only show the participant's feet. All data obtained during this study will be stored as paper files or in digital form and will be kept in a locked cabinet for at least three years. After three years, your data files will be archived within our lab but all personal information such as name and contact information will be destroyed. Your name or identity will not be revealed in any subsequent publication or presentation of results in any journal and/or conference. In the event you suffer from a physical injury as a direct result of these research procedures, you will receive first aid. If you should require additional medical treatment, you will be responsible for the cost. You are free to withdraw from the study at any time without penalty.

3. RISKS AND BENEFITS

POSSIBLE RISKS AND DISCOMFORTS: You may feel a little tired after completing the treadmill protocol. There is a minimal risk that you could trip/fall while utilizing the treadmill

POTENTIAL BENEFITS: There is no direct benefit to you from this research. Given the purpose of this research, manufacturers may be able to build more accurate physical activity monitors available for personal use.

4. FINANCIAL CONSIDERATIONS

You will not receive any financial reward for participating in this study.

5. CONTACTS

If you have any questions about this research study, its procedures, or risks and benefits, you can contact either the adviser investigator, Dr. Nancy Getchell at (302) 831-6682 or the student investigator, Andrew Giannini at (610) 505-9219. You can also ask the research assistants any questions that you may have.

6. SUBJECT ASSURANCES

Your signature below indicates you have read the informed consent document. The purpose, procedures, and risks/benefits of this study have been explained to you. You knowingly assume the risks involved with regard to yourself, and understand that you may withdraw your consent to participate in this study at any time without penalty. Your signature also indicates you have received a copy of this consent document.

7. WHO SHOULD YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?
If you have any questions about this study, please contact the Principal Investigator, Andrew Giannini at (610)505-9219 or giannini@udel.edu.
If you have any questions or concerns about your rights as a research participant, you may contact the University of Delaware Institutional Review Board at 302-831-2137.

8. CONSENT SIGNATURES

Your signature below indicates that you have read and understand the above information, that you have agreed to participate in the study, and that a copy of this form has been given to you.

Participant’s Name (printed):____

Participant’s Signature:____

I certify that I have explained the purpose and procedures of this study to the participant. I have explained the potential risks and benefits of this study and have answered any questions or concerns that were raised. I have witnessed the above signature and I have provided the participant with a copy of this consent form.

Principal Investigator’s Signature:______________________________ Date:_______

Appendix C

CHILD ASSENT

INFORMED ASSENT FOR MINOR PARTICIPANTS

UNIVERSITY OF DELAWARE

(To be read to minor)

We are asking you to participate in a study to determine if a physical activity monitor works the way it is supposed to work. Andrew Giannini and Dr. Nancy Getchell are in charge of the study. We are looking at the numbers and values the physical activity monitor records. We want to see if the physical activity monitor can record the intensity with which you walk on a treadmill. We hope to use the information from this study to help make physical activity monitors better. Your parents or legal guardians know about this study and have agreed to let you participate, but the final decision is yours.

<u>What types of movements will you do?</u>

If you decide to take part in this study, you will watch a short video clip and you will walk on a treadmill at three different speeds. You will walk for a total of 5 minutes at each speed for a total of 15 minutes of walking. The three speeds are slow, medium, and fast. We will give you breaks in between your movements in case you get tired.

<u>Are there good things and bad things about the study?</u>

We hope to find some good things from this study. What we find in this study may be used to make more accurate physical activity monitors. But we don't know for sure that these good things will help you or not. Treadmill walking is an activity that many children have tried before. You might feel a little tired after walking, especially if you do not typically do this activity.

Will you have to do everything you are asked to do?

We would like it if you could do all of the walking we ask you to do. However, you are allowed to stop at any time if you don't want to finish.

Who will know that you are in the study?

When we are done with the study, we will write a paper about what we learned. The things you do and any information we write about you will not have your name with it, so no one will know that you were in this study unless you tell them. The researchers will not let anyone other than themselves see any information about you. We will not share any of this information with your teachers, principal, and parents.

Do you have to be in the study?

No one will get angry or upset with you if you don't want to be in this study. Just tell us if you don't want to be in the study. And remember, if you decide to be in the study but later you change your mind, then you can tell us you do not want to be in the study anymore.

Do you have any questions?

You can ask questions at any time. You can ask now or you can ask later. You can talk to us or you can talk to someone else at any time during the study. Here are the telephone numbers to reach us: Andrew Giannini at (610) 505-9219 or Dr. Nancy Getchell at (302) 831-6682.

You or your parents will not get any money for your participation in this study.

IF YOU AGREE TO BE IN THIS STUDY, SIGN YOUR NAME ON THE LINE BELOW.

______________________________ ________________________

(Signature of child) (Print Child's name)

______________________________ ____________

(Signature of the Witness) (Date)

______________________________ ____________

(Signature of the Investigator) (Date)

Appendix D

PARENTAL INFORMED CONSENT

University of Delaware
Parental Informed Consent Form

Title of Project: Validity of the FitBit Zip physical activity monitor.

Adviser Investigator: Dr. Nancy Getchell
Student Investigator: Andrew Giannini

Other Investigators:

You are being asked to participate in a research study. This form tells you about the study including its purpose, what you will do if you decide to participate, and any risks and benefits of being in the study. Please read the information below and ask the research team questions about anything we have not made clear before you decide whether to participate. Your participation is voluntary and you can refuse to participate or withdraw at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to participate, you will be asked to sign this form and a copy will be given to you to keep for your reference

1. PURPOSE/DESCRIPTION OF THE RESEARCH

Your child is being asked to participate in a research project at the University of Delaware. The purpose is to determine if the FitBit Zip physical activity monitor can validly measure physical activity levels in children.

Previous studies have been conducted to measure validity and reliability of laboratory-grade physical activity monitors in children. This study will use similar procedures to assess the validity of personal physical activity monitor that is more commercially available to the general public.

Your child has been chosen for this study because he/she is between the ages of 8 and 14 years old. Your child will be one of at least 20 child participants in this research study. There will also be 20 adult participants in this research study.

The total length of your child's participation will not exceed 60 minutes. Full participation will require one visit to the Human Performance Laboratory at the University of Delaware. Your child's height, weight, and age will be recorded through the use of a scale and tape measure.

Your child will first be asked to watch a video clip describing the FitBit Zip and then asked to walk on a treadmill at three different speeds while wearing the FitBit Zip physical activity monitor and the ActiCal accelerometer on a neoprene belt. Your child will walk for 5 minutes in each speed interval for a total length of 15 minutes of treadmill activity. The treadmill speed intervals will be set at 1.2mph (slow), 2.5mph (medium), and 4.5mph (fast). A videocamera will record only the area of your child's feet to count the total number of steps taken.

2. CONDITIONS OF SUBJECT PARTICIPATION

Information about your child obtained from this study will be kept strictly confidential. Your child will not be individually identified, except by a subject number that is known only to the researchers. Video records will only be taken at an angle that only shows the child's feet. All data obtained during this study will be stored as paper files or in digital form and will be kept in a locked cabinet for at least three years. After three years, your child's data files will be archived within our lab but all personal information such as child's name and contact information will be destroyed. Your child's name or identity will not be revealed in any subsequent publication or presentation of results in any journal and/or conference. In the event your child suffers from a physical injury as a direct result of these research procedures, your child will receive first aid. If your child should require additional medical treatment, you will be responsible for the cost. You are free to withdraw your child from the study at any time without penalty.

3. RISKS AND BENEFITS

POSSIBLE RISKS AND DISCOMFORTS: Your child may feel a little tired after completing the treadmill protocol. There is a minimal risk that your child could trip/fall while utilizing the treadmill

POTENTIAL BENEFITS: There is no direct benefit to your child from this research. Given the purpose of this research, manufacturers may be able to build more accurate physical activity monitors available for personal use.

4. FINANCIAL CONSIDERATIONS

Your family will not receive any financial reward for participating in this study.

5. CONTACTS

If you have any questions about this research study, its procedures, or risks and benefits, you can contact either the adviser investigator, Dr. Nancy Getchell at (302) 831-6682 or the student investigator, Andrew Giannini at (610) 505-9219. You can also ask the research assistants any questions that you may have.

6. SUBJECT ASSURANCES

Your signature below indicates you have read the parental informed consent document. The purpose, procedures, and risks/benefits of this study have been explained to you. You knowingly assume the risks involved with regard to your child, and understand that you may withdraw your consent for your child to participate in this study at any time without penalty. Your signature also indicates you have received a copy of this consent document.

7. WHO SHOULD YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?
If you have any questions about this study, please contact the Principal Investigator, Andrew Giannini at (610)505-9219 or giannini@udel.edu.
If you have any questions or concerns about your rights as a research participant, you may contact the University of Delaware Institutional Review Board at 302-831-2137.

8. CONSENT SIGNATURES

Your signature below indicates that you have read and understand the above information, that you have discussed the study with your child, that you have agreed to let your child participate in the study, and that a copy of this form have been given to you.

Parent/Guardian's Name (printed):_______________________________________

Parent/Guardian's Signature:____
I certify that I have explained the purpose and procedures of this study to the parent/guardian of the potential child participant. I have explained the potential risks and benefits of this study and have answered any questions or concerns which were raised. I have witnessed the above signature and I have provided the parent with a copy of this consent form.

Principal Investigator's Signature:_____________________________
Date:___________