

**VALIDATION OF THE BODYMEDIA SENSEWEAR PRO ARMAND® TO ESTIMATE
ENERGY EXPENDITURE IN SEVERELY OVERWEIGHT CHILDREN DURING
VARIOUS MODES OF ACTIVITY**

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Developing valid and reliable portable devices to assess energy expenditure (EE) has been and still remains a challenge to researchers. The SenseWear Pro Armband® (SWA) is a device that utilizes a combination of measurement techniques in an attempt to increase the accuracy of predicting EE. Current research has produced conflicting results when validating this device in children and no research has focused on the validity of this device in severely overweight children. **PURPOSE:** The primary aim of this investigation was to examine the validity of the SWA to assess EE during various modes of activity in severely overweight children.

METHODS: Twenty severely overweight children (10 boys, 10 girls) between 9-12 years of age participated in validation trials for three modes of exercise that included treadmill walking, a walk video, and Dance, Dance Revolution (DDR). During each exercise protocol, EE was measured simultaneously by indirect calorimetry (IC) and the SWA. **RESULTS:** There were significant differences between IC (70.84 ± 29.65) and the armband (96.18 ± 36.33) for assessing EE for the walk video ($p=0.002$). There were trends towards significance between EE from IC (78.26 ± 29.65) and the SWA (88.99 ± 31.18) for treadmill walking ($p=0.097$) and between IC (62.30 ± 15.53) and the armband (75.60 ± 31.67) for DDR ($p=0.054$). For all exercise modes, EE

estimated from the armband was greater than EE measured by IC. There was a significant correlation between these two devices when assessing EE during treadmill walking ($r=0.591$, $p=0.006$), the walk video ($r=0.849$, $p\leq 0.001$), and DDR ($r=0.654$, $p=0.008$). Results also demonstrated that there was no significant effect of gender on the validity of the armband to estimate EE compared to IC. **CONCLUSION:** The SWA overestimated EE for all modes of activity. The accuracy of the armband does not appear to vary by gender for these activities in severely overweight children. These findings demonstrate the need to increase the accuracy of this device in estimating EE in severely overweight children during these modes of activity. Future studies should be conducted to confirm the findings of this investigation and to expand on the research related to refinement of the SWA technology and algorithms to estimate EE in severely overweight children.

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CHAPTER 1

INTRODUCTION AND RATIONAL

1.1 INTRODUCTION

Childhood overweight and obesity is increasing at alarming rates, which is partly due to a decline in physical activity during childhood, as well as an increase in participation of sedentary activities such as video games, watching television, and the internet (2). The percentage of children aged 6 to 11 who are considered overweight has more than doubled in the last two decades, increasing from 7% in 1980 to 18.8% in 2004 (49), with some estimates indicating that one in five children in the United States is obese (10). Overweight and obesity during childhood leads to an increased risk for many adverse health outcomes including hypertension, high cholesterol, type II diabetes, bone and joint problems, asthma, sleep apnea, and psychological consequences (14). In addition, approximately 60% of overweight children have at least one risk factor for heart disease, such as high cholesterol or high blood pressure. Overweight children are more likely than normal weight children to become overweight or obese as an adult, and 50% of obese children will remain obese into adulthood (62). Therefore, childhood overweight and obesity has become a major public health concern.

The increasing rates of youth who are overweight during childhood suggest that children are experiencing a chronic positive energy balance in which energy intake exceeds energy expenditure (49). Physical activity accounts for 20% to 30% of total energy expenditure (35). Unfortunately, total energy expenditure has declined in children, which is a direct result of a

decline in physical activity among children, and an accompanying increase in sedentary activities (2). Children spend up to five or six hours per day participating in some form of sedentary activity (22), with approximately 25% of children in the United States spending four or more hours a day watching television. Additionally, children who watch more than three hours of television per day are 50% more likely to be obese as compared to children who watch fewer than two hours per day (62,66). Engaging in sedentary activity leads to a reduction in time spent participating in physical activity, thereby leading to a reduction in total daily energy expenditure (14). Thus, to better understand the contribution of physical activity to total daily energy expenditure in children and adolescents, and to understand how this contributes to overweight and related chronic disease risk factors, it is important to implement techniques to accurately assess energy expenditure.

Assessment tools including self-reporting, accelerometers, pedometers, portable metabolic systems, indirect calorimetry, and doubly-labeled water are currently available to measure energy expenditure and physical activity in children (58). However, each of these techniques has limitations that can affect the validity, reliability, or clinical utility of the energy expenditure data obtained. Therefore, there is a need for a portable device that accurately assesses energy expenditure in children. This may aid in clarifying the role energy expenditure has in energy balance, which may further explain the relationship between physical activity and health outcomes, as well as to facilitate the development of general exercise recommendations for children. The SenseWear Pro Armband[®] (BodyMedia, Inc., Pittsburgh, PA) has been shown to provide a valid measure of energy expenditure during periods of physical activity in adults (32). However, studies conducted in children have provided mixed results (4,13). Therefore,

this study further examined the accuracy and validity of the SenseWear Pro Armband[®] to assess energy expenditure during physical activity in severely overweight children.

1.2 RATIONALE

The gold standards for measuring energy expenditure include doubly labeled water and indirect calorimetry. However these methods are expensive, require properly trained technicians, and have limitations that may prevent a thorough understanding of energy expenditure and physical activity in free-living conditions (58). As a result, additional physical activity tools have been developed to assess energy expenditure in free-living conditions, which include self-report methods (physical activity diaries, interviews, surveys, and questionnaires), physiological data (heart rate and body temperature), and motion sensor devices (pedometers and accelerometers). Unfortunately, many of these techniques also have limitation that affect their ability to accurately measure and quantify energy expenditure in children.

Self-report techniques, which include questionnaires, interviews, and diaries, are convenient ways to assess physical activity (52). However, self-report relies on the ability of children to accurately recall their activity (6). Due to the sporadic nature of children's physical activity, as well as the lower cognitive function of children as compared to adults, it is often difficult for children to accurately report the intensity, frequency, and duration of their activity. Research demonstrates that children have difficulty with recall (5), are not conscious of time (5,33), and do not exercise in consistent bouts (7,37,48), all of which make it difficult for self-report to accurately assess physical activity and energy expenditure in children.

Energy expenditure can be estimated with the use of heart rate monitoring, which primarily relies on the linear relationship between heart rate and oxygen consumption (6).

Unfortunately, this method of estimating energy expenditure is not without limitations. Heart rate provides accurate assessments of energy expenditure for moderate intensity activity; however, the linear relationship between heart rate and oxygen consumption provides a less accurate assessment of energy expenditure during low or high intensity activity (22,53). Heart rate can also be affected by factors other than body movement such as environmental and psychological stressors, caffeine, and certain medications (34,42), which can result in an increase in heart rate without a significant increase in oxygen consumption. Additionally, the varying fitness level of children may limit the ability to estimate energy expenditure from heart rate (8), with more fit children having a lower heart rate for a given energy expenditure compared to their less fit counterparts (18).

Accelerometry is a method of predicting energy expenditure based on the ability to detect body motion and measure accelerations produced by a body segment/limb as it moves through space (41). Children's physical activity is often characterized by intermittent activity patterns, alternating between vigorous activity and rest periods, making it difficult to assess energy expenditure (64). However, accelerometers, unlike other methods, are capable of accurately detecting and predicting the energy cost of physical activity under conditions of both low and high activity in children (69). Unfortunately, accelerometry is not without limitations in a youth population. Single plane (uniaxial) accelerometry is limited in its ability to detect a wide variety of movements typical of children during normal play (58). However, three-dimensional accelerometers are able to provide a more accurate assessment of youth physical activity, strongly predicting energy expenditure for a variety of free-play activities. The accuracy of accelerometry is highly dependent upon the type of activity performed. Accelerometers inaccurately predict energy cost of certain activities such as cycling, swimming, rowing, upper

body exercise, stair-climbing, lifting, carrying a heavy load, and walking/running on a graded surface (64). This may limit the utility of accelerometers for estimating energy expenditure in certain applications.

In an attempt to increase the accuracy of predicting energy expenditure, the SenseWear Pro Armband[®] utilizes a combination of measurement systems; accelerometry, galvanic skin response, near-body ambient temperature, skin temperature, and heat flux. The literature focuses mostly on the accuracy of the SenseWear Pro Armband[®] in an adult population. Although the majority of these published studies have found the SenseWear Pro Armband[®] to accurately measure energy expenditure, this device may overestimate or underestimate the energy cost for certain activities (26,32,36). The accuracy of the armband may depend on algorithms that are population or activity specific, thereby creating possible measurement error. The algorithm for the SenseWear Pro Armband[®] was designed for individuals between the ages of 18-75; however, individuals younger than 18 have different physiology and may require different algorithms designed specifically for them (3).

Although no peer reviewed studies have been published on the accuracy of the SenseWear Pro Armband[®] in younger subjects, data are available from published abstracts (4,13). In adolescents, Crawford, et al. (13) found that the SenseWear Pro Armband[®] significantly underestimated energy expenditure for activities such as cycle ergometry and treadmill walking/jogging. However, Andreacci and colleagues (4) found that the SenseWear Pro Armband[®] was able to provide accurate assessments of energy expenditure during intermittent sub-maximal treadmill exercise in children. These initial studies provide conflicting results, demonstrating the need to further investigate the validation of the SenseWear Pro Armband[®] in younger subjects.

1.3 SPECIFIC AIMS

The primary specific aim of this study was:

1. To examine the validity of the SenseWear Pro Armband[®] to assess energy expenditure during various modes of physical activity in severely overweight children.

The secondary specific aim of this study was:

1. To examine the accuracy of the SenseWear Pro Armband[®] to assess energy expenditure based upon gender in severely overweight children.

1.4 RESEARCH HYPOTHESIS

The following primary hypothesis was examined:

1. Energy expenditure measured by the SenseWear Pro Armband[®] during various modes of physical activity will not be significantly different from energy expenditure measured by the criterion measure of open-circuit indirect calorimetry in severely overweight children.

The following secondary hypothesis was examined:

1. There will be no significant difference between energy expenditure measured by the SenseWear Pro Armband[®] and the criterion measure of open-circuit indirect calorimetry based upon gender in severely overweight children.

1.5 SIGNIFICANCE

Obesity has reached epidemic proportions in the United States, especially in our youth. Being overweight during childhood places children at an increased risk of developing many chronic diseases, which could lead to premature death (14,38,59). These epidemic rates suggest that children are experiencing a chronic positive energy balance, which is due in part to an

increase in sedentary behaviors and an accompanying decrease in physical activity during childhood (49). A portable monitor that accurately assesses energy expenditure in children could aid researchers and clinicians in clarifying the contribution of energy expenditure to energy balance, as well as in the development of appropriate physical activity guidelines, recommendations, and prescriptions for children to optimize growth and overall health. Furthermore, accurately assessing energy expenditure can also clarify the role of energy expenditure in weight loss and weight maintenance in severely overweight children. This study focused on validating the SenseWear Pro Armband[®] to measure energy expenditure during periods of physical activity in severely overweight children.

CHAPTER 2

REVIEW OF LITERATURE

2.1 INTRODUCTION

The accurate assessment of physical activity energy expenditure has been and still remains a challenge to researchers. The criterion measures for assessing physical activity in adults and children include indirect calorimetry and doubly labeled water; however the expensive nature of these techniques, as well as the expertise needed to conduct such measurements makes it impractical for the general population. As a result, researchers have relied on less precise measures including self-report methods (physical activity diaries, interviews, surveys, and questionnaires), physiological data (heart rate), and motion sensor devices (pedometers, accelerometers). The purpose of this study was to examine the accuracy and validity of the SenseWear Pro Armband[®] in measuring energy expenditure during physical activity in severely overweight children. The following literature review will focus on some of the techniques currently available to assess physical activity energy expenditure and will demonstrate the need for a portable device that will provide a valid estimate of energy expenditure in children.

2.2 CRITERION METHODS OF ASSESSING ENERGY EXPENDITURE

Open-circuit indirect calorimetry and doubly labeled water are considered “gold standards” for the assessment of physical activity in adults and children (63). These techniques are very accurate methods of assessing daily energy expenditure, both in laboratory (44), as well as free-

living conditions (56). Unfortunately, both require sophisticated instrumentation and are fairly expensive, making them impractical for widespread applications for the general population (63).

2.2.1 Doubly Labeled Water

Doubly labeled water (DLW) is a technique that estimates carbon dioxide production using isotope dilution to determine total energy expenditure (TEE) over longer periods of time (1-3 weeks), which provides a good estimate of average daily TEE (19). More specifically, this technique involves an orally administered dose of a radio-labeled isotope ($^2\text{H}_2^{18}\text{O}$) (58). Within a few hours following consumption, these isotopes mix with the hydrogen and oxygen already present in body water. Urine samples are measured to determine the elimination rates of each isotope. The $^2\text{H}_2$ is eliminated as water, while the ^{18}O is eliminated as water and CO_2 . The difference between the two isotope elimination rates is directly proportional to CO_2 production, which is used to determine energy expenditure. The DLW technique has been validated against indirect calorimetry and is considered a “gold standard” for determining energy expenditure in free-living conditions (45). Validations of DLW against respiratory gas exchange have shown this method to be accurate within 2-8%, depending on the isotope dose and the length of the elimination period (55,56,57).

Schoeller and Webb (57) compared the DLW method to a respiratory gas exchange procedure. Five subjects lived in a laboratory/apartment for five days. During this time, respiratory gas exchange was measured using a facemask and urine samples were collected twice a day. All subjects were given a specific daily amount of food, which equaled their estimated sedentary energy expenditure based on fat-free mass and dietary need based on exercise. Subjects exercised on either a cycle ergometer or treadmill two or three times a day at specific workloads. Energy expenditure measured by DLW and the respiratory gas exchange procedure

differed by only 6% and the coefficient of variance between methods was 8%. Researchers concluded that this difference between the two methods was not statistically significant.

Seale et al. (55) set out to determine the precision and accuracy of DLW in comparison to a room-sized respiratory calorimeter. Nine subjects spent 5-7 days in this calorimeter and urine samples were collected twice a day. Results from the calorimeter were compared to those obtained from the DLW method for daily water production, CO₂, and energy expenditure. There was no significant difference between the two methods for determining energy expenditure. This was true for all three different DLW methods utilized in this study; 1) regression 1 – analysis of isotope concentration data from A.M. urine, 2) regression 2 – analysis of concentration data from A.M. and P.M. urine, 3) two-point method – analysis of initial day 1 A.M. urine and final day 8 A.M. urine isotope concentrations. The percent difference for energy expenditure between calorimetry and each DLW method (regression 1, regression 2, and regression 3) was 1.55 ± 2.57 , 0.98 ± 8.19 , and 1.59 ± 4.50 (mean \pm SD), respectively.

Despite the accuracy and precision of DLW, this technique has several major limitations. DLW requires expensive isotopes, with a given dose ranging from \$800-\$1500 per subject (39). Although DLW provides an accurate representation of daily energy expenditure in free-living environments, it does not provide information regarding patterns of physical activity (58). More specifically, since it is necessary to collect urine for a period of 7–14 days, DLW can only provide data related to average daily TEE, rather than more acute bouts of physical activity. This limits the use of this technique to determine how patterns of activity or acute bouts of activity contribute to TEE and health-related outcomes.

2.2.2 Indirect Calorimetry

Open-circuit indirect calorimetry is commonly used as a criterion method when assessing energy expenditure in a laboratory setting and is considered an accurate and valid measure of short term energy expenditure. This technique measures heat production based on respiratory gas exchange by analyzing oxygen consumption (VO_2) and carbon dioxide (CO_2) production by the body (23). The accuracy and precision of indirect calorimetry in measuring energy expenditure has made it a criterion method by which other techniques are validated.

Although indirect calorimetry is accurate in determining energy expenditure, there are several limitations that affect its utility to assess energy expenditure under free-living conditions, and restricts testing to a controlled laboratory setting. Respiratory metabolic systems are required to assess energy expenditure using the indirect calorimetry technique. The cost of this equipment ranges from approximately \$20,000 to \$100,000 per system, and requires well-trained personnel. The use of a respiratory metabolic system requires that either a mouthpiece or a face mask be used to collect breath samples, and these devices are often times uncomfortable for children (54). Moreover, when used with children, often times the mouthpiece or mask does not fit properly, which results in errors in measurements due to expired air escaping from the system. Thus, these limitations affect the utility of this technique to assess energy expenditure in free-living children.

2.3 PORTABLE SYSTEMS TO MEASURE ENERGY EXPENDITURE

2.3.1 Heart Rate Methods

Heart rate monitoring relies on the linear relationship between heart rate and oxygen consumption as a means of predicting energy expenditure (54). This technique provides accurate assessments of energy expenditure for moderate intensity activity (between 110-150 bpm);

however, the linear relationship between heart rate and oxygen consumption provides a less accurate assessment of energy expenditure during low (<110 bpm) or high (> 150 bpm) intensity activity (22,51,53).

Eston, et al. (22) examined the validity of heart rate monitoring during typical children's activity including crayoning, catching, and hopscotch, as well as walking at 4 and 6 km/h and running at 8 and 10 km/h. Heart rate monitoring was compared to oxygen uptake measured by on-line gas analysis (sVO₂). Averaged across all activities, heart rate was strongly correlated with sVO₂ (r = 0.80). When analyzing only treadmill walking and running, energy expenditure determined by heart rate monitoring was slightly less correlated (r = 0.78) with sVO₂, with a correlation of r = 0.85 between heart rate and sVO₂ during periods of un-regulated play activities. Moreover, the heart rate method had the greatest absolute error when predicting sVO₂ during crayoning. This demonstrates the lack of validity for heart rate to accurately measure energy expenditure during levels of low intensity physical activity.

In an attempt to examine the validity of heart rate to predict energy expenditure during different intensities of activity in children, Welk et al. (69) compared this technique to direct observation using the Children's Activity Record System (CARS). CARS is a tool used to classify levels of physical activity based upon five different activity categories. Direct observation was applied during a 40 minute classroom time period (minimal physical activity), as well as during a 30 minute physical education (PE) class (intermittent bouts of moderate to vigorous physical activity). Heart rate was also obtained during these activities. There was a strong correlation between heart rate and direct observation during periods of physical activity (r = 0.79), however the magnitude of the correlation during classroom activities was much lower (r

= 0.49). Therefore, heart rate may be a valid measure of activity during increased activity, but not during times when physical activity is limited, such as during classroom activity.

There are a number of factors that can impact the accuracy of the heart rate method to estimate energy expenditure in children. For example, heart rate can be influenced by factors other than body movement such as environmental and psychological stressors, caffeine, and certain medications (34,42). These extraneous factors can result in an increase in heart rate without a significant increase in oxygen consumption. Additionally, the varying fitness level of children may limit the ability to estimate energy expenditure from heart rate (8), with more fit children having a lower heart rate for a given energy expenditure compared to their less fit counterparts (18). Heart rate response may also lag behind changes in physical movement, and this can be problematic when assessing energy expenditure and physical activity in children (25). Children typically engage in activity characterized by rapid transitions between rest and high intensity activity. Due to the lag of heart rate, these quick transitions in movement patterns may not be captured by heart rate monitoring, leading to inaccurate predictions of energy expenditure. These limitations have led researchers to question the validity of heart rate to accurately predict energy expenditure.

Flex Heart Rate Method: The method often utilized to obtain the best indicator of energy expenditure is the FLEX heart rate method (FLEX HR) (20,41). The FLEX HR method involves simultaneous monitoring heart rate and oxygen consumption for each individual while lying down, sitting, standing, and performing various intensities of physical activity. This information is used to develop individual heart rate/oxygen consumption calibration curves by averaging the highest heart rate from resting and sedentary activity and the lowest heart rate from light exercise. FLEX HR is used as a reference point to determine how energy expenditure will

be calculated. If a subject's heart rate during an experimental trial is below the FLEX HR, resting metabolic rate is used to determine energy expenditure. However, if a subject's heart rate is above the FLEX HR then the subject's individual heart rate/oxygen consumption calibration curve is utilized to predict energy expenditure.

Livingstone and colleagues (41) examined the accuracy of the FLEX HR method as a measure of total energy expenditure in free-living children compared to DLW. Total energy expenditure was measured by DLW for 10-15 days and heart rate was monitored for three 24 hour periods during this isotope measurement period. Individual errors for estimates of total energy expenditure from FLEX HR ranged from -16.7% to $+18.8\%$; however, the mean estimate for the group was within 10% of total energy expenditure measured by DLW. In children, the FLEX HR method may be a more appropriate technique for estimating total energy expenditure for a group of children than estimating each child individually.

Emons, et al. (41) analyzed the accuracy of the FLEX HR method to predict energy expenditures in boys and girls (mean age of 9.3 and 8.1 years, respectively) as compared to indirect calorimetry and DLW. Energy expenditure was measured during a 24 hour stay in an indirect calorimeter, as well as for a 2-week period of free-living. Estimates of energy expenditure were obtained from individual calibration curves determined by heart rate and oxygen consumption measured in a calorimeter during sleep, standing, and walking on a treadmill. Energy expenditure was estimated by the FLEX HR method during the stay in the calorimeter and on a normal school day. FLEX HR significantly overestimated energy expenditure by 10.4% and 12.3% when compared to indirect calorimetry and DLW, respectively. Furthermore, FLEX HR led to greater overestimations of energy expenditure during low intensity activity as compared to high intensity activity. This limits the ability to use heart rate as

a measure to accurately predict energy expenditure in children since children typically engage in activity often characterized by intermittent low and high intensity.

2.3.2 Accelerometers

Accelerometers are electronic devices that are able to detect acceleration produced by a body segment/limb as it moves through space. Electric transducers and microprocessors detect this movement and convert this acceleration into digital signals that are used to predict energy expenditure. This technique is based on the theoretical concept that acceleration is directly proportional to muscular force and, therefore, energy expenditure (25). There are numerous types of accelerometers varying in size, price, and capabilities; however these devices can be classified as uni-axial or tri-axial. Uni-axial accelerometers only record movement in a single, vertical plane, whereas tri-axial accelerometers are able to detect movement in three planes of motion; mediolateral, anteroposterior, and vertical.

Uniaxial Accelerometers: The Caltrac (Muscle Dynamics Fitness Network, Torrence, GA) and Computer Science and Applications Actigraph (CSA; Shalimar, FL) are uniaxial accelerometers used in physical activity research (67). The validity and accuracy of these two monitors in children has been conducted in controlled laboratory settings, as well as in free-living conditions. Trost et al. (65) examined the validity of the CSA activity monitor during treadmill walking at various speeds (3, 4, and 6 mph) in children 10 to 14 years of age. Mean energy expenditure predicted by the CSA ($6.17 \pm 2.36 \text{ kcal}\cdot\text{min}^{-1}$) was not significantly different from energy expenditure measured by indirect calorimetry ($6.16 \pm 2.63 \text{ kcal}\cdot\text{min}^{-1}$), averaged across all treadmill speeds ($p < 0.01$). The mean absolute difference between energy expenditure predicted by the CSA and energy expenditure measured by indirect calorimetry was 0.47, 0.60,

and 0.81 kcal·min⁻¹ for 3, 4, and 6 mph, respectively. Mean energy expenditure predicted by the CSA was strongly correlated to the mean energy expenditure determined by indirect calorimetry ($r = 0.93$, $p < 0.001$). Correlations between predicted and actual energy expenditure measured at each speed were statistically significant (0.85, 0.62, and 0.81 for 3, 4, and 6 mph, respectively; $p < 0.01$). Results demonstrated the CSA to be a valid and reliable tool for predicting energy expenditure during treadmill walking and running in children.

Similarly, Maliszewski and colleagues (43) examined the validity of the Caltrac to predict energy expenditure during various treadmill walking speeds ranging from 3.3 to 6.7 km·hr⁻¹. In children, there was no significant difference between measured oxygen consumption and energy expenditure predicted by the Caltrac during these speeds. This research supports the validity of the Caltrac to accurately quantify treadmill walking and running in children.

Many of the accelerometer validation studies in children have focused on treadmill walking/running and current equations to predict energy expenditure are based upon treadmill exercise in a controlled laboratory setting. Therefore, it is important to determine the accuracy of these devices during other forms of physical activity in children. Eisenmann, et al. (18) conducted an investigation to examine the validity of the prediction equations published for the Caltrac and CSA activity monitors to estimate energy expenditure in children during activities of daily living (basketball, sweeping, and bowling). Averaged across all activities, moderate to strong correlations were found between energy expenditure measured using indirect calorimetry and estimated from the Caltrac ($r = 0.82$) and the CSA ($r = 0.78$). However, the prediction equations used for both devices significantly underestimated energy expenditure as compared to indirect calorimetry for all activities ($p < 0.05$). It was concluded that treadmill-derived prediction equations for these devices may not be applicable to lifestyle activities of children.

In a study of young girls comparing energy expenditure derived from the Caltrac accelerometer and 24-hour whole room indirect calorimetry, Bray and colleagues (8) reported significant correlations for total energy expenditure ($r = 0.80$), daily sedentary energy expenditure ($r = 0.84$), and walking energy expenditure ($r = 0.85$). Despite these observed correlations, the Caltrac significantly underestimated total energy expenditure by $13.3 \pm 8.6\%$, daily sedentary energy expenditure by $6.8 \pm 7.3\%$, and walking energy expenditure by $30.4 \pm 8.5\%$. Johnson and colleagues (34) also reported that the Caltrac accelerometer significantly overestimated daily energy expenditure in comparison to DLW (956 kcal/d vs. 469 kcal/d, respectively) ($p < 0.001$). These results demonstrate the limitations of uniaxial accelerometers for predicting energy expenditure across a wide spectrum of physical activities. This may be a result of uniaxial accelerometer's ability to detect movement in a single plane rather than multiple planes, which may be necessary to accurately predict energy expenditure during activities typical of children in free-living conditions.

Tri-axial Accelerometers: Tri-axial accelerometers were developed to assess body acceleration in multiple planes of space, with the assumption that recording motion in more than one plane would increase the validity and accuracy of predicting energy expenditure (64). This was thought to be especially important for assessing sporadic physical activity typical of children during normal play. The TriTrac-R3D (Hemokinetics, Inc. Madison, WI) is a triaxial accelerometer that is worn on the waist, with energy expenditure predicted from accelerometry counts and other parameters including body weight, age, and gender (39).

Welk and Corbin (69) examined the validity of the TriTrac-R3D to estimate energy expenditure during physical activity in children by comparing this device to heart rate monitoring and direct observation using the Children's Activity Record System (CARS). Heart

rate monitoring and direct observation were applied during a 40 minute classroom time period (minimal physical activity), as well as during a 30 minute physical education class (intermittent bouts of moderate to vigorous physical activity). Correlations between the TriTrac-R3D and heart rate were $r = 0.77$ during physical education class and $r = 0.70$ during the classroom period. A similar correlation was present between heart rate monitoring and observation scores during physical education class ($r = 0.79$); however, the magnitude of the correlation during the classroom period was $r = 0.49$. These results should be interpreted with caution because they reflect correlations and not the error in absolute energy expenditure between the TriTrac-R3D and these other methods of assessing energy expenditure. Moreover, as summarized above, there are limitations when using the heart rate method for assessing energy expenditure in children.

Another study conducted by Welk and Corbin (68) examined the validity of the TriTrac-R3D to measure daily physical activity in children, with heart rate as the criterion measure. Across three days of monitoring, moderate correlations ($r = 0.58$) were reported. Each day was further analyzed based upon different time segments. Correlations between heart rate monitoring and the TriTrac were strongest during free play conditions ($r = 0.89$ during recess activity, $r = 0.83$ during after school activity), with correlations being lower during a classroom period ($r = 0.41$) and physical education class ($r = 0.69$). Ott and colleagues (50) reported correlations ranging from $r = 0.66$ to $r = 0.73$ between the TriTrac-R3D and heart rate during periods of free-play that included playing a video game, throwing and catching, walking, bench stepping, hopscotch, basketball, aerobics, and running.

Summary: Based on the results of the studies summarized above, there appears to be a significant correlation between accelerometry and criterion measures of energy expenditure during periods of physical activity in children. However, these devices significantly

underestimate absolute energy expenditure. Thus, this may limit the utility of these devices to quantify energy expenditure during periods of structured and free-living physical activity in children.

2.3.3 Combination of Heart Rate and Accelerometry

The combination of both heart rate and accelerometry into the estimate of energy expenditure may provide an opportunity to improve the estimate of energy expenditure. Strath, et al. (60) compared energy expenditure from a combined accelerometer and heart rate system to a criterion measure of energy expenditure (indirect calorimetry). A non-significant difference in energy expenditure was reported for this combined system (3.75 ± 0.86 METs) compared to indirect calorimetry (3.7 ± 0.76 METs) ($p > 0.34$). When used as separate units, the accelerometry underestimated energy expenditure by an average of 1.1 METs ($p < 0.001$); whereas heart rate significantly overestimated energy expenditure by an average of 0.4 METs ($p < 0.001$). The correlation between indirect calorimetry and the heart rate-accelerometer technique was $r = 0.81$, which was improved compared to the correlation between indirect calorimetry and heart rate ($r = 0.67$) or accelerometry ($r = 0.54$). These data indicate that the combination of heart rate and accelerometry improves the estimation of energy expenditure during selected activities as compared to either method alone. Similar results were reported in a follow-up study conducted by Strath, et al. (61), with a correlation of $r = 0.81$ ($p < 0.001$) between energy expenditure measured by indirect calorimetry and a combination system (heart rate and accelerometry). Moreover, there was no significant difference between total energy expenditure measured by indirect calorimetry (749 ± 138 MET·min⁻¹) and the combination system (748 ± 178 MET·min⁻¹).

Trueth, et al. (63) examined the accuracy of a combined heart rate and activity monitor system for estimating energy expenditure in children. The criterion of energy expenditure was a whole-room calorimeter. For the combined system, the activity monitor was a leg vibration sensor. There was no significant difference in 24 hour energy expenditure from the whole-room calorimeter and the combined heart rate and activity monitor system, with an average percent error of -0.75 ± 0.57 and a correlation coefficient of $r = 0.75$. The results demonstrated that a system which combines heart rate and activity monitoring may provide a method to accurately estimate energy expenditure in children. However, further validation research is necessary to determine the ability of this technique to estimate energy expenditure during various forms of physical activity in this population.

2.3.4 SenseWear Pro Armband[®]

The SenseWear Pro Armband[®] (BodyMedia, Inc., Pittsburgh, PA) is a portable device that incorporates multiple parameters into the estimate of energy expenditure. These parameters include a dual-axis accelerometry, heat flux, galvanic skin response, skin temperature, and a near-body ambient temperature. Data for each of these parameters, in addition to demographic characteristics (age, gender, weight, height, right or left handedness, smoker or non-smoker), are used in proprietary algorithms to estimate energy expenditure. The implementation of multiple measurements may enable the SenseWear Pro Armband[®] to overcome the limitations of other assessment devices (26), and potentially allow for the accurate assessment of energy expenditure during non-weight bearing activities such as cycling, stair stepping, resistance exercise, activities involving only upper body movement, or non-ambulatory physical activity.

Validation Studies Conducted in Adults: Fruin and Rankin (26) conducted an investigation to examine the validity of the SenseWear Pro Armband[®] to estimate energy expenditure during rest, treadmill walking, and cycling. Indirect calorimetry was used as the criterion method. During the period of rest, energy expenditure predicted by the SenseWear Pro Armband[®] ($1.3 \pm 0.1 \text{ kcal}\cdot\text{min}^{-1}$) was not significantly different from the criterion measure ($1.3 \pm 0.1 \text{ kcal}\cdot\text{min}^{-1}$). There were significant correlations between the energy estimated from the SenseWear Pro Armband[®] and the criterion measure ($r = 0.76$) ($p < 0.004$). During cycling, total energy expenditure predicted by the SenseWear Pro Armband[®] ($352.9 \pm 20.3 \text{ kcal}\cdot\text{min}^{-1}$) did not differ significantly from indirect calorimetry ($372.2 \pm 60.4 \text{ kcal}\cdot\text{min}^{-1}$) ($p > 0.28$); however the energy expenditure from these two methods were poorly correlated ($r = 0.11$) ($p > 0.77$). The SenseWear Pro Armband[®] significantly over-estimated energy expenditure by 38% when walking at $80.5 \text{ m}\cdot\text{min}^{-1}$ and by 14% when walking at $107.3 \text{ m}\cdot\text{min}^{-1}$ ($p < 0.02$). The SenseWear Pro Armband[®] significantly under-estimated energy expenditure by 22% during inclined walking ($p < 0.01$). Modest correlation coefficients were reported between energy expenditure estimated from the SenseWear Pro Armband[®] and indirect calorimetry during walking, with correlations ranging from $r = 0.47$ to $r = 0.69$ ($p < 0.04$). These results suggest that there may be some limitations to the SenseWear Pro Armband[®] for accurately estimating energy expenditure during various forms of physical activity in adults.

King et al. (36) conducted an investigation that compared the validity of the SenseWear Pro Armband[®] to estimate energy expenditure during treadmill walking and running. Subjects performed a treadmill walking/running protocol that consisted of 10 minutes stages at each speed, which progressed in sequence as follows: walking at 53.6, 80.4, and $107.2 \text{ m}\cdot\text{min}^{-1}$ (2.0, 3.0, and 4mph, respectively) then running at 134.0, 160.8, 187.6, and $214.4 \text{ m}\cdot\text{min}^{-1}$ (5.0, 6.0, 7.0,

and 8.0 mph, respectively). The SenseWear Pro Armband[®] over-estimated energy expenditure by 4.34 ± 0.49 , 4.83 ± 0.69 , 6.07 ± 0.62 , 10.97 ± 1.47 , 11.70 ± 1.49 , 12.61 ± 1.53 , and 13.44 ± 1.7 kcals for females and by 5.26 ± 0.43 , 5.99 ± 0.46 , 7.37 ± 0.51 , 13.26 ± 1.31 , 14.50 ± 1.81 , 14.63 ± 3.27 , and 16.13 ± 1.49 kcals for men at the walking and running speeds, respectively. Correlations between the SenseWear Pro Armband[®] and indirect calorimetry were 0.50, 0.76, 0.71, 0.80, 0.84, 0.73, and 0.81 at the walking and running speeds of 53.6, 80.4, 107.2, 134.0, 160.8, 187.6, and 214 m·min⁻¹, respectively. These results again demonstrated the potential limitations of the SenseWear Pro Armband[®] to estimate energy expenditure.

Jakicic and colleagues (32) examined the accuracy of the SenseWear Pro Armband[®] to estimate energy expenditure during four separate modes of activity that included treadmill walking, stair stepping, cycle ergometry, and arm ergometry. During each exercise protocol, energy expenditure was simultaneously measured by indirect calorimetry, which was the criterion measure of energy expenditure. Original algorithms developed by the manufacturer revealed intraclass correlations for energy expenditure of 0.77 (CI: 0.57–0.88), 0.28 (CI: -0.05–0.56), 0.63 (CI: 0.39-0.79), and 0.74 (CI: 0.55-0.86) for treadmill walking, cycling, stair stepping, and arm ergometry, respectively. However, the SenseWear Pro Armband[®] significantly underestimated total energy expenditure during walking (14.0 ± 17.5 kcals), cycling (32.4 ± 18.8 kcals), and stair stepping (28.2 ± 20.3 kcals), while total energy expenditure for arm ergometry was significantly overestimated by 21.7 ± 8.7 kcals. When exercise-specific algorithms were applied to the data, intraclass correlations for the SenseWear Pro Armband[®] generally were 0.87 (CI: -.75-0.93), 0.89 (CI: 0.74-0.95), 0.82 (CI: 0.58-0.92), and 0.66 (CI: 0.28-0.86) for walking, cycling, stepping, and arm ergometry, respectively. Of importance, these exercise-specific algorithms resulted in no significant differences in total energy expenditure

between the SenseWear Pro Armband[®] and indirect calorimetry. These findings demonstrated the potential of the SenseWear Pro Armband[®] to estimate energy expenditure when refined algorithms were applied to the data. A small study of 40 subjects demonstrated that the SenseWear Pro Armband[®] provides an acceptable estimate of energy expenditure in adults when compared to indirect calorimetry (32), which is considered the “gold standard” for assessing energy expenditure.

Validation Studies Conducted in Children and Adolescents: There has been limited research on the validity of the SenseWear Pro Armband[®] to estimate energy expenditure in children and adolescents. Crawford and colleagues (13) examine the validity of the SenseWear Pro Armband[®] during walking and cycling exercise in adolescents (age = 13.8 ± 1.8 years). Because specific algorithms were not developed for children and adolescents, the algorithms developed for adults were applied to the data in this study. Results are presented below. Results demonstrate that when adult algorithms were applied to data for these adolescents, there was a significant underestimation in energy expenditure compared to indirect calorimetry, which served as the criterion measure of energy expenditure.

| Type of Exercise | SenseWear Pro Armband [®] (kcal/min) | Indirect Calorimetry (kcal/min) | Mean Difference (kcal/min) |
|--|---|---------------------------------|----------------------------|
| <u>Treadmill Walking</u> | | | |
| 3.0 mph, 0% grade | 4.02±0.53 | 4.24±0.88 | 0.22±0.75 |
| 4.0 mph, 0% grade | 5.11±0.65 | 5.98±1.03 | 0.86±0.84* |
| 4.0 mph, 5% grade | 5.61±0.71 | 7.74±1.52 | 2.13±1.40* |
| 4.5 mph, 5% grade | 7.45±1.37 | 10.42±1.89 | 3.00±1.56* |
| <u>Cycle Ergometry</u> | | | |
| 50 rpm, 25 Watts | 1.60±0.57 | 3.13±0.41 | 1.53±0.60* |
| 50 rpm, 50 Watts | 2.02±1.05 | 4.51±0.53 | 2.48±0.95* |
| *indicates significant difference at $p \leq 0.01$ | | | |

Andreacci and colleagues (4) examined the accuracy of the SenseWear Pro Armband[®] for estimating energy expenditure in children during treadmill exercise. Overall, estimates of energy expenditure predicted by the SenseWear Pro Armband[®] did not differ significantly (31.3 ± 6.9 kcal) from indirect calorimetry measurements (31.5 ± 11.2 kcal). The mean absolute percentage of error for estimating energy expenditure was 13.1%, 10.4%, and 9.6% for speeds of 1.7mph, 2.5mph, and 3.4mph, respectively. Results from this study contradict those found by Crawford, et al. (13) described above.

These initial studies provide conflicting results, demonstrating the need to further investigate the validation of the SenseWear Pro Armband[®] in children. This may reflect the need to develop algorithms that are modeled for children and adolescents to improve the estimate of energy expenditure from the SenseWear Pro Armband[®]. An additional limitation of these previous studies is the lack of validity data specific to overweight children. Therefore, this proposed study focused on further examining the accuracy of the SenseWear Pro Armband[®] to estimate energy expenditure in severely overweight children.

2.4 CONCLUSION

There is a need for improved methods to assess energy expenditure in free-living individuals, with this need extending to children. Criterion measures of energy expenditure (DLW, indirect calorimetry) may not be feasible for use in free-living children, and these techniques of assessing energy expenditure provide limited data regarding specific physical activity patterns. Currently available portable devices (accelerometers, heart rate monitors, pedometers, etc.) may provide an alternative technique for assessing energy expenditure in children, yet there are significant limitations to each of these techniques. A more recent technology that warrants further study is the SenseWear Pro Armband[®]. There has been limited

study of this device in children, with no published studies examining the validity of this technology to assess energy expenditure for severely overweight children. Therefore, the primary aim of this study was to examine the validity of the SenseWear Pro Armband[®] to estimate energy expenditure during periods of physical activity in severely overweight children.

CHAPTER 3

METHODOLOGY

3.1 INTRODUCTION

The Center for Disease Control and Prevention (CDC) has demonstrated that the prevalence of overweight and obesity in children aged 6 to 11 has more than doubled in the past two decades (49). Epidemic rates of overweight and obesity in today's youth suggest that children are experiencing a chronic positive energy balance, due in part to a decline in physical activity and an accompanying increase in sedentary behaviors (2). Furthermore, the sharpest decline in physical activity seems to occur between 11 to 13 years of age, with lower levels of physical activity continuing into adulthood. As a means of avoiding and potentially preventing this sharp decline in physical activity, it is necessary to intervene before children reach 11 years of age.

Accurate and reliable techniques to assess total energy expenditure in children would provide information that may affect weight management in children and adolescents (40). Unfortunately, many of the current techniques are hampered by numerous limitations, which affect their utility in clinical and/or research settings. However, the SenseWear Pro Armband[®], with the use of multiple measurement systems, may offer a potentially accurate and reliable means of measuring total energy expenditure and physical activity in children. Therefore, the purpose of this study was to examine the validity of the SenseWear Pro Armband[®] to assess energy expenditure during various modes of physical activity in severely overweight children.

3.2 SUBJECTS

3.2.1 Subject Demographics

A total of 20 healthy, severely overweight children (10 boys and 10 girls) between 9-12 years of age were recruited to participate in this study. Individuals were considered eligible if they had a body mass at or above the 97th percentile for age and sex and were free from any medical condition that would limit or prevent them from participating in physical activity. The racial, gender, and ethnic characteristics of the subject population reflected the demographics of Pittsburgh, Pennsylvania and the surrounding area (Allegheny County). No exclusion criteria were based on race, gender, or ethnic status. Individuals meeting the following criteria were considered ineligible for participation in this study.

3.2.2 Exclusion Criteria:

1. Reported orthopedic, musculoskeletal, neurological, cardiac, and/or any medical conditions that prohibited exercise.
2. Reported diabetes, hypothyroidism, or any other medical conditions that would affect energy metabolism.
3. Had systolic blood pressure ≥ 140 mmHg or diastolic blood pressure ≥ 90 mmHg.
4. Reported taking medications that may affect heart rate, blood pressure, metabolism, and/or energy expenditure responses.
5. Had a body mass below the 97th percentile for age and sex.
6. Reported an inability to perform physical activity.

3.2.3 Recruitment

Subjects were recruited using various media resources including: 1) advertisements in local newspapers, 2) targeted mailings to schools within the community, and 3) targeted mailings

and pamphlets to parents and children involved in various community programs hosted by the University of Pittsburgh (PAWS, Saturday Kids, Kinder Kinetics, etc.). The parents of potential subjects were informed to contact the University of Pittsburgh Physical Activity and Weight Management Research Center. Upon contacting the research center, a general description of the investigation was provided and, in order to determine initial eligibility, the parent/guardian was asked to participate in a brief telephone interview (See Appendix A). Only those meeting the initial inclusion criteria were able to take part in the orientation/screening procedures to determine final eligibility. The child's parent/guardian was required to complete a physical activity readiness questionnaire (PAR-Q) for their child (See Appendix B), as well as a detailed medical history questionnaire to determine if any medical conditions were present that would indicate exercise to be unsafe for their child. Written consent and assent was obtained from eligible subjects and their parent/guardian prior to further participation in the investigation (See Appendix C).

3.3 EXPERIMENTAL DESIGN

This investigation was a cross-sectional study in which subjects participated in laboratory validation trials for three separate modes of exercise; treadmill walking, an in-home walking video, and an interactive video game. A counter-balanced design was used to randomly assign the order of these experimental trials. Twenty subjects consisting of 10 girls and 10 boys between the ages of 9-12 years were recruited to participate in this validation study. This investigation consisted of an orientation/screening session and three experimental testing sessions (See Figure 3.1). These experimental testing sessions are described in detail below in Section 3.4.2, which outlines the procedures of each experimental session.

| Figure 3.1. Experimental Design and Timeline. | | | | |
|---|--|---|---|---|
| Initial Screening | Orientation and Screening Session | Experimental Trial 1 | Experimental Trial 2 | Experimental Trial 3 |
| <ul style="list-style-type: none"> • Telephone interview | <ul style="list-style-type: none"> • Explain experimental procedures • Medical history • Informed consent and assent • Screening procedures to determine final eligibility • Activity familiarization session for Trial 1 | <ul style="list-style-type: none"> • Height/weight • Trial 1 activity session • Trial 2 activity familiarization session | <ul style="list-style-type: none"> • Height/weight • Trial 2 activity session • Trial 3 activity familiarization session | <ul style="list-style-type: none"> • Height/weight • Trial 3 activity session |

3.4 EXPERIMENTAL PROCEDURES

3.4.1 Orientation/Screening Session

Prior to participation in this investigation, initially eligible subjects (as determined by the telephone interview) and their parent/guardian were required to attend an orientation/screening session, in which the purpose and overall procedures of the study were presented. Subjects and their parent/guardian were encouraged to ask any questions regarding participation in the study. If interested in participation, the parent/guardian was required to complete a PAR-Q and a detailed medical history questionnaire about their child prior to participation. In addition, a written informed consent was obtained from all subjects and a written informed assent was obtained from their parent/guardian.

Upon completion of the medical and consent/assent forms, subjects underwent a series of screening procedures to determine final eligibility. These procedures included measurements of height and weight. If all inclusion criteria were met, subjects were cleared for participation in this investigation.

After final eligibility was determined, subjects then underwent a familiarization session to orient them to the procedures and activity that would be used at the first experimental session. To orient subjects to the equipment that was utilized during the experimental sessions, subjects were fitted for the indirect calorimetry equipment and the SenseWear Pro Armband[®].

3.4.2 Experimental Sessions

Following the orientation/screening session, subjects completed three experimental trials; treadmill walking, a walking video (Leslie Sansone's *Kid's Walk*), and an interactive video game involving *Dance Dance Revolution* (DDR). Prior to participation the exercise trials, subjects were asked to abstain from food and caffeine intake for four hours, and vigorous exercise for 24 hours. All subjects were asked to wear standardized clothing (short sleeve cotton t-shirt and shorts) during each exercise session. Both indirect calorimetry and the SenseWear Pro Armband[®] were used during each session to determine energy expenditure, with indirect calorimetry used as the criterion measure (see description of these procedures below). The activity during any one of the three experimental sessions was terminated if the subject exceeded a heart rate of 170 beats per minute.

Treadmill Experimental Trial

The child performed a 15 minute walking session on a motorized treadmill. The walking speed was 3.0 mph at 0% grade. Energy expenditure during this activity was measured simultaneously using indirect calorimetry (Viasys Oxycon Mobile) and the SenseWear Pro Armband[®] (BodyMedia, Inc.). In addition, heart rate was measured using a Polar Heart Rate Monitor. These techniques are described in detail below. The protocol for this experimental session (See Appendix D) involved the following:

- Upon entering the testing laboratory, the child was weighed and fitted with the Viasys Oxycon Mobile, the SenseWear Pro Armband[®], and the Polar Heart Rate Monitor.
- The child was seated in a resting position for 5 minutes to allow for acclimation to the testing environment, the metabolic testing equipment (Oxycon Mobile and SenseWear Pro Armband[®]), and the Polar Heart Rate Monitor. The child was instructed to remain as still as possible during this period of time.
- The child walked on a motorized treadmill for a period of 15 minutes. Walking occurred at 3.0 mph at 0% grade. During this walking session, energy expenditure was measured simultaneously using indirect calorimetry (Viasys Oxycon Mobile) and the SenseWear Pro Armband[®]. Heart rate was measured at each minute using a Polar Heart Rate Monitor.
- The child was in a seated resting position for 5 minutes to allow for a cool-down from the activity period. During this time energy expenditure and heart rate continued to be monitored.

Walking Video Experimental Trail

The child performed a 15 minute activity session following the *Kid's Walk* indoor walking video with Leslie Sansone. This is a commercially available video that uses choreographed routines for walking in place and is designed for use by children. Energy expenditure during this activity was measured simultaneously using indirect calorimetry (Viasys Oxycon Mobile) and SenseWear Pro Armband[®] (BodyMedia, Inc.). In addition, heart rate was measured using a Polar Heart Rate Monitor. These techniques are described in detail below.

The protocol for this experimental session (See Appendix E) involved the following:

- Upon entering the testing laboratory, the child was weighed and fitted with the Viasys

Oxycon Mobile, the SenseWear Pro Armband[®], and the Polar Heart Rate Monitor.

- The child was in a seated resting position for 5 minutes to allow for acclimation to the testing environment, the metabolic testing equipment (Oxycon Mobile and SenseWear Pro Armband[®]), and Polar Heart Rate Monitor. The child was instructed to remain as still as possible during this period of time.
- The child performed the activity in the *Kid's Walk* indoor walking video for a period of 15 minutes. During this activity session, energy expenditure was measured simultaneously using indirect calorimetry (Viasys Oxycon Mobile) and the SenseWear Pro Armband[®]. Heart rate was measured at each minute using a Polar Heart Rate Monitor.
- The child was in a seated resting position for 5 minutes to allow for cool-down from the activity period. During this time, energy expenditure and heart rate continued to be monitored.

Interactive Video Experimental Trial

The child performed a 15 minute activity session using *Dance, Dance Revolution*. *Dance, Dance, Revolution* (DDR) is a music video game that is commercially available and produced by Konami[™]. The game is played on a dance pad with four arrow panels: left, down, up, and right. These panels are pressed using the player's feet, in response to arrows that appear on the screen in front of the player. The arrows are synchronized to the general rhythm or beat of a chosen song, and success is dependent on the player's ability to time his/her steps accordingly. Energy expenditure during this activity was measured simultaneously using indirect calorimetry (Viasys Oxycon Mobile) and the SenseWear Pro Armband[®] (BodyMedia, Inc.). In addition, heart rate was measured using a Polar Heart Rate Monitor. These techniques are described in

detail below. The protocol for this experimental session (See Appendix F) involved the following:

- Upon entering the testing laboratory, the child was weighed and fitted with the Viasys Oxycon Mobile, the SenseWear Pro Armband[®], and the Polar Heart Rate Monitor.
- The child was in a seated resting position for 5 minutes to allow for acclimation to the testing environment, the metabolic testing equipment (Oxycon Mobile and SenseWear Pro Armband[®]), and Polar Heart Rate Monitor. The child was instructed to remain as still as possible during this period of time.
- The child performed activity using *Dance, Dance, Revolution* for a period of 15 minutes. During this activity session, energy expenditure was measured simultaneously using indirect calorimetry (Viasys Oxycon Mobile) and the SenseWear Pro Armband[®]. Heart rate was measured at each minute using a Polar Heart Rate Monitor.
- The child was in a seated resting position for 5 minutes to allow for cool-down from the activity period. During this time energy expenditure and heart rate continued to be monitored.

3.5 ASSESSMENTS

3.5.1 SenseWear Pro Armband[®] to Assess Energy Expenditure

The SenseWear Pro Armband[®] (BodyMedia, Inc., Pittsburgh, PA) was worn on the posterior surface of the right upper arm over the belly of the triceps muscle, and was held in place with a velcro strap. This position was standardized as the midpoint between the acromion and olecranon processes, which is the same location as is typically used for assessing the triceps skinfold. The procedures outlined in the Anthropometric Standardization Manual were followed

when identifying this location. The SenseWear Pro Armband[®] was placed on the arm for a period of 15 minutes prior to data collection to allow for the device to acclimate to skin and environmental temperature (Note: this is recommended by the manufacturer). During the activity session, data was stored in the SenseWear Pro Armband[®] and these raw data were downloaded at the conclusion of each activity trial. Raw data included accelerometry counts, heat flux, galvanic skin response, skin temperature, and near-armband temperature. These data was used to estimate energy expenditure using the proprietary algorithms incorporated into the InnerView Research Software provided with the SenseWear Pro Armband[®].

3.5.2 Indirect Calorimetry to Measure Energy Expenditure

Indirect calorimetry was used as the criterion measure of energy expenditure. A Viasys (Yorba Linda, CA) Oxycon Mobile Metabolic Measuring System was used to assess energy expenditure during all activity sessions. This system was calibrated prior to each activity period using known gas volumes and gas concentrations according to the procedures outlined by the manufacturer. Expired gas volumes and concentrations were assessed on a breath-by-breath basis, and these values were averaged at one minute intervals. Oxygen uptake was converted to kcal/min based on the non-protein caloric equivalent, which was based on the respiratory quotient.

3.5.3 Assessment of Heart Rate During Physical Activity Sessions

Heart rate was assessed during all of the physical activity sessions described above. A Polar portable heart rate monitor was used to assess heart rate. This system allowed us to monitor heart rate at one-minute intervals and store minute-by-minute heart rate data. This allowed us to estimate the intensity of each of the physical activity sessions. NOTE: Monitoring

heart rate during these sessions allowed us to enhance the safety of these exercise sessions. The exercise sessions were terminated if the subject exceeds a heart rate of 170 beats per minute.

3.5.4 Demographic and Eligibility Variables

Body Weight: Body weight was measured by a calibrated balance-beam scale (Health-O-Meter Inc., Bridgeview, IL) to the nearest 0.25 lb (0.1 kg) and was assessed at the screening session, as well as prior to each experimental session to allow for an accurate assessment of energy expenditure. Subjects were weighed wearing light clothing (t-shirt and shorts) with their shoes removed.

Height: Height was measured during the screening visit using a calibrated, wall mounted stadiometer (Perspective Enterprises, Inc., Kalamazoo, MI) to the nearest 0.1 centimeters. Subjects were instructed to remove their shoes and stand with their back and heels of their feet against the wall.

3.6 STATISTICAL ANALYSIS

Statistical analyses were performed using SPSS for Windows (Version 14.0) and statistical significance was accepted at $p \leq 0.05$. Descriptive characteristics of subjects were presented as means \pm standard deviations. Data was analyzed separately for each exercise trial. To test the primary hypothesis, total energy expenditure was calculated as a sum across each exercise trial and a two-way repeated measures analysis of variance (device x exercise) was performed across all exercise modes to examine differences between indirect calorimetry and the SenseWear Pro Armband[®] for total energy expenditure. Separate dependent t-tests were performed for each exercise mode to compare total energy expenditure from indirect calorimetry to total energy expenditure from the armband.

To test the secondary hypothesis examining the effect of gender on the accuracy of the SenseWear Pro Armband[®], a two-way ANOVA (device x gender) with repeated measures was used to test for significant differences for energy expenditure.

As an exploratory analysis, correlation coefficients were calculated to describe the strength of the relationship between the two measuring devices for determining energy expenditure.

3.7 POWER ANALYSIS

The observed difference between the SenseWear Pro Armband[®] and indirect calorimetry reported by Crawford, et al. (13) was used to conduct a power analysis prior to recruitment of subjects. The mean difference for walking exercise between the SenseWear Pro Armband[®] and indirect calorimetry was 0.86 ± 0.84 kcal/min. Therefore, it was proposed that this study be powered to detect at least 0.86 ± 0.84 kcal/min reported by Crawford, et al. (13). Based on this power analysis, with the type I error rate set at 0.05, power set at 0.80, and to allow for a 10% attrition rate, 38 subjects were initially proposed for this study.

Recruitment efforts resulted in 56 individuals expressing interest in their child participating in this study. Of these 56 potential subjects, 20 were eligible and participated, 13 were eligible but did not participate, and 23 were ineligible. Thus, recruitment efforts resulted in fewer subjects than anticipated, which potentially suggests that this study was underpowered. However, because the accuracy of the SenseWear Pro Armband[®] has not been examined in severely overweight children, this study will provide data to determine the appropriate sample size for a larger study to adequately examine this area of research.

CHAPTER 4

RESULTS

The primary aim of this investigation was to examine the validity of the SenseWear Pro Armband[®] to assess energy expenditure during various modes of physical activity in severely overweight children. The secondary aim of this investigation was to examine the accuracy of the SenseWear Pro Armband[®] to assess energy expenditure based upon gender in severely overweight children.

4.1 SUBJECTS

Twenty severely overweight children (10 boys, 10 girls) participated in this validation study at the University of Pittsburgh's Physical Activity and Weight Management Research Center. Subjects were between 9-12 years of age with a body mass at or above the 97th percentile for age and sex. All subjects attended an orientation/screening session and three experimental testing sessions; treadmill walking, a walking video, and Dance, Dance Revolution (DDR). Descriptive statistics (mean \pm standard deviation) for subjects are presented in Table 4.1.

Table 4.1 Descriptive characteristics of subjects (mean ± standard deviation)

| Variable | All Subjects (N=20) | Subjects with | | | | |
|---|------------------------|---|---|--|--|---|
| | | Valid Treadmill Exercise Data (N = 20) | Subjects with Valid Walk Video Data (N = 13) | Subjects with Valid DDR Data (N = 15) | Subjects with Invalid Walk Data (N = 7) | Subjects with Invalid DDR Data (N = 5) |
| Age (years) | 10.6 ± 1.23 | 10.6 ± 1.23 | 10.6 ± 1.39 | 10.7 ± 1.33 | 10.6 ± 0.98 | 10.2 ± 0.84 |
| Height (cm) | 150.1 ± 9.55 | 150.1 ± 9.55 | 149.7 ± 9.93 | 150.9 ± 10.47 | 150.9 ± 9.51 | 147.8 ± 6.38 |
| Weight (kg) | 68.7 ± 14.95 | 68.7 ± 14.95 | 68.8 ± 14.39 | 71.6 ± 15.83 | 68.5 ± 16.25 | 59.9 ± 7.0 |
| Age and Gender Specific Body Mass Index Percentile | 98.3 ± 0.86 | 98.3 ± 0.86 | 98.4 ± 0.96 | 98.5 ± 0.92 | 98.1 ± 0.69 | 97.8 ± 0.45 |
| Minority Representation | N = 9 (45 %) | N = 9 (45 %) | N = 6 (46 %) | N = 8 (53 %) | N = 3 (43%) | N = 1 (20%) |
| Gender Representation | | | | | | |
| Males | N = 10 (50 %) | N = 10 (50 %) | N = 8 (62 %) | N = 8 (53 %) | N = 2 (29%) | N = 2 (40%) |
| Females | N = 10 (50 %) | N = 10 (50 %) | N = 5 (38 %) | N = 7 (47 %) | N = 5 (71%) | N = 3 (60%) |

4.2 COMPARISON OF ENERGY EXPENDITURE BY MEASUREMENT TECHNIQUE (Indirect Calorimetry and SenseWear Pro Armband®)

A two-factor repeated measures ANOVA (device x exercise) was performed to examine differences between the SenseWear Pro Armband® and indirect calorimetry in assessing energy expenditure across all exercise modes (See APPENDIX G). This ANOVA included data from the 13 subjects with valid energy expenditure data for all of the exercise modes. The lack of valid data for all subjects was a result of the indirect calorimetry system. Thirteen subjects had complete data for the walking video, 15 subjects had complete data for DDR, and 20 subjects

had complete data for treadmill walking. Results of the repeated measures ANOVA revealed significant differences between the armband and indirect calorimetry for assessing energy expenditure, regardless of the exercise mode ($p = 0.006$). The armband provided a higher estimate of energy expenditure than the measured energy expenditure from indirect calorimetry. Energy expenditure values were significantly different across all three modes of activity ($p = 0.003$). There was no significant device x exercise interaction effect, suggesting the pattern of difference on energy expenditure across modes of activity was not significantly different between indirect calorimetry and the SenseWear Pro Armband[®] ($p = 0.282$). Results demonstrate that the SenseWear Pro Armband[®] consistently overestimates energy expenditure for the exercises examined in this study.

Separate dependent t-tests were also performed for each exercise mode to compare total energy expenditure from indirect calorimetry to total energy expenditure from the armband (Table 4.2). There was a significant difference between total energy expenditure determined by indirect calorimetry (70.84 ± 16.58 kcal) and armband total energy expenditure (96.18 ± 36.33 kcal) ($p = 0.002$) for the walk video, with the armband significantly overestimating energy expenditure. There were trends towards significance between energy expenditure from indirect calorimetry (78.26 ± 29.65 kcal) and the SenseWear Pro Armband[®] (88.99 ± 31.18 kcal) for treadmill walking ($p = 0.097$) and between indirect calorimetry (62.30 ± 15.53 kcal) and the armband (75.60 ± 31.67 kcal) for DDR ($p = 0.054$). For all exercises (treadmill walking, walk video, DDR), energy expenditure estimated from the armband was greater than energy expenditure measured by indirect calorimetry.

Pearson product moment correlation coefficients were calculated to determine the relationship between total energy expenditure from indirect calorimetry and the armband for all

modes of exercise (Table 4.2). Results demonstrated a significant correlation between total energy expenditure from indirect calorimetry and the armband for both treadmill walking ($r = 0.591$, $p = 0.006$) and DDR ($r = 0.654$, $p = 0.008$). In addition, there was a significant relationship between total energy expenditure derived from indirect calorimetry and the armband for the walk video ($r = 0.849$, $p \leq 0.001$).

Table 4.2 Comparison of energy expenditure measured by indirect calorimetry and the SenseWear Pro Armband[®] for various modes of physical activity.

| Exercise (N=20) | Correlation Coefficients between Indirect Calorimetry and the SenseWear Pro Armband | Energy Expenditure | | Difference Score | |
|-------------------------------|--|-----------------------------------|---------------------------------|---|---------------------------|
| | | Indirect Calorimetry (kcal) | SenseWear Pro Armband (kcal) | Indirect Calorimetry minus SenseWear Pro Armband | p-value for difference |
| Treadmill Walk (n = 20) | $r = .591$ p-value = .006 | 78.26 ± 29.65 | 88.99 ± 31.18 | -10.7 ± 27.55 | 0.097 |
| Walk Video (n = 13) | $r = .846$ p-value = .000 | 70.84 ± 16.58 | 96.18 ± 36.33 | -25.34 ± 23.99 | 0.002 |
| DDR (n = 15) | $r = .654$ p-value = .008 | 62.30 ± 15.53 | 75.60 ± 31.67 | -13.29 ± 24.52 | 0.054 |

4.3 ASSESSMENT OF ENERGY EXPENDITURE BASED UPON GENDER

A two-way repeated measures ANOVA (device x gender) was performed to examine the accuracy of the SenseWear Pro Armband[®] to assess energy expenditure based upon gender (See APENDIX G). Separate ANOVAs were performed for each exercise mode, with gender (boy, girl) as the between subjects factor and device (indirect calorimetry, armband) as the within subjects factor.

Treadmill Walk: For treadmill walking (Table 4.3.1), there was no significant main effect of device ($p = 0.095$), no significant main effect of gender ($p = 0.911$), and no significant interaction effect ($p = 0.261$). The armband over-estimated energy expenditure by 17.82 ± 35.22 kcal for boys ($n = 10$) and 3.67 ± 15.82 kcal for girls ($n=10$).

Table 4.3.1 Effect of Gender on Validity of the SenseWear Pro Armband to Measure Energy Expenditure for Treadmill Walking (N = 20)

| Gender | <u>Energy Expenditure (kcal/)</u> | | Device Effect | <u>p-values</u> | |
|----------------|-----------------------------------|---------------------------------|---------------|-----------------|-----------------|
| | SenseWear Pro Armband (kcal/min) | Indirect Calorimetry (kcal/min) | | Gender Effect | Device X Gender |
| Boys (n=10) | 93.24 ± 33.72 | 75.42 ± 26.76 | 0.095 | 0.911 | 0.261 |
| Girls (n = 10) | 84.76 ± 29.57 | 81.09 ± 33.49 | | | |

Walk Video: For the walk video, the repeated measures ANOVA revealed a significant device effect ($p = 0.005$), with the armband providing a higher estimate of energy expenditure than the measured energy expenditure from indirect calorimetry. However, there was no significant gender effect ($p = 0.442$) or gender x device interaction ($p = 0.743$), suggesting that gender did not affect the observed pattern of results. The difference between the armband and indirect calorimetry was 27.2 ± 24.6 kcal for boys ($n = 8$) and 22.4 ± 25.5 kcal for girls ($n = 5$).

Table 4.3.2 Effect of Gender on Validity of the SenseWear Pro Armband to Measure Energy Expenditure for Walk Video (N = 13)

| Gender | Energy Expenditure (kcal/) | | Device Effect | p-values | |
|---------------|----------------------------------|---------------------------------|---------------|---------------|-----------------|
| | SenseWear Pro Armband (kcal/min) | Indirect Calorimetry (kcal/min) | | Gender Effect | Device X Gender |
| Boys (n = 8) | 101.64 ± 35.72 | 74.45 ± 16.70 | 0.005 | 0.442 | 0.743 |
| Girls (n = 5) | 87.45 ± 39.64 | 65.05 ± 16.40 | | | |

DDR: Repeated measures ANOVA showed a trend towards significance for a device effect ($p = 0.058$), with energy expenditure estimated from the armband being higher than energy expenditure measured by indirect calorimetry (75.6 ± 31.7 kcal vs. 62.3 ± 15.5 kcal). There was no significant gender effect ($p = 0.600$) or gender x device interaction ($p = 0.602$), again suggesting no effect of gender on the pattern of results. The differences between energy expenditure estimated from the armband for boys ($n = 8$) and girls ($n = 7$) were 10.1 ± 17.9 kcal and 17.0 ± 31.6 kcal, respectively.

Table 4.3.3 Effect of Gender on Validity of the SenseWear Pro Armband to Measure Energy Expenditure for Dance, Dance Revolution (N = 15)

| Gender | Energy Expenditure (kcal/) | | Device Effect | p-values | |
|---------------|----------------------------------|---------------------------------|---------------|---------------|-----------------|
| | SenseWear Pro Armband (kcal/min) | Indirect Calorimetry (kcal/min) | | Gender Effect | Device X Gender |
| Boys (n = 8) | 76.87 ± 24.41 | 66.81 ± 16.59 | 0.058 | 0.602 | 0.600 |
| Girls (n = 7) | 74.15 ± 40.50 | 57.14 ± 13.54 | | | |

4.4 SUMMARY

The primary aim of this study was to examine the validity of the SenseWear Pro Armband[®] to assess energy expenditure during various modes of physical activity in severely overweight children. Results from this investigation demonstrated that the SenseWear Pro Armband[®] significantly overestimated energy expenditure during the walking video as compared to indirect calorimetry. Although there was no significant difference between energy expenditure estimated by the armband and indirect calorimetry for treadmill walking or DDR, there were trends towards significance between these two devices, with the armband overestimating energy expenditure compared to indirect calorimetry. The secondary aim of this study was to examine the accuracy of the SenseWear Pro Armband[®] to assess energy expenditure based upon gender in severely overweight children. There was no significant effect of gender on the validity of the armband to estimate energy expenditure compared to indirect calorimetry.

CHAPTER 5

DISCUSSION

5.1 INTRODUCTION

Childhood overweight and obesity are increasing at alarming rates, which is partly due to a decline in physical activity, as well as an increase in participation of sedentary activities (2). Weight gain is primarily influenced by energy balance, more specifically energy expenditure and energy intake. The increasing rates of overweight during childhood suggest that children are experiencing a chronic positive energy balance in which energy intake exceeds energy expenditure (49). Physical activity accounts for 20% to 30% of total energy expenditure (35). To better understand the contribution of physical activity to total daily energy expenditure in children and to understand how this contributes to overweight and related chronic disease risk factors, it is important to implement techniques to accurately assess energy expenditure. Accurate and reliable techniques to assess energy expenditure in children could provide useful information that may affect weight management in children.

The accurate assessment of physical activity energy expenditure has been and still remains a challenge to researchers. The criterion gold standards for measuring energy expenditure include doubly labeled water and indirect calorimetry. While these methods provide accurate assessments of energy expenditure, they are expensive, require properly trained technicians, and have limitations that may prevent a thorough understanding of energy expenditure and physical activity in free-living conditions (58). As a result, other methods (self-

report techniques, heart rate monitoring, pedometers, accelerometers, and combination techniques) have been developed to assess energy expenditure in free-living conditions. Unfortunately, these techniques also have limitations that affect their ability to accurately measure and quantify energy expenditure in children (5,7,8,18,25,33,34,37,42,53,58,64).

The BodyMedia SenseWear Pro Armband[®] is a portable energy expenditure device that utilizes a combination of measurement techniques in an attempt to increase the accuracy of predicting energy expenditure. This device monitors multiple parameters including dual-accelerometry, galvanic skin response, near-body ambient temperature, skin temperature, and heat flux. The data collected from these parameters, in addition to specific demographic characteristics (age, gender, weight, height, right or left handedness, smoker or non-smoker) are entered into a proprietary algorithm to determine energy expenditure. The implementation of multiple parameters into one device may enable the SenseWear Pro Armband[®] to overcome the limitations of other assessment devices (26), allowing for the accurate assessment of energy expenditure across various modes of activity.

There has been limited research on the validity of the armband to estimate energy expenditure in children and adolescents (4,13). Initial research has produced conflicting results, which demonstrates the need to further investigate the validity of the SenseWear Pro Armband[®] in children (4,13,70). Furthermore, no research has analyzed the validity of this device in severely overweight children. Therefore, the primary aim of this study was to examine the validity of the SenseWear Pro Armband[®] to assess energy expenditure during various modes of physical activity in severely overweight children. It was hypothesized that energy expenditure measured by the SenseWear Pro Armband[®] during various modes of physical activity would not be significantly different from energy expenditure measured by the criterion measure of open-

circuit indirect calorimetry in severely overweight children. The secondary aim of this study was to examine the accuracy of the SenseWear Pro Armband[®] to assess energy expenditure based upon gender in severely overweight children. It was hypothesized that there would be no significant difference between energy expenditure measured by the SenseWear Pro Armband[®] and the criterion measure of open-circuit indirect calorimetry based upon gender in severely overweight children.

5.2 CONCLUSION

5.2.1 Validity of the SenseWear Pro Armband[®] to Measure Energy Expenditure

A primary finding of this investigation was that the SenseWear Pro Armband[®] significantly overestimated total energy expenditure for the walk video when compared to indirect calorimetry. While the differences between the armband and indirect calorimetry when assessing total energy expenditure during treadmill walking or Dance, Dance Revolution (DDR) were not statistically significant with $p = 0.097$ and $p = 0.054$, respectively, these differences were trending towards statistical significance.

The findings from this investigation do not support the primary hypothesis that energy expenditure measured by the SenseWear Pro Armband[®] during various modes of physical activity would not be significantly different from energy expenditure measured by indirect calorimetry. The armband significantly overestimated total energy expenditure by 36% for severely overweight children when compared to indirect calorimetry for the walk video. The SenseWear Pro Armband[®] overestimated energy expenditure compare to indirect calorimetry by 13% and 17% for treadmill walking and DDR, respectively.

The results for the treadmill walking exercise are not consistent with previous research by Crawford, et al. (13), which showed that the SenseWear Pro Armband[®] significantly

underestimate energy expenditure in adolescents during treadmill exercise by 17%. In contrast, Andreacci and colleagues (4) demonstrated that estimates of energy expenditure from the SenseWear Pro Armband[®] were not significantly different from indirect calorimetry measurements during treadmill walking in children, with the percentage of error between the two measurement techniques ranging from 9.6% to 13.1% during treadmill walking speeds between 1.7 to 3.4mph. Dorminy and colleagues (70) reported that the armband overestimated energy expenditure by 43% for treadmill exercise in 10 to 14 year old African American children when compared to indirect room calorimetry. By comparison, the findings of this current investigation demonstrated that the armband overestimated energy expenditure by 13% during 15 minutes of treadmill walking in severely overweight children. A potential reason for these differences in findings between studies may be a result of each study using a different version of the proprietary algorithms to estimate energy expenditure. For example, this current study used algorithms from the SenseWear Professional 6.1 software provided by the manufacturer. However, prior research mostly likely used earlier versions of the proprietary algorithms. Thus, due to the inconsistent pattern of the findings, additional research may be required to further refine the proprietary algorithms for estimating energy expenditure and to better understand the factors contributing to these inconsistent findings across studies.

The published research reporting on the accuracy of the SenseWear Pro Armband[®] in children has included treadmill walking, cycling, 24 hour energy expenditure, and daily activity (4,13,70). This investigation is the first to analyze the accuracy of the armband in children while performing a walking video and DDR. Therefore, there are no data for comparison and future research should focus on the validity of the armband in determining energy expenditure during these modes, as well as other modes of activity, in children.

Examining results of published research demonstrates that the inability of portable devices to accurately estimate energy expenditure in children is not limited to the SenseWear Pro Armband[®]. For example, Bray and colleagues (8) found that a uniaxial accelerometer (Caltrac) significantly underestimated energy expenditure 7% to 30% for a variety of activities in children. Johnson, et al. (34) reported the Caltrac to significantly overestimate daily energy expenditure as compared to doubly labeled water in children. Starth, et al. (60) found accelerometry to underestimate energy expenditure during various activities, while also reporting that extrapolation of heart rate overestimated energy expenditure during the same activities. In contrast, Trost and colleagues (65) found no significant difference between energy expenditure predicted by the Computer Science and Applications activity monitor (CSA accelerometer) and indirect calorimetry in children during treadmill walking at 3,4, and 6 mph. However, although no significant difference was detected, the CSA overestimated energy expenditure at 3 mph and underestimated energy expenditure at 6mph. This may suggest that exercise intensity may affect the accuracy of accelerometers to estimate energy expenditure in children. Future research should be conducted to determine if there is an exercise intensity effect on the accuracy of the SenseWear Pro Armband[®] to estimate energy expenditure in children.

5.2.2 Correlation between the SenseWear Pro Armband[®] and Indirect Calorimetry

Despite finding significant differences in energy expenditure between the SenseWear Pro Armband[®] and indirect calorimetry for the walk video, analysis of data showed significant correlations ($r = 0.846$) between the armband and indirect calorimetry for this mode of exercise. Significant correlations of total energy expenditure were also found between these two devices for both treadmill walking ($r = .591$) and DDR ($r = 0.654$). For comparison, Crawford and

colleagues (13) reported correlations of $r = 0.137$ to $r = 0.622$ between the SenseWear Pro Armband[®] and indirect calorimetry for treadmill walking in children. Thus, the current study of severely overweight children shows that current algorithms provide similar or improved correlations with energy expenditure from indirect calorimetry when compared to prior research that most likely used earlier versions of the proprietary algorithms to estimate energy expenditure.

By comparison, Trost, et al. (65) reported significant correlations between the Caltrac and indirect calorimetry for treadmill speeds of 3 mph ($r = 0.85$), 4 mph ($r = 0.62$), and 6 mph ($r = 0.81$). Eisenmann, et al. (18) found moderate to strong correlations between energy expenditure measured by indirect calorimetry and energy expenditure estimated from the Caltrac ($r = 0.82$) and the CSA ($r = 0.78$). Strath and colleagues (61) reported a correlation of 0.81 between energy expenditure measured by indirect calorimetry and a combination system (heart rate and accelerometry). Compared to other devices, the current investigation found correlations of similar magnitude between energy expenditure estimated by the SenseWear Pro Armband[®] and energy expenditure measured by indirect calorimetry.

5.2.3 Effect of Gender on the Validity of the SenseWear Pro Armband[®]

A secondary aim of this study was to examine the accuracy of the SenseWear Pro Armband[®] to assess energy expenditure by gender in severely overweight children. The findings from this investigation support the hypothesis that there would be no significant difference in energy expenditure estimated by the armband based upon gender. When analyzing the error in assessment of energy expenditure between indirect calorimetry and the armband, there was no significant difference between girls and boys for treadmill ($p = .991$), the walk video ($p = 0.442$),

or DDR ($p = 0.602$). In addition, the pattern of energy expenditure differences between measuring devices were consistent for boys and girls during all three exercise modes. These results conflict with Crawford and colleagues (13) who reported that the pattern of energy expenditure differences between measuring devices was not consistent for females and males during treadmill exercise. A potential explanation for the differences between the results from the current study and those reported by Crawford, et al. (13) may be that different versions of the proprietary algorithm were used to estimate energy expenditure with the SenseWear Pro Armband[®]. The current study used version 6.1 of the SenseWear Professional Software, which has recently been provided by the manufacturer, whereas Crawford, et al. (13) would have used a prior version of the software. Thus, this difference in findings may be explained by the refinement in the algorithms available in the current software; however, further confirmation of this assumption should be examined in future research as the algorithms most likely will continue to undergo refinement by the manufacturer.

5.3 LIMITATIONS AND FUTURE RESEARCH

This investigation is not without limitations. These limitations should be taken into consideration when interpreting the results of this study, as they may affect the application of the findings. Moreover, future studies should address these potential limitations.

1. This study examined the ability of the SenseWear Pro Armband[®] to accurately estimated energy expenditure during treadmill walking, a walk video, and DDR in severely overweight children. The results from this investigation can only be generalized to these specific modes of activity. Previous research has analyzed the accuracy of the armband during treadmill walking, cycling, 24 hour energy expenditure, and activities of daily

living (4,13,70). However, the accuracy of the armband is unknown for other modes of activity such as intermittent activity, resistance training, stair climbing, lifestyle activities, and both individual and team sports that may be common in children. Future research should examine the accuracy of the armband to estimate energy expenditure across a broad spectrum of activities in children.

2. In this investigation, subjects were severely overweight children between 9 to 12 years of age. This appears to be the first study to examine the accuracy of the SenseWear Pro Armband[®] in children with this demographic characteristic. Thus, results from this study need to be confirmed by additional studies that examine the validity of the SenseWear Pro Armband[®] to estimate energy expenditure in severely overweight children.

Moreover, it may be important to compare the accuracy of the SenseWear Pro Armband[®] across the range of lean, overweight, and severely overweight children.

3. The length of each activity period for this current study was 15 minutes and activity intensity remained relatively constant across each of the activity periods. Thus, future studies should examine if the validity of the SenseWear Pro Armband[®] is affected by variations in the duration and/or intensity of the activity that is performed.
4. This initial study included 20 severely overweight children (10 boys, 10 girls). Due to loss of data from the indirect calorimetry system, 13 subjects had complete data for the walking video, 15 subjects had complete data for DDR, and 20 subjects had complete data for treadmill walking. Future studies should confirm the findings from this current investigation by increasing the sample size of both boys and girls to allow for sufficient statistical power.

5. This investigation did not account for potential co-founding variables such as fitness or measures of body fatness, which could have had an affect on the results of this study. Future research should consider assessing these parameters to allow researchers to examine if the validity of the SenseWear Pro Armband[®] is affected by varying levels of these measurements in severely overweight children.
6. This investigation used the proprietary algorithm in version 6.1 of the SenseWear Professional software provided with the SenseWear Pro Armband[®]. Future research should examine whether additional refinements in the algorithm may improve the accuracy to estimate energy expenditure in severely overweight children, and this may require activity-specific, age-specific, BMI-specific, or fitness-specific algorithms. These refinements may include the following:
 - a. Refinement of the proprietary algorithm. This may require sharing of data from both the criterion measure of energy expenditure and the SenseWear Pro Armband[®] with the manufacturer to allow additional data to be available for the machine learning approach that is applied to the development of the algorithms.
 - b. Development of a “correction factor” that can be applied to the existing proprietary algorithm.
 - c. Development of an algorithm by investigators that is based on the raw data available that will not be proprietary.

5.4 Summary

The results of this investigation did not support the hypothesis that energy expenditure estimated by the SenseWear Pro Armband[®] would not be significantly different than energy expenditure measured by indirect calorimetry. The armband overestimated energy expenditure

for all modes of activity (treadmill walking, a walk video, DDR). These findings demonstrate the need to increase the accuracy of the SenseWear Pro Armband[®] in estimating energy expenditure in severely overweight children during these modes of activity. This may require that additional research be conducted that will allow for refinement of the prediction algorithms that are applied to severely overweight children. An encouraging finding from this investigation is that the accuracy of the SenseWear Pro Armband[®] does not appear to vary by gender for the activities for this investigation in severely overweight children. Although the present investigation is not without limitations, this is the first study to investigate the accuracy of the armband to estimated energy expenditure in severely overweight children. It is also the first study to examine the accuracy of the armband during activities using a walk video or DDR.

The lack of statistically significant differences in energy expenditure between indirect calorimetry and the SenseWear Pro Armband[®] for treadmill walking and DDR, along with the lack of a significant effect of gender, should be interpreted with cautions due to the small sample size in this study. Moreover, this study was originally not powered to detect gender effects, as this was considered to be a secondary outcome in this investigation. Therefore, the small sample size may have resulted in this study being underpowered, which resulted in the inability to detect significant findings. Future studies, which are adequately powered, should be conducted to confirm the findings presented here and to expand the research related to refinement of the SenseWear Pro Armband[®] technology and algorithms to estimate energy expenditure in severely overweight children.

APPENDIX A

RECRUITMENT FORM:

1. Thank you for your interest in our program. My name is _____ and I would briefly like to tell you about this research program.
2. **Procedure for Describing the Study and Obtaining Verbal Consent to Conduct the Phone Screen:** A description of the study will be read to participants, and this description includes important components of the informed consent process (see attached script). Individuals who express an interest in participating in this study will be told the following to obtain verbal consent:

Investigators Component of Informed Consent: *This study is being conducted by Drs. Marcus, Jakicic, Kalarchian and colleagues at the University of Pittsburgh.*

Source of Support Component of Informed Consent: *Funding for this study is provided by internal funds through the University of Pittsburgh Mind/Body Institute.*

Description Component of Informed Consent: *We are interested in recruiting 40 children 9-12 years of age to participate in this study. This study will focus on examining how effective different types of physical activity are for burning calories in children, and how much children enjoy these activities. To do this, eligible children will be required to come to our University of Pittsburgh offices on the South Side on 6 different occasions. During these 4 of these visits the child will be required to participate in an activity session that include walking on a treadmill, following an exercise video, or playing a video game. Each of these sessions will last approximately 1 hour. In addition, your child will be required to participate in 2-weeks of home-based activity using either the exercise video or the video game. Your child can earn up to \$45 in gift cards for completing all aspects of this study.*

If you are interested in your child participating in this study, I will need to ask you a few questions about your child's physical health to determine if he/she appears to be eligible to participate in this study. It will take approximately 5 minutes to ask you all of the questions. If we complete the interview, I will ask you for some specific information (your complete name, date of birth, and mailing address) so that we can contact you regarding your child's participation in this study. I will then schedule you and your child to attend an orientation session that will explain all of the procedures of this study in greater detail. The average time to complete this Phone Screen is approximately 5 minutes."

Risks and Benefits Component of Informed Consent: *The only known risk to you for completing the Phone Screen is that it will take a few minutes of your time and you may experience disappointment if it is determined that you are not eligible to participate in the larger study. It is likely that you will experience one or both of these situations by completing this Phone Screen, which means that this occurs in more than 25% of people (more than 25 out of*

100 people). The benefit of completing this Phone Screen is that you may be able to participate in the exercise study that I described to you.

Costs and Payments Component of Informed Consent: You will not incur any cost nor will you receive any payment for participating in the Phone Screen.

Confidentiality Component of Informed Consent: If your answer to a particular question tells me clearly that your child will not be eligible for this study, I will stop the interview, and not ask you any more personal questions.

Right to Participate or Withdraw from Participation Component of Informed Consent: Your participation in this phone screen is voluntary. You may refuse to answer any of the questions asked. Your responses to these questions are confidential, and the information related to your child's health history or current behaviors that you are about to give me will be destroyed after this interview.

Do you have any questions related to any of the information that I have provided to you? Staff member will answer any questions or will defer these questions to the Principal Investigator or Co-Investigator when appropriate prior to proceeding. If the individual would like to think about their participation prior to proceeding with the Phone Screen, they will be provided with the telephone number that they can call if they decide to participate in the future.

Voluntary Consent Component of Informed Consent: Do you agree that the procedures that will be used to conduct this Phone Screen have been described to you, all of your questions have been answered, and you give me permission to ask you questions now as part of the initial Phone Screen? If "YES" indicate the participant's agreement with this statement on the top of the next page, and sign your name and date the form, and then complete the Phone Screen. If "NO", thank the individual for calling and do not complete the Phone Screen.

PHONE SCREEN INTERVIEW

The caller gives verbal permission to conduct the Phone Screen:

_____ YES _____ NO

Verbal Assent was given to:

Staff Member Signature

Date Verbal Consent was given:

Eligible based on telephone screening: Yes No

If "No", list reason for ineligibility: _____

Ask the following questions about the child.

1. Gender: Male Female

2.a. Age: (9-12) 2.b. Date of Birth: / /

3. Which of the following best describes your child's racial heritage? (you may choose more than one category):

- q American Indian or Alaska Native
- q Asian
- q Black or African-American
- q Hispanic, Latino, or Cape Verdean
- q Native Hawaiian or Other Pacific Islander
- q White
- q Other (Specify:_____)

4. Current Weight: pounds *Office Use: BMI Percentile for Age and Gender =*

5. Current Height: feet inches

7. Is your child able to walk for exercise?
YES No

If "no", specify reason: _____

7. Have you ever been told by a doctor or other medical person that your child has any of the following conditions? If "yes", Specify:

- a. Heart Disease Yes **NO** _____
- b. Angina Yes **NO** _____
- c. Hypertension Yes **NO** _____
- d. Heart Attack Yes **NO** _____
- e. Stroke Yes **NO** _____
- f. Diabetes (sugar) Yes **NO** _____
- g. Cancer Yes **NO** _____

9. Is your child presently being treated by a doctor or other medical person for any other physical or psychological problems?

Yes **NO**

If "yes", specify: _____

10. Does your child take any prescription medications?

Yes **NO**

If "yes", specify the following:

| Medication Name | Used to Treat: |
|-----------------|----------------|
| | |
| | |
| | |

15. Is your child currently participating in other research studies?

Yes **NO**

If "yes", specify: _____

Contact Tracking Form

**** THIS PAGE IS COMPLETED ONLY IF THE RESPONDANT APPEARS TO QUALIFY FOR PARTICIPATION IN THIS STUDY AND IS SCHEDULE FOR THE ORIENTATION VISIT. ****

4.2 Date: ____/____/____ Staff Member Completing Form:

Name of Parent: _____

Name of Child: _____

Street Address: _____

City: _____ State: ____ Zip Code: _____

Home Phone: _____ Work Phone: _____

OFFICE USE ONLY:

| | | |
|-------------------------|----------------|----|
| Eligible: | Yes | No |
| Invited to Orientation: | Yes | No |
| Date of Orientation: | ____/____/____ | |

If eligible schedule the participant for their group orientation session based on the schedule of available dates. A follow-up reminder will be send via the mail.

PAGE 1 WILL BE RETAINED FOR DEMOGRAPHIC STATISTICS

PAGES 2-3 MUST BE SHREDDED AT THE CONCLUSION OF THIS INTERVIEW

APPENDIX B

PHYSICAL ACTIVITY READINESS QUESTIONNAIRE (PAR-Q)

Subject ID: _____

Please read the questions carefully and answer each one honestly: check YES or NO

1. Has your doctor ever said that your child has a heart condition and that he/she should only do physical activity recommended by a doctor?

yes no

2. Does your child feel pain in his/her chest when he/she does physical activity?

yes no

3. In the past month, has your child had chest pain when he/she was not doing physical activity?

yes no

4. Does your child lose his/her balance because of dizziness or does he/she ever lose consciousness?

yes no

5. Does your child have a bone or joint problem that could be made worse by a change in his/her physical activity?

yes no

6. Is your doctor currently prescribing drugs (for example, water pills) to your child for blood pressure or a heart condition?

yes no

7. Do you know of any other reason why your child should not do physical activity?

yes no

Reference: American Medical Association: Guides to the Evaluation of Permanent Impairment. AMA, Chicago, 1990.

APPENDIX C

Approval Date: February 29, 2008
Renewal Date: February 28, 2009
University of Pittsburgh
Institutional Review Board
IRB #0704004

CONSENT FOR A CHILD TO BE A PARTICIPANT IN A RESEARCH STUDY

TITLE: Energy Expenditure in Severely Overweight Children

PRINCIPLE INVESTIGATOR: Marsha D. Marcus, Ph.D.
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SOURCE OF SUPPORT: Pittsburgh Mind Body Center

What is this study about and why is it being done?

Drs. Marcus, Jakicic, and Kalarchian are conducting a study of severe overweight in children aged 8 to 12. In this study, a definition of severe overweight in children will be based on BMI (body mass index), a measure of weight based on height. Children will be considered to have met the criterion for severe overweight if BMI is equal to or above the 97th percentile for the child's

age and sex. This research study is for the purpose of developing techniques for helping overweight children become more physically active.

Who is being asked to take part in this research study?

You and your child have been invited to participate in this study of approximately 30 children because your child is between the ages of 8 and 12 and suffers from severe overweight.

What procedures will be performed for research purposes?

This study will include a total of 6 visits to the clinic: one orientation session (including some screening procedures) and two phases. Phase 1 will consist of three separate clinic visits. Each visit, including the orientation session, will take approximately one hour to one hour and fifteen minutes, and all clinic visits, including introductory screening visit, must be at least 24 hours apart and not more than one week apart. One visit will be to pick up equipment that your child will use, Dance, Dance Revolution or the Kid's Walk indoor walking video, and Sony Play Station or DVD player, for Phase 2 activities. Lastly, one final visit will be for the purpose of returning study equipment to the clinic and completing questionnaires after Phase 2 is complete (explained below).

Screening Procedures:

During the orientation session, you and your child will attend a staff-led introduction. To confirm eligibility, your child will then have some screening measurements taken (height and weight), and you will complete a physical activity readiness questionnaire that will assess his or her medical history and readiness to complete physical activity. This is known as the PAR-Q, and will be completed prior to his or her participation in this study.

If your child exhibits any of the following, your child will be ineligible to participate in this study:

- orthopaedic, musculoskeletal, neurological, and/or medical conditions which prohibit exercise; this refers to injuries or disorders pertaining to bones, muscles, nerves, tendons, ligaments, joints, cartilage and spinal disc, or the nervous system;
- diabetes, hypothyroidism (an insufficient production of the thyroid hormone), or other medical conditions that affect energy metabolism;

- a history of cardiac conditions, also known as, heart conditions;
- systolic blood pressure (pertaining to the contraction phase of heart beat or the “top” number) greater than or equal to 140 mmHg or diastolic blood pressure (pertaining to resting or relaxation phase of heart beat or the “bottom” number) greater than or equal to 90 mmHg;
- is taking medication that may affect his or her heart rate or blood pressure;
- is classified as “high risk” with respect to cardiovascular (related to the heart and blood vessels), pulmonary (related to the lungs), metabolic (related to chemical reactions in the body, specifically nutrient absorption) disease, or orthopedic issues;
- any inability to complete the exercise sessions for this study.

Experimental Procedures:

In Phase 1, if eligible, your child will be introduced to both our measurement procedure of his/her energy expenditure and the first activity that he or she will complete, treadmill walking, during the orientation session. Before completing any activity, your child will sit still in a resting position during which he or she will be instructed not to move so that he or she can get used to the testing environment and any equipment we will be using, Viasys Oxycon Mobile, Sensewear Pro Armband, and Polar Heart Rate Monitor, which will be explained in further detail below.

During each of the following three clinic visits (all part of Phase 1), your child will partake in one of three physical activities: walking on a treadmill, exercising using “Dance, Dance Revolution”, and exercising using “Kid’s Walk” indoor walking video. During each visit, we will also adjust a piece of study equipment called SenseWear Pro Armband™ used to measure your child’s unique energy expenditure so that we can get it ready for you to use for home assessments, which will take place in Phase 2 (explained below).

In addition, we will measure energy expenditure, the amount of energy, measured in calories, that your child uses, or calories your child “burns” using a method called indirect calorimetry. In order to do this, your child will wear the SenseWear Pro Armband™ and a face mask (Viasys Oxycon Mobile) while he or she performs the various study activities. A Polar Heart Rate Monitor will also be used to measure your child’s heart rate while performing these activities.

In Phase 2 of the study, your child will be randomly assigned (a method using the same odds as flipping a coin) to participate in one of two activities that he or she preformed during Phase 1, either “Dance, Dance Revolution” or “Kid’s Walk”

indoor walking video. Dance, Dance Revolution is a music video game series that is commercially available and produced by Konami. The game is played on a dance pad with four arrow panels: left, down, up, and right. These panels are pressed using the player's feet, in response to arrows that appear on the screen in front of the player. The arrows are synchronized to the general rhythm or beat of a chosen song, and success is dependent on the player's ability to time his/her steps accordingly. Kid's Walk, by Leslie Sansone, is a commercially available video that uses choreographed routines for walking in place and is designed for use by children.

Your child will be instructed how to correctly perform the activity he or she is being assigned to complete and will be provided with the necessary equipment, Sony Play Station or DVD player and DVD/video, to perform these activities. You will be responsible for providing your child access to a TV that will allow connection for this equipment. The equipment we provide your child in order to complete these tasks must be returned to the investigator at the end of the study.

Your child will then complete the task he or she was assigned, Dance, Dance Revolution or Kid's Walk, for a period of at least 30 minutes on 5 days during each week (10 days total across the 2 week period). During each activity session, your child will be instructed to wear the SenseWear Pro Armband that will record data, allowing us to have a record of your child's participation.

At the end of the two week period and no more than one week later, your child will complete a questionnaire evaluating his or her enjoyment of the activity assigned, as well as how well he or she adhered to the exercise plan and instructions. The questionnaire will take approximately 10 minutes to complete, and is included in the one hour to one hour and fifteen minute time expectancy for this visit.

What are the possible risks, side effects, and discomforts of this research study?

The risks of participation in the treadmill exercise sessions for children are those associated with any recreation program, including the possibilities of injury, soreness or fatigue as a result of play or structured activity. Additional risks of participating in these exercise sessions may include falling, muscle sprains, general muscle fatigue, and other common injuries that may occur with exercise. In the event that any of these occur during the exercise session, the exercise session will be terminated and you and your child will be advised to seek medical advice from your primary care physician. In the event that any of these result in

a serious medical condition (e.g., broken bone, etc.) emergency medical personnel will be contacted to provide your child with appropriate medical treatment.

In addition, during exercise, your child's heart rate and blood pressure will increase, and under extreme conditions, this can lead to a serious cardiac event (i.e., heart attack). The risk of experiencing a serious cardiac event (e.g., heart attack) is rare (occurs in less than 1% or 1 out of 100 people). The possibility of experiencing a serious cardiac event has been estimated to be less than 1 per 20, 000 in exercising adults, with the risk being even lower in children. In the event that a serious cardiac event occurs, CPR will be initiated and continued until emergency medical personnel arrive to take over emergency procedures.

When energy expenditure is assessed, your child may experience a dry mouth due to the nature of the mouthpiece on the face mask (Viasys Oxycon Mobile). To minimize additional risks, study equipment will be sterilized prior to each use. There are no expected discomforts associated with the measurement of energy expenditure.

When wearing the Sensewear Pro Armband™ some people may experience mild skin irritation at the site where the armband is worn. One cause of skin irritation may be the build-up of sweat that can be trapped between the skin and the armband, which can cause pink pustules on a pink base of various sizes and shapes to appear. To minimize this risk, the sensing unit will be wiped with rubbing alcohol and dried thoroughly before each use.

Should your child experience any negative side effects during the study procedures, he or she will be able to stop the activity at any time.

What are the possible benefits from taking part in this study?

You or your child will receive no direct benefits for taking part in this research study. You may, however, benefit from gaining knowledge related to the exercise and activity monitors used in this research study.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?

If any new information, good or bad, about the treadmill, "Kid's Walk" indoor walking video, or "Dance, Dance Revolution" comes to light that may affect your willingness to participate, you will be told.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?

None of the services and/or procedures, such as the exercise program and the monitoring of heart rate and energy expenditure, you receive during this research study will be billed to you or your health insurance. If you receive a bill or believe that your health insurance has been billed for something that is part of the research study, notify a member of the research team or UPMC Patient Billing Services.

Will I be paid if I take part in this research study?

You will receive \$25 upon completion of each of two study phases and \$50 upon completion of the study (after returning study equipment). These payments are intended to help with the expense of coming to the University for assessment appointments. Your child will receive \$10 gift certificates upon completion of each of two study phases and a \$25 gift certificate upon completion of the study (after the returning study equipment).

How will my child's privacy rights be protected?

Under the Health Insurance Portability and Accountability Act (HIPAA), your child's records cannot be used for the research purposes of this study without your permission. You will be informed of the specific uses and disclosures of your child's records and medical information for the purpose of this research study and who will have access to your child's information. Your child will be assigned a unique ID number which will be used to identify his or her data without using his/her name. However, information linking your child's identifiable information to his or her unique ID number will be kept in a secure and locked location that only the Investigators and study staff will have access to.

Will this research study involve the use or disclosure of my child's identifiable medical information?

This research study will involve the recording of current and/or future identifiable medical information from your child's hospital and/or other (e.g., physician office) records. The information that will be recorded will be limited to information concerning your child's energy expenditure in calories and his or her heart rate. This information will be used for the purpose of measuring energy expenditure in overweight children during a heightened physical activity session and evaluating the accuracy of the device that we use to measure energy expenditure.

This research study will result in identifiable information that will be placed into your child's medical records held at the University of Pittsburgh Medical Center. The nature of the identifiable information resulting from your child's participation in this research study that will be recorded in your child's medical record includes all information collected for the study, including questionnaires.

Who will have access to my child's records or medical information related to his/her participation in this research study?

In general, research records are kept confidential. Paper records are stored in locked cabinets and computerized records are passwords protected. There are, however, some disclosures of your child's research-related medical information that may occur.

In addition to the investigators listed on the first page of this authorization form and their research staff, the following persons may have access to your child's identifiable private health information related to your child's participation in this research study.

- Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your child's identifiable research information (which may include his or her identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study. In unusual cases, the investigators may be required to release identifiable information (which may include your child's identifiable medical information) related to his or her participation in this research study in response to an order from a court of law. If the investigators learn that your child or someone with whom your child is involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.
- Authorized representatives of the sponsor of this research study, the Pittsburgh Mind Body Center, will review and/or obtain identifiable information (which may include your child's identifiable medical information) related to his or her participation in this research study for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data.

Authorized representatives of the study sponsor may also be present during your participation in certain research procedures. While the study sponsor understands the importance of maintaining the confidentiality of your child's identifiable research and medical information, the UPMC and University of

Pittsburgh cannot guarantee the confidentiality of this information after it has been obtained by the study sponsor.

The investigators involved in the conduct of this research study may receive funding from the sponsor to perform the research procedures and to provide the sponsor with identifiable research and medical information related to your participation in the study.

- Authorized representatives of the University of Pittsburgh Institutional Review Board. The IRB is responsible for assuring the ethical conduct of research at Children's Hospital of Pittsburgh. The IRB sometime asks for names and addresses and telephone numbers of research subjects. By agreeing to participate in this study, you also agree that representatives of the IRB can contact you. Of course, you don't have to answer the committee's questions if you don't want to.
- Authorized representatives of the Office for Human Research Protections (OHRP) may review and/or obtain your child's identifiable health information for the purpose of ensuring that the research is being conducted according to the Department of Health and Human Services Guidelines. While the OHRP has provided its assurance that it will not release your child's identifiable medical information to anyone else, the University of Pittsburgh cannot guarantee this.

In unusual cases, the investigators may be required to release your child's research information in response to a court order. Research investigators may be required under Pennsylvania law to report any suspicion of child abuse to child protection services. If the investigators learn that your child or someone with whom your child is involved is in serious danger of potential severe harm, they may need to warn those who are in danger and contact other agencies to ensure safety.

May I have access to my child's records resulting from participation in this research study?

In accordance with the UPMC Notices of Privacy Practices document that you and your child have been provided, you are permitted access to your child's information (including information resulting from his or her participation in this research study) contained within his or her medical records filed with his or her health care provider unless otherwise specifically stated below.

May I stop my child's participation in this study and may I withdraw permission for the use of my child's medical information for the purpose of this research study?

You have the right to stop your child's participation in this study at any time. Additionally, you may withdraw, at any time, your permission for the use of your child's medical information for the purpose of this research study. Of course, if you withdraw your permission for the use of your child's health information, your child may no longer participate in this research study. To the extent that researchers have already used your child's health information in data analysis and/or scientific publication, this information cannot be withdrawn (although any publication of information will be such that your child's information will not be identifiable). If you decide to withdraw your permission you should notify one of the investigators listed on the front page of this document in writing along with the date of your decision. Your decision to withdraw your permission for the use of your child's private health information for this research study will have no effect on you or your child's current or future medical care at UPMC hospitals or affiliated health providers or the University of Pittsburgh.

If agree to have my child participate in this study, can he or she be removed from the study without my consent?

Your child may be removed from the study without your consent if your child does not follow instructions given to them by the study investigator.

For how long will the investigators be permitted to use my child's identifiable health information?

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your child's identifiable medical information) related to your child's participation in this research study until the end of this study. Also, it is a University policy that all research records must be maintained for at least 5 years following study completion.

Will there be any compensation if my child is injured or becomes ill as a result of participating in this study?

University of Pittsburgh researchers and their associates who provide services at University of Pittsburgh Medical Center (UPMC) recognize the importance of your voluntary participation in their research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe that your child is injured as a result of the research procedures being performed, please contact immediately the Principal Investigator listed on the first page of this form.

Emergency medical treatment for injuries solely and directly related to your child's participation in this research study will be provided to him or her by the hospitals of UPMC. It is possible that UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your child's research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.

VOLUNTARY CONSENT AND AUTHORIZATION

I have read this form, or it has been read to me. All of my current questions have been answered. I will be given a copy of this form for future reference. I understand that throughout my child's participation in this research, I am encouraged to ask any additional questions I may have about the research and use of my child's identifiable private health information. Dr. Marsha Marcus (412-246-6371), Dr. John Jakicic (412-648-4517), or Dr. Melissa Kalarchian (412-647-6530) will be available for questions about this research, my child's rights, and any possible research-related injury. I may also call the Human Subjects Protection Advocate at the University of Pittsburgh IRB Office (1-866-212-2668) concerning questions about my child's rights as a research subject. By signing this form, I agree to permit my child to participate in this research.

Consent for Child's Participation

Printed Name of Child (Research Subject): _____

Printed Name of Parent(s) or Guardian(s): _____

I understand that, as a minor (age less than 18 years), the above-named child is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for his/her participation in this research study.

Parent or Guardian's Signature

Date

Parent or Guardian's Signature

Date

CERTIFICATION of INFORMED CONSENT

“I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.”

Printed Name of Person Obtaining Consent

Role in Research Study

Signature of Person Obtaining Consent

Date

APPENDIX D

TTREADMILL WALK DATA FORM

ID#: _____ Date: _____
 Age: _____ years Height: _____ cm. Weight: _____ lbs.
 SenseWear Armband: _____

| Time (minutes) | Speed (mph) | %Grade | Heart Rate |
|----------------|-------------|--------|------------|
| 0:00-1:00 | Seated | | |
| 1:01-2:00 | Seated | | |
| 2:01-3:00 | Seated | | |
| 3:01-4:00 | Seated | | |
| 4:01-5:00 | Seated | | |
| | | | |
| 0:00-1:00 | 3.0 | 0.0% | |
| 1:01-2:00 | 3.0 | 0.0% | |
| 2:01-3:00 | 3.0 | 0.0% | |
| 3:01-4:00 | 3.0 | 0.0% | |
| 4:01-5:00 | 3.0 | 0.0% | |
| 5:01-6:00 | 3.0 | 0.0% | |
| 6:01-7:00 | 3.0 | 0.0% | |
| 7:01-8:00 | 3.0 | 0.0% | |
| 8:01-9:00 | 3.0 | 0.0% | |
| 9:01-10:00 | 3.0 | 0.0% | |
| 10:00-11:00 | 3.0 | 0.0% | |
| 11:01-12:00 | 3.0 | 0.0% | |
| 12:01-13:00 | 3.0 | 0.0% | |
| 13:01-14:00 | 3.0 | 0.0% | |
| 14:01-15:00 | 3.0 | 0.0% | |
| | | | |
| 0:00-1:00 | Recovery | | |
| 1:01-2:00 | Recovery | | |
| 2:01-3:00 | Recovery | | |
| 3:01-4:00 | Recovery | | |
| 4:01-5:00 | Recovery | | |
| | | | |

Overall RPE: _____

Additional Comments:

APPENDIX E

WALK VIDEO DATA FORM

ID#: _____ Date: _____
 Age: _____ years Height: _____ cm. Weight: _____ lbs.
 SenseWear Armband: _____

| Time (minutes) | Activity | Heart Rate |
|----------------|----------|------------|
| 0:00-1:00 | Seated | |
| 1:01-2:00 | Seated | |
| 2:01-3:00 | Seated | |
| 3:01-4:00 | Seated | |
| 4:01-5:00 | Seated | |
| | | |
| 0:00-1:00 | | |
| 1:01-2:00 | | |
| 2:01-3:00 | | |
| 3:01-4:00 | | |
| 4:01-5:00 | | |
| 5:01-6:00 | | |
| 6:01-7:00 | | |
| 7:01-8:00 | | |
| 8:01-9:00 | | |
| 9:01-10:00 | | |
| | | |
| 10:00-11:00 | | |
| 11:01-12:00 | | |
| 12:01-13:00 | | |
| 13:01-14:00 | | |
| 14:01-15:00 | | |
| | | |
| 0:00-1:00 | Recovery | |
| 1:01-2:00 | Recovery | |
| 2:01-3:00 | Recovery | |
| 3:01-4:00 | Recovery | |
| 4:01-5:00 | Recovery | |
| | | |

Overall RPE: _____

Additional Comments:

APPENDIX F

DANCE, DANCE REVOLUTION DATA FORM

ID#: _____ Date: _____
 Age: _____ years Height: _____ cm. Weight: _____ lbs.
 SenseWear Armband: _____

| Time (minutes) | | Heart Rate |
|----------------|-------------------|------------|
| 0:00-1:00 | Seated | |
| 1:01-2:00 | Seated | |
| 2:01-3:00 | Seated | |
| 3:01-4:00 | Seated | |
| 4:01-5:00 | Seated | |
| | | |
| 0:00-1:00 | Kelly Clarkson | |
| 1:01-2:00 | Funkytown | |
| 2:01-3:00 | | |
| 3:01-4:00 | Video Radio Star | |
| 4:01-5:00 | Let's Shout | |
| 5:01-6:00 | | |
| 6:01-7:00 | Battle | |
| 7:01-8:00 | Centerfold | |
| 8:01-9:00 | | |
| 9:01-10:00 | Turn on The Radio | |
| 10:00-11:00 | Let's Dance | |
| 11:01-12:00 | | |
| 12:01-13:00 | Do You Wanna | |
| 13:01-14:00 | | |
| 14:01-15:00 | Kelly Clarkson | |
| | | |
| 0:00-1:00 | Recovery | |
| 1:01-2:00 | Recovery | |
| 2:01-3:00 | Recovery | |
| 3:01-4:00 | Recovery | |
| 4:01-5:00 | Recovery | |
| | | |

Overall RPE: _____

Additional Comments:

APPENDIX G
STATISTICAL TABLES

Two-factor repeated measures ANOVA (device x exercise)

| Source | Type III Sum of Squares | df | Mean Square | F | Sig |
|-------------------|--------------------------------|-----------|--------------------|----------|------------|
| Device | 6045.253 | 1 | 6045.243 | 11.206 | 0.006 |
| Exercise | 5500.193 | 2 | 2750.097 | 7.719 | 0.003 |
| Device * Exercise | 683.624 | 2 | 341.812 | 1.337 | 0.282 |

Two-way repeated measures ANOVA (device x gender) for each mode of exercise

| Exercise Mode | Source | Type III Sum of Squares | df | Mean Square | F | Sig | Partial Eta Squared |
|----------------------|----------------------|--------------------------------|-----------|--------------------|----------|------------|----------------------------|
| Treadmill | Measurement | 1153.947 | 1 | 1153.947 | 3.096 | 0.950 | 0.147 |
| | Gender | 19.765 | 1 | 19.765 | 0.013 | 0.001 | 0.001 |
| | Measurement * Gender | 500.909 | 1 | 500.909 | 1.344 | 0.069 | 0.069 |
| Walk Video | Measurement | 3782.05 | 1 | 3782.05 | 12.163 | 0.005 | 0.525 |
| | Gender | 856.587 | 1 | 856.587 | 0.636 | 0.442 | 0.055 |
| | Measurement * Gender | 35.10 | 1 | 35.1 | 0.113 | 0.743 | 0.01 |
| DDR | Measurement | 1366.779 | 1 | 1366.779 | 4.314 | 0.058 | 0.249 |
| | Gender | 287.356 | 1 | 287.356 | 0.289 | 0.600 | 0.022 |
| | Measurement * Gender | 90.340 | 1 | 90.340 | 0.285 | 0.602 | 0.021 |

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