Can A Vegetarian Diet Affect Resting Metabolic Rate or Satiety:

A Pilot Study Utilizing a Metabolic Cart and the SenseWear Armband

by

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ABSTRACT

Dietary protein is known to increase postprandial thermogenesis more so than carbohydrates or fats, probably related to the fact that amino acids have no immediate form of storage in the body and can become toxic if not readily incorporated into body tissues or excreted. It is also well documented that subjects report greater satiety on high- versus low-protein diets and that subject compliance tends to be greater on high-protein diets, thus contributing to their popularity. What is not as well known is how a high-protein diet affects resting metabolic rate over time, and what is even less well known is if resting metabolic rate changes significantly when a person consuming an omnivorous diet suddenly adopts a vegetarian one. This pilot study sought to determine whether subjects adopting a vegetarian diet would report decreased satiety or demonstrate a decreased metabolic rate due to a change in protein intake and possible increase in carbohydrates. Further, this study sought to validate a new device called the SenseWear Armband (SWA) to determine if it might be sensitive enough to detect subtle changes in metabolic rate related to diet. Subjects were tested twice on all variables, at baseline and post-test. Independent and related samples tests revealed no significant differences between or within groups for any variable at any time point in the study. The SWA had a strong positive correlation to the Oxycon Mobile metabolic cart but due to a lack of change in metabolic rate, its sensitivity was undetermined. These data do not support the theory that adopting a vegetarian diet results in a long-term change in metabolic rate.

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DEDICATION

I would like to thank all the people that made this thesis possible, both in my personal and academic lives, and to those who loved and supported me through the ups, but most importantly the downs. They know who they are.

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CHAPTER 1

INTRODUCTION

It is nearly impossible to have a discussion about weight loss or gain without including the topic of metabolism, or thermogenesis. Thermogenesis refers to the heat produced by mammals as a result of metabolic processes. It is also commonly referred to as 'metabolic rate', 'metabolism', or 'energy expenditure'. It can be altered by many factors and is associated with body weight and composition, especially fat free mass (FFM). Thermogenesis has been studied on many levels in an effort to determine its role in nutrition and health, and more specifically—obesity (1). Understanding how the human body adapts to underfeeding may be key in reversing obesity prevalance worldwide.

Measuring 24-h energy expenditure (EE) is, however, fraught with difficulties related to expense, subject inconvenience, and time involvement (2). Many studies only measure metabolic rate for a few minutes or hours, while those that monitor subjects over several hours or days can be somewhat costly and time intensive. Still, none of the traditional means of measuring EE have been able to easily monitor subjects continuously over much longer time spans such as several weeks, months, or even years.

Additionally, while much research has been conducted on diet-induced thermogenesis (DIT) with regard to diet composition of a test meal such as high-versus low-protein, less research has been conducted using vegetarians. To this author's knowledge, no research exists that monitors the possible change in resting metabolic rate (RMR) or total daily energy expenditure (TDEE) when a sub-

ject first adopts a vegetarian lifestyle after having consumed a mixed diet for several years.

Given this information, this study intends to investigate the potential use of a new device called the SenseWear Armband (SWA) (BodyMedia Inc., Pittsburgh, PA) in future research involving free-living subjects by comparing it to indirect calorimetry as measured by the Oxycon™ Mobile (Jaeger Oxycon Mobile, VIASYS Healthcare, Germany), a portable metabolic cart. Additionally this study intends to determine whether or not a relationship exists between RMR or self-reported satiety when a change in diet occurs.

Hypotheses

1. The SWA is a valid device that can be used in future nutrition research involving the metabolic rates of free-living individuals.

2. Subjects adopting a vegetarian diet will report a decrease in satiety.

3. Subjects adopting a vegetarian diet will demonstrate a slight decrease in metabolic rate measured at post-test (28th day of intervention).

Definitions of terms (2,3)

1. Basal Metabolic Rate (BMR): the energy needed to sustain the metabolic activities of cells and tissues and to maintain circulatory, respiratory, gastrointestinal, and renal processes, also sometimes referred to as sleeping metabolic rate (SMR)

2. Diet-induced Thermogenesis (DIT): *see* 'thermic effect of food'

3. Direct Calorimetry: directly measuring the heat expended by an individual by placing the individual in a metabolic chamber and monitoring the rate at which heat is lost from the body to the environment

4. Doubly Labeled Water (DLW): used to measure total energy expenditure (TEE) in free-living people using two stable isotopes of water (deuterium [^2H_2O] and oxygen-18 [$H_2^{18}O$]); the difference in the turnover rates of the two isotopes measures the carbon dioxide production rate, from which total energy expenditure can be calculated

5. Indirect Calorimetry: indirect measurement of energy expenditure rather than by directly measuring heat transfer; typically through the use of a metabolic cart or doubly labeled water

6. Lacto-vegetarian: person who consumes dairy products, but no meat, fish, poultry, or eggs

7. Metabolic Cart (MetCart): computerized instrument attached to a face mask or hood that measures the rate of O_2 uptake and CO_2 production, offering an estimate of energy expenditure as well as cardiovascular and respiratory function

8. Metabolic Equivalents of Task (METs): the measure of caloric expenditure by the amount of oxygen consumed per minute per kilogram of body weight; 1 MET = ~3.5 ml oxygen consumed per kilogram of body weight per minute in adults

9. Physical activity energy expenditure (PAEE) or exercise activity thermogenesis (EAT) refers to the energy expended during exercise or physical activity

10. Pesco-lacto-vegetarian: person who consumes fish (seafood) and dairy products, but no meat, fish, poultry, or eggs

11. Respiratory Exchange Ratio (RER): ratio of the volume of carbon dioxide expired from the lungs to the volume of oxygen consumed. Ranges from $0.7 - 1.2$; it is measured with a mask or hood attached to or that wirelessly communicates with a computer, collectively called a metabolic cart

12. Respiratory Quotient (RQ): similar to and usually equals RER, but RQ measures gas exchange at the cellular level and ranges from $0.7 - 1.0$

13. Resting Energy Expenditure (REE) also referred to as Resting Metabolic Rate (RMR): the energy expended while the body is at rest for the maintenance of normal body functions and homeostasis; represents the largest portion of total energy expenditure; may be as much as 10-20-% higher than basal energy expenditure, allowing for the energy spent as a result of the thermic effect of food or excess postexercise oxygen consumption

14. Thermic effect of food (TEF): the increase in energy expenditure associated with the processes of nutrient digestion, absorption, and metabolism; represents approximately 10% of the sum of the RMR and the energy expended in physical activity; often called diet-induced thermogenesis (DIT)

15. Thermogenesis: generation of heat by physiological processes

16. Total Daily Energy Expenditure (TDEE): the sum of REE, PAEE, and the TEF; the total energy expended by an individual, typically express as kilocalories (kcal) or millijoules (mJ) per 24 hour day.

17. Total Energy Expenditure (TEE): The total kcal or mJ expended in a given time, such as for the period of data collection

Limitations & Delimitations

Several possible limitations exist. The SWA is not a perfect device and while relatively accurate when measuring TDEE, becomes more inaccurate with increases in physical activity intensity levels (discussed below). It is unknown if, but unlikely that the SWA is sensitive enough to detect changes in EE related to TEF, as it has been validated predominantly against the metabolic cart as well as doubly labeled water (DLW) during alternating periods of rest and physical activity for only short periods of time, typically less than 2-3 h, or 1-2 wk with DLW. There could also be user error involved in wearing the device, as it must be worn in the appropriate position with the sensors making contact with the skin at all times.

It is possible subjects may not comply with the diet or the SWA. There is no way of knowing for sure whether or not the subjects consume any flesh foods during the month they are supposed to be refraining. Because they will be given little dietary advice, it will be impossible to control their macronutrient intake, either as total kilocalories consumed or in meal composition. Subjects may decide they need protein and decide to increase intake of vegetarian protein sources such as dairy or soy, which could alter thermogenesis. It will also be difficult to control

for all factors affecting EE, including—but not limited to—alcohol consumption, supplements and medications, physical activity, and caffeine intake (4,5,6).

The subject pool is expected to be small and will come from students and faculty at Arizona State University Polytechnic campus in and around the Phoenix metropolitan area, given the late start of this substudy, with a narrow age range and ethnic background, thereby greatly limiting generalizability. The original pilot study used to develop the larger study from which these subjects will be drawn had a disproportionate number of women, which may expand to this study as well.

CHAPTER 2

REVIEW OF LITERATURE

METHODS AND DIFFICULTIES RELATED TO MEASURING THER-

MOGENESIS

The indirect calorimetry gold standard measurement of energy expenditure

(EE) is arguably the metabolic cart, in which a subject must breathe into an in-

strument—either a mask or a tube, or wear a hood while oxygen consumption and

carbon dioxide production are measured to calculate a ratio. This method is only

used for short periods of time and is difficult to conduct outside of a laboratory

for more than short durations of time due to the nature of the device.

The metabolic cart measures metabolic rate by monitoring the rate of car-

bon dioxide production (VCO_2) and the rate of oxygen consumption (VO_2), re-

ported as a ratio referred to as the respiratory exchange ratio (RER) (3,7). An

RER of 0.7 indicates fat is being metabolized while an RER at or near 1.0 indi-

cates the use of carbohydrates for fuel, with protein at approximately 0.8 (8). For

every one liter of oxygen consumed, ~5 kcal are expended, thus providing an es-

timate of metabolic rate (8).

A commonly measured variable in exercise research is what is known as

VO_{2max}, or the maximal rate of oxygen consumption for a person while exercis-

ing. It is considered a measure of aerobic fitness, as those who are more fit have a

higher VO_{2max} than those who are less fit, indicating an increased ability to pro-

duce ATP, thus contributing to improved endurance (7). VO_2 increases as physi-

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cal activity begins, but then plateaus, regardless of physical intensity or fitness (9). This plateau is VO_{2max}. It is thought the plateau occurs because as activity continues, an imbalance starts to develop between the muscles' demand for oxygen and the body's ability to deliver it (9). Studies of aerobic endurance and metabolism often have subjects exercise at a certain percentage of their VO_{2max} to control for physical intensity.

Direct calorimetry measures body heat expended by entirely containing a subject within a metabolic chamber (10). Again, this method is costly and cannot be conducted outside of a laboratory setting. Typically, metabolic chambers only measure EE for a relatively short period of up to 48 h and require the subject to remain in the chamber throughout the duration of the study. Although some chambers allow the subject to move around in order to mimic 'free-living' situations, this is only a ruse. The subject of course cannot go to work, drive a car, cook a meal, take a shower, or do most of the activities free-living subjects do in their daily lives.

Doubly labeled water (DLW) is another technique for measuring indirect calorimetry and has also been considered a gold standard measurement of EE (11), especially for free-living individuals. Subjects ingest a specified amount of a special type of water containing non-radioactive stable isotopes. The urinary elimination of the deuterium isotope as water and the oxygen isotope as CO_2 is measured. EE is then calculated from the difference (12). This method enables researchers to measure total carbon dioxide production over a longer period of time (five to twenty days) but only requires periodic urine sampling. Subjects can

continue their normal routines because special devices are not necessary (11).

However, this method requires the initial cost of the DLW as well as costs for

testing urine samples, requires the ingestion of DLW by subjects who may be un-

comfortable with the notion, and may require subjects to collect urine in some cir-

cumstances.

None of these methods provides a very simple or inexpensive approach to

measuring EE in free-living individuals over the course of several days or even

months, and none are continuous measurements, but rather periodic. As a result,

researchers are often only collecting a small snapshot of data over the course of a

few hours or days. A new device call the SenseWear Armband (SWA) has be-

come available to both researchers and consumers in just the last few years, which

may provide a promising approach to measuring TEE in free-living individuals.

THE SENSEWEAR ARMBAND

Technology changes and expands rapidly, and the field of weight loss and

exercise certainly has not been exempt from technological advances. Many gadg-

ets have been devised to aid consumers in weight loss by tracking physical activ-

ity and/or energy expenditure (EE). These commonly include devices such as pe-

dometers, heart rate monitors, and accelerometers.

The SenseWear Armband (SWA) is a multisensor device manufactured by

BodyMedia Inc. Currently, it is worn around the upper left arm over the tricep

(see App D) for the purpose of measuring energy expenditure, but previous ver-

sions were designed to be worn on the upper right arm. The current "mini" ver-

sion is vented on one side, and if the armband is worn on the right arm, the vent

may be at times blocked as the device rests against the body. It is worn throughout the day even while sleeping, being taken off only to charge the battery, shower or swim, or upload data. It can store up to 28 consecutive days worth of information and the battery lasts for 5-7 days at a time (13).

According to the manufacturer, the SWA measures EE through four physiological sensors: accelerometer, heat flux, galvanic skin response, and skin temperature (11). It also claims to measure sleep patterns, 'knowing' when the user is lying down and awake versus lying down and actually sleeping. It is manufactured both for researchers as well as for consumers. Consumers are required to purchase additional software that stores the device's data as well as allows the user to enter a food diary and track weight loss, which must be paid for as a monthly subscription. For the purposes of this study, the research grade version (SenseWear Armband Model MF-SW using SenseWear Professional software version 7.0) was purchased directly from the manufacturer through contact with a company representative.

The SWA has been validated in several studies of EE, discussed below. The results generally demonstrate that it slightly overestimates or is accurate for REE and TDEE (14-16,18,21,24-27,35), and underestimates it during physical activity, with increasing inaccuracy as physical activity intensifies (17-20,29,30), but has good test-retest reliability (20,35,36). Overall, it is found to be an accurate, consistent, and reliable measure of TEE in free-living individuals. Although the SWA may not be sensitive enough to detect minute changes in individual

RMR, it may be useful in future nutrition-related research, both for estimating EE and physical activity levels.

Validity and Limitations of the SWA

Fruin and Rankin (14) compared the original SWA (using InnerView Research Software version 1.0, build 41) with indirect calorimetry both at rest and during exercise in healthy nonsmoking adults between 18-35 years old. At rest, the SWA was found to be a valid and reliable measure of EE but it significantly overestimated EE while walking on a flat treadmill and significantly underestimated EE with a 5% incline. It was also found that the SWA's EE estimates did increase as treadmill speed increased, but the same was not true of the incline, indicating a weakness in the ability to detect intensity level when the rate of motion does not change (14). The authors did not specify which arm the SWA was placed on, but the original version was designed for the right arm.

St-Onge et al. compared the original SWA (using InnerView Research Software Version 4.02) to DLW in 45 subjects over 10 d. RMR was initially obtained by indirect calorimetry (ventilated hood) and the researchers estimated the thermic effect of food as 10% of daily EE (15). The SWA estimated daily EE as an average of 117 kcal/d lower than DLW indicating the SWA may indeed be useful in estimating TDEE in free-living subjects. It should be noted there were major limitations of the study related to the research sample, which included individuals with diabetes (whose carbohydrate-related thermogenesis may be affected by their ability to remove glucose from the bloodstream, low to moderate alcohol consumption (defined as ≤2 drinks/day), and subjects with a BMI that placed

them in the obese I category. Body weight affects metabolic rate and alcohol is well known to increase thermogenesis more so than protein (12).

Malavolti conducted the largest validation study of the SWA Pro2 (with InnerView Research Software version 4.0) using 99 healthy non-obese adult subjects (16). Results were compared against indirect calorimetry utilizing the Weir formula (8,16). Resting energy expenditure was measured with both devices. No significant differences were found between the SWA and the metabolic cart and both devices showed a high correlation between REE and BMI.

A 2011 study by Drenowatz and Eisenmann sought to validate the original SWA's MET estimates at high levels of intensity using 20 (10 F, 10 M) endurance trained subjects at 65, 75, and 85% of their VO_{2max} and compared the results to those from the same Oxycon metabolic cart that was used in this author's experiment (17). They found that the SWA (using software version 6.1) has a "ceiling effect" around 10 METs (235 W) which was roughly equivalent to 65% VO_{2max} for most of the subjects. As physical intensity increased, the SWA failed to show a MET increase beyond ~10 METs (running speed of 6 mph). The authors concluded that the SWA was not reliable at high intensity levels. As the authors note, these findings contradict the findings of a 2004 study by King et al. (18) that found the SWA tended to overestimate EE at intensities of up to 8 mph, but it is also pointed out that the proprietary algorithm of the SWA had been updated to increase the accuracy of the device at lower intensities, which may be directly related to the contrasting findings.

Koehler at al. found similar results when using the newer SWA Pro3 as well as software version 6.1 compared against DLW in reference to 14 male endurance athletes monitored over 7 d, during which participants performed two separate monitored exercise trials in which a breath-by-breath analysis was also obtained. Again, although the SWA provided an accurate TEE, it significantly overestimated low and significantly underestimated high EE, with increasing error as intensity level increased (19). It seems clear the SWA is lacking in regard to physical intensity.

The King et al. study compared the original SWA (software version 3.0) and four other activity monitors designed for research and concluded that the SWA was found to be the most accurate measure of EE (19). The SWA was compared to two accelerometers: the Computer Science Applications (CSA), Inc. activity monitor and the TriTrac-R3D, as well as two other motion sensors: the RT3 Triazial Research Tracker and the BioTrainer-Pro. All were compared against indirect calorimetry (metabolic cart) during treadmill walking and running. Although the SWA did overestimate EE at most treadmill speeds as previously mentioned, it was found to give the most accurate estimate of total EE at most speeds compared to the other monitors tested.

In the largest study published about the SWA, Papazoglou et al. evaluated the SWA Pro2 (using InnerView Research Software version 4.0) for use in obese individuals (20). A total of 142 obese individuals (BMI >30) were assessed at rest, while 29 of those subjects also participated in 3 short exercise sessions. Only 25 lean and overweight adults served as controls, and they did not participate in

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the exercise sessions. Results were compared against the metabolic cart. A test for reliability was built into the study design to allow researchers to assess the repeatability of the SWA, which the researchers found to be high, with a correlation of r = 0.88 between the two tests. While the correlation overall between SWA and metabolic cart was high, the SWA underestimated REE and highly overestimated PAEE during the exercise sessions in the obese individuals. Interestingly, the SWA's estimates of REE correlated more strongly with calculated estimates using the Harris-Benedict equation (HBE), indicating to the authors that the SWA may rely more on subject characteristics to calculate REE and is not very sensitive to small changes. The authors note that REE, as estimated by SWA, was significantly correlated with FFM and that the estimates of EE were more accurate in lean and overweight individuals. They also note that in individuals with higher EE, both at rest and during exercise, the SWA's accuracy decreases (20).

Erdogan et al. asked 43 overweight and obese individuals (average BMI = 31.2 ±3.7) to perform indoor rowing exercises at 50% and 70% of VO_{2max} (21). Subjects wore the armband for 15 min to allow for acclimation to individual skin temperature. After a warm-up, each intensity level was performed for 10 m, with a 20 m break in-between. The results of the SWA were compared the results of the original SWA (software version 6.1) with the Cosmed metabolic cart. Again, the SWA significantly correlated with indirect calorimetry at both intensity levels, but significantly overestimated EE at the lower intensity while accurately measuring it during the moderate intensity exercise (21). Like Papazaglou et al. (20), this

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study also found that in those subjects with the highest EE, the error of the SWA increased. Improvements to the SWA in obese populations appear warranted.

Soric et al. validated the SWA Pro3 using software version 7.0 during in-line skating on a circular asphalt track (22). Results were compared against the Cosmed K4b^2 portable metabolic cart. While the SWA correlated fairly well overall with the Cosmed, researchers did find that in all 19 subjects, the SWA significantly underestimated energy expenditure and MET values by by ~25-55%. Because in-line skating involves more lateral movement and less vertical move-ment compared to an activity like running, it would appear the accelerometer of the SWA is lacking in its ability to detect both intensity levels and energy expen-diture.

In a study by Benito and colleagues, the SWA Pro 2 (InnverView Re-search Software version 4.02) was compared against the Oxycon mobile during circuit resistance training using different loads during a variety of exercises (e.g. leg lifts, shoulder press) to further test the accuracy of the SWA in relation to in-tensity (23). At all intensities, the SWA differed significantly from the metabolic cart for both men and women, as well as for all the subjects grouped together. This finding is of course supported by other studies and comes as no surprise. However, a significant difference between genders was discovered when looking at the delta values between the cart and armband. The difference between the de-vices for men was much greater than for the women, measured both in kcal and METs. This difference in delta values was significant at 50 and 70% 15 RM, but not at 30%. The authors did not measure VO_{2max} in this case because they were

not measuring cardiovascular exercise. They instead used a method in which the subject's ability to perform 15 repetitions by adjusting the weight load for each machine used. The 15 repetition maximum (RM) was established over 2 weeks time by repeating the tests. Then subjects performed the exercises at 30, 50, and 70% of the 15 RM while wearing the Oxycon and SWA. The authors speculate that the women may have thought they were working harder than they really were, such that 50% of 15 RM was not truly 50%. This writer speculates that perhaps the men, fueled by the knowledge that they were being assessed, experienced increased adrenaline levels and actually exceeded their usual maximums. The researchers used t-tests to determine differences between the metabolic cart and SWA as well as to compare the delta values of the males against the females, but did not report any r values. It is also important to note that while the SWA Pro2 is meant to be worn on the upper right arm, in this study it was placed on the subject's dominant arm. Data collected by the SWA were analyzed using an older software version (4.02), which may have also been a possible source of error.

Brazeau et al. wanted to look at the SWA Pro3's accuracy during prolonged exercise (24). Almost all other studies involving physical activity only involve short bursts of activity. This study measured 45 min of ergocycling at 50% VO_{2max} in 31 healthy adults following a test meal, and compared the results from the SWA (using software version 6.1) against DLW. SWA significantly underestimated EE compared to DLW. Interestingly, after excluding the first 10 min of data collected by the SWA, where ~56% of the error was measured, the discrepancy between the two methods disappeared (24). The reason for this is unclear.

Perhaps subjects find the armband awkward and need a few minutes to adjust and resume normal movement. The authors also note that the accuracy of the armband decreases as BMI goes up, consistent with the findings of Papazaglou et al. (25). If this early increased error of the SWA is consistent, perhaps it explains some discrepancy in validation studies that have used shorter exercise bouts. Perhaps it would serve other studies to trim their data and rerun their statistical analyses. For this author's research, 5 min of data were trimmed from the beginning and end of the test period, and subjects were additionally at rest.

Bernsten et al. also compared 4 activity monitors, including the SWA Pro2 (InnerView Professional Research Software version 5.1), ActiGraph, ikcal, and ActiReg with indirect calorimetry and found that SWA overestimated moderate to vigorous physical activity by 2.9%, not significantly different from indirect calorimetry. Again, accuracy was greatest during moderate exercise as opposed to vigorous or very vigorous activity (25).

A validation study that received a grant from BodyMedia Inc. sought to validate the latest SWA, the MF-SW, also referred to as the SenseWear "Mini" Armband due to its lighter and smaller design (26); the same armband used in this study. The research team actually compared both the Mini (software version 7.0, algorithm V.2.2.4) and the previous SWA Pro3 (software version 6.1, algorithm V.2.2.3) model to DLW over the course of 14 d. Subjects (n = 30) were able to simultaneously wear the armbands because each is meant to go on a different arm (Pro3 on right, Mini on left). Gaps in data were filled in according to pre-established patterns of the participants or by using known EE models. For exam-

ple, if the subject removed the armband to swim for an hour (denoted by a diary kept by each subject), the gap was filled in using known models of swimming METs. During showering times, the researchers used the established METs for "self-care activities", and so on. No significant effects of gender were found to have influenced the results, so all subjects were combined for statistical analyses. While the SWAs tended to underestimate TEE compared to DLW, the difference was not significant. The difference from DLW was smaller for the Mini than the Pro3 but, as the researchers note, the error rates were similar and the difference between them was not significant. It is interesting to note that for persons with lower TEE, the SWAs overestimated, while they underestimated in those with the highest TEE. Both monitors underestimated PAEE compared to DLW, which has been commonly seen in other studies. The authors conclude that the slightly improved performance of the Mini is probably due to the triaxial accelerometer over the 2-axis Pro3 and that both monitors need improvement at estimating higher EE levels.

Van Remoortel et al. also included the SWA Mini (using SenseWear Professional software 6.0) in a validation study of 6 activity monitors compared to the Oxycon metabolic cart, with specific reference to patients with chronic obstructive pulmonary disease (COPD) (27) because they tend to be physically inactive (28). Thirty-nine subjects who had not had an exacerbation of their illness in at least 4 weeks wore all 6 monitors in addition to the portable Oxycon pack (worn on the chest) with the corresponding rubber mask which covers the mouth and nose. They then participated in several activities such as walking, stair climb-

ing, and sweeping the floor, all of which lasted a total of 59 min. When means were correlated, the SWA was the top performer with r = 0.76. However, minute-by-minute calculations demonstrated an r = 0.48, pushing the SWA to 3rd best performer after the ActiWatch and MiniMod, monitors worn on the hip. When faster walking speeds were compared to slightly slower ones, the SWA did detect this difference, but it ultimately delivered the worst performance of the 6 moni-tors. Finally, none of the activity monitors were able to detect a difference in treadmill incline although the metabolic cart clearly demonstrated their was extra effort involved. The authors concluded that the SWA finished overall in the top 3, and that its estimates of EE were accurate for the level of activity reported by most COPD patients (26).

Jakicic et al. found that the original SWA (using InnerView Research Software version 3.2) underestimated EE during walking, cycling, and stepping but overestimated EE during arm ergometer exercise (29). When the manufacturer designed algorithms specific to the type of exercise being done, the differences between the SWA and indirect calorimetry (metabolic cart) became non-significant. These results indicate the technological accuracy of the device is complicated by type of exercise, especially where either the lower or upper half of the body is the main focus of the activity. This also may support speculation that the armband's estimate of EE is related almost entirely to the algorithm pre-programmed into it, rather than to its actual ability to measure EE as the meta-bolic cart or DLW does.

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Due to its simplistic design, validation studies of the SWA have been conducted for specific subject groups in the hopes the device can be used to aid doctors, dietitians, and other health care professionals in treating patients. Cole et al. compared the original SWA (using Innerview Research Software 2.2 and 4.0) to indirect calorimetry (metabolic cart) in 24 cardiac patients during arm ergometry and rowing, recumbent stepping, and treadmill walking and jogging (30). Looking at the results from the newer software (version 4.0), they found that the differences between the SWA and indirect calorimetry were most inaccurate for combined leg and arm ergometry. The armband did significantly underestimate EE with recumbent stepping and arm ergometry, and a tendency for it to overestimate for higher intensities on the treadmill. Again, it was discovered that when algorithms specific to cardiac patients were used, accuracy of the armband increased.

A small number of studies have been conducted with children. Calabro et al. used a sample of 21 healthy children to estimate EE on a variety of activities such as walking, coloring, playing computer games, resting and biking using the original SWA and a metabolic cart. They compared the armband's older software (version 4.2) to the newer software released at the time of the study (version 6.1) to see if the newly updated algorithms improved the accuracy of the SWA. They found the older algorithm overestimated EE, on average, by ~32% while the newer algorithm overestimated EE by an average of about 1.7% (31). Overall, the average minute-by-minute correlations between the SWA and the metabolic cart were 0.71 for the new algorithm and 0.72 for the older one (31), again indicating

that generally speaking, the SWA is accurate for estimating TEE but not as accurate for individual activities.

Arvidsson et al. also looked at the SWA Pro2's accuracy (using InnerView Professional Research Software 5.1) when used with children (n=20) participating in a variety of activities, and compared results with the Oxycon Mobile metabolic cart. The SWA underestimated EE in most activities, and the error was increased with increasing intensity (32). Calabro, as discussed above, used the newer software version (6.1) and appeared to obtain stronger correlations with indirect calorimetry (31), indicating the SWA appears to improve as the software, and therefore the algorithms, is updated.

In an additional study by Arvidsson and colleagues, software version 5.1 and 6.1 were compared to DLW in a sample of 20 healthy 14-15 yo children over the course of about 14 d. Overall, the 2 versions were not statistically significant from one another in their estimation of total daily EE (TDEE), although version 6.1 was more accurate (33). Version 5.1 overestimated TDEE while 6.1 underestimated it and the error was strongly related to physical activity levels, which were significantly greater for boys than girls. The authors conclude the SWA does not show an improvement in estimating EE over single-sensor activity monitors, especially when considering its relatively higher cost, and that the SWA needs improvement before being reliable when used with children (33).

A Swedish study conducted by Backlund, Sundelin, and Larsson used the SWA Pro2 with a group of 22 healthy children aged 8-11 yo, who were overweight and obese and compared the results from InnerView Professional Research

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Software version 5.1 to the newer SenseWear Professional version 6.0 against

DLW over the course of 14 d (34). Anthropometric variables did not differ be-

tween boys and girls, nor did PAL or BMR. Version 5.1 showed an underestima-

tion of EE that was not significant. However, version 6.1 significantly underesti-

mated EE when compared to DLW for both genders. The reason for this discrep-

ancy is unclear but may be related to the fact that the children were overweight

(34). The findings clearly demonstrate the need for further improvement in the

precision of the SWA for use with children.

Hill et al. also used 26 COPD patients and compared the original SWA

(software version 6.1) to indirect calorimetry measured with a metabolic cart (35).

Standardized tasks were performed in addition to treadmill walking at 2 two

speeds, both slow due to the population studied. They found that measurements of

the SWA were in fair agreement with indirect calorimetry and that results were

repeatable. The armband was able to detect small differences in walking speeds.

The researchers concluded that the SWA is a valid device for estimating EE in

COPD patients (35).

One common limitation of validation studies related to the SWA is that

few investigated at test-retest reliability of the SWA. Brazeau et al. did exactly

that, using the SWA Pro3 (using InnerView Research Software version 6.1) (36).

They recruited 34 healthy subjects (17 F/17 M) to determine if the results from a

set of activities performed on one day would match the same set of activities per-

formed the next day. Intraclass correlations were high, with the lowest correlation

$r = 0.63$ for the structured 30 min sedentary activity of working on a puzzle. For

lying down while awake, walking, and bicycling, r values were ≥ 0.85 (36). These data indicate that the SWA is consistent (repeatable) in measurements of EE over time and across various physical activities in addition to its established overall validity during rest to moderate intensity physical activity.

Although designed to aid in weight loss, the SWA has yet to be validated over an extended period or for its accuracy during significant weight loss or gain. Because the software requires users to update their weight in order to track weight loss, the algorithm for BMI readjusts, so one could expect that it remains accurate as physiological characteristics change. The armband may not, however, be sensitive enough to track changes in EE related to lowered RMR that can result from the body's sense of starvation during times of weight loss, and it is probable the SWA would overestimate EE as weight loss occurs.

Advantages of the SWA

The armband's design offers several advantages over other measures of EE like DLW or indirect calorimetry. Namely, that it offers researchers easier and less expensive opportunities to conduct studies involving EE in free-living individuals. There is a one-time cost to incur the device and software, but data analysis simply consists of attaching a USB cable and uploading the data to a computer. Consumers can additionally purchase a device that allows the SWA to upload the data to their computer wirelessly, so that subjects need only remove the armband to charge the battery and shower or swim. Subjects do not have to spend any time in a laboratory, other than possibly to pick up and drop off the device and to verify anthropometric data. There is no blood or urine to collect or analyze

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and it is completely non-invasive. Subjects simply slip the device onto their arm and can go about their day as normal. It can be worn nearly twenty-four hours per day (13) over extended periods of time such as months or years. Consumers typically purchase this device with the intent of wearing it over several weeks or months while losing weight, and it can be utilized the same way by researchers if so chosen. Due to these aforementioned benefits, subject compliance could be expected to be reasonably high because so little is required of the subject.

HIGH-PROTEIN DIETS

Evidence indicates that high protein diets are effective for promoting weight loss, both in the long and short term (37,38,39). Several mechanisms may be at work, including reduced caloric intake related to increased satiety and increased thermogenesis, especially in the postprandial phase related to the immediate need for the body to process amino acids (39,40). More than likely, a complex combination of factors is responsible for this phenomenon. It is, however, well documented that protein increases postprandial and post-absorptive thermogenesis more so than carbohydrates or lipids and is considered by some to be a key component in the success of high-protein diets for weight loss (37,40).

It is important to note that many studies often manipulate dietary intake into unrealistic eating patterns and meal compositions. True mixed diets of free-living individuals may be affected by other factors such as fiber content, macronutrient source, thermogenic spices and supplements, meal frequency, and alcohol consumption (1,5,6,41). It is also important to note that while some studies define high protein as a percentage of total calories, others define it as a total amount,

and still others speak in terms of g/kg body weight (38,40). Still other studies speak comparatively, referring to one treatment group as having a higher protein diet when compared with another group. When controlling caloric intake in weight loss studies, the use of percentages may not provide an entirely accurate picture of protein intake, especially if subjects are in negative nitrogen balance and at risk for loss of FFM. As suggested by Westerterp-Plantenga et al. when referring to weight loss (negative energy balance) it is appropriate to speak in terms of absolute protein content and that subjects should consume the absolute amount of protein during a weight loss diet that they were consuming at 10-15% of an energy balanced diet (40). In other words, if an energy-balanced diet provided 80 g protein per d at 10-15% of total kcal, the individual should continue to consume 80 g/d when reducing total kcal for weight loss, such that the percent protein of the total kcal will increase. This method ensures the individual remains in positive nitrogen balance, preserving FFM.

Further, the total protein intake for an individual could be below the general Recommended Dietary Allowance of 0.8 g/kg body weight per day, but still be a high percentage of the overall diet. Thus, the definition of 'high-protein' is not clearly defined in the literature. Dr. Westerterp-Plantenga suggests research should report protein as both a whole amount in grams as well as percent energy intake (42) in order to obtain an accurate portrait of protein intake. To report protein as a percent of energy when a subject is being under or overfed does not provide an accurate picture of how much protein the subject is actually ingesting relative to their protein needs (40,42,43).

Satiety

Satiety is an objective measure of a person's feeling of fullness, which can make it difficult to measure. In this study a validated satiety scale developed by Cardello et al. (App C) in a three-part experiment was utilized. The purpose of the first phase of the study was to quantify the meanings of phrases commonly used to describe hunger and fullness. A sample of 58 subjects was taken from a larger pool recruited to participate in sensory food tests. Subjects were given 47 phrases individually and asked to rate the magnitude of their semantic meaning by assigning a number freely. From those results, the phrases were then ordered by magnitude, with 'greatest imaginable fullness' as the strongest indicator of satiety and 'greatest imaginable hunger' as the strongest indicator of hunger. From this list, the SLIM (Satiety Labeled Intensity Magnitude) scale was developed using 10 of the original 47 phrases.

In the second phase of the Cardello et al. study, the newly developed SLIM scale was tested for sensitivity and reliability. Another 50 subjects were chosen from the same larger pool of subjects used for the first phase of the study. Subjects read 9 phrases designed to evoke cognitive levels of satiety such as 'right after a complete Thanksgiving dinner', then asked to make a slash mark on the SLIM scale, which was measured as distance across the scale in millimeters (mm) from -100 to +100. The ratings corresponded with the phrases. That is, the highest satiety ratings corresponded with the phrase that indicates the greatest feeling of fullness. The authors concluded the scale showed a higher level of sensitivity and greater test-retest reliability than other visual analogue scales.

In the third phase, Cardello et al. sought to determine if the SLIM scale was sensitive and reliable when using real food as stimuli. Twenty subjects were drawn from the same larger pool as the other 2 phases and came into the lab 3 mornings each week for 2 consecutive weeks after an overnight fast. They rated their baseline hunger/fullness and then were presented with 1 of the 3 chosen test foods without a beverage, and were given 10 min to consume the food completely. Immediately after, and at 10 min intervals after that for 30 min, subjects rated their hunger/fullness. All subjects reported an increase in satiety after eating, and these levels of satiety were fairly consistent ($r = 0.54$) on the SLIM scale between the 2 test days for the same food. The SLIM scale's reliability was significantly higher than that for 2 other scales that were tested simultaneously. Overall, the authors conclude that the SLIM scale is a simple instrument for assessing satiety and has good reliability and better sensitivity than other scales, especially at the extreme ends of hunger and fullness.

Protein and Satiety

Much research has determined the hierarchy of satiating effect of macronutrients. The most satiating is protein, then carbohydrate followed by fat (39,40), which also happens to be the priority with which the body metabolizes these nutrients (45,40). Protein is well known to have the highest TEF and this higher increase in metabolic rate over carbohydrates or fat is thought to be associated with protein's satiating effects (46). High protein diets are not only shown to increase self-reported satiety levels immediately following a meal, but are associated with

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greater continuous satiety throughout the day when compared to a normal protein diet (45).

In a review by Halton and Hu (1), it was found that in 11 of 14 studies comparing high-protein to at least one other macronutrient, protein significantly increased ratings of satiety. Westerterp-Plantenga et al. measured satiety throughout the day in combination with metabolic rate in a respiration chamber (47). They found that for each meal, both during the meal as well as postprandially, satiety was greater for the high-protein group compared with the high-fat group, who consumed three times less protein per meal (47). Another study found that over 16 weeks, subjects consuming a higher protein diet still reported greater satiety post-meal than those consuming a high-fat or standard protein diet (48).

In a crossover trial conducted by Poppitt et al, standard lunches were served to 12 lean women on separate days. Either 1 MJ of protein, carbohydrate, fat or alcohol was added to a standard meal. Subjects were significantly less hungry following the protein meal, and furthermore, only protein was shown to have an effect on satiety, while there were no differences between carbohydrate, fat, or alcohol when served in isocaloric meals (49).

The secret to the success of high protein weight loss diets may be its satiating effect (50). When diets are isocaloric, a higher percentage of protein does not produce greater weight loss; rather greater weight loss from a high protein diet occurs in ad libitum conditions (40,51,52), presumably because protein's satiating effect creates an earlier feeling of fullness, resulting in reduced caloric intake.

It is further important to note that subject compliance to a higher-protein diet is greater than that of subjects given a low-protein diet, at least short-term. A study by Due et al. reported significantly greater compliance in subjects consuming the higher protein diet— with an 8% drop out compared to a 28% drop out in the lower-protein group of a 12-mo trial monitoring weight loss in overweight subjects (53).

Reduced Caloric Intake

Those on a high-protein diet may tend to have lower caloric intake due to the increase in satiety (40). Subjects may feel fuller sooner and eat less at each meal, in turn contributing to greater weight loss when coupled with the increased thermogenic effect of protein. Because protein is not as readily converted to fat as carbohydrates or dietary fat, and has a higher energy cost to metabolize (54), it essentially has the net effect of having fewer calories than an equivalent meal of lower protein content.

Research suggests that when subjects are given isocaloric meals of varying protein content, there is little difference in weight loss between the higher and lower protein groups. However, when subjects are allowed to eat ad libitum, those on the higher protein diet will eat fewer calories while reporting greater satiety, and in turn demonstrate greater weight loss (1,40).

To demonstrate this, a crossover design study by Johnson et al. had 14 subjects ingest 3 isocaloric preload meals on separate days of whipped cream, pasta, or chicken. Subjects were then allowed to eat ad libitum. Those receiving

the protein preload consumed the fewest calories while those presented with the whipped cream consumed the most (55).

THERMOGENESIS

Thermogenesis refers to the generation of heat in mammals resulting from physiological processes such as the digestion, absorption, and metabolism of nutrients. It is a measure of energy expenditure commonly used in metabolic research. Generally speaking, the warmer a person is, the more energy he/she is expending, or rather the more substrates he/she is oxidizing.

Thermogenesis is typically divided into 3 categories (37,47,56):

1. Exercise-associated thermogenesis (EAT), also referred to as physical activity energy expenditure (PAEE) is the energy expended during physical activity, and may include non-exercise activity thermogenesis (NEAT); EE associated with movement that is not typically defined as exercise (e.g. walking to a bus stop, vacuuming, etc). Makes up ~10% of TDEE.

2. Resting energy expenditure (REE) or resting metabolic rate (RMR), which can include basal metabolic rate (BMR) or basal energy expenditure (BEE), sometimes referred to as sleeping metabolic rate (SMR). In general, the energy expended while the body is at rest. Makes up ~80% of TDEE, the largest component by far.

3. Diet-induced thermogenesis (DIT) also known as thermic effect of food (TEF), which is the increase in thermogenesis related to the ingestion and metabolism of a meal. Makes up ~10% of TDEE.

Together they make up total energy expenditure (TEE), often expressed as Total Daily Energy Expenditure (TDEE) over a 24 h period. Put another way, TEE is the sum of RMR, TEF, and EAT. Exercise associated EE may be the most easily manipulable factor from day to day, but RMR makes up the largest portion of total EE (37,47,56).

While protein is well documented to have a higher thermic effect than either fat or carbohydrate (37,57), the total energy content of the food is the most influential factor on TEF (58), followed by the protein fraction (40). Generally, it has been found to account for typically 20-35% of energy consumed while CHO accounts for 5-15% (40). In a randomized crossover study by Johnston et al. (59), young, lean, female subjects aged 19-22 y were found to have a 100% increase in thermogenesis 2.5 hours post-meal when consuming a high-protein low-fat diet versus consuming a high-carbohydrate diet. Mikkelson, Toubro, and Astrup found that when carbohydrate was substituted with 17-18% of energy as either soy protein or pork meat, 24 h EE was 3% higher, and the animal protein resulted in a 2% higher EE than soy (60), presumably related to the higher biologic value of animal proteins over vegetable ones. Tan, Batterham, and Tapsell, however, did not find a difference in EE between meat and soy protein (61).

Lejuene et al. recruited a dozen women for a crossover study of high-protein diets utilizing a metabolic chamber. Subjects participated in 2 36-h sessions held 4 wk apart. For 3 d prior to each session, subjects were provided with either an adequate protein (AP) or high protein (HP) diet, and total energy was based on each subject's RMR such that each diet was energy balanced. When

consuming the HP diet, subjects had a higher TEE, SMR, and DIT while reporting less hunger (increased satiety). Interestingly, PAEE was lower in the HP condition, presumably because the AP diet contained more carbohydrates, thereby providing stored energy during physical activity (62).

The exact mechanism for increased thermogenesis related to protein intake is unclear. Because protein, or rather amino acids have no significant form of storage, they must be metabolized quickly, being actively oxidized or eliminated (40). It is possible the increase in protein turnover and subsequent need for the body to rid itself of excess amino acids accounts for most of the thermogenic effect (57,60). The Stock Hypothesis takes the view that the increase in thermogenesis is an effort to "homeostatically waste energy" when fed an unbalanced diet, due to the energy inefficiency of protein (1, 63). As suggested in a review by Westerterp-Plantenga et al., increased protein consumption increases oxidation and body temperature, which may lead to a feeling of being deprived of oxygen, and therefore increased satiety (40). Whatever the mechanism behind protein's higher increase in post-meal thermogenesis may be, the outcome is well documented.

Vegetarians and Thermogenesis

Few studies of thermogenesis have taken the time to look at long-term vegetarians versus more recent converters, but those that have included vegetarian subjects studied individuals who have been on vegetarian diets for a substantial amount of time, possibly allowing for adaptations in thermogenesis to have already occurred.

A study by Poehlman et al. (64) looked at both RMR (measured with a ventilated hood) as well as postprandial thermogenesis of male vegetarians following a controlled test meal made up of about half carbohydrate and one-quarter each fat and protein. The non-vegetarians in the study were slightly younger and heavier, but otherwise height, BMI, percent body fat, and aerobic fitness (respiratory quotient, heart rate, blood pressure) were similar. As expected, vegetarian diets consisted of a higher intake of fiber but lower intakes of protein and fat, with a greater percentage of daily energy composed of carbohydrates. No differences were found between the 2 groups for RMR, but non-vegetarians exhibited a 25% greater increase in postprandial thermogenesis than the vegetarians despite finding no significant differences in plasma glucose and insulin, either pre- or post-meal (64). Of particular detriment to the study, however, was the fact that postprandial thermogenesis was measured for only 180 min, regardless of peak EE. It may be possible the vegetarians in the study would have achieved the same thermic effect of the test meal had they been given enough time to do so.

Oberlin, Melby, and Poehlman (65) further researched RMR and the thermic effect of a liquid meal using healthy non-obese females. The vegetarians had been so for at least one year, and none of the subjects took oral contraceptives or smoked. Subjects were tested during the preovulatory phase of their menstrual cycles to control for possible fluctuations in RMR related to menses. Physical characteristics did not differ between the vegetarians and non-vegetarians. Again, vegetarians had lower intakes of protein and fat but higher carbohydrate intakes. Total daily energy intakes did not differ after excluding 2 amenorrheic vegetari-

ans. Again, there were no differences in RMR and additionally, no differences in thermic effect of the test meal. Again, the ventilated hood was used for only 180 m following the meal. The vegetarians did have significantly lower plasma glucose 60 min postprandially and significantly higher insulin 30 min postprandially compared to non-vegetarians (65).

Toth and Poehlman examined both RMR and sympathetic nervous system activity in young male vegetarians (66). There were no significant differences in age, height, body mass, fat mass, FFM, percent body fat, waist-to-hip ratio, VO_{2max}, or diastolic blood pressure between vegetarians and non-vegetarians. Vegetarians did exhibit significantly lower systolic blood pressure, however. They also consumed less fat and derived more of their energy intake from carbohydrates, however percent intakes of protein and total sodium intake were similar between the groups. Vegetarians did have a higher RMR (11%) and RQ as well as lower fasting plasma insulin concentrations and higher norepinephrine, including higher rate of appearance of norepinephrine. No differences in glucose were found. When RMR was adjusted for differences in carbohydrate and fat intake, however, statistical significance disappeared (66).

Bissoli et al. looked at the RMR and TEF of both male and female vegetarians versus subjects following a typical Mediterranean diet (67). Weight, age, and BMI were the same between the groups. Non-vegetarians had significantly higher protein intakes while vegetarians had significantly higher fiber intakes as well as a greater percentage of calories coming from carbohydrates. Indirect calorimetry was measured with a ventilated hood and the test meal subjects consumed

consisted of pasta with tomatoes and olive oil with bread. Postprandial thermogenesis was measured for 180 min following the test meal. No significant differences in RMR, TEF, or RQ were found between the groups (67). This suggests that vegetarians do not absorb or metabolize nutrients differently than omnivores.

Clearly, more research is needed to determine if vegetarians truly exhibit differences in metabolic rates either in the long-term or just postprandially, and whether or not those differences can be attributed to sympathetic nervous system activity, as suggested by Poehlman and colleagues (64). Additionally, studies with larger sample sizes and a wider variety of subjects would be ideal. None of the aforementioned studies looked at vegetarians who had been so for several years or even decades, and all had very small sample sizes.

Alcohol and Thermogenesis

Alcohol is known to increase thermogenesis, and increases postprandial thermogenesis more so than any other macronutrient (6). Like protein, it must be metabolized quickly in order to avoid toxicity, and is essentially a poison whose effects can be fatal. It is a priority nutrient that takes precedence in the metabolic chain of command. That is, alcohol is typically absorbed prior to other nutrients and drugs, and it is easily and readily absorbed by tissue cells without the aid of transporters, making it one of the few nutrients which can be absorbed in the gastric lining of the stomach (2), contributing to gastric and esophageal cancer.

Morgatroyd et al. performed a crossover study of alcohol's effects on thermogenesis using a metabolic chamber where subjects were allowed to partake in sedentary activities such as watching TV or reading (68). Eleven healthy men

and women were kept overnight after being asked to refrain from alcohol consumption for at least 48 h prior to each test date, with at least 48 h between test dates. They were given breakfast and lunch and then the dinner meal was manipulated with either no alcohol in the control group, alcohol in the form of red wine substituted for 50% of the carbohydrate calories, or alcohol in addition to the control meal, thereby increasing the meal's caloric content. Urine was also collected. It was found that those subjects who consumed alcohol in addition to their test meal had significantly increased rates of thermogenesis over those subjects who did not consume any alcohol, which accounted for 15% of the added energy, but there were no differences between the controls and those who had alcohol substituted for carbohydrate calories. Both groups who consumed alcohol demonstrated significant suppression of carbohydrate oxidation, but more so in the substitution group. Suppressed fat oxidation also occurred when alcohol was consumed. As the researchers predicted, protein oxidation was not influenced by alcohol.

Fiber and Thermogenesis

Fiber intake has been considered as having a possible effect on EE, but while much research exists demonstrating the satiating effects of fiber, little research has study fiber's impact on thermogenesis. Raben et al. (69) as well as Scalfi et al. (41) both demonstrated that post-prandial thermogenesis was suppressed after a high fiber meal when compared to a low fiber meal. However, Khossousi et al. looked at the acute effects of psyllium on thermogenesis in overweight and obese men and found psyllium did not alter diet-induced thermogenesis (70). Keogh et al. also found no change in EE in healthy female subjects who

consumed either a low fiber wheat meal or high fiber barley meal after adjusting for total energy intake (57).

It should be noted that the sample sizes in all of the aforementioned studies were quite small, the largest being the Raben et al. study consisting of 14 subjects (69). Clearly, thorough research is needed to draw any strong conclusions about the effect of fiber on post-prandial thermogenesis.

Functional Food Ingredients and Thermogenesis

In the never-ending quest for weight loss, dietary supplements have found a permanent home on the shelves of pharmacies and supermarkets, marketed to consumers who range from the extremely obese desiring to lose a significant amount of weight, to the most slender who may simply be looking to lose 5 pounds in order to squeeze into a bikini or wedding dress or who desire to increase muscle tone. They are often aimed at increasing caloric expenditure, providing energy or alertness, and suppressing appetite. Their efficacy is of great controversy, and the science behind them tends to be shaky at best. Some supplements do, however, have a legitimate role in increasing thermogenesis.

The thermogenic properties of several ingredients have been well established. These include caffeine, green tea, ephedra, black pepper and capsaicin (4, 71-76). Their effects are typically seen post-prandially. More long-term data is necessary to draw conclusions about the role of these agents in weight loss.

Rashti et al. tested an energy drink which contained 230 mg of anhydrous caffeine and a host of herbal compounds: methyl tetradeclythioacetic acid, yerba mate extract, methyl-synephrine, methylphenylethylene, 11-hydroxy yohimbine,

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yohimbine HCL, α-yohimbine, and methyl-hordenine HCL (77). Subjects consisted of 10 healthy and physically active young women who were asked to refrain from consuming any caffeine on the day of testing. A metabolic cart was used to measure VO_2 for 3 hours after consumption of either the energy drink or a placebo drink. During the first hour, no differences were noted, but during the second and third hours, significant increases in REE (11%) and systolic blood pressure were seen after consumption of the energy drink, while diastolic blood pressure and heart rate remained the same. Despite the increase in EE, subjects did not subjectively report any differences in energy, fatigue, alertness, or ability to focus from the placebo.

Rudelle et al. also studied the effects of a thermogenic drink designed in the test lab using green tea extract, caffeine, and calcium in 31 young, healthy subjects (both male and female) who consumed <5 cups of coffee or tea per day using a metabolic chamber where they were allowed to partake in sedentary activities (78). Urine was also collected for measurements of urinary urea nitrogen, and catecholamine concentrations. TEE was found to be significantly greater after treatment, although it is unclear which compound was responsible for this, or if it resulted from some combination. No differences were found in blood pressure, heart rate, or urinary catecholamine excretion.

Regardless of the noted immediate effects in the post-absorptive stages, it is unclear whether long-term use of these substances promotes weight loss, lasting weight loss, or has any lasting effects on metabolic rate.

CHAPTER 3

METHODS

Participants & Study Design

This study used a subset of 8 human subjects, (M=5, F=3) taken from a larger study aiming to explore the relationship between vegetarian and pesco-vegetarian diets and their possible effects on mood. Subjects were recruited on the Arizona State University Polytechnic campus in Mesa, AZ between February-April 2011 using flyers, face-to-face contact in classrooms, email, and word-of-mouth referrals. For their participation, subjects were offered a Target gift card for $25, at the beginning and end of the study. Interested subjects provided an email address and were sent, or went directly to, an Internet link providing a short screener questionnaire, at the end of which they were asked to provide further contact information (see Figure 1 below for a timeline of data collection).

Criteria for subject inclusion in the larger study included having a body mass index (BMI) between 18.5-29.9 (mean 24.6 ±0.6 larger study; 25.9 ±3.4 pilot) with age >18 years (19-48 y, mean 23.6 ±0.9 larger study; 19-31 y, mean 23.9 ±3.9 pilot). There were no criteria based on such demographics as race or ethnicity, gender, socioeconomic status, or education level. Criteria for exclusion included smoking, obesity, a diagnosis of any significant illnesses such as diabetes or hypertension, thyroid disorders, the use of medications such as cardiac drugs, or mood stabilizers, but not birth control; or intake of dietary supplements known to raise thermogenesis. Subjects participated on a volunteer basis prior to randomization, and thus were not randomized for this pilot study.

Qualified subjects were then asked to meet with researchers for approximately 15 min in order to take a written survey, which verified the inclusion and exclusion criteria in the online survey. In addition, subjects completed 2 questionnaires pertaining to mood (POMS and DASS), to sign the consent form explaining the risk, benefits, and parameters of the study (app B), and to schedule the first of 2 fasted bloods draws, one on the day the dietary intervention began and the second on the day the intervention ended. These were also the days participants received the gift cards. At this initial visit, subjects were asked if they would additionally like to participate in this pilot study, which included 2 additional visits to measure resting metabolic rate (RMR) using both a metabolic cart, manufactured by Oxycon™ Mobile (Jaeger Oxycon Mobile, VIASYS Healthcare, Germany) and an armband known as the SenseWear Armband (SWA) and marketed to the public as The BodyBugg or GoWear Fit. In exchange for their time, subjects were provided with their RMR data. Subjects were told during recruitment sessions that they could choose to additionally participate in this pilot study.

At the time of the initial blood draws, subjects came into the lab early, having fasted for at least 8 h prior to the draw, but free to consume as much water as desired. Blood samples were collected by venous puncture by a Registered Nurse. Subjects were then asked to remove their shoes and socks in order to obtain height and weight. Height was taken using a manual stadiometer, then entered into a Tanita scale (Tanita Corporation, Tokyo, Japan), which in turn provided a printout of weight, body fat percent, and body mass index (BMI). The use of the Tanita was repeated at the second visit using the height measured during the first

visit. Subjects then sat down with the lead researcher who revealed the diet group (see below) to the subject, with some basic dietary instructions. Food records for the previous 3 d were collected from the subjects and a blank record was provided for use during the last 3 d of the intervention. Subjects additionally marked their usual level of hunger just prior to eating dinner on a satiety scale (App C). Subjects were given the gift card and provided with contact information in case they had any questions, and were scheduled a time for the final visit 28 d later.

The 3 study groups were vegetarian, pescovegetarian, or control (usual mixed diet). Vegetarians were instructed to refrain from all meat sources and eggs but were allowed dairy products. Pescovegetarians were given the same instructions, with the additional requirement that they eat at least 3-4 servings of fish or seafood each week. Those in the control group were instructed to continue eating their usual diet. All subjects completed a food log for the 3 d prior to this visit, and again for the last 3 d of the intervention. Each week, subjects were sent an email to provide eating tips, recipes, and coupons in order to encourage dietary compliance. During the fourth week subjects were additionally reminded to fill out the food record and of the time/day of their final fasted blood draw.

On the morning of the final visit, subjects returned a second set of 3 d food records, had blood drawn, and again stood barefoot on the Tanita scale. They again filled out the mood questionnaires, as well as the satiety scale, and were given the second gift card, having completed the study. At that time, no further contact was required with the subjects.
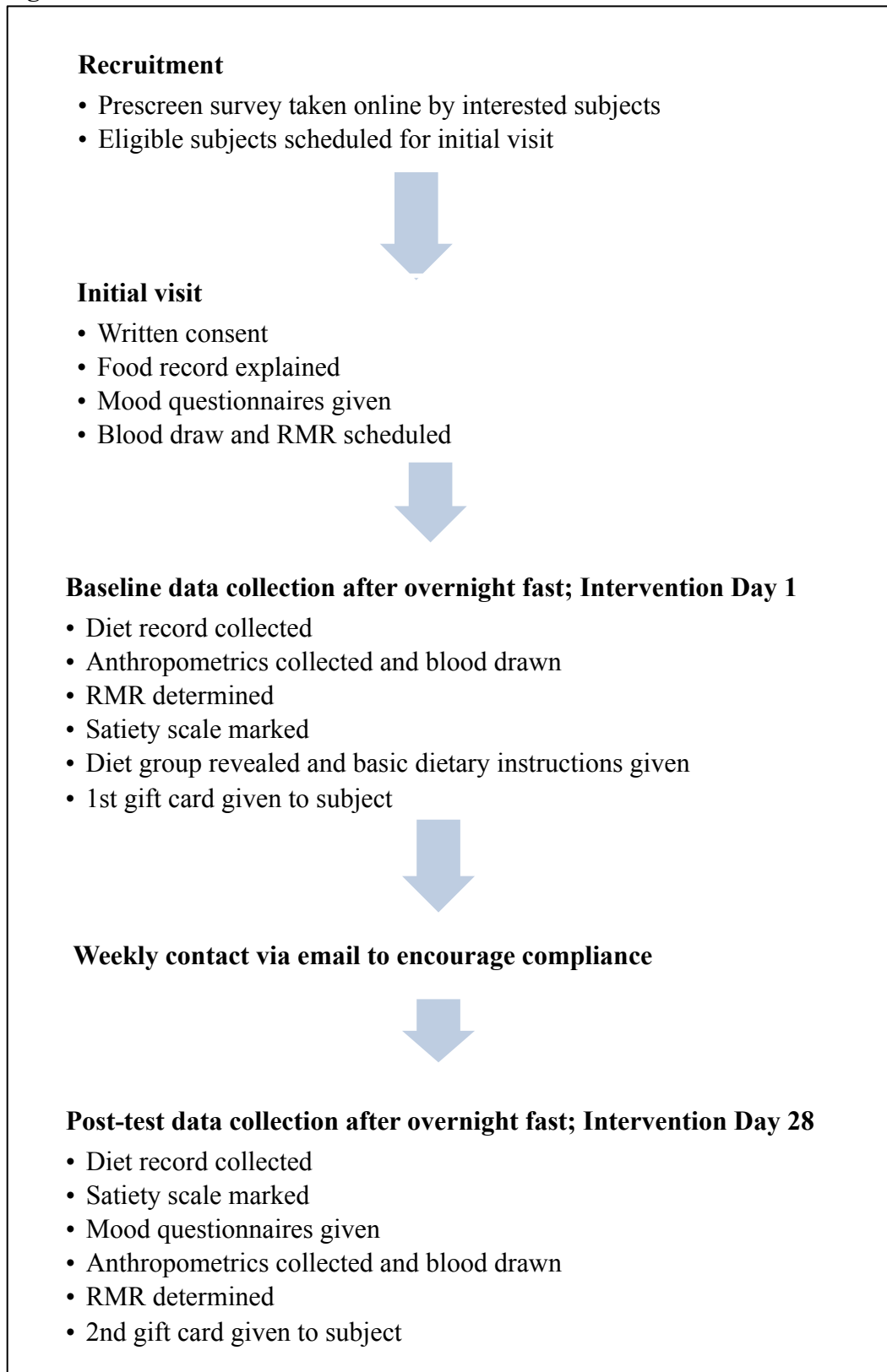
For those volunteers who desired to participate in this pilot substudy (n=8), a time to determine RMR via metabolic cart was scheduled on the same days as the blood draws, with the subject being fasted at least 8 h prior. Upon entering the lab, subjects were weighed, as needed for the computer software to run both the Oxycon and SWA. The metabolic cart required the subject to wear a soft rubber mask that covered the mouth and nose, which was secured in place by straps that went over and around the subject's head. The subject wore a pack like a backpack, which prevented them from sitting back in their chairs and which wirelessly transmitted data to the actual metabolic cart. The SWA was simply strapped around the subject's left upper arm, as instructed by the manufacturer (App D). Subjects were fitted with both devices and asked to sit as still and quiet as possible at a table for 30 min. They were allowed only to read and listen to music during that time. Subjects' music choices were not monitored, but subjects were asked not to listen to anything too upbeat. Subjects were also asked to repeat whatever they did during the initial visit during the second visit.

All diet interventions lasted 28 d. Subjects were scheduled for the RMR test prior to randomization, and therefore no control was exercised over how many subjects from each group were included in this pilot. Five subjects refrained from eating meat, poultry, or eggs (Vegetarian group) for 4 wk while 3 subjects served as controls, regularly consuming flesh foods. All subjects were asked to keep other dietary and lifestyle habits the same such as exercise regime, sleep patterns, and caffeine consumption. They were also asked to refrain from starting or

stopping an exercise program or taking or stopping regular medications, such as birth control.

This study was approved by the Institutional Review Board at Arizona State University (App A) prior to any recruitment of subjects for this substudy, and all participants provided written consent (App B) at the initial visit, which included consent for both the SWA and metabolic cart, although the metabolic cart was more directly spoken of during recruitment due to time constraints. Subjects were asked verbally at the time of the metabolic cart test if they were willing to additionally wear the SWA, which this researcher explained was for validation purposes. No subject refused. On one occasion, the SWA software failed, resulting in an inability to program the armband for the individual subject, and ultimately resulting in only seven subjects with complete SWA data.

Fig. 1. Flowchart of Data Collection

Recruitment

• Prescreen survey taken online by interested subjects
• Eligible subjects scheduled for initial visit

Initial visit

• Written consent
• Food record explained
• Mood questionnaires given
• Blood draw and RMR scheduled

Baseline data collection after overnight fast; Intervention Day 1

• Diet record collected
• Anthropometrics collected and blood drawn
• RMR determined
• Satiety scale marked
• Diet group revealed and basic dietary instructions given
• 1st gift card given to subject

Weekly contact via email to encourage compliance

Post-test data collection after overnight fast; Intervention Day 28

• Diet record collected
• Satiety scale marked
• Mood questionnaires given
• Anthropometrics collected and blood drawn
• RMR determined
• 2nd gift card given to subject

Dependent Variable

The goal of this study was to determine whether or not a change in EE related to diet could be measured, whether or not the SWA is sensitive enough to detect differences in RMR based on diet change in order to determine its usefulness in future studies of metabolic rate in free-living individuals, and additionally to determine if those on a vegetarian diet reported a change in satiety.

RMR was measured using both the Oxycon Mobile and a validated device called the SenseWear Armband (SWA), which measures total EE in both kilocalories (kcal) and metabolic equivalents of task (METs). The SWA computes EE through a proprietary algorithm using height, weight, age, and gender in addition to the data it collects, as listed by the manufacturer, BodyMedia Inc. (below):

Table 1. Specific types of data collected by the SenseWear Armband, according to the manufacturer (BodyMedia Inc.)

Data Type	Definition
Motion	The SWA contains a tri-axial accelerometer
Steps	The accelerometer is used to count steps taken by measuring the distinct patterns created by walking and/or running
Galvanic Skin Response	Measure of the electrical conductivity of the skin, which changes in response to sweat and emotional stimuli
Skin Temperature	A sensitive electronic thermometer monitors skin temperature
Heat Flux	Measure of the amount of heat dissipating from the body

The SenseWear MF-SW Armbands (also known as the "Mini") were purchased directly from BodyMedia Inc., Pittsburgh, PA. At the end of each RMR

visit, data was uploaded to a computer for analysis using the current software (SenseWear 7.0, BodyMedia Inc., Pittsburgh, PA), specifically designed for use in research, which was also purchased from the manufacturing company for data collection and analysis.

Statistical analysis

Given the small sample size, non-parametric tests were used for all analyses. The baseline RMR in kcal was compared to the post-treatment RMR between groups using the independent variable of diet group and the dependent variable of RMR. Findings were considered statistically significant if $p < 0.05$ in independent and related samples tests. In order to validate the armband against the Oxycon, and to investigate the correlation of RMR to FFM, as well as RMR measurements between methods, Spearman's rho correlations were used. All data were analyzed using the Statistical Package for Social Sciences (SPSS (PASW), version 20, IBM Corporation. Somers, NY). Mean RMR is an expression of kilocalories expended per minute, derived from a 20 min segment of data, unless otherwise noted.

CHAPTER 4

RESULTS

The RMR data was collected for 30 consecutive minutes, of which the

middle 20 min were used for statistical analyses in order to limit changes in RMR

related to subject anxiety. Subjects sat in a quiet room while resting almost en-

tirely motionless at a table. Subjects fasted for at least 8 h prior to testing, and the

post-trial test was scheduled for the same time and day of the week as the baseline

test, exactly 4 weeks (28 d) later. Table 2 below lists the means for several subject

variables.

Due to the small number of subjects, the lacto-pesco-vegetarians and con-

trol group were collapsed into one control group (n=5), and compared with the

vegetarians (n=3). An independent samples test indicated no statistically signifi-

cant differences between the treatment groups at baseline or at post-test for any

variable (see Tbl. 2, following page). Related samples tests revealed no significant

within-group differences. There appeared to be no significant change in RMR

from baseline to post-trial for either group. The results of the satiety scale also

indicated no significant differences in self-reported satiety from baseline to post-

test (Tbl. 2). Correlations did show a significant positive correlation of the SWA

to the Oxycon and an even higher correlation to Harris-Benedict equation HBE).

HBE was calculated using height (cm), weight (kg), and age (y), as meas-

ured in the lab at baseline and post-test as follows (79, 80):

Males: BEE = 66.5 + (13.75 x kg) + (5.003 x cm) - (6.775 x age)

Females: BEE = 655.1 + (9.563 x kg) + (1.850 x cm) - (4.676 x age)

Table 2. Means for each variable and a comparison of the change in means from baseline to post-test between groups (p value)

| | Control group | | Vegetarian Group | | p value |
	Baseline	Post-test	Baseline	Post-test	Δ
Gender (M/F)	3/2	-	2/1	-	-
Age (years)	*21.7 ±2.5	-	25.2 ±4.2	-	-
BMI (kg/m2)	26.7 ±3.4	26.7 ±3.0	25.4 ±3.7	25.7 ±3.4	**0.180
Body Fat (%)	28.7 ±1.3	27.9 ±1.6	19.3 ±7.1	18.9 ±7.1	0.230
FFM (kg)	61.3 ±21.9	61.7 ±21.3	54.9 ±12.6	55.9 ±12.9	0.230
Satiety scale (mm)	-23.3 ±40.0	-16.7 ±45.1	-20.0 ±40.0	-42.0 ±31.9	0.216
Oxycon (kcal/m)	1.2 ±0.35	1.3 ±0.31	1.1 ±0.27	1.1 ±0.34	0.881
SWA (kcal/m)	1.6 ±0.61	1.6 ±0.43	1.3 ±0.33	1.3 ±0.24	0.724
HBE (kcal/min)	1.4 ±0.40	1.4 ±0.39	1.1 ±0.17	1.1 ±0.17	0.177
HBEx1.2 (kcal/min)	1.6 ±0.48	1.6 ±0.47	1.3 ±0.21	1.3 ±0.21	0.177

*Means computed using one-way ANOVA

**Computed by 2 independent samples test (Mann-Whitney), significant $p < 0.05$

Correlations

Spearman's rho was used to determine relationships between Oxycon, SWA, HBE, and FFM (Tbl. 3-5, Fig. 2-7). Results indicate a strong positive correlation between SWA and both Oxycon and HBE, but no correlation between Oxycon and HBE. SWA and HBE both correlated with FFM, but Oxycon did not. Correlations between HBE and SWA were high but means matched more closely when HBE was multiplied by an activity factor of 1.2 (Tbl 2).

Table 3. Correlation of SWA and HBE to
Oxycon (kcal/min)

	r	p value	n
Baseline			
SWA	0.87	*0.014	7
HBE	0.55	0.160	8
Post-test			
SWA	0.81	0.015	8
HBE	0.79	0.021	8

Spearman's Rho p value significant at < 0.05

Fig. 2. Baseline Correlation to Oxycon

Fig. 3. Post-test Correlation to Oxycon
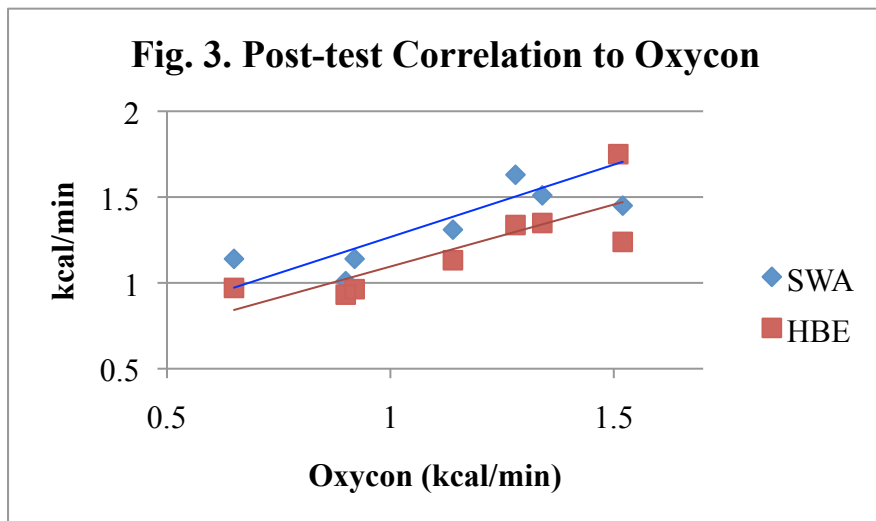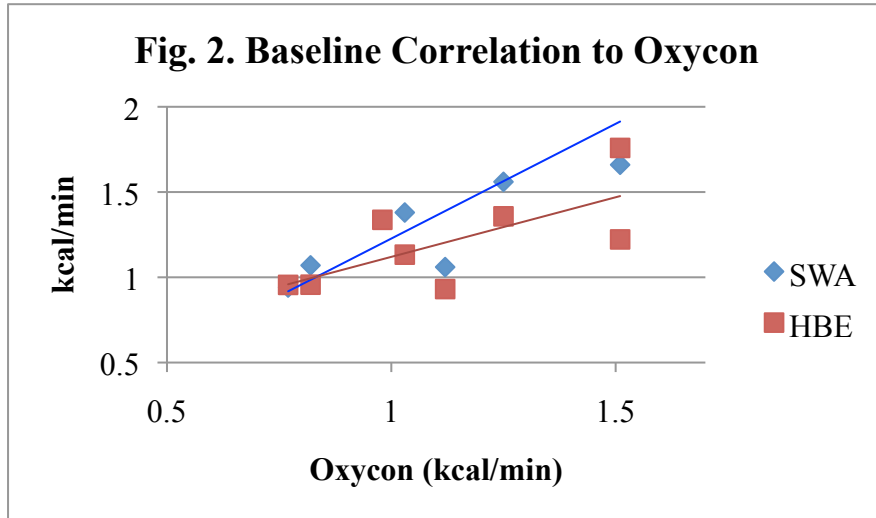
Table 4. Correlation of SWA to HBE (kcal/min)

	r	p value	n
Baseline	0.93	*0.023	7
Post-test	0.95	0.000	8

Spearman's Rho p value is significant at < 0.05

Fig. 4. Baseline Correlation of SWA to HBE
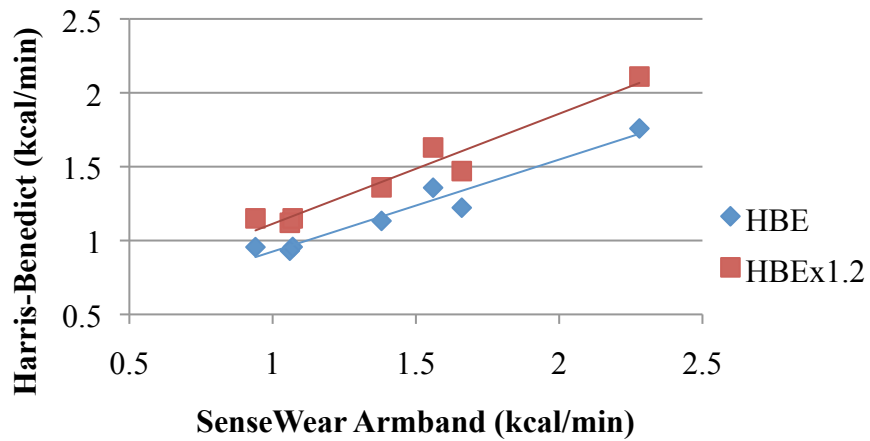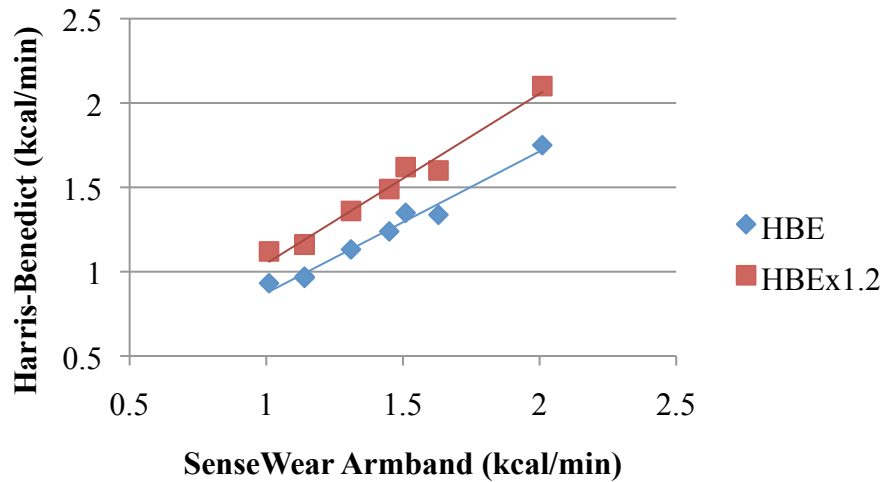

Fig. 5. Post-test Correlation of SWA to HBE

Table 5. Means ±SD for all subjects and significance of the relationship between HBE and SWA (p value)

|	Total kcal/day	Total kcal/min	Relationship to SWA
Baseline			
HBE	*1737.2 ±404.3	1.2 ±0.28	**0.028
HBEx1.2	2084.7 ±485.2	1.4 ±0.37	0.735
SWA	2050.0 ±672.3	1.4 ±0.47	-
Post-test			
HBE	1740.9 ±396.1	1.2 ±0.28	0.012
HBEx1.2	2089.1 ±475.3	1.5 ±0.33	0.036
SWA	2017.1 ±464.1	1.4 ±0.32	-

*Means computed using 2-related samples test
**Wilcoxon signed ranks p value is significant at <0.05

Table 6. Correlation of RMR (kcal/min) from the Oxycon,
SWA, and HBE to FFM (kg)

	r	p value	n
Baseline			
Oxycon	0.45	*0.260	8
SWA	0.86	0.014	7
HBE	0.83	0.010	8
Post-test			
Oxycon	0.76	0.028	8
SWA	0.91	0.002	8
HBE	0.86	0.007	8

Spearman's Rho p value is significant at < 0.05

Fig. 6. Baseline Correlation to FFM

Fig. 7. Post-test Correlation to FFM

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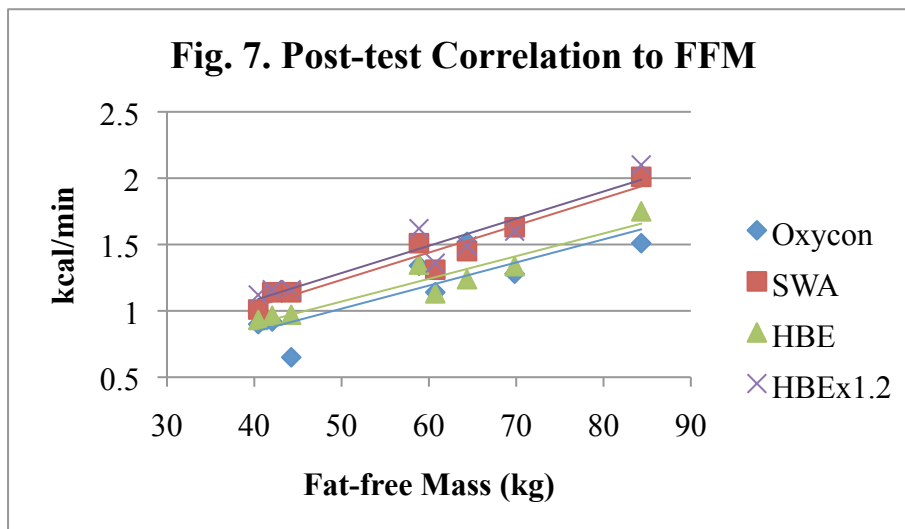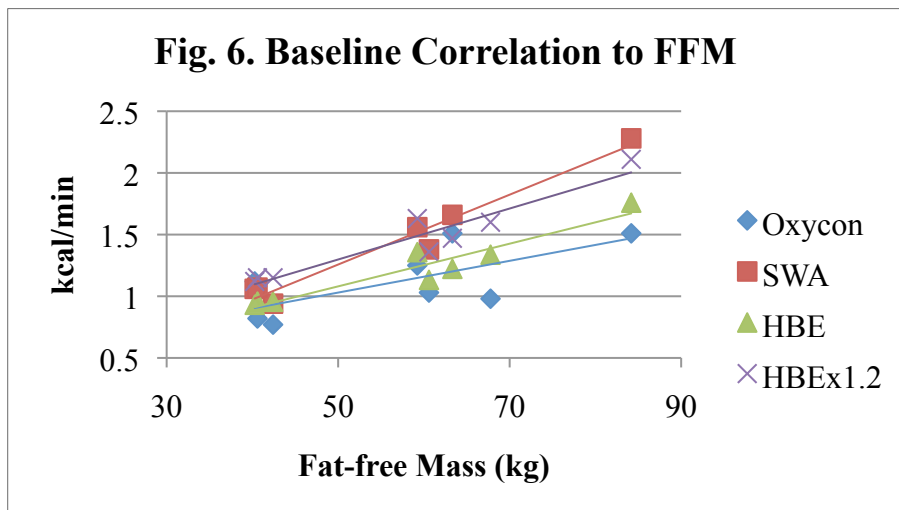
CHAPTER 5

DISCUSSION

This study did not discover a significant change in RMR or self-reported satiety after subjects adopted a vegetarian diet free of flesh foods and eggs, but not dairy, for 28 d, measured by either indirect calorimetry or a multisensor armband. This study did, however demonstrate a high correlation between the SenseWear Armband and the Oxycon Mobile portable metabolic cart, at least while subjects were at rest. The HBE and FFM (kg) did not correlate with the results of the Oxycon at baseline, but did at post-test. This discrepancy may be related to the small sample size and possibly related to the fact that bioelectrical impedance can be affected by hydration status and body fat distribution, thereby affecting body fat percentage, and therefore FFM.

Interestingly, the SWA and HBE correlated better with FFM than the Oxycon, at least at rest. This may be related to the fact that HBE relies directly on anthropometric measures to determine its estimate of daily EE, the same anthropometric data entered into the SWA (age, gender, height, weight). Because the subjects in this study were at rest, the SWA's accelerometer was virtually silent. It is unlikely that the armband's other features such as heat flux and Galvanic Skin Response are sensitive enough to measure RMR alone. Therefore, these findings strongly indicate the SWA is simply calculating RMR using some equation like the HBE using the anthropometric data it is given during the initialization process. The study discussed earlier by Papazoglou et al. (20) also suggested the SWA

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may be using HBE because they found that in obese subjects, the SWA correlated better with HBE than indirect calorimetry. These findings also support the findings of studies that used subject-specific algorithms and found the accuracy of the SWA was greatly improved (29,30).

This study went one step further and used an activity factor of 1.2 with HBE with the theory that the SWA may be using a sedentary activity factor while subjects are at rest. At baseline, means of the TDEE from the SWA and the HBE(x1.2) as well as means of EE in kcal/min were compaired using 2-related samples tests. Although the means of the SWA and the HBE(x1.2) appeared closer at first glance than the means between the SWA and HBE alone, p values revealed HBE(x1.2) was significant only at post-test, while the HBE without an activity factor was significantly related to the SWA at both time points (see Tbl. 6 above). This discrepancy may have been influenced by the low number of subjects (n=7 at baseline and n=8 at post-test for due to a failed armband for one subject) and the amount of deviation. User error may have played a role as well. This author was less skilled at operating the Oxycon and placing the face masks on subjects at the beginning of the study but was more adept during post-testing.

Of course the greatest limitation of this study was the very small number of subjects, making it impossible to draw strong conclusions about diet and RMR from the results, which demonstrated no significant changes resulting from a diet intervention, as measured by either Oxycon or SWA. It is possible that a larger sample size would yield different results and it is suggested that any future replications of this pilot study should seek to increase the subject pool to at least 24

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males and 24 females (n=48), as determined by a power analysis seeking a difference in the means of 0.25 ±0.03 kcal/min (power 0.80).

This pilot also found that is that it is fairly easy to find willing subjects and that it is a simple study to conduct, with the greatest expense related to the metabolic cart. The greatest challenge on the part of the researchers is scheduling subjects in the lab and time related to use of the Oxycon, while for the subjects it is probably dietary compliance for those who were randomized to a group that required a diet change. Seeing that there is no need to blind subjects as to the desired outcome of this study, as metabolic rate is not something they can willfully control, recruitment is open to any department of the university, providing a large subject pool from which to choose. Subject recruitment for this pilot study was limited by exclusion criteria of the larger study, which originally sought to only recruit subjects from outside departments who would not be as likely to understand the true motivations of the researchers who were attempting to determine if diet type was related to mood.

Regardless of sample size, it is possible that if there is a change in RMR once a person stops eating meat, that change may only be detectable within the first few days, but then disappears once the body adapts. Future studies of this topic should consider measuring RMR daily or perhaps every other day for the first week. Additionally, differences in RMR may be more noticeable when a subject goes from consuming a mixed diet to consuming a vegan diet, void of any animal protein. Although this diet is considered extreme by some, measuring RMR for only 1 wk instead of 4 increases the likelihood of compliance, as most

subjects who are willing to sign up for such a study in the first place would be willing to change their diet for only 1 wk. It may be of additional interest to the researchers to run this experiment as a crossover trial, in which subjects consume a mixed diet, a vegetarian diet, and a vegan diet for 1 wk each, with a washout period of 1 wk in between each diet, wherein they resume consuming their usual mixed diets. Perhaps some subjects may show a greater sensitivity to one diet type over another. For example, someone who rarely or never consumes seafood while on a mixed diet may show a greater change in RMR than someone who consumes seafood regularly.

It is possible the lack of change in RMR supports the idea of Set-Point Theory (80). That is, regardless of the diet type, metabolic rate did not change, possibly indicating the human body in a fed state is entirely in control of maintaining a constant RMR and is affected little by outside influences. Therefore, the idea that one's metabolism can be manipulated through diet alone appears to be incorrect. Based on the body of research discussed earlier, it seems logical that the human body will maintain its desired overall metabolic rate (albeit with noticeable but temporary changes postprandially) regardless of the type of fuel coming in. That is, if a specific subject needs 1,500 kcal/d to support the normal bodily functions it must perform each day to survive, that number is not going to change because the type of fuel source does, at least not in the long run and as long as weight remains constant. Indeed, long-term studies of the metabolic rates of vegetarians indicate no significant differences from that of meat-eaters, although sometimes differences can be seen in the postprandial phase (64). Again, it would

have probably been more beneficial to this particular study if RMR had been monitored much more closely during the first 1-2 wks.

Another purpose of this study was to determine if a change in satiety would occur related to adopting a vegetarian diet. This study failed to find a significant change in self-reported satiety using a validated scale (44). It was theorized that if subjects on high-protein diets report increased satiety (40,45,47), perhaps someone suddenly adopting a vegetarian diet would inversely report less satiety. Despite the lack of significant changes in this pilot study as well as the larger study, it may still be plausible this is the case, especially if subjects were to adopt a vegan diet void of animal protein, which is shown to increase postprandial thermogenesis even more so than plant sources of protein such as soy (40).

Given that the meals of these subjects were not in any way controlled, it could be that the vegetarians compensated for the lack of satiety by simply eating more food or more calorically dense food, or that an increase in fiber from plant foods had virtually the same affect on satiety as protein. The 3 d food logs did not indicate a difference in total kilocalories in any group after the intervention, but such a record may not be sensitive enough to capture a difference in caloric intake, especially if the difference was most noticeable in the first week or so of the diet change when the most dramatic dietary changes were occurring. Again, it may be beneficial to ask that subjects keep a 3 d food log before and immediately following the diet change, then again at the end of the study. If the study were to be conducted for only 1 wk, as suggested above, perhaps it would be wise to ask

the subjects to keep a record in the 3 d prior to the intervention as well for the entire week of the intervention.

Another purpose of this study was to validate the SenseWear Armband against the metabolic cart — the gold standard for measuring metabolic rate. Of notable significance was the strong positive correlation between the 2 devices. At baseline, r = 0.87, and at post-test correlation r = 0.81 (see Fig. 2 and Fig. 3). These results support the findings of several other studies, as previously discussed. Of notable importance is the fact that in this study the SWA was validated against the Oxycon while subjects were at rest. Previous studies have found the SWA is more accurate at rest or during moderate activity, while accuracy declines as physical intensity level increases. While the SWA is promising for use in free-living individuals, it may be wise to ask subjects to refrain from very intense physical activity during the course of the study, especially if the study is hoping to measure small differences in metabolic rates of individual subjects over time.

It is extremely likely the SWA is not capable of measuring small fluctuations in metabolic rate the way a metabolic cart is, but as a general tool for consumers, it is consistent and fairly accurate. The SWA may have a place in future research due to relatively low cost versus its ability to be used by freely living subjects who can complete most of the normal activities of daily life while wearing it, sans swimming, showering and engaging in full-contact sports. For the general public to whom the SWA is marketed as a weight loss tool, the strong correlation indicates it may indeed be a useful aid, especially for those who are ini-

tially unconscious of how much energy they are consuming versus how much they actually need to consume in comparison to their daily expenditure.

The SWA is probably not as useful a tool to lean and fit people who work out regularly as it is to those who are sedentary and possibly overweight. As previously discussed, research indicates it is not sensitive enough to detect fluctuations in metabolic rate related to heavy exercise, especially because its biggest weakness is its declining accuracy compared to level of intensity, but not speed of movement. For example, if an athlete is wearing the SWA hoping to see a difference in calories "burned" by increasing the slope of the treadmill every day or the amount of weight they lift and hold in a given amount of time, they will probably be disappointed by the results of the device. Compare this to a sedentary person who begins walking slowly for a few min and gradually increases in time and speed while making several dietary changes – more representative of the market the consumer version of the SWA, known as The BodyBugg or GoWear Fit, is aimed at, as evidenced by its advertisement on the famous weight loss competition show, "The Biggest Loser".

While no significant findings emerged from the limited data collected in this pilot study regarding metabolic rate and satiety, future research in this field is warranted. The exact mechanism behind the reported increases in satiety by those on high-protein diets has yet to be proven and remains under debate. Perhaps future versions of this study should consider a crossover trial in which there is a control group that remains on a mixed diet versus a vegan group that refrains from consuming any animal products and a high-protein group that increases its usual

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intake. The more extreme diet changes may be more likely to elicit a noticeable difference in RMR or satiety, thus providing further clues about the mechanisms attributing to the popularity of high-protein diets.

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APPENDIX A

IRB APPROVAL

Office of Research Integrity and Assurance

To:	Bonnie Beezhold HEALTH SCI
From:	Carol Johnston, Chair Biosci IRB
Date:	02/08/2011
Committee Action:	**Expedited Approval**
Approval Date:	02/08/2011
Review Type:	Expedited F3 F7
IRB Protocol #:	1101005924
Study Title:	Restriction of Meat, Fish, and Poultry in Omnivores: A Randomized Controlled Trial
Expiration Date:	02/07/2012

The above-referenced protocol was approved following expedited review by the Institutional Review Board.

It is the Principal Investigator's responsibility to obtain review and continued approval before the expiration date. You may not continue any research activity beyond the expiration date without approval by the Institutional Review Board.

Adverse Reactions: If any untoward incidents or severe reactions should develop as a result of this study, you are required to notify the Biosci IRB immediately. If necessary a member of the IRB will be assigned to look into the matter. If the problem is serious, approval may be withdrawn pending IRB review.

Amendments: If you wish to change any aspect of this study, such as the procedures, the consent forms, or the investigators, please communicate your requested changes to the Biosci IRB. The new procedure is not to be initiated until the IRB approval has been given.

Please retain a copy of this letter with your approved protocol.

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APPENDIX B

SUBJECT CONSENT FORM

DIETARY FACTORS AND WELL-BEING

INTRODUCTON

The purposes of this form are to provide you (as a prospective research study participant) information that may affect your decision as to whether or not to participate in this research and to record the consent of those who agree to be involved in the study.

RESEARCHERS

Drs. Bonnie Beezhold and Carol Johnston, ASU Nutrition Faculty, and their students, Amy Moore and Amanda Jensen, have invited your participation in a research study.

STUDY PURPOSE

The purpose of the research is to investigate how diet may contribute to physical and mental well-being.

DESCRIPTION OF RESEARCH STUDY

If you qualify for the study and decide to participate, then as a study participant you will be placed randomly into one of three experimental groups: meat (M), fish (F), or vegetarian (V). Participants are expected to consume their respective diets for four weeks. Participants will complete 3-d diet records prior to the start of the study and at study week 4. Participants will wear small measuring devices attached to their upper arms during the 3-d periods that diet records are maintained. These devices measure body motion and body temperature and are the size of a large watch. Participants will also complete short questionnaires regarding mental function at the start of the trial and again at the end of the trial.

This study entails three visits to the nutrition laboratories at the Health Science Center at the ASU Polytechnic campus. At **study visit 1**, which will take ~30 minutes, you will complete health and wellness questionnaires, have body weight and height assessed, and receive diet records to complete and SenseWear armbands (if selected). You will be scheduled for the next 3 visits and given instructions to prepare for fasting blood draws at two of these visits. (Fasting entails abstaining from all food or drink aside from water for 8 hours.) At **study visit 2** (~30 minutes) you will provide a blood sample, have weight and body composition measured, and return your diet records (and SenseWear armbands if applicable). At **study visit 3**, you will receive diet records and SenseWear armbands. At **study visit 4** (~30 mins), you will provide a blood sample, have weight and body composition measured, complete wellness surveys, and return your diet records and SenseWear armbands. Two tubes of blood will be taken per sampling for a total of 1.5-2 tablespoons per sampling. Approximately 50 subjects will be participating in this study.

RISKS

If you decide to participate in this study, you may be frustrated with not being able to eat beef, chicken, or fish for four weeks. The fasting required for the blood draws may be associated with weakness and faintness. There is a possibility of fainting, bruising, and/or infection when blood is collected from the arm vein. A skilled, certified phlebotomist will perform the blood draws using sterile and standard techniques minimizing these risks. As with all experimental research, it is possible that you may be subject to risks that have not yet been identified.

BENEFITS

The main benefit of your participation in this study is to contribute to research that may be used to formulate new theories on diet and mental function.

NEW INFORMATION

If the researchers find new information during the study that would reasonably change your decision about participating, then they will provide this information to you.

```
          ASU IRB
          Approved
Sign _____
Date 2/8/11  —  2/7/12
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CONFIDENTIALITY

All information obtained in this study is strictly confidential unless disclosure is required by law. The results of this research study may be used in reports, presentations, and publications, but the researchers will not identify you. In order to maintain confidentiality of your records, Drs. Beezhold and Johnston will use only subject codes on the data collected, maintain a master list separate and secure from all data collected, and limit access to all confidential information to the study personnel.

WITHDRAWAL PRIVILEGE

It is OK for you to say no. Even if you say yes now, you are free to say no later, and withdraw from the study at any time. Your decision will not affect your relationship with Arizona State University, nor cause penalty or prejudice toward you or otherwise cause a loss of benefits to which you might otherwise be entitled.

COSTS AND PAYMENTS

The researchers want your decision about participating in the study to be absolutely voluntary. Yet they recognize that your participation may pose some inconvenience. You will receive a $25 Target gift certificate after your baseline visit and another $25 gift certificate at the completion of the study.

COMPENSATION FOR ILLNESS AND INJURY

If you agree to participate in the study, then your consent does not waive any of your legal rights. However, in the event of harm, injury, illness arising from this study, neither Arizona State University nor the researchers are able to give you any money, insurance coverage, free medical care, or any compensation for such injury.

VOLUNTARY CONSENT

Any questions you have concerning the research study or your participation in the study, before or after your consent, will be answered by Dr. Carol Johnston (480-727-1713) or Dr. Bonnie Beezhold (480-727-1469), faculty members in the Nutrition Program, Arizona State University.

If you have questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects Institutional Review Board, through the ASU Research Compliance Office, at 480-965 6788.

This form explains the nature, demands, benefits and any risk of the project. By signing this form you agree knowingly to assume any risks involved. Remember, your participation is voluntary. You may choose not to participate or to withdraw your consent and discontinue participation at any time without penalty or loss of benefit. In signing this consent form, you are not waiving any legal claims, rights, or remedies. A copy of this consent form will be given (offered) to you.

Your signature below indicates that you consent to participate in the above study.

Subject's Signature	Printed Name	Date

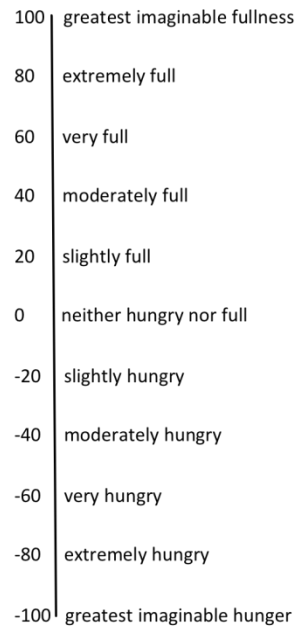Contact information   Email and/or phone number   Please circle your preferred mode of contact

INVESTIGATOR'S STATEMENT

"I certify that I have explained to the above individual the nature and purpose, the potential benefits and risks associated with participation in this research study, have answered any questions that have been raised, and have witnessed the above signature. These elements of Informed Consent conform to the Assurance given by Arizona State University to the Office for Human Research Protections to protect the rights of human subjects. I have provided (offered) the subject/participant a copy of this signed consent document."

Signature of Investigator_____   Date_____

APPENDIX C

PERCEIVED SATIETY SCALE

100	greatest imaginable fullness
80	extremely full
60	very full
40	moderately full
20	slightly full
0	neither hungry nor full
-20	slightly hungry
-40	moderately hungry
-60	very hungry
-80	extremely hungry
-100	greatest imaginable hunger

APPENDIX D

SENSEWEAR ARMBAND INSTRUCTIONS FOR USE

The SenseWear system components include the Armband and the optional Display device. The Armband collects data through sensors to analyze physiological and lifestyle data. The Display shows up-to-the-minute user information.

Armband Operating Instructions

Proper Wear

Wear your Armband on the back of the upper left arm (the tricep). To work properly, the Armband logo must face upward towards the shoulder and the silver sensors on the underside of the Armband will be in contact with your skin.

1. Be sure the upper left arm is clean, dry, and free of lotion or oil then slide the Armband onto your left arm.

2. Adjust the strap so that it fits comfortably, and then secure the Velcro pull-tab. Ensure that the sensors on the underside of the Armband maintain continuous contact with your skin and that the Armband does not slide off your arm.

3. Do not secure the strap too tightly. You should be able to place two fingers beneath the strap. Once the strap is adjusted to a comfortable fit, there is no need to readjust the Velcro tab. Simply slide the Armband on and off your arm by stretching the strap.

4. Wear the Armband no more than 23 hours a day. Be sure to leave it off 1 hour per day.

5. Replace the strap if it has lost its elasticity. Information on obtaining replacement parts can be obtained where you purchased the Armband.

The Armband will turn on and begin collecting data within 10 minutes. Activation is indicated by a series of audio tones. Please note that there is no power button on the Armband.

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