

**CHANGES IN RESTING METABOLIC RATE AND THE PERCEPTION OF  
HUNGER AND SATIETY IN PATIENTS WITH EATING DISORDERS  
THROUGHOUT RESIDENTIAL TREATMENT**

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## **Dedication**

I would like to dedicate this thesis to the Fulbright Foundation in Greece for giving me the opportunity to expand my personal and professional horizons, and to my mother, Evangelia Konstantinou, my family and friends for always being there for me.

## **Abstract**

**Objective:** This prospective observational study examined changes in resting metabolic rate (RMR) and the perception of hunger and satiety in a group of patients with eating disorders receiving treatment in a residential setting.

**Methods:** Seventeen women admitted at the Anna Westin House residential program, aged 18-41 (mean 27.2) years, were followed upon admission, each month of treatment and a post-discharge follow-up. RMR measurements were conducted via indirect calorimetry. Questionnaires were used to assess eating disorder diagnosis, as well as physical sensations, mood, and preoccupation with thoughts of food before and after meals.

**Results:** Upon admission 5 subjects had anorexia nervosa, 3 bulimia nervosa and 9 eating disorder not otherwise specified. There was an increase in weight for the whole group between admission and discharge but no change in RMR. A positive correlation was noted between weight and RMR at admission and at discharge. The percentage of subjects reporting having no gastric feelings of hunger decreased between admission and discharge. At discharge, there was a decrease in the percentage of subjects who reported irritability, tenseness, depression and preoccupation with thoughts of food around meals.

**Conclusions:** The results suggest a relationship between weight and RMR as well as a progression towards normalization of the perception of hunger and satiety throughout treatment. Further studies are needed to explore the trends observed in this study, their etiology and treatment implications.

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# **Introduction**

## **General Overview of Eating Disorders**

### **Diagnosis**

Eating disorders are defined in the Diagnostic and Statistical Manual of Mental Disorders as “disorders characterized by severe disturbance in eating behavior”<sup>1</sup>. Two main diagnostic categories, that of anorexia nervosa (AN) and that of bulimia nervosa (BN), are currently provided. A third diagnostic category, eating disorder not otherwise specified (EDNOS), is provided to allow for diagnosis of patients who do not meet the specific criteria for AN or BN. In addition, the manual provides research criteria for binge eating disorder (BED). BED is not a diagnostic entity on its own and patients with BED are officially being classified under the EDNOS category. The provided criteria intend to encourage more research on BED, which will allow for determination of whether it should be included as an official diagnosis at the next revision of the manual. Details of the diagnostic criteria for each disorder are presented in **Tables 1, 2 and 3**.

There is important diagnostic crossover between the different types of eating disorders since symptom use can change with time. In one study, 28.9% of patients maintained their initial eating disorder diagnosis, while 7.7% had crossed diagnosis from AN or BN to EDNOS and 7.1% had crossed diagnosis from AN to BN and vice versa<sup>2</sup>. Among the different diagnoses, EDNOS is the one most commonly used in outpatient settings. A recent study using a large, representative patient sample showed that 60% of patients seen in an outpatient setting fell under the EDNOS category<sup>3</sup>.

**Table 1:** DSM-IV-TR Diagnostic Criteria for Anorexia Nervosa<sup>1</sup>

<b>Criterion</b>	<b>Description</b>
<b>A</b>	Refusal to maintain body weight at or above a minimally normal weight for age and height (e.g., weight loss leading to maintenance of body weight less than 85% of that expected; or failure to make expected weight gain during period of growth, leading to body weight less than 85% of that expected).
<b>B</b>	Intense fear of gaining weight or becoming fat, even though underweight.
<b>C</b>	Disturbance in the way in which one's body weight or shape is experienced, undue influence of body weight or shape on self evaluation, or denial of the seriousness of the current low body weight.
<b>D</b>	In postmenarcheal females, amenorrhea, i.e., the absence of at least three consecutive menstrual cycles. (A woman is considered to have amenorrhea if her periods occur only following hormone, e.g., estrogen, administration.)
<u>Specify type:</u> <b>Restricting type:</b> During the current episode of anorexia nervosa, the person has not regularly engaged in binge-eating or purging behavior (i.e., self-induced vomiting or the misuse of laxatives, diuretics, or enemas). <b>Binge-eating/purging type:</b> During the current episode of anorexia nervosa, the person has regularly engaged in binge-eating or purging behavior (i.e., self-induced vomiting or the misuse of laxatives, diuretics, or enemas).	

**Table 2:** DSM-IV-TR Diagnostic Criteria for Bulimia Nervosa<sup>1</sup>

<b>Criterion</b>	<b>Description</b>
<b>A</b>	<p>Recurrent episodes of binge eating. An episode of binge eating is characterized by both of the following:</p> <p>(1) Eating, in a discrete period of time (e.g., within any 2-hour period), an amount of food that is definitely larger than most people would eat during a similar period of time and under similar circumstances.</p> <p>(2) A sense of lack of control over eating during the episode (e.g., a feeling that one cannot stop eating or control what or how much one is eating).</p>
<b>B</b>	<p>Recurrent inappropriate compensatory behavior in order to prevent weight gain, such as self-induced vomiting; misuse of laxatives, diuretics, enemas, or other medications; fasting; or excessive exercise.</p>
<b>C</b>	<p>The binge eating and inappropriate compensatory behaviors both occur, on average, at least twice a week for 3 months.</p>
<b>D</b>	<p>Self-evaluation is unduly influenced by body shape and weight.</p>
<b>E</b>	<p>The disturbance does not occur exclusively during episodes of anorexia nervosa.</p>
<p><u>Specify type:</u></p> <p><b>Purging type:</b> During the current episode of bulimia nervosa, the person has regularly engaged in self-induced vomiting or the misuse of laxatives, diuretics, or enemas.</p> <p><b>Nonpurging type:</b> During the current episode of bulimia nervosa, the person has used other inappropriate compensatory behaviors, such as fasting or excessive exercise, but has not regularly engaged in self-induced vomiting or the misuse of laxatives, diuretics, or enemas.</p>	

**Table 3:** DSM-IV-TR Eating Disorders Not Otherwise Specified <sup>1</sup>

The Eating Disorder Not Otherwise Specified category is for disorders of eating that do not meet the criteria for any specific eating disorder. Examples include:	
<b>1</b>	For females, all of the criteria for anorexia nervosa are met except that the individual has regular menses.
<b>2</b>	All of the criteria for anorexia nervosa are met except that, despite significant weight loss, the individual's current weight is in the normal range.
<b>3</b>	All of the criteria for bulimia nervosa are met except that binge eating and inappropriate compensatory mechanisms occur at a frequency of less than twice a week or for a duration of less than 3 months.
<b>4</b>	The regular use of inappropriate compensatory by an individual of normal body weight after eating small amounts of food (e.g., self-induced vomiting after the consumption of two cookies).
<b>5</b>	Repeatedly chewing and spitting out, but not swallowing, large amounts of food.
<b>6</b>	Binge eating disorder: recurrent episodes of binge eating in the absence of the regular use of inappropriate compensatory behaviors characteristic of bulimia nervosa

**Table 4:** DSM-IV-TR Research Criteria for Binge Eating Disorder<sup>1</sup>

<b>A</b>	Recurrent episodes of binge eating. An episode of binge eating is characterized by both of the following:  (1) Eating, in a discrete period of time (e.g., within any 2-hour period), an amount of food that is definitely larger than most people would eat during a similar period of time and under similar circumstances.  (2) A sense of lack of control over eating during the episode (e.g., a feeling that one cannot stop eating or control what or how much one is eating).
<b>B</b>	The binge eating episodes are associated with three (or more) of the following:  (1) Eating much more rapidly than normal (2) Eating until feeling uncomfortable full (3) Eating large amounts of food when not feeling physically hungry (4) Eating alone because of being embarrassed by how much one is eating (5) Feeling disgusted with oneself, depressed, or very guilty after overeating
<b>C</b>	Marked distress regarding binge eating is present.
<b>D</b>	The binge eating occurs, on average, at least 2 days a week for 6 months.
<b>E</b>	The binge eating is not associated with the regular use of inappropriate compensatory behaviors (e.g., purging, fasting, excessive exercise) and does not occur exclusively during the course of anorexia nervosa or bulimia nervosa.

## **Prevalence and Risk Factors**

In a study using a nationally representative sample from the United States, the lifetime prevalence of eating disorders in women was found to be 0.9% for AN, 1.5% for BN and 3.5% for BED<sup>4</sup>. The lifetime prevalence for men was found to be 0.3%, 0.5% and 2% for AN, BN and BED accordingly. In another recent general population study using sample from six European countries, the authors found that the lifetime prevalence of eating disorders in women was 0.93%, 0.88% and 1.92%, and in men 0%, 1.12% and 0.26% for AN, BN and BED accordingly<sup>5</sup>.

Jacobi et al completed a systematic review of risk factors for development of eating disorders from longitudinal and cross-sectional studies<sup>6</sup>. According to their review, the risk factors consistently presented in the literature include being female, being of ethnicity other than Asian, having a history of feeding, eating or gastrointestinal problems early in childhood, or having a childhood history of physical or sexual abuse. Additional risk factors include the period of adolescence, exhibiting negative self-evaluation or low self esteem, having other mental health problems (including mood and anxiety disorders) or exhibiting increased concern about weight or shape, body dissatisfaction or frequent dieting. According to the same systematic review, genetic factors have been shown to be involved in the development of eating disorders but the extent of this involvement is still unclear.



## **Related Conditions and Complications**

Eating disorders present significant comorbidity with other mental health diagnoses including most mood, anxiety, impulse control, personality and substance use disorders<sup>7</sup>. In a nationally representative sample, 56.2% of patients with AN, 94.5% of patients with BN and 78.9% of patients with BED also met the criteria for at least one more disorder presented in the Diagnostic and Statistical Manual for mental Disorders<sup>4</sup>.

In addition, eating disorders can have serious medical consequences affecting many of the major body systems<sup>7,8</sup>. For the integument system, patients may present with dry skin, lanugo hair growth, carotenoderma, acne, pruritus, purpura or self-injury marks. For the cardiovascular system, patients may present with arrhythmias, hypotension and acrocyanosis, while for the pulmonary system, they might present with respiratory muscle waisting or pneumomediastinum. Complications related to the central nervous system like mood and cognition changes might also occur. In addition, patients might have gastrointestinal complaints including dental caries, gingivitis, enlarged parotid glands, constipation, delayed gastric emptying, gastritis, pancreatitis or liver dysfunction. Reproductive abnormalities like oligomenorrhea or amenorrhea, regression of secondary sex characteristics or decreased libido are also often found in patients with eating disorders. Low weight patients might also present muscle waisting and decreased bone density which can lead to osteopenia and osteoporosis.

Several of the complications related to eating disorders could prove fatal. A recently published longitudinal assessment study, found that the crude mortality rates were 4%, 3.9% and 5.2% for AN, BN and EDNOS accordingly<sup>9</sup>. Studies have shown that mortality

rates both from natural causes and from suicide are significantly increased in patients with AN<sup>10</sup>, BN and eating disorder otherwise specified<sup>9</sup>.

## **Treatment**

Despite the serious impact that eating disorders can have in patients' lives, studies show that only a small percentage of patients seek mental health treatment for their eating disorder<sup>4,5</sup>. The American Psychiatric Association recommends the involvement of an interdisciplinary team of professionals including psychiatrists, physician specialists, dentists, psychologists, registered dietitians and social workers<sup>7</sup>. Nutritional rehabilitation, medication management and different types of psychosocial interventions are all important parts of eating disorders treatment.

In its practice guidelines, the American Psychiatric Association also describes the different levels of care for eating disorders treatment<sup>7,11</sup>. The level of care each patient needs depends on the patient's general medical, psychiatric and social needs. Inpatient programs involve 24-hour care in a hospital environment where specialist medical care is available. These are usually appropriate for patients who are medically unstable or at increased risk of becoming medically unstable, have other concurrent mental health problems for which hospitalization is advised, or who need a highly structured setting in order to benefit from treatment. Residential treatment programs are usually appropriate for patients who are not in immediate danger of medical instability but still have a low body weight, or still need a highly structured environment in order to avoid symptom use. Residential treatment might also be appropriate for patients with long duration of illness. Partial hospitalization programs should involve patients for at least five days per week for eight hours per day. Such programs are for medically stable, relatively motivated to recover patients who still need increased structure in order to avoid symptom use or

whose concurrent mental health conditions might benefit for increased structure. Finally, patients who are medically stable, have had a short duration of illness, are motivated to recover and have good support systems are good candidates to receive treatment at an outpatient setting. The patient's level of motivation to recover and their ability to be self-sufficient in managing their symptoms will dictate the intensity of outpatient treatment.

## **Resting Metabolic Rate (RMR)**

### **Definitions**

The human body spends energy conducting its basic functions like breathing and maintenance of homeostasis<sup>12,13</sup>. This energy expenditure is termed resting energy expenditure or resting metabolic rate. The body also spends energy in digestion, absorption and metabolism of the food it consumes and this form of energy expenditure is referred to as diet induced thermogenesis or as thermic effect of food. Finally, the human body spends energy in voluntary (for example running or walking) and involuntary (for example shivering) physical activities. This kind of energy expenditure is referred to as energy expended in physical activity or as activity induced thermogenesis. The sum of the resting energy expenditure, the diet induced thermogenesis and the energy expended in physical activity comprises the body's total energy expenditure or metabolic rate. In most people, resting energy expenditure is the largest component (>60%) of the total energy expenditure. A definition more stringent than resting energy expenditure is that of basal energy expenditure or basal metabolic rate or sleeping energy expenditure. This term is used to indicate the minimal amount of energy that a person needs to spend in order to stay alive when physically and mentally at rest in a thermoneutral environment. In reality, the ideal conditions needed for measurement of basal metabolic rate are very difficult to achieve. Thus, what is more often measured in practice is the resting metabolic rate of individuals which can be easily measured using indirect calorimetry. The terms basal metabolic rate, basal energy expenditure, resting metabolic rate and resting energy expenditure are often used interchangeably in the literature<sup>14</sup>.

## **Measurement Techniques for Resting Metabolic Rate**

There are two main techniques which can be used to measure RMR<sup>12</sup>. In the first technique, called direct calorimetry, the person is placed in a room called whole room calorimeter. Complex engineering is used to measure the energy the person spends in the form of heat. This technique is not commonly used because of the expensive and complex equipment involved. The second technique is called indirect calorimetry. During this test, the person is asked to breathe into a mouthpiece, mask or oxygen hood and the equipment collects data on the oxygen consumption and carbon dioxide production during breathing. This information is used to calculate the respiratory quotient ( $RQ = \frac{\text{Expiration CO}_2}{\text{Inspiration O}_2}$ ), find the amount of heat produced by the body ( $\text{kcal/m}^2$  of body/hour) and finally give the energy expenditure per day. Indirect calorimetry is easier to use in a clinical setting since the equipment used is portable and of more reasonable cost.

## **Usefulness in the Treatment of Patients with Eating Disorders**

Part of nutritional rehabilitation treatment for patients with eating disorders is the establishment of a structured meal plan that will ensure appropriate nutritional intake<sup>7</sup>. For patients needing to restore weight it is important that this happens in a controlled manner, since patients who have had poor nutritional intake for long periods of time can experience refeeding syndrome if they are fed aggressively either orally, enterally or parenterally<sup>15</sup>. Refeeding syndrome is a life-threatening condition where fluid and electrolyte disturbances can lead to neurologic, cardiovascular, pulmonary, metabolic and hematologic complications. Patients with AN and patients who have lost a very significant amount of weight (even though they might still be at or above their expected weight) are at risk for developing refeeding syndrome<sup>16</sup>.

RMR measurements can be used to design, implement and evaluate nutritional rehabilitation programs for patients with eating disorders. Studies have found that equations which are frequently used in clinical settings to predict RMR, widely underestimate or overestimate the requirements of patients with AN<sup>17</sup> and BN<sup>18</sup> making indirect calorimetry the recommended option for calculation of energy requirements in these patients in a clinical setting. Indirect calorimetry measurements can be used to design a nutritional rehabilitation program based on each patient's individual metabolic needs, thus helping to avoid refeeding complications. In addition, indirect calorimetry measurements can be used to improve the monitoring of eating disorders patients and to clarify whether a potential inability to restore weight is due to treatment adherence issues or to changes in the metabolic needs of the patient<sup>14</sup>. RMR measurements using indirect

calorimetry can also be used as part of a psychodynamic approach. They can help the patients better understand how their body reacts at each point of the treatment, thus facilitating the conversation between the healthcare team and the patients regarding the caloric prescription<sup>19</sup>.



## **Findings in Patients with Eating Disorders**

In their study, Winter et al measured the RMR of 8 patients with AN at the beginning of treatment and 17 healthy controls<sup>20</sup>. They found that the RMR of patients with AN was significantly lower than the RMR of the controls. Similar results have been obtained by other studies examining both adolescents and adults with AN before treatment in comparison with healthy controls<sup>21-25,25</sup>. There are contradictory results, though, on whether the difference in the RMR of patients with AN and controls remains when RMR is adjusted for fat free mass<sup>22,23</sup>. The inconclusive results on this point may mean that the lower RMR of patients with AN is not only due to their lower fat free mass<sup>13</sup>.

Different studies have shown that the RMR in patients with AN increases during treatment. In one study of 10 adult females participating in a partial hospitalization program, both RMR and RMR per pound of fat free mass increased throughout treatment<sup>26</sup>. In this study, higher body mass index (BMI) on admission was associated with a trend of smaller increases in RMR. Similar results were presented in another study examining 22 female hospitalized adolescents, even though the increase in RMR per kg of fat free mass did not reach statistical significance in this study<sup>17</sup>. A study by Obarzanek et al also showed a significant increase in RMR for the patients with AN but noted that this increase was disproportionately large compared to the increase in weight<sup>23</sup>. Some studies showed no significant difference between the RMR of patients with AN after treatment and that of healthy controls<sup>22,24,25</sup>, while in other studies, the RMR of the patients remained significantly lower than that of controls after the end of the refeeding

process<sup>20,21</sup>. The difference in these findings may be related to the exact conditions used in each study. For example, one study collected data for the comparison when the patients with AN were at the 8<sup>th</sup> week of treatment<sup>25</sup>, while another after patients had reached their target weight or had an increase of at least two points in their body mass index<sup>21</sup>. A recent study comparing RMR measurements of 16 women who were recovered (defined as no use of compensatory behaviors and a body mass index greater than 18.5 kg/m<sup>2</sup>) from AN for two or more years and 18 controls, found no difference in the RMR of the two groups<sup>27</sup>. Same results were obtained by an earlier study comparing women with AN who had maintained a body mass index greater than 18.5 kg/m<sup>2</sup> for more than one year and healthy controls<sup>22</sup>.

Studies examining RMR in patients with BN are fewer, not very recent, and have inconclusive results. One study which examined 21 female patients with BN with 31 healthy controls, found that the RMR of the patients was significantly higher than that of controls before treatment but decreased when symptom use was interrupted during an one week hospitalization<sup>28</sup>. At the end of the week there was still a significant difference in RMR between groups. Another study found no difference in the RMR of women with BN and healthy controls and no significant change in the RMR of the patients before treatment and after a decrease in self-induced vomiting following outpatient treatment<sup>29</sup>. An earlier study had also found no difference in the RMR of patients before and after 7 weeks of inpatient treatment<sup>30</sup>. In another study, Obarzanek et al examined patients with BN after 2 to 3 weeks of inpatient treatment and found that their RMR was significantly lower than that of the controls even when it was adjusted for lean body mass, body

weight or body surface area<sup>31</sup>. Similar results were also obtained in an earlier study by Devlin et al<sup>32</sup>. A review of RMR in patients with BN attributed the different results of these studies in a variety of potential factors including differences in clinical status, history of symptom use, recent food intake and anthropometric characteristics of the subjects<sup>13</sup>.

To my knowledge there are no studies who have examined the RMR of patients with different presentations of EDNOS as a group. It has been proposed in the literature that this diagnostic category is being neglected in research<sup>3,33</sup>. There have been some studies, though, examining the RMR of obese women who have episodes of binge eating. Two studies<sup>34,35</sup> conducted in this population found no significant difference between the RMR of obese women who had episodes of binges eating and those who did not. One study<sup>36</sup> examined the RMR of obese women who met the criteria for BED and found no difference with the RMR of obese controls.

## **Hunger and Satiety**

### **Findings in Patients with Eating Disorders**

Gooldin recently published an analysis of the role of hunger in patients with AN from an anthropological perspective<sup>37</sup>. The author based her conclusions on narratives of patients and observation of their interactions with the therapists. Gooldin argues that patients perceive hunger like a suffering which they manage to overcome, a thought process that gives them almost a sense of accomplishing something heroic through their self-sufficiency and willpower. This description appears in agreement to studies showing that patients with eating disorders, interpret symptoms of severe dietary restraint such as hunger and heightened satiety, in terms of control, a thought process that might facilitate their illness<sup>38,39</sup>. In addition, Corstorphine et al found that the binge-purge cycles in BN can be reinforced by a decrease in the feelings of hunger after bingeing (accompanied by guilt, shame, anxiety) and a decrease in the feelings of satiety after self-induced vomiting (accompanied short-term by increased happiness, relief and lower levels of anxiety and worry)<sup>40</sup>. The authors suggested that, discussion of these reinforcement pathways should be presented to the patients as part of treatment. The American Psychiatric Association recognized the importance of achieving normal perceptions of hunger and satiety and indicates the normalization of these perceptions as one of the goals in the treatment of AN and BN<sup>7</sup>.

Studies that discuss how patients with eating disorders perceive hunger and satiety in terms of physical sensations, emotions and thoughts are scarce and not recent. A study conducted by Garfinkel et al found that patients with AN and healthy controls

perceived hunger in a similar way but AN patients showed higher preoccupation with food thoughts, stronger urge to eat and higher anxiety levels related to the feeling of hunger<sup>41</sup>. The authors also noted that, unlike the controls, the patients with AN did not describe satiety in terms gastric fullness. A similar study by Chiodo et al examining BN patients also did not find any significant difference in the perception of hunger between patients and controls<sup>42</sup>. The authors noted, though, that patients with BN tended to report irritability, nervousness, tenseness and depression after the meal. To my knowledge, there are no data on whether the way these patients perceive hunger and satiety changes throughout treatment.

## **Study Design and Objectives**

This is a prospective observational study designed to assess RMR and the perception of hunger and satiety in patients with eating disorders, at admission to residential eating disorder treatment, monthly while in treatment, and at a follow-up post discharge. This study intends to explore potential changes in metabolic rate and the way patients perceive feelings of hunger and satiety over time during treatment. In addition, the objective of the study is to test the following hypotheses:

1. The resting metabolic rate of patients who will restore weight throughout treatment will increase, while the resting metabolic rate of patients who will maintain their weight stable throughout treatment will not change.
2. There will be an increase in the number of patients who perceive hunger and satiety in terms of gastric sensations.
3. There will be a change in the reported mood before and after meals as shown by decreased levels of self-reported anxiety, irritability, nervousness, tenseness and depression.
4. There will be a decrease in the reported preoccupation with thoughts of food.

Patients needing residential treatment are medically stable to the extent that they do not need continuous medical supervision but their eating disorder is still so strong that a highly structured environment is needed for them to avoid symptoms use and to restore weight if necessary<sup>7</sup>. A residential setting was chosen for this study because it can allow longer-term access to patients receiving 24-hour care compared to an inpatient setting. As such, it can allow us to observe changes in the variables for longer periods of time. In

addition, previous studies in this area have focused in patients during inpatient, partial hospitalization or outpatient treatments. Choosing a residential setting will allow us to see if the findings at this level of care are comparable with those of previous studies in other levels of care. The Anna Westin House (AWH) was chosen because it was the only residential treatment facility for eating disorders in the State of Minnesota at the time when this study began.

## **Methods**

### **Sample, Recruitment and Informed Consent**

Patients admitted at the AWH are female adolescent and adult patients between the ages of 15 and 64 years old with any diagnosis of eating disorders. All patients admitted to the AWH between September 2008 and August 2009 were invited to participate in the study. Patients were recruited on a rolling basis over this period of time. The only pre-determined exclusion criterion was inability to read or write English since this would interfere with the administration of the questionnaires. No subjects were excluded from the study on this basis.

Upon admission to the AWH all the patients undergo a nutritional assessment by a dietitian. During this assessment meeting, the dietitian was describing the study to the subjects and asking them if they would be willing to participate. If the subjects appeared to be interested, the dietitian was informing them further about the objectives and the methods of the study and was obtaining informed consent. In case of minors or adults under guardianship who were unable to provide consent, the same procedure was to be followed in order to obtain informed consent by the guardian and assent by the minor or the adult under guardianship.



### **The Anna Westin House**

The AWH is a residential eating disorders treatment program for adolescent and adult women located in Chaska, Minnesota<sup>43</sup>. The program was created from a collaboration between the Anna Westin Foundation and The Emily Program. According to the AWH website, “the program seamlessly integrates psychological, nutritional, medical, psychiatric, and complementary therapy treatments in a holistic, comprehensive approach, all in a nurturing, empowering environment”. The goal of the program is to provide individualized treatment that addresses the impact eating disorders have in all aspects of a person’s life. The program involves a range of individual and group sessions as well as three therapeutic meals and snacks per day. The length of stay in the program varies according to each resident’s individual needs, but the mean length of stay is 3 to 4 months for adolescents and 4-6 months for adults.

## **Measures**

The study involved measurements upon admission of the subject at the AWH, at every month of treatment and at a 3-month follow-up after discharge from the AWH. All measurements were obtained by two dietitians who were part of the staff at the AWH. Subjects were given the option to attend the follow-up measurements in person at the offices of the Emily Program or to complete the study questionnaires via mail. All documents used to communicate with the subjects during the study are presented in **Appendix A.**

The measurements obtained during the study included:

1. **RMR measurements:** RMR was measured via indirect calorimetry using the Cosmed's FitMate indirect calorimetry machine. The machine has proven reliability and validity<sup>44</sup>. Data from these measurements were obtained upon admission, at every month of treatment, and at the follow-up. RMR measurements are routinely performed upon admission and every month of treatment as part of the standard clinical care at the AWH. Thus, the only additional RMR measurement that was performed for the purposes of this study, was the one during the in-person follow-up assessment. The RMR measurements were performed after overnight sleep and fasting (approximately nine hours after the previous meal) within one hour of waking and before any active movement or meals. The subject was asked to lie relaxed in a supine position for about 15 minutes prior to the test. Subsequently, with the subject at the same position, the test mask was placed over the subject's mouth and nose and the subject was asked to breath normally in it for 20 minutes until the test measurement was obtained. The subjects who were able to attend

the follow-up measurement in person were asked to come to the offices of the Emily Program early in the morning after a night fast and to refrain from eating breakfast or doing any significant physical activity until after the test.

2. Height and Weight measurements: During the subjects' stay at the Anna Westin House these measurements were performed in regular intervals as part of the standard clinical care. The required information for this study was obtained from the subjects' medical record. At the follow-up assessment, height and weight were assessed on site before the RMR measurement and after the administration of the hunger scale of the HSQ.

3. Modified version of the Hunger-Satiety Questionnaire (HSQ): This is a structured, self-rating questionnaire with two scales which was initially developed by Monello et al<sup>45</sup>. For the purpose of this study, the modified version as presented by Garfinkel et al<sup>41</sup> was used. The hunger scale of the questionnaire assesses gastric, mouth, throat, cerebral and general sensations of hunger, mood when hungry, preoccupation with thoughts of food and urge to eat. The satiety scale assesses gastric, cerebral and general sensations, mood, preoccupation with thoughts of food and urge to eat at the end of a meal. Feedback received from the subjects at the beginning of the study indicated that the first question of the satiety scale of the HSQ did not give an answer that was applicable to them during their stay at the AWH. Some of the subjects were required to finish the food portioned in their plate based on their meal plan as part of their treatment. Thus, one extra choice was added to that question reading "I finished the food on my plate". (See **Appendix B**) The HSQ was administered upon admission and at every month of

treatment. During the subjects' stay at the AWH, the hunger scale of the HSQ was completed in a paper-and-pencil form before the RMR measurement. Subsequently, the RMR measurement was performed and the subjects were having their normal breakfast at the AWH as defined by their meal plan and their treatment team. After the end of the breakfast, they were asked to fill in a paper-and-pencil form of the satiety scale of the HSQ. The satiety scale asks participants to rate how they feel after a meal. Because of inability to provide a meal during the follow-up measurements, the participants were asked to complete only the Hunger scale at that measurement. At the follow-up visit, the subjects who attended the measurements in person filled in the Hunger scale of the HSQ before the RMR measurements. The subjects who completed the follow-up via mail were asked to complete the hunger scale in the morning as soon as they woke up and before eating or drinking anything.

4. Eating Disorder Diagnostic Scale (EDDS): This is a brief self-reported scale assessing whether the subject meets the DSM-IV diagnostic criteria for eating disorders. (See **Appendix B**) The EDDS was developed by Stice et al<sup>46</sup> and it has proven reliability and validity<sup>47</sup>. The scoring algorithm provided by the authors allows diagnosis of AN, BN, and BED and their subthreshold forms (defined by the authors as cases in which patients present all the symptoms of the respective disorder but at least one of these symptoms is present at a subdiagnostic severity). The scale was administered upon admission to the AWH and at the follow-up visit to help us recognize any changes in the eating disorder diagnoses. The EDDS upon admission was administered at the end of all other measurements and after the administration of the satiety scale of the HSQ. For the

subjects who completed the follow-up measurements in person, the EDDS was completed after the RMR measurement. The subjects who completed the follow-up via mail were asked to complete the EDDS at any time during the same day when they would complete the hunger scale of the HSQ.

### **Human Subjects Protection**

This study was initially approved by the University of Minnesota Institutional Review Board on June 2008 (study number 0805M34461). Revisions in the study that allowed subjects to complete the follow-up measurements via mail were approved on May 2009. Approval for the study was renewed on May 2009.

### **Study Funding and Subject Compensation**

This study was funded by the Graduate program in Nutrition from the Department of Food Science and Nutrition at the University of Minnesota.

Subjects who completed the follow-up measurement either in person or via mail were compensated with a \$20 gift card for their time.

## **Statistical Analysis**

Statistical analysis was performed using the SPSS statistical software (PASW Statistics, version 17.0). Statistical significance was accepted at  $p\text{-value} < 0.05$ . The authors of EDDS have provided a scoring code for SPSS<sup>47</sup>. For the purposes of this study the algorithm was adjusted to provide diagnoses for AN and BN and to combine BED, all the subthreshold forms and patients who purge without binging at one EDNOS category. The code also provides results for no diagnosis. Subjects were categorized into groups based on the EDDS diagnosis at the time of admission at the AWH. Descriptive data for the whole group and for the group split by diagnosis are presented. Comparisons within and among the groups as well as correlations between RMR and weight were conducted using non-parametric statistics because of the small sample size. In addition, counts of subjects who selected each of the choices in the HSQ are presented.

A total of 20 subjects were recruited for the study. Few subjects were excluded from the study or the data analysis for reasons including failure to obtain parental consent for a minor (1 subject), unavailability of EDDS data at baseline (1 subject) and pregnancy (1 subject). The pregnant subject was excluded from the data analysis because pregnancy could affect RMR results as well as the subject's classification under a diagnostic group based on EDDS by unduly influencing questions relating to amenorrhea and weight. One subject was still in the AWH when the study was completed. Her results have been normally included in the analysis.

## Results

### Overview of the data

Results from 17 people were finally included in the statistical analysis. The total duration of time each subject stayed at the AWH is indicative of the number of measurements that they participated in. **Table 5** shows the number of people per measurement for the group as a whole and per diagnostic group. Based on this table, 24% of the subjects only stayed at the AWH for one month and thus completed only one measurement while in treatment. From the subjects who participated in two or more measurements while in treatment, 46% completed three or four measurements. Given that the time subjects stayed at the AWH varied so much, and that the overall number of subjects in the study was small, it was not possible to split the results of each person into different periods during treatment. Thus, the first measurement [admission (adm) at the AWH] and the last measurement [last month prior to discharge (d/c) from the AWH] were used in the following analysis in order to examine differences at variables over treatment. In the group of patients with BN there was only one subject who stayed more than one month in the AWH. Consequently, the analysis for this group was only conducted for the data collected upon admission. The mean number of months from discharge until follow-up was 5 months (range 3 to 9 months). In addition, any comparisons involving the follow up data were possible only for the group of patients with EDNOS since this was the only group with more than 2 subjects at follow up.

**Table 5:** Number of subjects at each measurement point

<b>Measurement</b>	<b>All subjects</b>	<b>AN</b>	<b>BN</b>	<b>EDNOS</b>
1	17	5	3	9
2	13	4	1	8
3	6	1	1	4
4	2	0	0	2
Follow-up via mail	5	2	1	2
Follow-up in person	2	0	0	2



## Descriptive Statistics

The mean age at admission was 27.2 years (range 18-41 years), the mean weight was 53 kg ( $\pm 14.8$  kg) and the mean RMR was 1212 kcal/day ( $\pm 208.3$  kcal/day). **Table 6** presents descriptive statistics for the group as a whole and split based on diagnosis upon admission to the AWH. Kruskal Wallis test between the three diagnostic groups revealed significant differences for weight and BMI (p-value=0.01) but no significant differences for age, height and RMR. Post hoc Mann-Whitney exact tests (with Bonferroni correction, significance set at p-value<0.0167) showed that the AN group had lower wt and BMI compared to the EDNOS group (1-tailed p-value=0.00).

**Table 6:** Descriptive Statistics on admission to the AWH

Group	Statistic	Age (years)	Height (m)	Weight (Kg)	BMI (Kg/m <sup>2</sup> )	RMR (Kcal/day)
<b>All (N=17)</b>	Mean $\pm$ SD	27.2 $\pm$ 6.5	1.6 $\pm$ 0.05	53.4 $\pm$ 14.8	20.4 $\pm$ 6	1212 $\pm$ 208.3
	Median	26	1.63	50.9	18.8	1143
	Range	18-41	1.5-1.7	34.6-93.2	12-36.4	896 $\pm$ 1576
<b>AN (N=5)</b>	Mean $\pm$ SD	29 $\pm$ 5.3	1.6 $\pm$ 0.07	38.6 $\pm$ 2.4 <sup>#</sup>	14.6 $\pm$ 1.7 <sup>*</sup>	1073 $\pm$ 57
	Median	27	1.6	39.1	14.8	1077
	Range	23-36	1.5-1.7	34.6-40.9	12-16.7	986-1143
<b>BN (N=3)</b>	Mean $\pm$ SD	27.7 $\pm$ 10.6	1.6 $\pm$ 0.04	56.3 $\pm$ 8.5	22.5 $\pm$ 3.3	1123 $\pm$ 329
	Median	26	1.57	60	23.6	972
	Range	18-39	1.5-1.6	46.6-62.3	18.8-25.2	896-1500
<b>EDNOS (N=9)</b>	Mean $\pm$ SD	26.1 $\pm$ 6.2	1.5 $\pm$ 0.04	60.7 $\pm$ 14.8 <sup>#</sup>	22.9 $\pm$ 6.2 <sup>*</sup>	1319 $\pm$ 174
	Median	26	1.63	56.1	21.1	1354
	Range	20-41	1.6-1.7	48.2-93.2	17.6-36.4	995-1576

<sup>#, \*</sup> Differences between groups based on Mann-Whitney test. One tailed p-value=0.00

SD: Standard Deviation

### **Eating Disorders Diagnostic Scale**

Based on the EDDS results upon admission to the AWH, 5 subjects were classified in the AN group, 3 in the BN group and 9 in the EDNOS group. From the subjects who participated in the follow-up measurements, 2 subjects (28.6% of the subjects who completed the EDDS at follow-up) had maintained the same diagnosis they had upon admission. In follow-up, 2 subjects qualified for a diagnosis of AN, 0 for a diagnosis of BN, 2 for a diagnosis of EDNOS, and 3 for no diagnosis.

Upon admission to the AWH, the mean composite score of EDDS for all the subjects (N=17) was 51.7. The mean composite score during follow-up (for N=8) was 30.6. A Wilcoxon signed rank test (exact) did not reveal a significant difference at the EDDS composite scores between admission and follow-up ( $z=-1.69$ , 2-tailed  $p$ -value=0.109). When the subjects were grouped by diagnosis, the only group that had sufficient number of subjects for comparisons at the follow-up was the EDNOS group (N=4). The difference in the EDDS composite score between admission and follow-up for the EDNOS group was also not significant ( $z=-1.83$ , 2-tailed  $p$ -value 0.125). **Table 7** shows descriptive statistics for the EDDS composite score for all subjects and the EDNOS at admission and follow-up.

**Table 7:** Descriptive statistics for EDDS composite scores between admission and follow-up

<b>Group</b>	<b>Statistic</b>	<b>EDDS score adm</b>	<b>EDDS score fu</b>
<b>All</b>	Mean ± SD	51.7±21.5*	30.6 ±13.1*
	Median	51	31
	Range	21-99	13-48
<b>AN<sup>1</sup></b>	Mean ± SD	48.4±29.7	30±24
	Median	42	30
	Range	21-99	13-47
<b>BN</b>	Mean ± SD	59.3±19.3	
	Median	53	
	Range	44-81	
<b>EDNOS</b>	Mean ± SD	51±19 <sup>#</sup>	29±13.9 <sup>#</sup>
	Median	51	26.5
	Range	22-93	15-48

<sup>#,\*</sup> Within group comparisons with Wilcoxon signed rank test, non-significant.

<sup>1</sup>Data for EDDS composite scores in the AN group for follow-up were available for only two subjects. Within group comparison not conducted.

### **Weight and Resting Metabolic Rate**

Data on weight and RMR were available for the whole group of subjects, for the AN, and for the EDNOS groups at admission and at discharge. For the follow up, self-reported weight data were available for most subjects who participated at the follow-up since they were asked to fill in their weight at one of the questions in EDDS. The AN group at the follow-up had only two subjects, so it was not included in the comparisons. Similarly, RMR data at the follow-up were available only for 2 subjects from the EDNOS group and, consequently, they have not been included in the comparisons. Description of the data for RMR and weight at different measurements is presented in **Table 8**.

A Wilcoxon signed rank test (exact) for all subjects between admission and discharge showed a significant increase in weight ( $z=-2.83$ , 2-tailed  $p$ -value=0.002), but no difference for RMR ( $z=-0.59$ ,  $p$ -value=0.59). Similar comparisons within the AN group showed no significant change in weight ( $z=-1.83$ , 1-tailed  $p$ -value=0.63) or RMR ( $z=0.37$ , 2-tailed  $p$ -value=0.88). Comparisons within the EDNOS group for admission and discharge showed a significant increase in weight ( $z=-2.03$ , 2-tailed  $p$ -value=0.047) but not in RMR ( $z=-0.98$ , 2-tailed  $p$ -value=0.383). A within group comparison for EDNOS between discharge and follow-up found no significant change for weight ( $z=0$ , 2-tailed  $p$ -value=1). Between groups comparisons for admission were discussed at the descriptive statistics section. Wilcoxon rank sum test (exact) between the AN and EDNOS group for discharge showed that the EDNOS group had significantly higher weight (2-tailed  $p$ -value=0.004) and RMR (2-tailed  $p$ -value=0.008) compared to the AN group.

**Table 8:** Weight and RMR at admission, discharge and follow-up

<b>Group</b>	<b>Statistic</b>	<b>Weight (Kg) adm</b>	<b>RMR (Kcal/day) adm</b>	<b>Weight (Kg) d/c</b>	<b>RMR (Kcal/day) d/c</b>	<b>Weight (Kg) fu</b>
<b>All</b>	Mean $\pm$ SD	53.4 $\pm$ 14.8*	1212 $\pm$ 208.3	58.1 $\pm$ 14.7*	1324 $\pm$ 299	60.5 $\pm$ 14.9
	Median	50.9	1143	55	1432	59.1
	Range	34.6-93.2	896 $\pm$ 1576	39.6-92.6	910-1551	45.5-76.4
<b>AN<sup>1</sup></b>	Mean $\pm$ SD	38.6 $\pm$ 2.4	1073 $\pm$ 57	43.1 $\pm$ 4 <sup>#</sup>	1037 $\pm$ 128.7 <sup>#</sup>	47.7 $\pm$ 0
	Median	39.1	1077	42	1020	47.7
	Range	34.6-40.9	986-1143	39.6-48.6	910-1199	47.7-47.7
<b>ED-NOS</b>	Mean $\pm$ SD	60.7 $\pm$ 14.8*	1319 $\pm$ 174	64.3 $\pm$ 13.4 <sup>*,#</sup>	1440 $\pm$ 144.6 <sup>*,#</sup>	63.6 $\pm$ 15.9
	Median	56.1	1354	61.2	1466	70.5
	Range	48.2-93.2	995-1576	52.1-92.6	1191-1551	45.45-75

<sup>1</sup>Data for weight measurement in the AN group for follow-up were available for only two subjects.

\* Wilcoxon signed rank test (exact). Increase in weight, p-value<0.05

<sup>#</sup>Wilcoxon rank sum test (exact). EDNOS has higher weight and RMR, p-value<0.01

In addition, Spearman's correlations between weight and RMR were conducted for the group as a whole and for each diagnostic group separately (where available data were sufficient). The results are presented in detail in **Table 9**. The only significant correlations for weight and RMR were at admission ( $r=0.669$ , 1-tailed  $p$ -value= $0.002$ ) and at discharge ( $r=0.657$ , 1-tailed  $p$ -value= $0.007$ ) for the group as a whole and at admission for the EDNOS group ( $r=0.857$ , 1-tailed  $p$ -value= $0.02$ ).

**Table 9:** Spearman Correlation for weight and RMR at admission and discharge

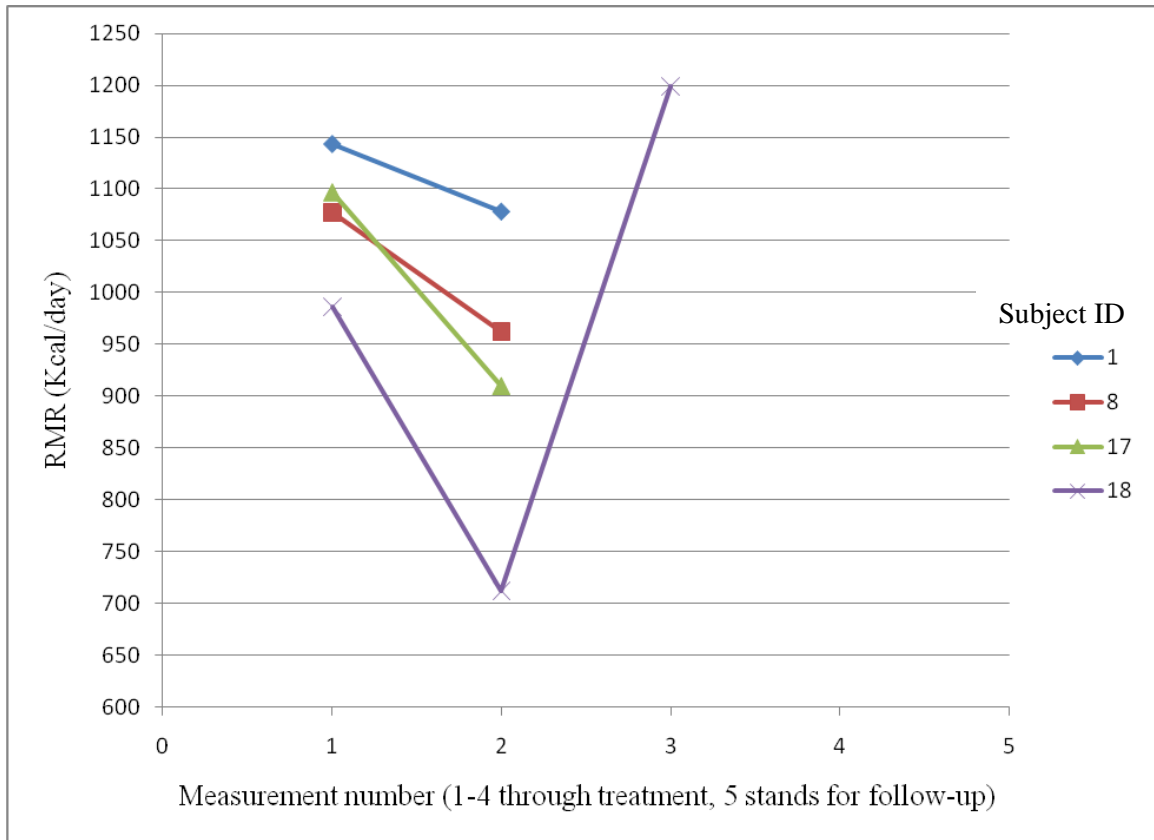
<b>Group</b>	<b>Statistic</b>	<b>Weight (Kg) vs RMR (Kcal/day) adm</b>	<b>Weight (Kg) vs RMR (Kcal/day) d/c</b>
<b>All subjects</b>	Correlation coefficient	0.669 <sup>#</sup>	0.657 <sup>#</sup>
	1-tailed p-value	0.002 <sup>#</sup>	0.007 <sup>#</sup>
<b>AN</b>	Correlation coefficient	-0.5	0.2
	1-tailed p-value	0.196	0.4
<b>BN</b>	Correlation coefficient	0.5	
	1-tailed p-value	0.33	
<b>EDNOS</b>	Correlation coefficient	0.857 <sup>*</sup>	-0.95
	1-tailed p-value	0.002 <sup>*</sup>	0.411

\*P-value <0.05

<sup>#</sup>P-value<0.01

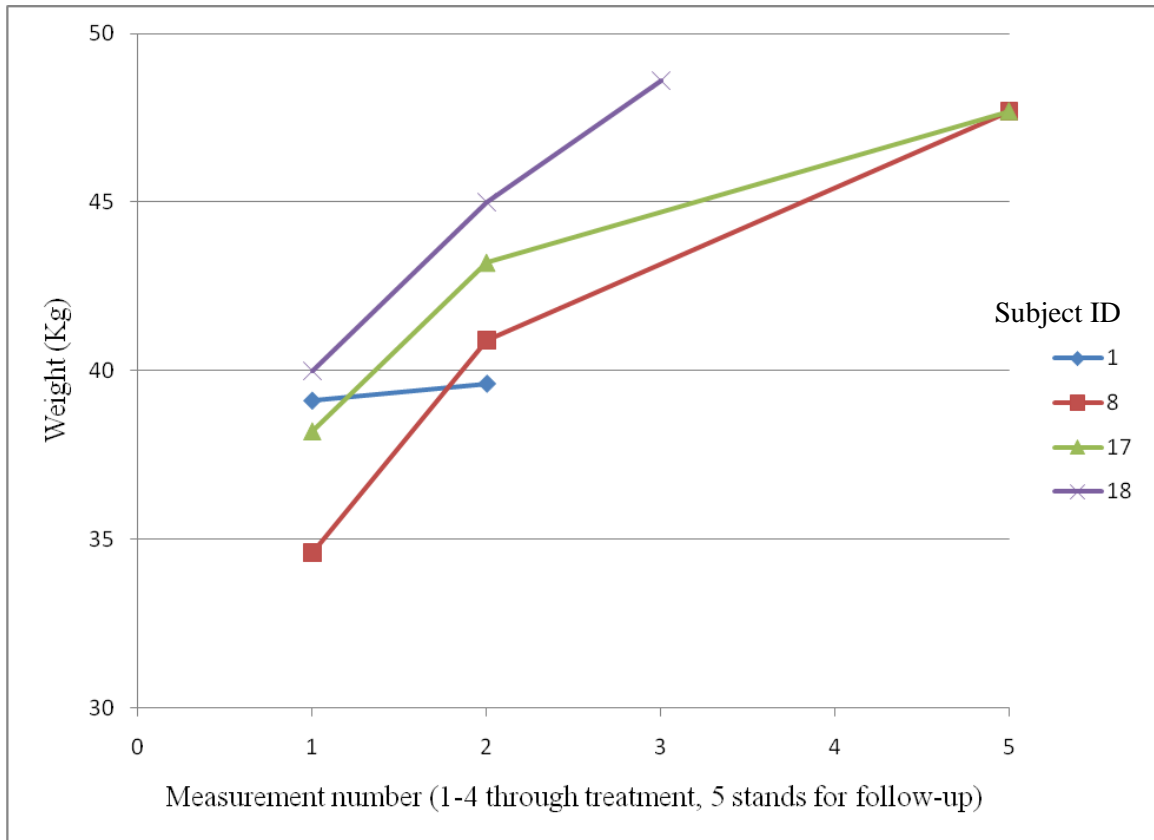
In the current analysis of weight and RMR only data for admission and discharge have been presented. This implies loss of the intermediate data for the subjects who remained at the AWH for more than 2 months. In order to explore any trends in these data points, graphical plots were created picturing all available RMR and weight data points for all subjects split per diagnostic group (**Figures 1-6**) across the different time points. **Figures 2** and **3** represent the BN group for which only one subject had more than 1 measurement available.

**Figure 1:** RMR throughout treatment and at follow-up for AN. Data shown separately for each subject in the group with two or more measurements

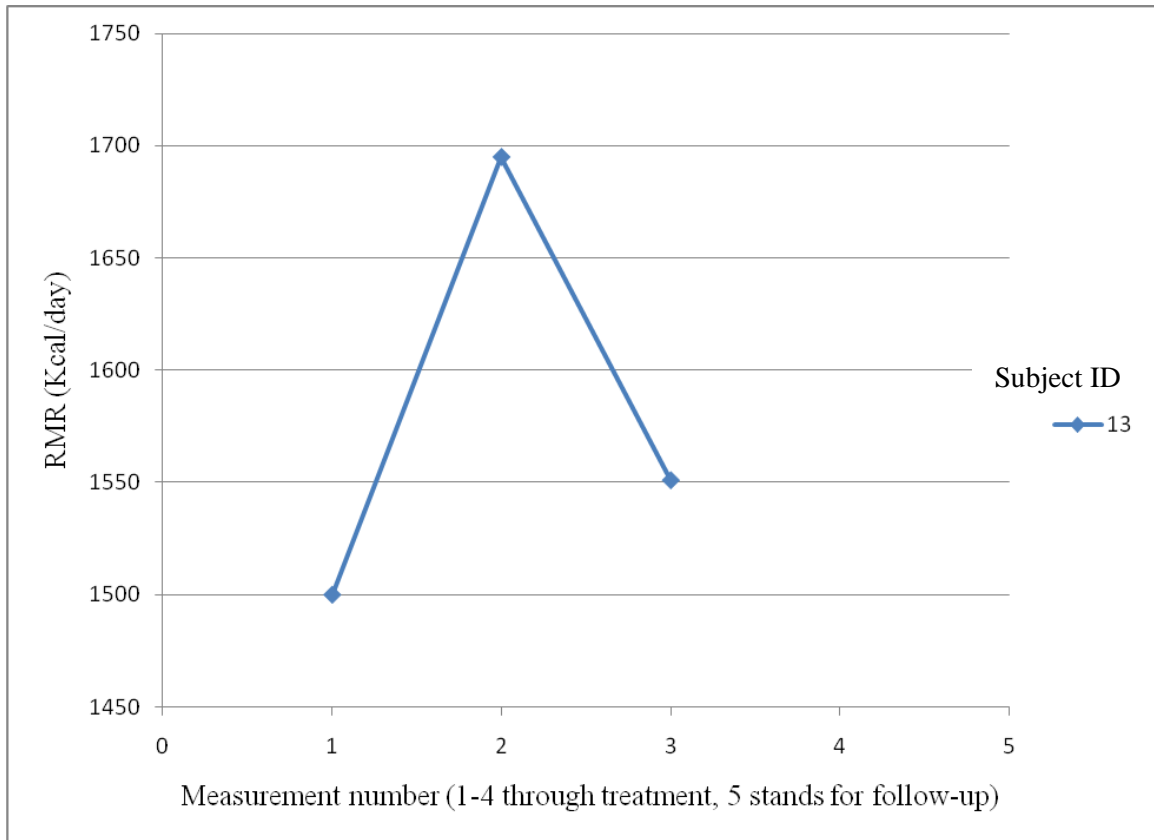




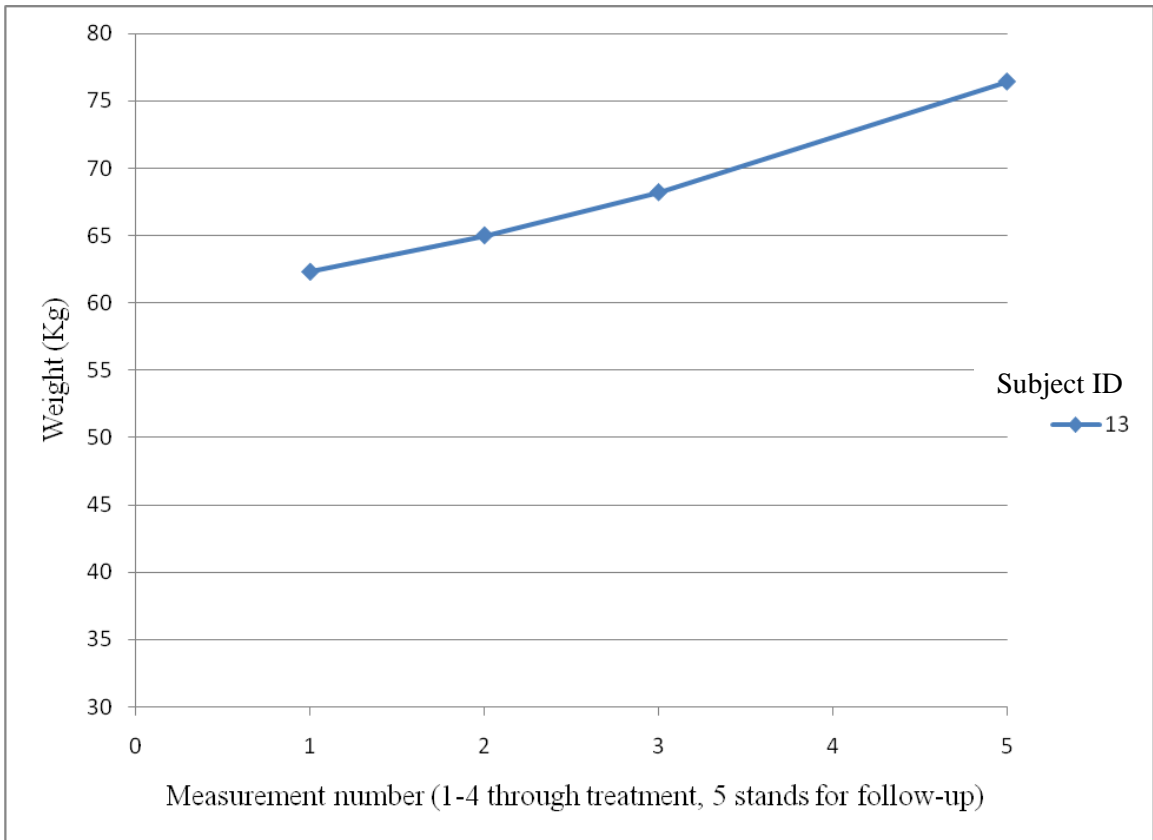
**Figure 2:** Weight throughout treatment and at follow-up for AN. Data shown separately for each subject in the group with two or more measurements



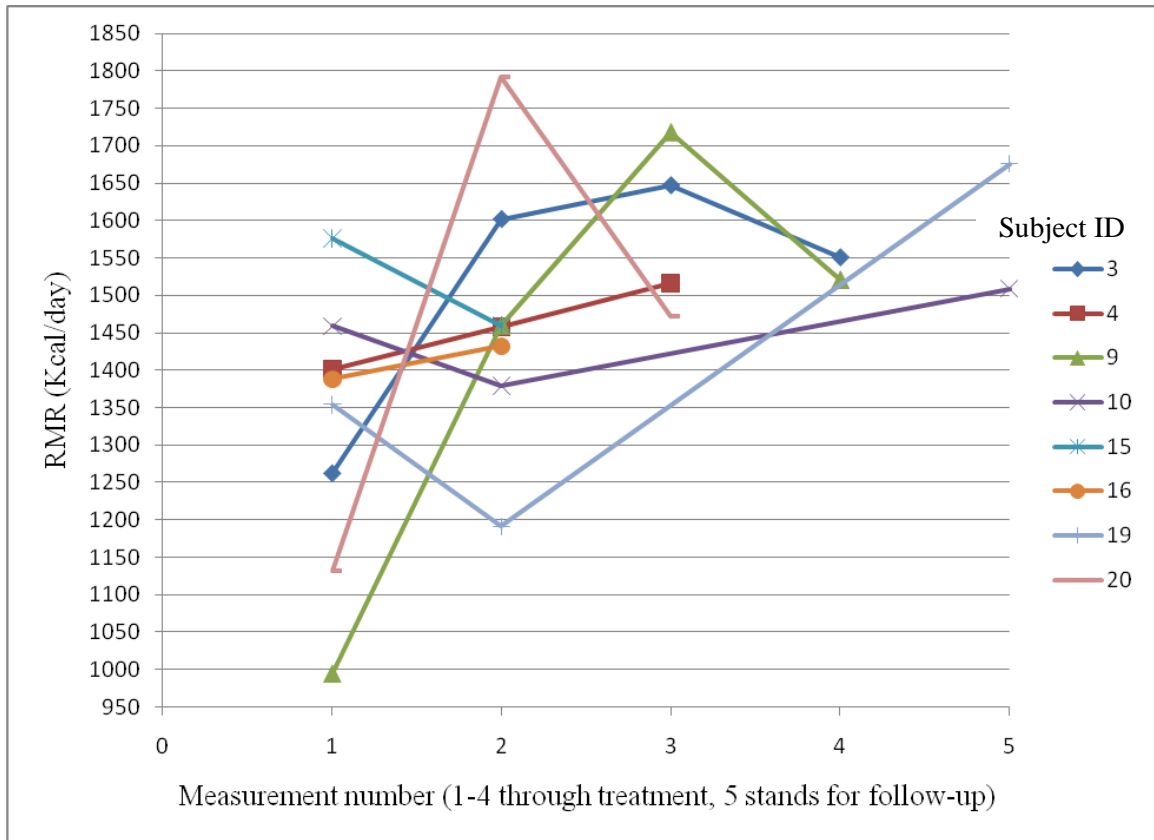
**Figure 3:** RMR throughout treatment and at follow-up for BN. Data shown separately for each subject in the group with two or more measurements



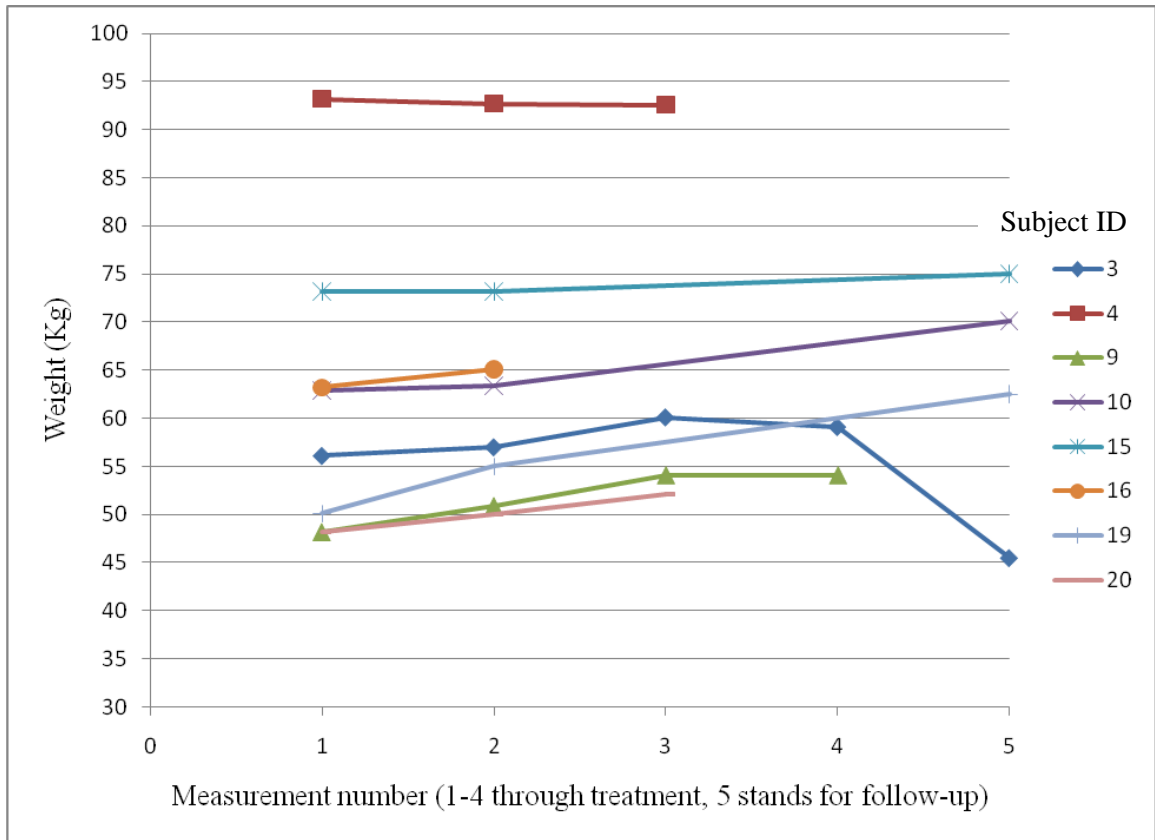
**Figure 4:** Weight throughout treatment and at follow-up for BN. Data shown separately for each subject in the group with two or more measurements



**Figure 5:** RMR throughout treatment and at follow-up for EDNOS. Data shown separately for each subject in the group with two or more measurements



**Figure 6:** Weight throughout treatment and at follow-up for EDNOS. Data shown separately for each subject in the group with two or more measurements



Based on the trends seen in the graphs, within group comparisons were also conducted in order to compare measurements at admission and after one month of treatment. The weight of the subjects in the AN group was trending upwards and their RMR was trending downwards between admission and the the first month of treatment, but none of them reached statistical significance at a Wilcoxon signed rank test (exact) ( $z=-1.826$ , 1-tailed  $p$ -value=0.63 for weight,  $z=-1.826$ , 2-tailed  $p$ -value=0.125 for RMR). The weight and RMR of the subjects in the EDNOS group, exhibited an increasing trend between these two time points. Again, statistical significance was not reached at the Wilcoxon signed rank test ( $z=-1.960$ , 2-tailed  $p$ -value=0.55 for weight,  $z=-0.840$ , 2-tailed  $p$ -value=0.461 for RMR). **Table 10** presents a description of weight and RMR per diagnostic group at admission and at 1 month of treatment.

**Table 10:** Weight and RMR at admission and 1 month of treatment

<b>Group</b>	<b>Statistic</b>	<b>Weight (Kg) admission</b>	<b>RMR (Kcal/day) admission</b>	<b>Weight (Kg) 1 month</b>	<b>RMR (Kcal/day) 1 month</b>
<b>AN</b>	Mean $\pm$ SD	38.6 $\pm$ 2.4*	1073 $\pm$ 57*	42.2 $\pm$ 2.4*	915.5 $\pm$ 152.8*
	Median	39.1	1077	42	936
	Range	34.6-40.9	986-1143	39.6-45	712-1078
<b>EDNOS</b>	Mean $\pm$ SD	60.7 $\pm$ 14.8*	1319 $\pm$ 174*	63.4 $\pm$ 14.1*	1472 $\pm$ 172.8*
	Median	56.1	1354	60.2	1459
	Range	48.2-93.2	995-1576	50-92.7	1191-1792

\*Wilcoxon signed rank test (exact),  $p$ -value $>$ 0.05, non significant

### **Hunger and Satiety Questionnaire**

The number of subjects per diagnostic group who chose each of the answers in the multiple choice questions of the questionnaire at admission and discharge is presented in the **Tables 11 and 12**. At admission at the AWH, 58% of all subjects reported no gastric sensations indicative of hunger. This percentage decreased to 46% at discharge. From the subjects who participated in the follow-up measurements, 57% reported recognizing gastric sensations of hunger (rumbling, feeling of emptiness) and only 14% reported no recognition of gastric sensations. In regards to satiety, more than 50% of subjects reported gastric sensations (full stomach, distention) at admission and at discharge from the AWH. At discharge, there was a 4% increase in the subjects who reported a feeling of “full stomach” while the percentages of people reporting distention, bloating, nausea and pain decreased by 11%, 34%, 16% and 26% accordingly.

At the time of admission, 29% of the subjects reported feeling nervous, 58.8% reported feeling irritable, 52.9% tense and 23.5% depressed before meals. Additionally, 64.7% reported feeling nervous, 70.5% irritable, 64.7% tense and 47% depressed after meals. At discharge, the percentage of subjects reporting feelings of irritability, tenseness and depression before meals had decreased to 30.8%, 30.8% and 15.4% respectively, while the feelings of nervousness, irritability, tenseness and depression after meals had decreased to 38.5%, 38.5%, 53.8% and 15.4% respectively. Despite these overall decreases in negative feelings, at discharge only less than 1% of subjects reported one or more positive feelings before and after meals. In addition, at admission, 35.3% of subjects reported being very preoccupied with thoughts of food before and after meals

accordingly. At discharge, this percentage decreased to 0% before and 23% after meals, while at follow up, the percentage of subjects very preoccupied with thoughts of food before meals increased again at 14.3%.

The last question of the hunger and the satiety scales allowed space for subjects to discuss their own thoughts about hunger and satiety in an open-ended format. These comments have been included in **Tables 13 and 14**.



**Table 11:** Number of subjects who chose each of the multiple choice answers of the Hunger Scale at admission and discharge and fu for all the subjects and per diagnostic group (where N>2)

<b>Question</b>	<b>All adm N=17</b>	<b>All d/c N=13</b>	<b>All fu N=7</b>	<b>AN adm N=5</b>	<b>AN d/c N=4</b>	<b>BN adm N=3</b>	<b>EDNOS adm N=9</b>	<b>EDNOS d/c N=8</b>	<b>EDNOS fu N=4</b>
<b>Gastric sensations:</b>									
Feeling of emptiness	5	6	4	1	2	3	1	3	2
Rumbling	3	2	4	0	0	1	2	2	2
Ache	1	1	1	1	0	0	0	1	1
Pain	2	1	0	1	0	0	1	1	0
Tenseness	1	1	0	0	0	0	1	1	0
Nausea	2	3	1	1	1	1	0	1	0
No gastric sensations to provide information for hunger	10	6	1	3	2	0	7	4	1

<b>Mouth and throat sensations:</b>									
Emptiness	2	2	1	1	0	1	0	1	1
Dryness	11	9	6	4	3	1	6	6	3
Salivation	0	1	1	0	0	0	0	1	1
Unpleasant taste or sensation	5	3	1	0	1	2	3	1	1
Pleasant	1	0	0	0	0	0	1	0	0
Tightness	0	1	3	0	4	0	0	1	3
<b>Cerebral sensations:</b>									
Headache	7	2	2	2	0	1	4	2	1
Dizziness	5	2	1	1	0	0	4	2	1
Faintness	3	1	0	1	0	1	1	0	0
Spots before the eyes	4	0	0	1	0	0	3	1	0
Ringing in ears	3	0	1	1	0	0	2	0	1
<b>General overall sensations:</b>									
Weakness	5	1	1	1	0	0	3	1	1
Tiredness	9	5	6	2	0	1	5	5	4
Restlessness	7	5	1	3	2	2	3	2	0
Cold	11	5	3	3	2	1	7	3	1
Warmth	0	1	1	0	0	0	0	1	0
Muscular spasms	4	0	0	1	0	1	3	0	0

<b>Mood when hungry:</b>									
Nervous	5	4	3	2	1	0	2	2	3
Irritable	10	4	3	4	1	1	4	2	1
Tense	9	4	3	4	1	2	4	2	2
Depressed	4	2	0	2	0	1	1	7	0
Apathetic	2	3	1	1	0	1	1	3	0
Cheerful	1	0	1	0	0	0	0	0	1
Excited	2	1	0	1	0	1	0	1	0
Calm	2	1	0	2	1	1	0	0	0
Relaxed	0	1	0	0	1	0	0	0	0
Contented	2	1	0	0	1	0	1	0	0
<b>Urge to eat:</b>									
No urge to eat	11	7	2	4	3	1	6	4	2
Mild-would eat if food were available but can wait comfortably	3	4	2	1	1	1	1	3	0
Fairly strong: want to eat soon, waiting is fairly uncomfortable	3	2	3	0	0	1	2	1	2
So strong you want to eat now, waiting is very uncomfortable	1	0	0	1	0	0	0	0	0

<b>Preoccupation with thoughts of food:</b>									
Not at all-no thoughts of food	2	6	0	0	1	1	1	5	0
Mild-only occasional thoughts of food	6	3	2	2	1	0	4	2	2
Moderate-many thoughts of food but can concentrate on other things	4	4	3	2	2	1	1	1	1
Very preoccupied-most of thoughts are of food at it is difficult to concentrate on other things	6	0	1	2	0	1	3	0	1

Cells highlighted in grey indicate choices selected from 50% or more of the group in the respective column of the table.

**Table 12:** Number of subjects who chose each of the multiple choice answers of the Satiety Scale at admission and discharge for all the subjects and per diagnostic group (where N>2)

Question	All admit N=17	All d/c N=13	AN admit N=5	AN d/c N=4	BN admit N=3	EDNOS admit N=9	EDNOS d/c N=8
<b>One most important reason for stopping eating:</b>							
No more food available	0	0	0	0	0	0	0
Eat until feeling of satisfaction	2	2	1	0	0	1	2
“Diet-limit” set for figure or health	8	4	2	2	2	4	2
I finished the food in my plate*	4	4	2	1	0	2	2
<b>Gastric sensations at end of eating:</b>							
Full stomach	15	12	4	4	3	8	7
Distended	11	7	4	2	3	4	5
Bloated	11	4	3	2	1	7	2
Nausea	4	1	2	1	0	2	0
Ache	4	4	2	1	0	2	3
Pain	7	2	2	0	2	3	2
Feeling of emptiness	0	0	0	0	0	0	0
No stomach sensations to provide information for stopping	0	0	0	0	0	0	0

<b>Cerebral sensations at end of eating:</b>							
Headache	2	3	0	3	1	1	2
Dizziness	2	0	0	0	0	2	0
Faintness	0	0	0	0	0	0	0
Spots before the eyes	0	0	0	0	0	0	0
Ringing in the ears	0	0	0	0	0	0	0
<b>General overall sensations at end of eating:</b>							
Weakness	1	0	1	0	0	0	0
Tiredness	10	7	2	1	1	7	6
Restlessness	10	3	4	1	1	5	2
Cold	7	4	3	2	1	3	2
Warmth	2	4	1	0	0	1	3
Muscular spasms	0	0	0	0	0	0	0
<b>Mood at end of eating:</b>							
Nervous	11	5	5	2	0	6	2
Irritable	12	5	3	1	3	6	4
Tense	11	7	5	4	1	5	3
Depressed	8	2	2	0	1	5	2
Apathetic	2	1	0	1	1	1	0
Cheerful	0	0	0	0	0	0	0
Excited	0	0	0	0	0	0	0
Calm	1	1	1	0	0	0	1
Relaxed	1	1	0	0	0	1	1
Contented	0	1	0	0	0	0	1

<b>Urge to eat at end of eating:</b>							
No urge to eat	13	13	4	4	2	7	8
Mild-would eat if food were available	3	0	0	0	1	2	0
Moderate-want to eat again soon; waiting is fairly uncomfortable	1	0	0	0	0	1	0
Strong-want to eat now, waiting is very uncomfortable	0	0	0	0	0	0	0
<b>Preoccupation with thoughts of food:</b>							
Not at all-no thoughts of food	3	5	0	0	2	1	5
Mild-only occasional thoughts of food	2	2	0	2	0	2	0
Moderate-many thoughts of food but can concentrate on other things	6	3	3	0	1	2	2
Very preoccupied-most of thoughts are of food and it is difficult to concentrate on other things	6	3	2	2	0	4	1

<b>Willpower required to stop eating:</b>							
None-stopping is an abrupt process	10	11	2	3	2	6	7
None-stopping is a gradual process	3	2	2	1	1	0	1
Some-willpower required since the urge to eat is still present	2	0	0	0	1	1	0
Considerable willpower is required	0	0	0	0	0	0	0

Cells highlighted in grey indicate choices selected from 50% or more of the group in the respective column of the table.

\* This answer choice was added later during the duration of the study



**Table 13:** Subject comments about hunger

AN:	Admission-Discharge	<ul style="list-style-type: none"> <li>- Haven't felt in a really long time</li> <li>- I never feel hungry unless I haven't eaten in a long time, like AM. Even then it doesn't always happen</li> <li>- Just didn't really have any hunger cues left</li> <li>- Feel it very little, but its frequency is increasing</li> </ul>
	Follow-up	<ul style="list-style-type: none"> <li>- Eating late at night because of fear of morning hunger</li> <li>- I don't feel I have hunger cues yet. Right now it is prescriptive eating. I eat when I do because I need to get my meal plan tallies in. Especially since I'm an anxious person it really causes me to feel nauseated + full, so very hard to know if hunger is present.</li> </ul>
BN:	Admission-Discharge	<ul style="list-style-type: none"> <li>- Feel better physically - not sick feeling anymore; don't feel the desire to eat everything in sight</li> </ul>
	Follow-up	<ul style="list-style-type: none"> <li>- If I wait too long to eat I get a headache and/or I feel nauseous. I know I am over hungry if I feel sick like that. If my stomach doesn't growl or rumble then it is hard to tell if I'm hungry or not.</li> </ul>
EDNOS:	Admission-Discharge	<ul style="list-style-type: none"> <li>- Seems to get more normal</li> <li>- Scary!</li> <li>- Still have really hard time feeling hunger...even with 1-word prompts in questions</li> <li>- I don't feel much hunger</li> <li>- Feeling hungry a lot more often</li> <li>- I feel extremely distended and full after meals, and uncomfortably full. However, I don't ever feel hunger</li> </ul>
	Follow-up	<ul style="list-style-type: none"> <li>- I honestly never feel hungry, I just feel pain or nauseous</li> <li>- I don't feel hungry very often</li> </ul>

**Table 14:** Subject comments about satiety

AN:	Admission- Discharge	<ul style="list-style-type: none"> <li>- I am always full!</li> <li>- I can't stand being full. I feel disgusting. Like I want to get out of my body, so uncomfortable</li> <li>- I hate feeling full. It makes me feel dirty, uncomfortable, yucky, in body especially if the food is yucky and/or challenging</li> <li>- It is the most uncomfortable feeling and I feel full all day long</li> <li>- Once I feel full, I would like to stop eating, but I usually feel full prior to finishing the amount of food on my meal plan. When this occurs I just want to stop but I know I need the food so I deal with the uncomfortable fullness that follows</li> </ul>
BN:	Admission- Discharge	<ul style="list-style-type: none"> <li>- Overly full/stuffed, unnatural, uncomfortable level of fullness at time of questionnaire.</li> </ul>
EDNOS:	Admission- Discharge	<ul style="list-style-type: none"> <li>- Very uncomfortable and hard to sit with</li> <li>- Anxiety is intense</li> <li>- Today's breakfast was condensed &amp; "fullness" more confusing than typical</li> <li>- Ate beyond satiety/comfort because of meal plan</li> <li>- I hate feeling full and uncomfortable and nauseous</li> <li>- Over full</li> <li>- I feel full all day and in the morning when I wake up</li> </ul>

## **Discussion**

### **Discussion of Study Findings**

As presented in the results, there was a statistically significant increase in weight for the group as a whole and for the EDNOS group between admission and discharge. There is a possibility that by interrupting symptom use and establishing a nutritionally adequate intake, the total energy intake of some subjects would increase compared to baseline, which could have explained an increase in their weight at discharge. This possibility could be especially applicable since the EDNOS group included 5 subjects who reported a history of purging without bingeing at the admission. Another possible explanation for this increase in weight could be related to the findings of a previous study in women with BN which had reported that weight suppression at the beginning of treatment significantly predicted weight gain during treatment for these patients<sup>48</sup>. Despite this increase in weight for the group as a whole and for the EDNOS, the increase in their RMR did not reach statistical significant. Consequently, the current available data cannot support our first hypothesis that RMR would increase for the people whose weight would increase during treatment. In contrast, the presence of significant positive correlations between weight and RMR for all subjects at admission and discharge and for the EDNOS subjects at admission only, suggests that there is a positive relationship between weight and RMR at different points during treatment. The inability to make within group comparisons for the BN group and the small sample size of the AN group, make it difficult to determine whether this correlation is only a characteristic of the EDNOS group or not.

In addition, the study found that the AN group had lower weight compared to the EDNOS group at admission and at discharge as well as lower RMR compared to the EDNOS group at discharge. The lower weight of the AN group at admission could potentially be expected since, in order to qualify for a diagnosis of AN in EDDS, subjects needed to have a body weight contributing to a  $BMI < 17.5 \text{ kg/m}^{247}$ . Regarding the lower weight and lower RMR at discharge, there have been no previous reports comparing RMR measurements in these two groups, making it difficult to determine whether this is a typical finding.

Other interesting findings of this study, even though not statistically significant, were the observed trends in RMR during the first month of treatment. For the AN group, there was a decreasing trend in RMR. Previous studies have reported an overall increase at the RMR of patients with AN<sup>17,26</sup>. Observation of the trends presented in this study suggests that the increase in RMR might not be uniformly present throughout treatment and call for further exploration of the clinical significance of a potential drop in RMR within the first month of treatment and the biological factors that might contribute in it. In contrast, the graph for BN showed an increasing trend during the same period of time. Given that there was only one person with more than one measurement during treatment for the BN group, the graphical representation of her RMR cannot be considered indicative of how the RMR of other patients with BN would behave, but it gives a first impression that would need to be further explored in future research. Interestingly, the graphical representation of the RMR for the subjects in the EDNOS group seemed to have a combination of both increasing and decreasing patterns during the first month of

treatment. Unfortunately, the sample size of this study was too small to attempt to distinguish if the EDNOS subjects exhibiting each of these patterns had some common factors with each other (for example, high or low BMI or different symptom use).

Before discussing the findings at the HSQ, it is important to mention that the following findings are based on observation of the percentages of subjects in each group who selected specific answers on the questionnaire as well as on an observation of the increase or decrease in these percentages over time. There was no statistical analysis conducted on these results, so it is not possible to say whether the observed differences are of statistical significance. The first important finding from the HSQ was an increase in the number of subjects who reported gastric sensations of hunger at the follow-up measurements compared to the measurements upon admission. The observed decrease in the percentage of subjects reporting no gastric sensations of hunger at discharge is in agreement with the hypothesis that more patients would perceive hunger in terms of gastric sensations at the end of treatment. The even larger difference observed at follow-up suggests that the ability to perceive hunger in terms of gastric sensations might take more time and not be entirely developed at the end of treatment. In terms of satiety, it was found that subjects seemed to understand gastric sensations of satiety before as well as after treatment. Interestingly, the reporting of some gastric symptoms of satiety (gastric fullness) increased during treatment while that of others decreased (distention, nausea, bloating, and pain). For the AN group, it was interesting to see that 80% and 100% of subjects with AN described satiety in terms of gastric fullness at admission and

discharge accordingly. These findings are in contrast with findings of a previous study suggesting that patients with AN do not describe satiety in terms of gastric fullness<sup>41</sup>.

Another finding was that at discharge fewer subjects reported irritability, tenseness and depression before and after meals compared to admission. This is in agreement with the hypothesis that there would be a change in the reported mood before and after meals at the end of treatment. Despite this decrease, more than 50% of subjects continued reporting at least one negative feeling at the end of eating at discharge. Positive feelings at the end of a meal (calm, relaxed, contented) were only reported by less than 1% of the participants. These results could indicate that, despite an improvement in mood before and after meals at the end of treatment, patients might still be facing fears or concerns about eating which could affect their mood. The authors of a previous study in patients with BN suggested that the persistence of negative mood state could be related to cognitive, affective and psychological characteristics of this population<sup>42</sup>.

Additionally, this study found that there was a decrease in the number of subjects reporting being very preoccupied with thoughts of food both before and after meals between admission and discharge as well as between admission and follow-up (for follow-up data available for before meals only). This finding is in agreement with the hypothesis that there would be a decrease in the reported preoccupation with thoughts of food after treatment. Finally, the open-ended questions at the end of HSQ offered an important insight on how patients with eating disorders perceive hunger and satiety in terms of bodily sensations and emotions in the patients' own words. Future research should attempt to determine whether this insight can be applicable in helping create more

effective treatments to help normalize the perception of hunger and satiety in patients with eating disorders.

### **Study Strengths and Weaknesses**

This study allowed observation of patients at multiple points throughout their treatment, thus giving the opportunity to explore changes in different variables over time. In addition, it allowed study of patients with different diagnoses who were receiving treatment in the same setting, thus enabling comparison between the different diagnostic groups. Additional strengths include the selection of a residential treatment setting, which has not been studied as much as other levels of care and the administration of follow-up measurements which allowed for observation of the variables under study after the end of treatment. Finally, the assessment of the perception of hunger and satiety in terms of physical and emotional sensations allowed for a deeper insight in the patients' point of view.

The greatest limitation of the current study is the small sample size which inhibited the statistical analysis for certain diagnostic groups and could have influenced the statistical significance of some of the results that were obtained. Given the duration of recruitment for the study, the capacity of the AWH (8 beds), the mean length of patient stay at the AWH, and the fact that the AWH was the only residential treatment facility for eating disorders at the State of Minnesota at the beginning of this study, it was not possible to recruit a larger number of patients. Also, since the AWH does not accept men for treatment, this study only included women. Despite the fact that both adult and adolescent women were eligible for the study, there were only adult women who enrolled. Consequently the findings of this study are only applicable to adult women.



In addition, the current study had a big range between discharge and the follow-up measurements (3-9 months). This could have influenced some of the follow-up findings since people could have been assessed in different points at their recovery process. Another limitation was the small overall participation at the follow-up measurements (44% of subjects) and the fact that only two of the subjects completed follow-up measurements in person, thus leading to insufficient RMR data at follow-up. The main reason for the decreased overall participation was inability to contact the subjects. The main reasons for not attending follow-up in person included distance, scheduling difficulties or other commitments and concern about deviating from meal plan (missing or postponing breakfast) in order to do the RMR measurement. In addition, the inability to conduct statistical analysis for the result of the HSQ did not allow for understanding of the extent to which the answers at the questionnaire changed over treatment. Finally, because of the observational nature of the study, there was no attempt to account for differences between subjects in other variables which could affect RMR including fat free mass, body surface area, menstrual cycle, or anxiety/depression<sup>12,25,49</sup>.

### **Implications for Future Research**

Future research should focus on examining the trends in RMR at each part of the treatment, their difference among patients with different diagnosis of eating disorders, their etiology, clinical significance, and potential treatment implications. Future research should also focus on defining what the normal perception of hunger and satiety entails and on determining which are the best treatment approaches that can help normalize the perception of hunger and satiety in patients with eating disorders.

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## **Appendix A**

- Initial Consent Form
- Initial Assent Form
- Revised Consent Form
- Revised Consent Form
- Letter to subjects regarding the Revised Consent Form
- Letter to subjects with guidelines for completion of questionnaires
- Thank you letter to subjects

**Initial Consent Form**

IRB Code # 0805M34461

Version Date : 07/23/2008

**University of Minnesota**

**ADULT INFORMATION AND CONSENT FORM**

**PARENTAL/GUARDIAN INFORMATION AND CONSENT FORM**

Changes in Resting Metabolic Requirements and the Perception of Hunger and Satiety in Patients with Eating Disorders throughout Residential Treatment

*This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand.*

You are invited to participate in a research study of the changes in resting metabolic rate and perceived hunger and satiety over the course of residential treatment and three months post discharge among adolescents and adults receiving residential eating disorder treatment at the Anna Westin House. You were selected as a possible participant because you are being admitted at the Anna Westin House. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by researchers from the University of Minnesota: Elpida Papadantonaki, B.Sc. (Graduate Student Researcher), Department of Food Science and Nutrition, University of Minnesota; Jillian Croll, Ph.D., The Emily Program and the Department of Food Science and Nutrition, University of Minnesota; Scott Crow, Ph.D., the Department of Psychiatry, University of Minnesota. It is funded by the Graduate Program in Nutrition of the Department of Food Science and Nutrition, University of Minnesota.

**Study Purpose**

The purpose of this study is to investigate changes in resting metabolic rate and perceived hunger and satiety over the course of residential treatment and three months post discharge among adolescents and adults participants receiving residential eating disorder treatment at the Anna Westin House. The goal is to better understand the potential changes in resting metabolic rate and hunger and satiety perceptions over the course of treatment to help inform treatment in this setting.

**Study Procedures**

If you agree to participate in this study, we would ask you to do the following: A dietitian from the Anna Westin House will measure your resting metabolic rate, which is the energy required to maintain your vital body functions while your body is at rest, using specialized equipment. This measurement will be done when you enter the Anna Westin House and at every month of your treatment and at your discharge. During these measurements, you will also be asked to complete a paper-and-pencil form of two short questionnaires that focus on how you feel when you are hungry and when you are full. These forms will take approximately 15 minutes to complete. You will also be asked to

return to the Emily Program three months after your discharge from the Anna Westin House to repeat these measurements. Additionally, upon your admission at the Anna Westin House and at the three months post discharge visit, you will be asked to complete a paper-and-pencil form of a short questionnaire that will help us evaluate the symptoms of your eating disorder. In order to perform the resting metabolic rate measurements we need to know your height and weight. During your treatment at the Anna Westin House this information will be obtained by your medical record as it is a part of the usual clinical practice. At the three month follow-up measurements your height and weight will be measured on site before the resting metabolic rate measurement. The measurement of your resting metabolic rate, height and weight during the period of your treatment, is a standard part of the Anna Westin House's evaluation. If you choose not to participate in this study, you will still complete these measurements as part of the treatment but the results will not be added to the database for this study and you will not need to complete the three month follow up assessment.

### **Risks of Study Participation**

The study has the following risks: Some of the information included in the questionnaires is personal and may be upsetting. You are free to not answer any of the questions included in the study. For the resting metabolic rate measurements you will be asked to wear a mask that will cover your mouth and nose and to breathe normally into it for the time period of the measurement. This, as well as the measurement of your height and weight at the follow-up assessment may make you feel uncomfortable. For this reason, all measurements will be performed in a private and confidential space and every effort will be made to make these measurements as comfortable for you as possible.

### **Benefits of Study Participation**

There are no benefits to study participation but the information we gather may inform treatment planning in the future.

### **Alternatives to Study Participation**

If you choose not to participate in this study, you will still complete the resting metabolic, height and weight measurements upon admission, during your treatment and before your discharge from the Anna Westin House. However, the results of these measurements will not be included in the study's database and you will not be asked to complete a three month follow-up assessment.

### **Study Costs/Compensation**

You will be compensated with \$20 for transportation costs related to the 3-month follow-up measurement.

### **Research Related Injury**

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you

think that you have suffered a research related injury, let the study investigators know right away.

### **Confidentiality**

The records of this study will be kept private. In any publications or presentations, we will not include any information that will make it possible to identify you as a subject. Your record for the study may, however, be reviewed by the Emily Program and departments at the University of Minnesota with appropriate regulatory oversight. Since the resting metabolic rate, height and weight measurements are performed during treatment as part of usual clinical care, these measurements will be included in your medical chart where they will be available to the Anna Westin House staff and your treatment team. The questionnaire assessments you complete will not be made part of your medical record, nor will your three month follow up assessment. Data entered by computer will be sent securely using the Internet.

The research investigators in the University of Minnesota in the Department of Food Science and Nutrition who are participating in this project will keep a list of all participants' names, date of birth and contact information in order to keep track of the data and be able to communicate with you regarding the follow-up measurements. All information on this list and any other personal information obtained for the purposes of this study will be kept confidential.

There are certain limitations in maintaining confidentiality that include, but are not limited to, the following: 1) if we are informed of any physical or sexual abuse sustained by a minor or vulnerable adult; 2) if we have reason to believe that you are at risk of endangering yourself or the life of another person; 3) if a judge issues a court order for the release of your records; 4) if State or Federal law authorizes the release of your records; 5) if we are informed of the use of certain drugs during pregnancy; in these circumstances, we are mandated by law to report this information to authorities. To these extents, confidentiality is not absolute.

### **Protected Health Information (PHI)**

Your PHI created or received for the purposes of this study is protected under the federal regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information.

### **Voluntary Nature of the Study**

Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with the University of Minnesota and the Emily Program. If you decide to participate, you are free to withdraw at any time without affecting those relationships.

## **Contacts and Questions**

The researchers conducting this study are Elpida Papadantonaki (Student Researcher from the Department of Food Science and Nutrition) and Drs. Jillian Croll and Scott Crow from the University of Minnesota. You may ask any questions you have now, or if you have questions later, **you are encouraged to** contact them at the following numbers: 612-245-7952 Elpida Papadantonaki (Advisor: Dr. Jillian Croll, Ph: 651.379.6133); 651.379.6133 Dr. Jillian Croll; 612-273-9807 Dr. Scott Crow. If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher(s), **you are encouraged to** contact the Fairview Research Helpline at telephone number 612-672-7692 or toll free at 866-508-6961. You may also contact this office in writing or in person at University of Minnesota Medical Center, Fairview-Riverside Campus, #815 Professional Building, 2200 Riverside Avenue, Minneapolis, MN 55454.

You will be given a copy of this form to keep for your records.

## **Statement of Consent**

I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Signature of Subject \_\_\_\_\_

Date \_\_\_\_\_

Signature of Individual Obtaining Consent \_\_\_\_\_

Date \_\_\_\_\_

Signature of Investigator \_\_\_\_\_

Date \_\_\_\_\_

**Initial Assent Form**

IRB Code # 0805M34461

Version Date: 07/23/2008

**University of Minnesota**

**ASSENT FORM**

**Changes in Resting Metabolic Requirements and the Perception of Hunger and Satiety in Patients with Eating Disorders throughout Residential Treatment**

*This form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand before signing this form.*

**What is this study about?**

This study is about eating disorders in teenagers and adults.

We are asking if you would be willing to be in this study because we are trying to learn how to do a better job of helping people with eating disorders and because you are being admitted in the Anna Westin House. This project is being led by researchers from the University of Minnesota.

**What will happen?**

If you agree to be in this study, a dietitian from the Anna Westin House will measure the energy your body uses while you are resting. You will also be asked to complete two short questionnaires that focus on how you feel when you are hungry and when you are full that take approximately 15 minutes. These measurements will be done when you enter the Anna Westin House, each month during your treatment and before you leave. You will also be asked to return to the Emily Program three months after you leave the Anna Westin House to repeat these measurements. Also, at two of these visits, you will be asked to complete a short questionnaire that will help us evaluate the symptoms of your eating disorder. To perform the energy measurements, we need to know your height and weight. During your stay at the Anna Westin House this information will be obtained from your chart. At the three month follow-up measurements your height and weight will be measured on site before the energy measurement. Measuring the energy your body uses, your height and weight during the period of your treatment, is a standard part of the Anna Westin House's evaluation. If you choose not to participate in this study, you will still complete these measurements as part of the treatment program but the results will not be used for this study and you will not have to return for measurements three months after you leave the Anna Westin House.

Being in this study is up to you and no one will be mad if you don't want to do it. If you decide to participate in this study, you can always change your mind if you decide later on that you no longer want to be in this study.

Please ask us any questions you have about the study before you sign this form. If you have a question later that you didn't think of now, you can ask us later on.

Signing here means that you have read this information and have asked any questions you have about this study. Your signature means that you want to be in this study. If you don't want to be in this study, don't sign. Remember, being in this study is up to you and no one will be mad if you don't sign this or even if you change your mind later.

Signature of Participant\_\_\_\_\_

Signature of Person Explaining the Study\_\_\_\_\_

Date\_\_\_\_\_

## **Revised Consent Form**

IRB Code # 0805M34461

Version Date: 02/10/2009

### **University of Minnesota**

#### **ADULT INFORMATION AND CONSENT FORM**

#### **PARENTAL/GUARDIAN INFORMATION AND CONSENT FORM**

Changes in Resting Metabolic Requirements and the Perception of Hunger and Satiety in Patients with Eating Disorders throughout Residential Treatment

*This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand.*

You are invited to participate in a research study of the changes in resting metabolic rate and perceived hunger and satiety over the course of residential treatment and three months post discharge among adolescents and adults receiving residential eating disorder treatment at the Anna Westin House. You were selected as a possible participant because you are being admitted at the Anna Westin House. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by researchers from the University of Minnesota: Elpida Papadantonaki, B.Sc. (Graduate Student Researcher), Department of Food Science and Nutrition, University of Minnesota; Jillian Croll, Ph.D., The Emily Program and the Department of Food Science and Nutrition, University of Minnesota; Scott Crow, Ph.D., the Department of Psychiatry, University of Minnesota. It is funded by the Graduate Program in Nutrition of the Department of Food Science and Nutrition, University of Minnesota.

### **Study Purpose**

The purpose of this study is to investigate changes in resting metabolic rate and perceived hunger and satiety over the course of residential treatment and three months post discharge among adolescents and adults participants receiving residential eating disorder treatment at the Anna Westin House. The goal is to better understand the potential changes in resting metabolic rate and hunger and satiety perceptions over the course of treatment to help inform treatment in this setting.

### **Study Procedures**

If you agree to participate in this study, we would ask you to do the following: a dietitian from the Anna Westin House will measure your resting metabolic rate, which is the energy required to maintain your vital body functions while your body is at rest, using specialized equipment. This measurement will be done when you enter the Anna Westin House and at every month of your treatment and at your discharge. During these measurements, you will also be asked to complete a paper-and-pencil form of two short questionnaires that focus on how you feel when you are hungry and when you are full. These forms will take approximately 15 minutes to complete. You will also be asked to



return to the Emily Program three months after your discharge from the Anna Westin House to repeat these measurements. Additionally, upon your admission at the Anna Westin House and at the three months post discharge visit, you will be asked to complete a paper-and-pencil form of a short questionnaire that will help us evaluate the symptoms of your eating disorder. If you are not able to attend the follow up measurements at the Emily Program we will mail you paper-and-pencil forms of the questionnaires. We will ask you to complete them and then return them to us.

In order to perform the resting metabolic rate measurements we need to know your height and weight. During your treatment at the Anna Westin House this information will be obtained by your medical record as it is a part of the usual clinical practice. At the three month follow-up measurements your height and weight will be measured on site before the resting metabolic rate measurement. The measurement of your resting metabolic rate, height and weight during the period of your treatment, is a standard part of the Anna Westin House's evaluation. If you choose not to participate in this study, you will still complete these measurements as part of the treatment but the results will not be added to the database for this study and you will not need to complete the three month follow up assessment.

### **Risks of Study Participation**

The study has the following risks: Some of the information included in the questionnaires is personal and may be upsetting. You are free to not answer any of the questions included in the study. For the resting metabolic rate measurements you will be asked to wear a mask that will cover your mouth and nose and to breathe normally into it for the time period of the measurement. This, as well as the measurement of your height and weight at the follow-up assessment may make you feel uncomfortable. For this reason, all measurements will be performed in a private and confidential space and every effort will be made to make these measurements as comfortable for you as possible.

### **Benefits of Study Participation**

There are no benefits to study participation but the information we gather may inform treatment planning in the future.

### **Alternatives to Study Participation**

If you choose not to participate in this study, you will still complete the resting metabolic, height and weight measurements upon admission, during your treatment and before your discharge from the Anna Westin House. However, the results of these measurements will not be included in the study's database and you will not be asked to complete a three month follow-up assessment.

### **Study Costs/Compensation**

You will be compensated with \$20 for your time spent in participating at the 3-month follow-up measurements.

## **Research Related Injury**

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let the study investigators know right away.

## **Confidentiality**

The records of this study will be kept private. In any publications or presentations, we will not include any information that will make it possible to identify you as a subject. Your record for the study may, however, be reviewed by the Emily Program and departments at the University of Minnesota with appropriate regulatory oversight. Since the resting metabolic rate, height and weight measurements are performed during treatment as part of usual clinical care, these measurements will be included in your medical chart where they will be available to the Anna Westin House staff and your treatment team. The questionnaire assessments you complete will not be made part of your medical record, nor will your three month follow up assessment. Data entered by computer will be sent securely using the Internet.

The research investigators in the University of Minnesota in the Department of Food Science and Nutrition who are participating in this project will keep a list of all participants' names, date of birth and contact information in order to keep track of the data and be able to communicate with you regarding the follow-up measurements. All information on this list and any other personal information obtained for the purposes of this study will be kept confidential.

There are certain limitations in maintaining confidentiality that include, but are not limited to, the following: 1) if we are informed of any physical or sexual abuse sustained by a minor or vulnerable adult; 2) if we have reason to believe that you are at risk of endangering yourself or the life of another person; 3) if a judge issues a court order for the release of your records; 4) if State or Federal law authorizes the release of your records; 5) if we are informed of the use of certain drugs during pregnancy; in these circumstances, we are mandated by law to report this information to authorities. To these extents, confidentiality is not absolute.

## **Protected Health Information (PHI)**

Your PHI created or received for the purposes of this study is protected under the federal regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information.

### **Voluntary Nature of the Study**

Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with the University of Minnesota and the Emily Program. If you decide to participate, you are free to withdraw at any time without affecting those relationships.

### **Contacts and Questions**

The researchers conducting this study are Elpida Papadantonaki (Student Researcher from the Department of Food Science and Nutrition) and Drs. Jillian Croll and Scott Crow from the University of Minnesota. You may ask any questions you have now, or if you have questions later, **you are encouraged to** contact them at the following numbers: 612-245-7952 Elpida Papadantonaki (Advisor: Dr. Jillian Croll, Ph: 651.379.6133); 651.379.6133 Dr. Jillian Croll; 612-273-9807 Dr. Scott Crow. If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher(s), **you are encouraged to** contact the Fairview Research Helpline at telephone number 612-672-7692 or toll free at 866-508-6961. You may also contact this office in writing or in person at University of Minnesota Medical Center, Fairview-Riverside Campus, #815 Professional Building, 2200 Riverside Avenue, Minneapolis, MN 55454.

You will be given a copy of this form to keep for your records.

### **Statement of Consent**

I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Signature of Subject \_\_\_\_\_

Date \_\_\_\_\_

Signature of Individual Obtaining Consent \_\_\_\_\_

Date \_\_\_\_\_

Signature of Investigator \_\_\_\_\_

Date \_\_\_\_\_

**Revised Assent Form**

IRB Code # 0805M34461

Version Date: 02/10/2009

**University of Minnesota**

**ASSENT FORM**

**Changes in Resting Metabolic Requirements and the Perception of Hunger and Satiety in Patients with Eating Disorders throughout Residential Treatment**

*This form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand before signing this form.*

**What is this study about?**

This study is about eating disorders in teenagers and adults.

We are asking if you would be willing to be in this study because we are trying to learn how to do a better job of helping people with eating disorders and because you are being admitted in the Anna Westin House. This project is being led by researchers from the University of Minnesota.

**What will happen?**

If you agree to be in this study, a dietitian from the Anna Westin House will measure the energy your body uses while you are resting. You will also be asked to complete two short questionnaires that focus on how you feel when you are hungry and when you are full that take approximately 15 minutes. These measurements will be done when you enter the Anna Westin House, each month during your treatment and before you leave. You will also be asked to return to the Emily Program three months after you leave the Anna Westin House to repeat these measurements. Also, at two of these visits, you will be asked to complete a short questionnaire that will help us evaluate the symptoms of your eating disorder. If you are not able to come to the follow up measurements at the Emily Program we will mail you the questionnaires. We will ask you to complete them and then return them to us by mail. To perform the energy measurements, we need to know your height and weight. During your stay at the Anna Westin House this information will be obtained from your chart. At the three month follow-up measurements your height and weight will be measured on site before the energy measurement. Measuring the energy your body uses, your height and weight during the period of your treatment, is a standard part of the Anna Westin House's evaluation. If you choose not to participate in this study, you will still complete these measurements as part of the treatment program but the results will not be used for this study and you will not have to return for measurements three months after you leave the Anna Westin House.

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Signature of Participant \_\_\_\_\_

Signature of Person Explaining the Study \_\_\_\_\_

Date \_\_\_\_\_

**Letter to subjects regarding the Revised Consent Form**

IRB Code # 0805M34461

Version Date:04/27/2009

**University of Minnesota**

Dear (name of study participant),

Thank you for participating in our research study, “Changes in Resting Metabolic Requirements and the Perception of Hunger and Satiety in Patients with Eating Disorders throughout Residential Treatment”.

You are receiving this letter because you are unable to attend the three-month follow-up measurements at the offices of the Emily Program. There have been changes in the study protocol which allow you to participate in the three-month follow-up measurements and receive your compensation for the time spent in the study via mail. Enclosed you may find an updated consent form for the study which includes these changes in protocol. If you wish to participate to the follow-up measurements via mail, please read the consent form carefully and if you agree, sign and date the form at the last page. Then place the consent form in the enclosed envelope and return the envelope to us by mail.

If you have any questions about the consent form or the study in general, please contact us at one of the following numbers:

612-245-7952 Elpida Papadantonaki (Student Researcher, Advisor Dr Jillian Croll)

651-379-6133 Dr Jillian Croll

612-273-9807 Dr Scott Crow

After we receive the consent form, we will mail you the study questionnaires and a copy of the updated consent form signed by the study investigators for your records.

We would like to remind you that participation in this study is voluntary and that you are free to withdraw at any time.

Thank you in advance for your cooperation.

Sincerely,

Elpida Papadantonaki

University of Minnesota

Department of Food Science and Nutrition

225 FScN

1334 Eckles Avenue

St Paul, MN 55108

**Letter to subjects with guidelines for completion of questionnaires**

IRB Code # 0805M34461

Version Date:02/10/2009

**University of Minnesota**

Dear (name of study participant),

Thank you for participating in our research study with title: “Changes in Resting Metabolic Requirements and the Perception of Hunger and Satiety in Patients with Eating Disorders throughout Residential Treatment”.

You are receiving this letter because you are unable to attend the three-month follow-up measurements at the offices of the Emily Program. Enclosed you will find two questionnaires: one titled “Hunger Scale” and the other titled “Eating Screen”.

Please complete the “Hunger Scale” questionnaire in the morning as soon as you wake up and before eating or drinking anything. Complete the “Eating Screen” questionnaire at any time during the same day. When you have completed both questionnaires please write the date you completed them on the first page. Then place them in the enclosed envelope and return the envelope to us by mail.

In order to protect your privacy, please do not write your name or address on the questionnaires or the envelope. When we receive your answers we will be able to identify you from the study code that is written on your questionnaires.

Also, we would like to remind you that participation in this study is voluntary and that you are free to withdraw at any time.

If you have any questions, please contact one of the following numbers:  
612-245-7952 Elpida Papadantonaki (Student Researcher, Advisor Dr Jillian Croll)  
651-379-6133 Dr Jillian Croll  
612-273-9807 Dr Scott Crow

Thank you in advance for your cooperation.

Sincerely,  
Elpida Papadantonaki  
University of Minnesota  
Department of Food Science and Nutrition  
225 FScN  
1334 Eckles Avenue  
St Paul, MN 55108

**Thank you letter to subjects**

IRB Code # 0805M34461

Version Date:02/10/2009

**University of Minnesota**

Dear (name of study participant),

We would like to thank you for participating in our research study with title: “Changes in Resting Metabolic Requirements and the Perception of Hunger and Satiety in Patients with Eating Disorders throughout Residential Treatment”.

Please find enclosed the compensation for the time you spent in participating at the follow-up measurements of the study.

Thank you again for your time and effort.

Sincerely,

Elpida Papadantonaki

University of Minnesota

Department of Food Science and Nutrition

225 FScN

1334 Eckles Avenue

St Paul, MN 55108



## **Appendix B**

- Eating Disorders Diagnostic Scale<sup>41</sup>
- Hunger and Satiety Questionnaire<sup>47</sup>

**Eating Disorders Diagnostic Scale**

**Eating Screen**

Please carefully complete all questions

<b>Over the <u>past 3 months</u>...</b>	Not at all		Slightly		Moderately		Extremely
1. Have you felt fat?.....	0	1	2	3	4	5	6
2. Have you had a definite fear that you might gain weight or become fat?.....	0	1	2	3	4	5	6
3. Has your weight influenced how you think about (judge) yourself as a person?.....	0	1	2	3	4	5	6
4. Has your shape influenced how you think about (judge) yourself as a person?.....	0	1	2	3	4	5	6

5. During the past **6 months** have there been times when you felt you have eaten what other people would regard as an unusually large amount of food (e.g., a quart of ice cream) given the circumstances?..... YES NO

6. During the times when you ate an unusually large amount of food, did you experience a loss of control (feel you couldn't stop eating or control what or how much you were eating? YES NO

7. How many **DAYS per week** on average over the **past 6 MONTHS** have you eaten an unusually large amount of food and experienced a loss of control? 0 1 2 3 4 5 6 7

8. How many **TIMES per week** on average over the **past 3 MONTHS** have you eaten an unusually large amount of food and experienced a loss of control? 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14

**During these episodes of overeating and loss of control did you...**

9. Eat much more rapidly than normal?.....	YES	NO
10. Eat until you felt uncomfortably full?.....	YES	NO
11. Eat large amounts of food when you didn't feel physically hungry?.....	YES	NO

12. Eat alone because you were embarrassed by how much you were eating?..... YES NO
13. Feel disgusted with yourself, depressed, or very guilty after overeating?..... YES NO
14. Feel very upset about your uncontrollable overeating or resulting weigh gain? YES NO
- 

15. How many **times per week** on average over the past **3 months** have you made yourself vomit to prevent weight gain or counteract the effects of eating? 0 1 2 3  
5 6 7 8 9 10 11 12 13 14

16. How many **times per week** on average over the past **3 months** have you used laxatives or diuretics to prevent weight gain or counteract the effects of eating? 0 1 2  
3 4 5 6 7 8 9 10 11 12 13 14

17. How many **times per week** on average over the past **3 months** have you fasted (skipped at least 2 meals in a row) to prevent weight gain or counteract the effects of eating? 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14

18. How many **times per week** on average over the past **3 months** have you engaged in excessive exercise specifically to counteract the effects of overeating episodes? 0 1 2  
3 4 5 6 7 8 9 10 11 12 13 14

---

19. How much do you weigh? If uncertain, please give your best estimate. \_\_\_\_\_ lbs.

20. How tall are you? \_ Please specify in inches (5ft.=60in.) \_\_\_\_\_ in.

21. Over the past **3 months**, how many menstrual periods have you missed? 0 1 2 3  
n/a

22. Have you been taking birth control pills during the past **3 months**?..... YES NO

## **Hunger and Satiety Questionnaire**

### **Hunger Scale:**

This questionnaire is about hunger. For each heading circle as many of the answers as are appropriate to how you feel now. You may leave a section out or answer more than once. At the end add any general comments about your usual feelings of hunger.

- I. Gastric sensations:
  1. Feeling of emptiness
  2. Rumbling
  3. Ache
  4. Pain
  5. Tenseness
  6. Nausea
  7. No gastric sensations to provide information for hunger
  
- II. Mouth and throat sensations:
  1. Emptiness
  2. Dryness
  3. Salivation
  4. Unpleasant taste or sensation
  5. Pleasant
  6. Tightness
  
- III. Cerebral sensations:
  1. Headache
  2. Dizziness
  3. Faintness
  4. Spots before the eyes
  5. Ringing in ears
  
- IV. General overall sensations:
  1. Weakness
  2. Tiredness
  3. Restlessness
  4. Cold
  5. Warmth
  6. Muscular spasms

V. Mood when hungry:

1. Nervous
2. Irritable
3. Tense
4. Depressed
5. Apathetic
6. Cheerful
7. Excited
8. Calm
9. Relaxed
10. Contented

VI. Urge to eat:

1. No urge to eat
2. Mild-would eat if food were available but can wait comfortably
3. Fairly strong: want to eat soon, waiting is fairly uncomfortable
4. So strong you want to eat now, waiting is very uncomfortable

VII. Preoccupation with thoughts of food:

1. Not at all-no thoughts of food
2. Mild-only occasional thoughts of food
3. Moderate-many thoughts of food but can concentrate on other things
4. Very preoccupied-most of thoughts are of food at it is difficult to concentrate on other things

VIII. Time of the day when hungriest:

IX. Other comments about hunger:

## **Satiety Scale:**

This questionnaire is about fullness. For each heading circle as many answers as are appropriate to how you've felt since completing the meal. You may leave a section out or answer more than once. At the end add any general comments about your fullness.

- I. One most important reason for stopping eating:
  1. No more food available
  2. Eat until feeling of satisfaction
  3. "Diet-limit" set for figure or health
  4. I finished the food in my plate
  
- II. Gastric sensations at end of eating:
  1. Full stomach
  2. Distended
  3. Bloating
  4. Nausea
  5. Ache
  6. Pain
  7. Feeling of emptiness
  8. No stomach sensations to provide information for stopping
  
- III. Cerebral sensations at end of eating:
  1. Headache
  2. Dizziness
  3. Faintness
  4. Spots before the eyes
  5. Ringing in the ears
  
- IV. General overall sensations at end of eating:
  1. Weakness
  2. Tiredness
  3. Restlessness
  4. Cold
  5. Warmth
  6. Muscular spasms
  
- V. Mood at end of eating:
  1. Nervous
  2. Irritable
  3. Tense
  4. Depressed
  5. Apathetic
  6. Cheerful
  7. Excited

8. Calm
9. Relaxed
10. Contented

VI. Urge to eat at end of eating:

1. No urge to eat
2. Mild-would eat if food were available
3. Moderate-want to eat again soon; waiting is fairly uncomfortable
4. Strong-want to eat now, waiting is very uncomfortable

VII. Preoccupation with thoughts of food:

1. Not at all-no thoughts of food
2. Mild-only occasional thoughts of food
3. Moderate-many thoughts of food but can concentrate on other things
4. Very preoccupied-most of thoughts are of food and it is difficult to concentrate on other things

VIII. Willpower required to stop eating:

1. None-stopping is an abrupt process
2. None-stopping is a gradual process
3. Some-willpower required since the urge to eat is still present
4. Considerable willpower is required

IX. Other comments about being full: