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**Pre- and post-treatment:
Do depression, physical activity and
symptom intensity of the eating disorder
predict quality of life in women with bulimia
nervosa or binge eating disorder?**

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ABSTRACT

Background Eating disorders (EDs) are among the top ten of the gender and age adjusted global burden of diseases in terms of poor quality of life, affecting young women in particular. Treatment of EDs generally focus on alleviating ED-symptomology and quality of life (QoL) is usually not considered an outcome measure, although women with EDs claim that well-being and learning to cope with the disease may be just as important as remission from the symptoms of disease. Therefore, an increased understanding of the relationship between EDs and QoL could be beneficial for improving treatment outcomes in this population.

Objective This study explored the influence of depression, level of physical activity and symptom intensity of eating disorders on quality of life in women with bulimia nervosa (BN) and binge eating disorder (BED) receiving either physical exercise and dietary therapy (PED-t) or cognitive behavioral therapy (CBT).

Method This study utilized data material obtained at the “PED-t trial”. Of the 149 who met at pre-therapy measures, 148 were included in the current thesis and 111 completed measures at post-therapy. Multiple regression analysis was conducted to estimate the influence of the explanatory power of the regression model and the unique contribution from depression, level of physical activity and symptom intensity of eating disorders on variance in QoL both on the complete sample and the two treatment groups. Pearson correlations was used to identify and describe changes in association between depression and symptom intensity of EDs from pre- to post-therapy.

Results The regression model consisted of depression, physical activity and symptom intensity of eating disorders, explaining 38 % - 60 % of the variance in QoL. Depression and level of physical activity made a significant unique contribution to variance of QoL, accounting for respectively 38 % - 42 % and 4.7 % of the unique variance in QoL in various analysis. The association between symptom intensity of eating disorder and depression changed from weak to moderate from pre- to post-therapy.

Conclusion Depression may be a more important explanatory variable for QoL than level of physical activity and symptom intensity of eating disorders. It can be beneficial to assess and address depression when treating EDs.

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This thesis is the final product of a master's degree that has given me many opportunities and taught me a lot. Not only have I understood some of the pro's and con's of the scientific world. I've also had the chance to really think about the importance of the field of studies I'm in, and more practically how I can apply the things I've learn to make a difference for a person's quality of life. I find that important, and even more - useful.

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ACRONYMS AND ABBREVIATIONS

APA	The American Psychiatric Association
AN	Anorexia Nervosa
BED	Binge Eating Disorder
BDI	Beck's Depression Inventory
BMI	Body Mass Index
BN	Bulimia Nervosa
CBT	Cognitive Behavioral Treatment
CPM	Counts Per Minute
DALY	Disability Adjusted Life Year
DSM-5	Diagnostic and Statistical Manual of Mental Disorders, fifth ed.
ED	Eating Disorder
EDE-Q	Eating Disorder Examination Questionnaire
HRQoL	Health Related Quality of Life
OSFED	Other Specified Feeding or Eating Disorders
PA	Physical Activity
PED-t	Physical Exercise- and Dietary Therapy
QoL	Quality of Life
SWLS	Satisfaction with Life Scale
UFED	Unspecified Feeding or Eating Disorders

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1 INTRODUCTION

The World Health Organization (WHO) (2019) defines health as “*A state of complete physical, mental and social well-being not merely the absence of disease or infirmity*”. This implies the need for more than measures of diseases to be able to capture the total well-being of an individual. Everyone should be able to enjoy good quality of life (QoL), but unfortunately not all are that privileged. There have been findings of reduced QoL within different mental and physical illnesses compared to the general population. (Megari, 2013; Vancampfort et al., 2013). EDs is a group of mental illnesses, affecting young women in particular (Hoek, 2016). It is among the top ten of the gender and age-adjusted global burden of diseases in terms of poor quality of life, with young women particularly affected (Hoek, 2016). The documentation on impaired health-related quality of life (HRQoL) in individuals suffering from eating disorders (ED) are rather comprehensive (Ágh, et al., 2016; de Zwaan et al., 2002; de Zwaan, Mitchell, Howell et al., 2002; Kolotkin et al., 2004; Hsu et al., 2002; Padierna, Quintana, Arostequi, Gonzalez & Horcajo, 2000; Pohjolainen et al., 2010; Rieger et al., 2005).

Treatment of the ED per se is not necessarily any guarantee for optimal QoL, as findings suggest that remission from EDs does not necessarily coincide with improvements in QoL (de la Rie, Noordenbos & van Furth, 2005). Acquiring more knowledge of explanatory variables of QoL could be beneficial for improving QoL in this population.

In excess of 300 million people worldwide suffer from depression (WHO, 2018). Depression has been identified as the second largest contributor to work related disability in young adults, and is highly comorbid with EDs (Fernandez-Aranda et al., 2007; Grenon et al., 2010; Hudson, Hirpi, Pope & Kessler, 2007; Latner, Vallance & Buckett, 2008; Masheb & Grilo, 2004; Padierna et al., 2000). In addition, depression has been shown to have a debilitating effect on several areas of daily life and is strongly associated with reductions in QoL (Judd et al., 2000; WHO, 2018). Furthermore, PA has been identified as an important agent in prevention and treatment of depression, but also as an independent contributor to QoL (da Silva, Cordeiro & Ramos, 2009; Grimmer et al., 2011; Hofman et al., 2017; Lustyk, Widman, Paschane & Olson, 2004; Netz, 2017; Rejeski & Mihalko, 2001; Vagetti et al., 2014; Wu et al., 2017).

1.1 Main aim, research questions and hypotheses

This study aims to explore possible explanatory variables of quality of life for women with BN and BED, and to study and compare the contribution of these variables according to two different therapies.

The following research question was addressed:

To what extent does symptoms of depression, level of physical activity and symptom intensity of eating disorders explain the variance in quality of life in women with bulimia nervosa or binge eating disorder receiving physical exercise- and dietary therapy and cognitive behavioral treatment?

The research question was then answered by testing the following general and variable-specific hypothesis:

H₀: Symptoms of Depression, level of PA and intensity of eating disorder symptomatology does not predict QoL in women with BN and BED.

H₁: Symptoms of Depression, level of PA and intensity of eating disorder symptomatology predicts QoL in women with BN and BED.

I will address the aim and answer the research question by testing the hypotheses by quantitative research methods.

2 THEORY

2.1 Eating disorders

Eating disorders (ED) are classified as mental disorders that significantly impairs physical health and psychosocial functioning (Jenkinson, Taylor & Laws, 2018). EDs are characterized by irregular eating habits and individuals may experience severe stress or concern regarding their weight or shape, accompanied by a distorted body image (APA, 2013). A study on the global burden of disease indicates that bulimia nervosa (BN) and anorexia nervosa (AN) are in combination ranked as the 12th leading cause of disability-adjusted life years (DALYs) in women aged 15-19 years in high-income countries, which constitutes 2,2 % of all DALYs (Hoek, 2016).

The causes of EDs are considered as a complex interplay between genetics and environment. It is common to differentiate between three different factors. The *disposing factors*, affecting the probability of development of EDs; *triggering factors*, certain experiences, demands or situations causing the onset of EDs; and the *upholding factors* contributing to the maintenance of the disease. The American Psychiatric Association (APA) (2013), have set forth three primary diagnostic groups of EDs. These are AN, BN, BED and two subcategories; other specified or unspecified feeding and eating disorders (OSFED/UFED) (APA, 2013). Due to the sample on which the current thesis is based, only women with BN and BED will be discussed further.

2.1.1 Bulimia nervosa (BN) and binge eating disorder (BED)

Bulimia nervosa and binge eating disorder (BED) are characterized by recurring episodes of overconsumption of food, with a concurrent feeling of loss of control, in a discrete period of time, commonly known as binge eating episodes. These binges are often accompanied by feelings of guilt, shame or disgust (APA, 2013). In BN these episodes are often followed by compensatory purging behavior, such as self-induced vomiting, use of diuretics, laxatives fasting or excessive exercising. Further diagnostic criteria for BN and BED set forth by the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-V) are presented in Table 1 and Table 2 respectively (APA, 2013). Compensatory purging behavior is usually absent in BED, and if it occurs it is less prevalent compared to the binge eating episodes. BED seems to be more common than BN and is more equally distributed between men and women (APA, 2013; Hudson, Hirpi,

Pope & Kessler, 2007; Striegel-Moore & Bulik, 2007; Udo & Grilo, 2018). The lifetime prevalence of BN and BED in women from western societies is 1-3 % and 1-4 % respectively (APA, 2013). Although not included as a diagnostic criteria for BED, individuals with BN and BED often struggle with a dysfunctional system for evaluation of self-worth and often overvaluation of body weight, shape, eating habits and their ability to control them (APA, 2000; APA, 2013; Fairburn, Cooper & Shafran, 2003; Grilo, White & Masheb, 2012; Hrabosky et al., 2007).

The presence or absence of purging as a compensatory behavior for binge eating is used to distinguish between the two subtypes of BN, purging BN and non-purging BN (APA, 2000). Sub-classification of BED is currently not clear due to inconsistency in findings related to specific risk factors and etiology (Manwaring et al., 2005).

Table 1: DSM-5 criteria for bulimia nervosa.

-
- A.** Recurrent episodes of BE. An episode of BE is characterized by both of the following:
- 1) Eating in a discrete period of time (for example, within a 2-hour period), an amount of food that is definitely larger than most people would eat in a similar period of time under similar circumstances;
 - 2) A sense of lack of control over eating during the episode (for example, a feeling that one cannot stop eating or control what or how much one is eating).
- B.** Recurrent inappropriate compensatory behaviors in order to prevent weight gain, such as self-induced vomiting; misuse of laxatives, diuretics, or other medications; fasting; or excessive exercise.
- C.** The binge eating and inappropriate compensatory behaviors both occur, on average, at least once a week for 3 months.
- D.** Self-evaluation is unduly influenced by body shape and weight.
- E.** The disturbance does not occur exclusively during episodes of anorexia nervosa.
- Specify if:*
- In partial remission:** after full criteria for bulimia nervosa were previously met, some, but not all, of the criteria, have been met for a sustained period of time.
- In full remission:** After full criteria for bulimia nervosa were previously met, none of the criteria have been met for a sustained period of time.
- Mild:** An average of 1-3 episodes of inappropriate compensatory behaviors per week.
- Moderate:** An average of 4-7 episodes of inappropriate compensatory behaviors per week.
- Severe:** An average of 8-13 episodes of inappropriate compensatory behaviors per week.
- Extreme:** An average of 14 or more episodes of inappropriate compensatory behaviors per week.
-

Abbreviations: DSM-5, Diagnostic and statistical manual of mental disorders, fifth edition; BN, bulimia nervosa; BE, binge eating

Table 2: DSM-5 criteria for binge eating disorder.

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- A.** Recurrent episodes of BE. An episode of BE is characterized by both of the following:
- 1) Eating in a discrete period of time (for example, within a 2-hour period), an amount of food that is definitely larger than most people would eat in a similar period of time under similar circumstances;
 - 2) A sense of lack of control over eating during the episode (for example, a feeling that one cannot stop eating or control what or how much one is eating).
- B.** The BE episodes are associated with three (or more) of the following:
- 1) Eating much more rapidly than normal;
 - 2) Eating until feeling uncomfortably full;
 - 3) Eating large amounts of food when not feeling physically hungry;
 - 4) Eating alone because of feeling embarrassed by how much one is eating;
 - 5) Feeling disgusted with oneself, depressed, or very guilty afterward.
- C.** Marked distress regarding BE is present.
- D.** The BE occurs, on average, at least once a week for 3 months.
- E.** The BE is not associated with the recurrent use of inappropriate compensatory behavior (for example, purging) and does not occur exclusively during the course of anorexia nervosa, or avoidant/restrictive food intake disorder.
- Mild:** 1-3 BE episodes per week.
- Moderate:** 4-7 BE episodes per week.
- Severe:** 8-13 BE episodes per week.
- Extreme:** 14 or more BE episodes per week.
-

Abbreviations: DSM-5, Diagnostic and statistical manual of mental disorders, fifth edition; BED, binge eating disorder; BE, binge eating.

2.1.2 Binge eating in BN and binge BED

Binge eating is an integral part of both BN and BED, still there are behavioral differences that are important when it comes to distinguishing and treating the different diagnosis (Wolfe, Baker, Smith & Kelly-Weeder, 2009). Binge eating as a behavior can be understood from a subjective or objective point of view (Wolfe et al., 2009). The objective approach refers to the diagnostic criteria's set forth in the DSM-V, while the subjective approach considers the individuals' perception of the episode and not the volume of food

consumed, nor the timeframe. The experience of lack of control, distress, anxiety and disgust occur in both subjective and objective interpretations of the disorders. Binge eating episodes can occur spontaneously during a meal or as a response to negative affect such as boredom, loneliness, frustration, or they can be planned and function as a reward (APA, 2013). It is important to differentiate between making deliberate choices to binge, compared to bingeing due to loss of control, or as a response to negative affect. Deliberate overfeeding is not considered a binge eating episode because it does not involve an experience of losing control of ones eating behavior. Several factors from an objective binge eating episode relies on a subjective evaluation of the amount of food, eating tempo, timeframe and lack of control. With regards to energy contents, findings from an objective binge eating study indicate that a typical binge eating episode ranges from 3000-7000 kcal (Wolfe et al., 2009). The food that is consumed is most often high in sugars and fats and are usually regarded as unhealthy (APA, 2013; Allison & Timmerman, 2007). Fats and sugars may be preferred over protein due to their consistency as well as protein's satiating properties. The timeframe of a binge episode can vary from 19 minutes up to a whole day, but 85.5 % of these episodes occur within a span of two hours (Wolfe et al., 2009). Binge eating episodes can occur at any time during the day although they are more likely to occur in the afternoon or evening, when the individual is alone (Wolfe et al., 2009).

2.1.3 Understanding binge eating behavior

The cognitive behavioral theory of the maintenance of BN proposes that the dysfunctional evaluation of self-worth, with an overvaluation of control, eating, shape and weight, is the primary driver for maintenance of the disease (Fairburn et al., 2003). Similar reasons may also be explanatory for maintenance of binge eating behavior in BED (Amianto, Ottone, Daga & Fassino, 2015). The theory states that the extreme focus on attaining the ideal body weight and shape may lead to severe dieting. In turn, this may produce feelings of stress, hunger and cravings, which often results in binge eating episodes. Further, the experience of guilt, shame and distress following a binge eating episode functions as a form of reinforcement where the individual alleviates his or her cognitive dissonance by an increased need/ idea of controlling one's own body weight and shape (Fairburn et al., 2003; Svartdal, 2018).

Another theory proposes a possible alternative explanation for binge eating episodes which is particularly interesting for individuals with BED. This theory states that a lack of positive affect or increased negative affect can result in a binge eating episode. There exists some evidence indicating an increased activation in brain regions associated with cravings due to emotion dysregulation. Eating can thereby be understood as a form of negative reinforcement where the individual tries to alleviate cravings by consuming food (Svartdal, 2013; Schulte, Grilo & Gearhardt, 2016).

Individuals with BED have been shown to exhibit more food- and affect impulsivity compared to healthy controls (Hudson et al., 2007; Schag, Schönleber, Teufel, Zipfel & Giel, 2013; Schulte et al., 2016). Certain foods, fats and sugar, have for individuals with impulsivity been shown to produce similar activation patterns in brain structures as those connected to dopamine release from addictive substances, (Gearhardt, Davis, Kuchner & Brownell, 2011). These findings lend some support to the theory that individuals with BED are more prone to develop food addiction (Gearhardt et al., 2011). Studies indicate that 42-57 % of individuals suffering from BED also suffer from food addiction (Schulte et al., 2016). Individuals with food addiction may have imbalances in their reward-related neural systems (Gearhardt et al., 2011). Binge eating episodes could occur because they are either hypo-sensitive or hypersensitive to a substance. This could cause them to either require an elevated dosage of a substance (hyposensitive) to experience the reward response, or to experience an elevated reward response (hypersensitive) leading them to further pursue the behavior (Schulte et al., 2016). The use of short-term reward strategies is also more pronounced in impulsive individuals (i.e. binge eating), even though they are aware of potential negative effects in the long term (Schulte et al., 2016; Schag et al., 2013).

2.1.4 Understanding purging in BN

Purging is understood as a compensatory mechanism in BN. It is primarily used as a means to compensate for the increased energy intake resulting from binge eating episodes (APA, 2013). Self-induced vomiting and excessive exercise seem to be the most common forms of purging, but fasting periods, skipping meals, use of diuretics, laxatives or the use of drugs meant to affect metabolism are also mentioned in the literature (APA, 2013; Ekeröth, Clinton, Norring & Birgegård, 2013; Welch, Birgegård, Parling & Ghaderi,

2011). The effect of purging on energy balance in individuals with BN is considered to be small, and individuals often remain in an overall positive energy balance even after self-induced vomiting (Kaye, Weltzin, Hsu, McConaha & Bolton, 1993). Theories suggest that purging behavior in BN should also be understood as a mechanism for affect regulation (APA, 2013; Meyer & Taranis, 2011). Feelings of shame, disgust and distress often arise following a binge eating episode and purging behavior in itself, not just the caloric-effects it produces, have been shown to relieve stress and anxiety in BN in these situations (APA, 2013; Meyer & Taranis, 2011).

2.1.5 Comorbidity in BN and BED

There exists a range of both physical and psychiatric comorbidities in women with BN and BED (Ágh et al., 2016; Blinder, Cumella & Sanathara, 2006; Grenon et al., 2010; Hudson et al., 2007; Hudson et al., 2010; Kessler et al., 2013; Mehler & Rylander, 2015; Milos, Spindler & Schnyder, 2004; Olguin et al., 2017; Raevuori, Suokas, Haukka, Gissler, Linna, Grainger & Suvisaari, 2015; Zaider, Johnson & Cockell, 2002). Physical comorbidities in BN are primarily associated with purging and bingeing behavior. The distorted eating patterns and weight fluctuation observed in BN may contribute to their increased risk of diabetes type 2, metabolic syndrome and cardiovascular risk (Monteleone, Satoastaso, Panniuto et al., 2005; Raevuori et al., 2015). Sufferers of BN often display pronounced purging behaviors through abuse of diuretics, laxatives, exercise or through self-induced vomiting. The aforementioned, purging behaviors may produce systemic imbalances in fluids and minerals. These imbalances can provoke states of metabolic alkalosis and hypokalemia which in turn can cause cardiac arrhythmias (Mehler & Rylander, 2015). In BED the most physical comorbidities are connected to the detrimental health effects of obesity, and body mass index has been identified as an explanatory variable for QoL (Hudson et al., 2007; Kessler et al., 2013). Findings from previous studies on the relationship between body mass index, symptoms of depression and QoL indicate that symptoms of depression is a more important explanatory variable for QoL (Masheb & Grilo, 2004). Furthermore, symptoms of depression have been found to partially mediate the relationship between HRQoL and body mass index in BED (Singelton, Kenny, Hallet & Carter, 2019).

Individuals with BED show increased risk of diabetes type 2, metabolic syndrome and cardiovascular disease (Hudson et al., 2010; Olguin et al., 2017; Raevuori et al., 2015).

The prevalence of psychiatric comorbidity is also increased in BN and BED compared to the general population (APA, 2013; Godart, Peredereau, Rein, Berthoz, Wallier, Jeammet & Flament, 2007; Hudson et al., 2007; Martinussen et al., 2016; Olugin et al., 2017; Sansone & Sansone, 2011; Sansone & Sansone, 2013). In the U.S, 94,5 % and 78,9 % respectively, of individuals with BN and BED met the criteria of at least one of the core DSM-IV disorders (Hudson et al., 2007). In a study of the prevalence of EDs in six European countries, over half of the participants reported some form of lifetime comorbid mental disorder (Preti et al., 2009). The prevalence of personality disorders in BN and BED are also elevated compared to controls (Martinussen et al., 2016). A few studies indicate that personality disorders often precede the development of eating disorders, and that once the personality pathology has been established it appears to influence and shape the eating pathology (Sansone & Sansone, 2011; Sansone & Sansone, 2013). Personality pathologies, such as borderline personality disorder, coincides with the impulsive eating behavior observed in BN and BED (Sansone & Sansone, 2011; Sansone & Sansone, 2013). Furthermore, this impulsivity may be a partial explanation of the increased substance abuse observed in BN and BED (Gearhardt et al., 2011; Hudson et al., 2007; Root, Pisetsky, Thornton, Lichstein, Pedersen & Bulik, 2009; Schag, Schönleber, Teufel, Zipfel & Giel, 2013; Schulte et al., 2016).

Mood and anxiety disorders are the most prominent comorbid psychiatric conditions in BN and BED (Blinder et al., 2006; Grenon et al., 2010; Milos, Spindler & Schnyder, 2004; Zaidler, Johnson & Cockell, 2002; Ágh et al., 2016). When suffering from BN or BED, the point-prevalence of having one or more anxiety disorders ranges from 55 % to 59 % (Blinder et al., 2006). Findings from the same study indicated that the likelihood having one or more mood disorders at any given time ranged from 93 % to 95 % for women with BN and BED. Although the relationship between BN, BED and mood disorders remains unknown, some research suggests that familial or genetic factors may have an impact (Hudson et al., 2007).

Some studies identify major depressive disorder the most prominent mood disorders with lifetime prevalence rates at approximately 54 % for BN and 42 % for BED respectively

(Blinder, Cumella & Sanathara, 2006; Bulik 2002 in Fairburn & Brownell 2002; Kessler et al., 2013).

2.1.6 Depression

According to WHO (2018) depression is the single largest contributor to global disability. Major depressive disorder has a lifetime prevalence rate of 16.2 % in the US and is one of the most common and serious mood disorders. Depression consists of several characteristic symptoms such as persistent feelings of sadness, hopelessness, apathy, loss of energy (DSM-5 criteria for major depression disorder presented in Table 3 (Malt, 2018). Based on the number and severity of symptoms a depressive episode can be categorized as mild, moderate or severe. Classification tools such as Beck depression inventory and DSM-5 are regularly used to determine the diagnosis (Strunk & Lane, 2016; WHO, 2018).

Table 3 DSM-5 Criteria for major depressive disorder.

5 or more of 9 symptoms (including at least 1 of depressed mood and loss of interest or pleasure) in the same 2-week period; each of these symptoms represent a change from previous functioning:

- Depressed mood (subjective or observed, in children and adolescents, mood can be irritable)
 - Loss of interest or pleasure
 - Change in weight or appetite
 - Insomnia or hypersomnia
 - Psychomotor retardation or agitation (observed)
 - Loss of energy or fatigue
 - Worthlessness or guilt
 - Impaired concentration or indecisiveness
 - Thoughts of death or suicidal ideation or suicide attempt
-

Abbreviations: DSM-5, Diagnostic and statistical manual of mental disorders, fifth edition

Several studies indicate a higher prevalence of symptoms of depression in sufferers of BED and BN compared to the general population (Fernandez-Aranda et al., 2007; Grenon, Tasca, Cwinn et al., 2010; Hudson, Hirpi, Pope & Kessler, 2007; Latner, Vallance & Buckett, 2008; Masheb & Grilo, 2004; Padierna et al., 2000). Major depressive disorder has been shown to have a significant impact on individuals QoL, and one study indicates that the severity of depression is correlated with the impairment in QoL (Judd, Hagop, Akiskal et al., 2000). These findings indicate that the increased prevalence of symptoms of depression observed in BN and BED could be an important explanatory variable for the reduced QoL in BN and BED (Fernandez-Aranda et al., 2007; Grenon, Tasca, Cwinn et al., 2010; Hofman, 2017; Hudson, Hirpi, Pope & Kessler, 2007; Katschnig, 2006; Latner, Vallance & Buckett, 2008; Masheb & Grilo, 2004; Padierna et al., 2000).

Studies examining the relationship between depression and onset of EDs show varied results (Blinder et al., 2006; Godart et al., 2007; Grenon et al., 2010; Zaider et al., 2002). It has been proposed that depression precedes the onset of EDs, but this finding has not replicated these findings (Zaider et al., 2002; Blinder et al., 2006; Grenon et al., 2010). A meta-analysis underlines these mixed findings, highlighting the fact that the relationship between onset chronology of symptoms of depression and EDs is not yet fully understood (Godart et al. 2007). Despite these findings, depression and BN or BED often co-exist (Blinder et al., 2006; Bulik 2002 in Fairburn & Brownell 2002; Kessler et al., 2013). This gives rise to the idea that there may exist a reciprocal relationship between EDs and depression contributing to the maintenance of one another (Fernandez-Aranda et al., 2007; Grenon, Tasca, Cwinn et al., 2010; Hudson, Hirpi, Pope & Kessler, 2007; Latner, Vallance & Buckett, 2008; Masheb & Grilo, 2004; Padierna et al., 2000).

Depression is usually treated through cognitive behavioral treatment, antidepressants or physical activity (Dunn, Trivedi, Kampert, Clark & Chambliss, 2005; Hofmann, Curtiss, Carpenter & Kind, 2017; NICE, 2017). The primary outcome of treatment is a reduction of symptoms of depression, and some studies also indicate that a reduction in symptoms of depression can improve psychosocial functioning and QoL (Hofman, 2017; Katschnig, 2006). PA, antidepressants and CBT have all been shown to produce significant reductions in symptoms of depression in the general population (Hofman et al., 2017; Netz, 2017).

The high rate of both physical and psychological comorbidity in women with BN and BED is associated with reduced quality of life, functional impairment and increased mortality (APA, 2013; Brownley, Berkman, Peat, Lohr, Cullen, Bann & Bulik, 2016; Dahlgren, Stedal & Wisting, 2018; Hudson et al., 2007; Kornstein et al., 2017; Martinussen, Friborg, Schmierer, Kaiser, Øvregård, Neunhoeffler, Martinsen & Rosenvinge, 2016; Mond, Hay, Rodgers & Owen, 2012; Olguin, Fuentes, Gabler, Guerdjikova, Keck & McElroy, 2017; Swanson et al., 2019). Physical activity as an option for treatment of EDs is not common due to the complicated relationship between EDs and exercise (Bouchard, Blair & Haskell, 2007; Mond, Hay Rodgers & Owen, 2006). Regular PA has consistently been shown to reduce symptoms of depression and reduce the risk of several physical comorbidities typically associated to BN and BED, making it an exciting potential treatment in this population. (Bahr, 2015; Carek, Laibstain & Carek,

2011; Rethorst, Wipfli & Landers, 2009; Krogh, Nordentoft, Sterne & Lawlor, 2011; Stephens, 1988).

2.2 Physical activity

PA can be defined as any bodily movement produced by skeletal muscle that requires energy expenditure which exceeds resting energy expenditure (Bahr, 2015). The Norwegian Directorate of health (2016) recommends that adolescents and adults perform a minimum of 300 and 150 minutes of moderate to vigorous intensity of PA per week, respectively. If the individual does not attain this recommended level of PA he/she is classified as physically inactive (Helsedirektoratet, 2016). Physical inactivity has been identified as the fourth leading cause of death on a global scale (WHO, 2018). Longitudinal studies (2009-2015) on PA in the Norwegian population indicate a 5 % increase in attainment of PA recommendations in the population (Anderssen 2010; Hansen, Kolle & Anderssen, 2014). Still, only $\frac{1}{3}$ of Norwegian adults are considered physically active (Hansen et al., 2014).

2.2.1 Effects of physical activity

The load of PA consists of intensity, frequency and duration. This total load of PA is connected to various health-outcomes often presented in a dose-response relationship (Pate, Pratt, Blair & Haskell, 1995). A dose-response relationship indicates a degree of association between the amount of PA and potential health-benefit in the population (Øye, 2018).

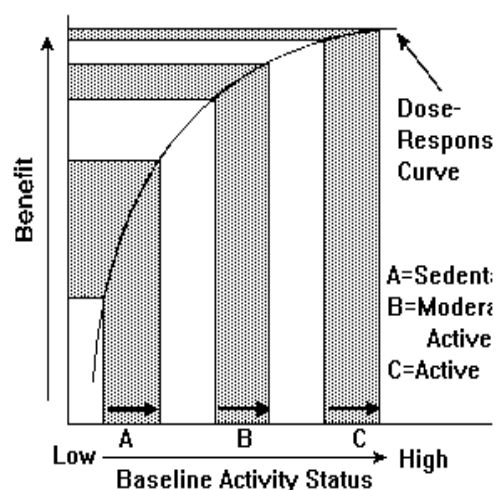


Figure 1: Dose-response relationship between PA load (X-axis) and health-benefits (Y-axis) (Pate et al., 1995).

PA leads to physiologic health-benefits such as increased muscle mass, improved circulation, increased respiratory volume, improved lipid profile, reduced blood pressure, improved immune system, increased bone mineral density and improved body composition (Bahr, 2015). PA may also contribute to improved mental health. Several studies indicate that PA can contribute to reducing symptoms of depression and anxiety (Carek et al., 2011; Rethorst et al., 2009; Krogh et al., 2011; Stephens, 1988). Several studies on the relationship between PA and QoL, indicate that PA is positively correlated with several areas of QoL and HRQoL in respectively, older individuals and younger individuals relationship between PA and QoL, indica (Wu, Han, Zhang, Luo, Hu & Sun, 2017; Rejeski & Mihalko, 2001; Vagetti et al., 2014; Grimmert et al., 2011; Lustyk, Widman, Paschane & Olson, 2004; da Silva, Cordeiro & Ramos, 2009). The frequency of PA seems to affect QoL positively, with studies finding higher frequency associating to better QoL (Grimmett et al., 2011; Lustyk et al., 2004; da Silva et al., 2009). Yet, the relationship between PA and QoL remains unclear. Theories on the relationship between PA and QoL often assume a direct association, alternatively that there are several psychological factors functioning as mediating variables (Lustyk et al., 2004; Rejeski & Mihalko, 2001; Vagetti et al., 2014; Vagetti et al., 2015; White et al., 2009). Studies on the relationship between exercise frequency, motivation and QoL in young adults with and without BN or BED, indicate that exercise motivation may be a better explanatory variable for differences in QoL than exercise frequency for these populations (Bratland-

Sanda, Mathisen, Sundgot-Borgen & Rosenvinge, 2019; Cook, Hausenblas Tuccitto & Giacobbi, 2011; Mathisen et al., 2018; Trojanowski & Fischer, 2018). These findings lend further support to the understanding of PA as an important explanatory variable for QoL in women with BN and BED.

2.2.2 Physical activity in BN and BED

In the general population PA is connected to a range of health benefits, while in EDs it is often understood as part of the expression of the disease. The tendency to abuse PA as a compensatory mechanism in EDs is well known, and for some it may become an addiction (Bouchard, Blair & Haskell, 2007). This may in turn, result in negative psychological, behavioral and medical effects (Bouchard, Blair & Haskell, 2007).

The literature contains a range of different terminologies which attempts to capture the dysfunctional relationship individuals with EDs have towards PA. Some of these terms describes this relationship as a quantitative measure, while others apply a qualitative approach (Patil, O’Keefe, Lavie, Magalski, Vogel & McCulloch, 2012; Mond, Hay Rodgers & Owen, 2006). In spite of all these terminologies there still does not exist a clear operational definition of the dysfunctional exercise (Mond et al., 2006). A qualitative approach and proposes that exercise can be considered excessive in individuals with EDs *“when its postponement is accompanied by intense guilt, or when it is undertaken solely to influence weight or shape”* (Mond et al., 2006). This interpretation of excessive exercise proposes that individuals with EDs may have or develop a dysfunctional relationship with PA, and PA behavior. A study on terms and definitions of exercise in eating disorders by proposes that compulsive exercise may be better suited at capturing the nuances of PA behavior EDs (Meyer & Taranis, 2011). Understanding exercise as compulsive rather than excessive is supported by more recent findings, indicating that motives for conducting PA could be a better explanatory variable than the level of PA when explaining the dysfunctional behavior observed in young individuals with and without BN and BED (Cook et al., 2011; Mathisen et al., 2018; Trojanowski & Fischer, 2018).

Some studies indicate that individuals with BED often perform an insufficient level of PA (Carr, Lydecker, White & Grilo 2019; Hrabosky, White, Masheb & Grilo, 2007; Vancampfort et al., 2013). Although obesity is not a criterion for BED diagnosis there

exists a positive association between BMI and BED, with around 65 % of patients with BED being classified as obese (de Zwaan, 2001; Hsu et al., 2002; Hudson et al., 2006). The presence of overweight and obesity may contribute to the reduced level of PA reported from evaluations of individuals suffering from BED. When looking at PA in BN some studies indicate a higher than average level of PA, compared to healthy controls (Bratland-Sanda, Sundgot-Borgen, Rosenvinge, Hoffart & Martinsen, 2010; Davis et al., 1997). However, a more recent study applying objective measures to evaluate PA levels in BN indicate a more normalized distribution of PA in BN and BED (Mathisen et al., 2018). The discrepancy between motives and actual PA behavior could possibly stem from previous research, where measures of PA have been obtained through interviews and where a direct translation of PA motives and PA behavior have been assumed. When comparing motives for PA to objective measures of PA behavior in women with BN and BED some findings identified a paradox (Mathisen et al., 2018). The study showed that although these individuals exhibit dysfunctional motives and thinking patterns towards PA, they do not necessarily translate this into actual PA behavior (Mathisen et al., 2018). In light of this, if we were to address their dysfunctional relationship and motives towards PA, perhaps a healthier approach could be adopted. This could possibly contribute to reducing the observed physical and psychological comorbidity, as well as improving the QoL in BN and BED (Bahr, 2015; Carek et al., 2011; Cook et al., 2011; Krogh et al., 2011; Mathisen et al., 2018; Rethorst et al., 2009; Stephens, 1988; Trojanowski & Fischer, 2018).

2.3 Quality of life in BN and BED

Quality of life (QoL) can be understood as the individual's perception of their position in life, in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns (WHO, 2019). Health status has clearly been shown to be implicated in an individual's assessment of their QoL (CDC, 2000). This has led to the development of the concept of health-related quality of life (HRQoL), which includes physical- and mental health perceptions (CDC, 2000). Health risks, health conditions, functional status, social support and socioeconomic status all affect HRQoL (McHorney, 1999). The increased prevalence of psychological and physical comorbidity

in BN and BED may have severe implications for health which in turn can cause reductions in QoL (Ágh, et al., 2016; Grenon et al., 2010; Hudson et al., 2007). Several findings indicate that most domains of HRQoL and QoL are impaired in individuals with BN and BED compared to the general population (Ágh, et al., 2016; APA, 2013; de Zwaan et al., 2002; de Zwaan et al., 2002B; Kolotkin et al., 2004; Mulliken et al., 2002; Padierna, Quintana, Arostequi, Gonzalez & Horcajo, 2000; Pohjolainen et al., 2010; Rieger et al., 2005). In addition, several studies indicate that intensity of eating disorder symptomatology is a strong explanatory variable for several domains of HRQoL and QoL in BN and BED (Ágh et al., 2016; Dahlgren, Stedal, & Rø, 2017; de la Rie, Noordenbos & van Furth, 2005; Latner et al., 2008; Padierna, et al., 2000; Wagner, Stefano, Cicero, Latner & Mond, 2016). Some studies have identified significant reductions in physical HRQoL, but not emotional HRQoL in individuals with BED (Perez & Warren, 2012). Obesity has been proposed as a potential mediating factor in the relationship between physical HRQoL and BED (Hudson et al., 2007; Kessler et al., 2013). Findings indicate that obesity is associated with levels of general impairment (Perez & Warren, 2012). The increased prevalence of obesity in BED may produce elevated levels of general impairment, and thereby have adverse effects on the physical HRQoL in BED (Hudson et al., 2007; Kessler et al., 2013; Perez & Warren, 2012).

If left untreated, EDs have been found to significantly impair individuals QoL and ability to participate in society (de Zwaan et al., 2002a; de Zwaan et al., 2002b; Doll, Petersen & Stewart-Brown, 2005; Hsu et al., 2002; Mond, Hay, Rodgers et al., 2004; Perez & Warren, 2012; Pokrajac-Bulian, Kukić & Bašić-Marković, 2015; Rieger et al., 2005; Swanson, Crow, Le Grange et al., 2011). Even individuals who have been through treatment for EDs and are considered healthy tend to report a lower QoL than the general population (de la Rie, 2005). These findings imply that many sufferers of BN and BED experience periods of reduced QoL, both before and after treatment. This could make us question whether the current forms of treatment (CBT) are sufficient when it comes to restoring QoL in individuals suffering from BN and BED. Increased knowledge of elements affecting QoL in this patient group could potentially improve treatment outcome by addressing these elements more specifically. Treatment of EDs are focused on alleviating symptoms of the specific diagnosis. However, sufferers of BN and BED indicate that well-being and learning to cope with the disease may be just as important as

remission from the symptoms of the ED itself (Bratland-Sanda et al., 2019; de Vos, Lamarre, Radstak, Bijkerk, Bohlmeijer & Westerhof, 2017; Hudson et al., 2007; Kessler, Berglund, Chiu et al., 2013; Masheb & Grilo, 2004).

3 METHODS

3.1 Research design

This master thesis is part of a research project named 'Physical exercise- and dietary therapy trial (PED-t)'. The PED-t trial was conducted at the Norwegian School of Sport Sciences between 2014 and 2016.

3.1.1 Original study

The objective of the study was to evaluate physical exercise- and dietary therapy as a potential alternative form of treatment to cognitive behavioral treatment (CBT), for women with BN and BED. A randomized controlled design, comparing the treatment effects between PED-t and CBT at pre- and post-test, with a waitlist control group, was utilized. The treatment protocol consisted of 20 therapy sessions conducted over a period of 16 weeks, in which participants received either PED-t or CBT in groups of 5-8 participants. Inclusion and exclusion criteria relevant for the current thesis is presented in Table 4.

Privacy protection and ethics

Voluntary participation was the basis of this study. All registered information was made anonym and participants were assigned an id-number. Information regarding the participants and their results were only available for authorized personnel.

The study was approved by the Norwegian regional committee for Medical and Health Research Ethics on the 16th of December 2013 (ID: 2013/1871, Appendix IV). Further, it was registered in Clinical Trials on the 17th of February 2014 (ID: NCT02079935). All participants (Appendix V), as well as their general practitioners, signed informed consents before treatment was initiated. Confidentiality declarations and informed consents regarding being videotaped during treatment were also signed.

To ensure participants health, certain safety measures were implemented. A planned stop-procedure during treatment was initiated if participants exhibited a worsening of ED symptoms (BMI<17.0 and/or rapid and significant weight loss of more than 3 kilogram (kg) from normal weight). Stop-procedures were also initiated if individuals expressed signs of severe depression or if severe osteoporosis were observed in individuals in the

PED-t group. None of the participants displayed any of the risk factors mentioned above, therefore stop-procedures were not implemented.

In relation to the exercise sessions performed in the PED-t condition, individuals who reported an insufficient intake of nutrition or feelings of illness were not allowed to participate in the exercise session that day. If participants reported distorted eating patterns (restrictive eating or severe purging) in the days leading up to the pre- and post-tests, no physical tests were performed. There was a medical health care team near the test site, and a defibrillator was available on site in case of emergency.

Recruitment of participants and randomization

Several information channels were used in recruitment; general practitioners, social media, posters and specific ideal organizations. When included in the study, participants were randomized by block size of eight to treatment groups. The website www.randomizer.org was used to create the randomization list. Participants were informed of which group they were randomized to after baseline measures. This ensured that researchers and test personnel remained blind with regard to group allocation. CBT and PED-t are obviously different treatment forms that does not allow for blinding of therapists and participants. Individuals awaiting treatment, functioned as a control group.

3.1.2 Current thesis

Data obtained from the PED-t trial was utilized to conduct multiple regression analysis to evaluate if symptoms of depression, physical activity and intensity of eating disorder symptomatology predicted QoL in the sample of women with BN and BED. Multiple regression analysis was performed on the whole sample and both treatment groups, at pre- and post-test.

Table 4: Relevant inclusion and exclusion criteria for the analysis in the current thesis.

Inclusion criteria	Exclusion criteria
Females between 18-40 years of age	Women who were pregnant or planning to become pregnant
DSM-5 diagnosis of BN or BED with a duration of at least 3 months with mild to severe symptoms (minimum one episode per week of compensatory behaviors or binge eating, respectively)	Competitive athletes
Fulfillment of pre- and/or post-test measures of QoL, depression, eating disorder symptomology and habitual level of physical activity	Concurrent severe symptom or personality disorder in need of other treatment
	Individuals who had received CBT for ED's during the last 2 years pre-trial

Abbreviations: DSM-5, Diagnostic and statistical manual of mental disorders, fifth edition; BN, Bulimia Nervosa; BED, Binge Eating Disorder; CBT, cognitive behavioral treatment; QoL, quality of life

3.2 Test procedure and outcome measures

Several variables were assessed in the PED-t trial. Referring to the aim of this thesis, only measures of symptoms depression, level of habitual physical activity, eating disorder symptomology and quality of life will be presented and discussed.

3.2.1 Symptoms of depression

Beck's Depression Inventory (BDI), BDI-IA is an instrument designed to measure the behavioral manifestations of depression in persons aged >13 years (Appendix I) (Beck, Ward, Mendelson, Mock & Erbaugh, 1961; Smarr & Keefer, 2011). The instrument is often applied to populations with psychiatric diagnoses such as eating disorders, addictions and anxiety disorders (Smarr & Keefer, 2011). The BDI-IA is composed of 21 categories of symptoms and attitudes. Every category explains a specific behavioral manifestation of depression and consists of a graded series of four to five statements of self-evaluation. To rate severity, the statements are ranked from neutral (0) to maximal severity (3). The total score range is between 0 and 63. The following guidelines have been suggested to interpret the BDI-IA: minimal range = 0-9, mild depression = 10-16, moderate depression = 17-29 and severe depression = 30-63 (Smarr & Keefer, 2011). Measures were self-reported by the participants and describe the symptoms of depression over the past two weeks (Beck et al., 1961; Smarr & Keefer, 2011).

3.2.2 Levels of Physical activity

Measures of physical activity (PA) and sedentary time were obtained objectively, using the ActiGraph accelerometer (ActiGraph GT3x and GT3x+, Actigraph, LCC, Pensacola, Florida, USA). An accelerometer is a precise measuring tool, utilizing acceleration to provide information regarding the intensity of the performed activity. Participants were instructed to place the accelerometer on their right hip and wear it for seven consecutive days. The accelerometer was only to be removed during water-activity and night-time sleep (Anderssen, 2010). Epochs were set to 60-seconds with 30 Hertz sampling rates. 600 minutes per day were set as the minimum requirement of wear time for a valid day, and a minimum of two valid days were required for the measurements to be included in the study. If continuous zero count epochs were measured over a time-interval of at least 60 minutes, this was classified as non-wear time (two exceptions during 60 minutes were allowed). Counts per minute (CPM) was included as measurement of PA in this thesis as it reflects the total level of PA.

3.2.3 Eating disorder symptomology

Although clinical interviews generally are recognized as the “gold standard” for making diagnosis of BN and BED, there is often a need for an easier and more cost-effective means of screening individuals with these diagnoses and measuring the core symptomology of the disorder (Grilo, Masheb & Wilson, 2001; Luce & Crowther, 1999). This has led to the development of questionnaires such as the Eating Disorder Examination (EDE-Q). Version 6.0 was used in this study (Appendix II). The EDE-Q retrieves information on behavior and feelings related to eating disorders and can identify risk behaviors. The EDE-Q consists of 28 items evaluating the individuals eating behavior over the past twenty-eight days. All items are scaled from 0-6, with 0 indicating that the behavior has not occurred at all in the past 28 days, while 6 indicates that the behavior has occurred on all past 28 days. Scores from each item is then added together constituting a global score. The EDE-Q also includes four subscales that measures eating restraint, eating concern, shape concern and weight concern. The mean global score for a Norwegian cohort of healthy female controls was found to be 1.25 with a standard deviation of 1.10, and national clinical cut-off points for probable BN and BED were set at 2.62 and 2.63, respectively (Rø, Reas & Stedal, 2015). Several publications indicate that the EDE-Q validly assesses the frequency and severity of ED features to produce ED

diagnoses according to the DSM-5 (APA, 2013; Friborg, Reas, Rosenvinge & Rø, 2013; Grilo et al., 2001; Luce & Crowther, 1999).

3.2.4 Quality of life

To assure a standardized, reliable and valid measurement of quality of life (QoL), satisfaction with life scale (SWLS) was utilized (Adler & Fagley, 2005). SWLS is a questionnaire (Appendix III) consisting of a short 5-item scale intended to assess an individual's global judgement of life satisfaction (Adler & Fagley, 2005). These five statements are then individually rated using a 7-point Likert scale ranging from 1 (never true) to 7 (always true). Scores can range from 5 to 35 and they are summarized and evaluated in 6 sub-categories: highly satisfied (30-35 points), satisfied (25-29 points), slightly satisfied (20-24 points), slightly dissatisfied (15-19 points), dissatisfied (10-14 points) and extremely dissatisfied (5-9 points). An age-matched mean normative value from a Norwegian cross-sectional health investigation is 26.3 (Clench-Aas, Nes, Dalgard & Aarø, 2011).

3.3 Statistical analysis

All statistical analyzes were performed using IBM SPSS Statistics version 24. Multiple linear regressions were calculated for the whole sample and separately for each treatment group, at pre- and post-test. The regression analysis implemented in this study describes and evaluates the relationships between QoL and depression, PA and intensity of eating disorder symptomatology. Normality of the dependent variable was assessed with Kolmogorov-Smirnov ($>.05$) and/or Shapiro-Wilk test ($>.05$), on the complete sample and on group level at pre- and post-test. The three independent variables that were included was tested for multicollinearity and heteroscedasticity, through tolerance and variance inflation factor with cut-offs set at $<.10$ and >10 respectively. Finally, the sample was checked for influential cases and/or outliers. If cases exceeded >3 standard deviations, they were excluded. The influence of potential outliers on results from the analysis was tested through Cook's distance and Mahalanobis distance. Cut-off values for cook's distance were set at >1 . For Mahalanobis cut-off values of 16.3 and 12.3, when including 3 or 2 independent variables in the regression analysis. Variables that

were identified as statistically significant explanatory variables for QoL in the bivariate correlations were included in the regression model ($p < 0.05$).

Statistical significance was set at $p \leq 0.05$. Pearson's correlation coefficients were applied to measure the association between variables. Values between variables ranging from .2-.49 were considered as weak correlation, values from .5-.79 were considered as moderate correlation and values $>.7$ were considered as a strong correlation.

The Control group were excluded from analysis due to a low number of participants in this group and lack of objective registration of PA.

4 RESULTS

4.1 Demographics and outcome measures

Of the total 148 women included in the pre-therapy analysis, 96 was diagnosed with BN and 52 with BED. There were no differences in distribution of diagnosis between the therapy groups. Table 5 contains descriptive data of participants at baseline when distributed to their randomized treatment groups.

Table 5: Demographics of participants at pre-therapy. All variables are presented as mean with standard deviation (\pm). Prevalence of diagnoses in each condition is presented as numbers and percent (%).

	PED-t (n=75)	CBT (n=73)
Age (years)	28.2 \pm 6.2	27.6 \pm 5.3
Weight (kg)	71.8 \pm 16.0	71.4 \pm 14.3
Height (cm)	167.8 \pm 6.5	167.8 \pm 6.3
BMI (kg/m²)	25.4 \pm 5.1	25.4 \pm 4.6
Bulimia nervosa (%)	48 (64)	48 (66)
Binge eating disorder (%)	27 (36)	25 (34)

n= number of participants, kg= kilogram, cm= centimeter, BMI= body mass index, \pm = Standard deviation; PED-t.= Physical Activity and Dietary Therapy, CBT= Cognitive Behavioral Therapy.

Mean scores for depression, physical activity level, symptom intensity of eating disorder and quality of life in PED-t and CBT, with between group differences at pre- and post-therapy is presented in Figure 2.

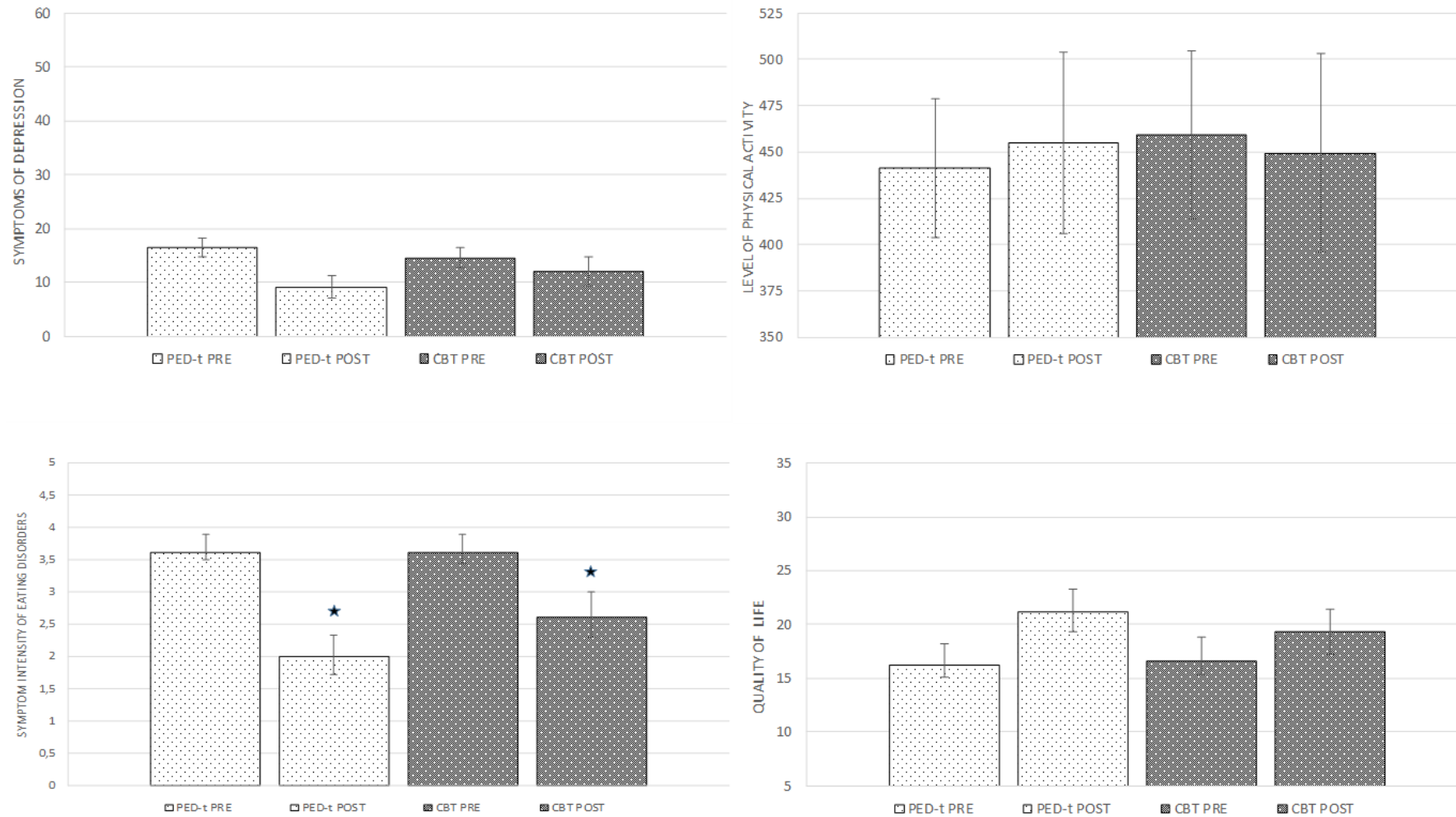


Figure 2: Mean scores of symptoms of depression, level of physical activity, symptom intensity of eating disorders and quality of life in PED-t and CBT, pre- and post-therapy. 95% confidence interval. Differences between groups at pre- and post-therapy. Significance is defined when $p < 0.05$. Significant differences between groups at pre- and post-therapy is illustrated with a * in the figure.

4.2 Pre-therapy: Evaluating the relationship between depression, level of physical activity, symptom intensity of eating disorders and quality of life

4.2.1 Multiple regression analysis on the complete sample

The bivariate correlation identified symptoms of depression ($p=.000$) and symptom intensity of EDs ($p=.028$) as significantly correlated with QoL. Level of PA was not significantly correlated with QoL ($p=.115$), and as such excluded from any further analysis.

The multivariate regression model consisted of symptoms of depression and symptom intensity of EDs. Together, symptoms of depression ($\beta = -.655$, 95 % confidence interval $[-.631, -.424]$) and symptom intensity of EDs ($\beta = -.003$, 95 % confidence interval $[-.919, .875]$) accounted for 42.9 % of the variance observed in QoL ($F(2, 143) = 53.804$, $p < .000$). Symptom intensity of EDs did not make a significant unique contribution ($p=.962$) to the regression equation. Symptoms of depression made a significant unique contribution to the equation, accounting for 40.4 % of the variance in QoL ($p=.000$).

4.2.2 Multiple regression analysis in PED-t group

In PED-t the bivariate correlation identified symptoms of depression ($p=.000$) as significantly correlated with QoL. Level of PA ($p=.397$) and symptom intensity of EDs ($p=.426$) were not significantly correlated with of QoL, and as such excluded from further analysis.

The univariate regression model consisted of symptoms of depression. Symptoms of depression ($\beta = -.606$, 95% confidence interval $[-.654, -.346]$), accounted for 36.7 % of the variance in QoL ($F(1, 72) = 41.724$, $p < .000$).

4.2.3 Multiple regression analysis in CBT group

In CBT the bivariate correlation identified symptoms of depression ($p=.000$), level of PA ($p=.026$) and symptom intensity of EDs ($p=.008$) as significantly correlated with QoL.

The multivariate regression model consisted of symptoms of depression, level of PA and symptom intensity of EDs. Together, symptoms of depression ($\beta = -.657$, 95% confidence interval $[-.674, -.375]$), level of PA ($\beta = -.219$, 95% confidence interval $[-.015, -.001]$) and symptom intensity of EDs accounted for ($\beta = -.157$ confidence interval $[-2.261, .204]$) 56.9 % of the variation observed in QoL ($F(3, 53) = 23.312$, $p < .000$). Symptom

intensity of EDs did not make a significant unique contribution to the equation ($p=.100$). Both symptoms of depression ($p=.000$) and level of PA ($p=.020$) made a significant unique contribution to the equation accounting for 43.1 % and 4.7 % respectively, of the variance in QoL.

4.3 Post-therapy: Evaluating the relationship between symptoms of depression, level of physical activity, symptom intensity of eating disorders and quality of life

Of the total 148 women who were included in the pre-therapy analysis, 111 remained in the post-therapy analysis. The dropout rate corresponded to 29.8%.

4.3.1 Multiple regression analysis on the complete sample

The bivariate correlation identified symptoms of depression ($p=.000$) and symptom intensity of EDs ($p=.000$) as significantly correlated with QoL. Level of PA was not significantly correlated with QoL ($p=.220$) and was as such excluded from any further analysis.

The multivariate regression model consisted of symptoms of depression and symptom intensity of EDs. Together, symptoms of depression ($\beta = -.773$, 95% confidence interval [-.789, -.516]) and symptom intensity of EDs ($\beta = .043$, 95% confidence interval [-.706, 1.224]) accounted for 56.0 % of the variance observed in QoL $F(2, 103) = 65.448$, $p < .000$). Symptom intensity of EDs did not make a significant unique contribution to the equation ($p=.595$). Only symptoms of depression made a significant unique contribution to the equation, accounting for 38.5 % of the variance in QoL ($p=.000$).

4.3.2 Multiple regression analysis in PED-t group

The bivariate correlation identified symptoms of depression ($p=.000$) and symptom intensity of EDs ($p=.002$) as significantly correlated with QoL. Level of PA was not significantly correlated with QoL and was as such excluded from further analysis ($p=.171$).

The multivariate regression model consisted of symptoms of depression and symptom intensity of EDs. Together, symptoms of depression ($\beta = -.785$, 95% confidence interval [-.927, -.499]) and symptom intensity of EDs ($\beta = .116$, 95% confidence interval [-.749,

2.194]) accounted for 51.9 % of the variation observed in QoL $F(2, 55) = 29.658, p < .000$). Symptom intensity of EDs did not make a significant unique contribution to the equation ($p = .330$). Symptoms of depression was the only variable making a unique significant contribution to the equation, accounting for 38.8 % of the variance in QoL ($p = .000$).

4.3.3 Multiple regression analysis in CBT group

The bivariate correlation identified symptoms of depression ($p = .000$) and symptom intensity of EDs ($p = .001$) as significantly correlated with QoL. Level of PA ($p = .458$) was not significantly correlated with QoL and was as such excluded from further analysis.

The multivariate regression model consisted of symptoms of depression and symptom intensity of EDs. Together, symptoms of depression ($\beta = -.763$, 95% confidence interval $[-.781, -.421]$) and symptom intensity of EDs ($\beta = -.022$, 95% confidence interval $[-1.498, 1.238]$) accounted for 60.1 % of the variation observed in QoL $F(2, 45) = 33.861, p < .000$). Symptom intensity of EDs did not make a unique significant contribution to the equation ($p = .849$). Symptoms of depression was the only variable making a unique significant contribution to the equation, accounting for 39.9% of the variance observed in QoL ($p = .000$).

4.4 Evaluating the relationship between symptoms of depression and symptom intensity of eating disorder from pre- to post-therapy

4.4.1 Evaluating the complete sample

The complete sample had a mean symptoms of depression score of 15.6 (7.7) and a mean symptom intensity of EDs score of 3.6 (0.8) pre-therapy. The correlation coefficient between symptoms of depression and symptom intensity of EDs indicated a weak relationship ($r = .236$). Post-therapy, the complete sample had a mean symptom of depression score of 10.5 (8.7) and a mean symptom intensity of EDs score of 2.3 (1.2). The correlation coefficient between symptoms of depression and symptom intensity of EDs indicated a moderate relationship ($r = .597$).

The mean score of symptoms of depression was reduced by 5.1 points (32.7 %), while the symptom intensity of EDs mean score was reduced by 1.3 points (36.2 %) from pre-

to post-therapy. The strength of the relationship between symptoms of depression and symptom intensity of EDs changed from weak ($r=.236$) to moderate ($r=.597$) from pre- to post-therapy conditions.

4.4.2 Evaluating PED-t

The PED-t group had a mean symptoms of depression score of 16.5 (7.6) and a mean symptom intensity of EDs score of 3.6 (0.8) pre-therapy. The correlation coefficient between symptoms of depression and symptom intensity of EDs indicated a weak relationship ($r=.240$). Post-therapy PED-t had a mean symptoms of depression score of 9.2 (8.0) and a mean symptom intensity of EDs score of 2.0 (1.1). The correlation coefficient between symptoms of depression and symptom intensity of EDs indicated a moderate relationship ($r=.607$).

The mean score of symptoms of depression score was reduced by 7.3 or 44.3 %, while the symptom intensity of eating disorders mean score was reduced by 1.6 or 44.5 % from pre- to post-therapy. Promoting a change in the strength of the association between symptoms of depression and symptom intensity of eating disorders from weak ($r=.240$) to moderate ($r=.607$), from pre- to post-therapy conditions.

4.4.3 Evaluating CBT

The CBT group had a mean symptoms of depression score of 14.6 (7.8) and a mean symptom intensity of eating disorders score of 3.6 (0.9) pre-therapy. The correlation coefficient between symptoms of depression and symptom intensity of eating disorders indicated a weak relationship ($r=.235$). Post-therapy the complete sample had a mean symptoms of depression score of 12.0 (9.3) and a mean EDE-q score of 2.6 (1.2). The correlation coefficient between the variables indicated a moderate relationship ($r=.560$).

The mean score of symptoms of depression was reduced by 2.6 or 17.9 %, while the EDE-q mean score was reduced by 1.0 or 27.8 % from pre- to post-therapy. Promoting a change in the strength of the association between the depression and EDE-q from weak ($r=.235$) at pre-therapy to moderate ($r=.560$) at post-therapy.

5 DISCUSSION

This thesis intended to answer whether symptoms of depression, level of physical activity and symptom intensity of EDs could explain QoL in women with BN and BED. The regression model consisting of various combinations of symptoms of depression, level of physical activity and symptom intensity of EDs explained 42 %, 38 % and 56 % of the variance in QoL respectively for the complete sample, PED-t and CBT at pre-therapy. At post-therapy the current model explained 56 %, 51 % and 60 % of the variance in QoL in the complete sample, PED-t- and CBT group. Findings from the current analysis show that the regression model has moderate predictive power of QoL in women with BN and BED, partially confirming the hypothesis.

The mean scores on symptoms of depression, level of physical activity, symptom intensity of EDs and QoL for this sample of women with BN and BED are consistent with previous research indicating a higher prevalence of symptoms of depression, increased symptom intensity of EDs and reduced QoL compared to a similar sample from the general population (Ágh et al., 2016; McMahon et al., 2017; Rø et al., 2015).

Depression was found to be the most important explanatory variable for QoL for women with BN and BED in all analysis. Symptoms of depression offered a significant unique contribution to the regression model explaining around 40 % of the variance observed in QoL in the all analysis; i.e. the complete sample, PED-t and CBT, and at both pre- and post-therapy. The findings indicated that a reduction in symptoms of depression contributes to improved QoL underlining the importance of symptoms of depression for QoL in women with BN and BED.

Level of PA was only found to offer a significant unique contribution to the regression model in CBT at pre-therapy, explaining around 4 % of the variance in QoL. Level of PA did not offer a significant unique contribution to the regression model in the complete sample or PED-t in analysis at neither pre- nor post-therapy. Symptom intensity of EDs was not found to be significant in any of the post-therapy analysis. The whole sample experienced a reduction of respectively 32.7 % and 36.2 % in mean score of symptoms of depression and mean symptom intensity of EDs. The correlation between depression and symptom intensity of EDs changed from weak to moderate from pre-to post-therapy.

5.1 Depression and quality of life in women with BN and BED

Our main finding, identifying symptoms of depression as a significant explanatory variable for QoL, is in line with previous findings in BN and BED (de la Rie et al., 2005; Faulconbirdge et al., 2013; Lenert, Sherbourne & Sugar, 2000; Mond et al., 2004; Padierna et al., 2000; Singelton et al., 2019). When comparing patients suffering from EDs to patients with a former ED-diagnosis, individuals with current BN and BED have been found to be significantly impaired in physical role functioning, vitality, general health perceptions, social functioning and mental health (de la Rie, 2005; Hay et al., 2010). Some research has indicated that impairments in several domains of QoL and overall QoL seems to be more severe in individuals with BN, BED and comorbid depression, compared to individuals with BN and BED without comorbid depression (Padierna et al., 2000).

Findings in this thesis indicate a moderate negative relationship between symptoms of depression and QoL. This implies that a reduction in symptoms of depression induce improved QoL in this population. This is in line with research from the general population and for individuals with BN and BED (Bijl, Ravelli & van Zessen, 1998; Faulconbirdge et al., 2013; Lenert et al., 2000; Padierna et al., 2000; Singelton et al., 2019; Trojanowski & Fischer, 2018). These studies support findings from this thesis, i.e. the existence of an intensity dependent negative relationship between symptoms of depression and QoL.

The explanatory power of symptoms of depression (approximately 40 %) for variance in QoL indicate that symptoms of depression have a substantially higher explanatory power for this sample compared to findings from previous studies on QoL. In the literature there exist studies indicating that the strength of symptoms of depression accounted for 9.5 %, 13.9 % and 22 % of the unique variance in QoL, in college- and BED-populations (Grenon et al., 2010; Singelton et al., 2019; Trojanowski & Fischer, 2018). Another study did not find symptoms of depression to account for any of the unique variance in QoL for women with BN and BED. Several plausible factors can contribute to explain the difference in the symptoms of depression these discrepancies. First, a difference in occurrence of intensity in of symptoms of depression between samples studied may explain the different findings. Therefore, we might hypothesize that the intensity

dependent negative relationship between symptoms of depression and QoL in part functions as an explanation of why symptoms of depression is a more important explanatory variable for variance in QoL in this sample compared to healthy college students (Bijl et al., 1998; Faulconbirdge et al., 2013; Lenert et al., 2000; Padierna et al., 2000; Singelton et al., 2019; Trojanowski & Fischer, 2018). Second, the inclusion of different variables in analysis may cause different findings. In the current regression model, symptoms of depression, level of physical activity and symptom intensity of EDs were included, which may not be the case for the other studies symptoms of depression (Grenon et al., 2010; Singelton et al., 2019). Third, our sample consisted of treatment seeking women, who are found to exhibit increased ED severity and elevated levels of symptoms of depression, compared to community samples of individuals with BN and BED (de la rie et al., 2005; Pollack, McCune, Mandal & Lundgren, 2015). As a consequence, this can possibly explain some of the differences in the explanatory power of symptoms of depression on the unique variance in QoL between our sample and community samples (Grenon et al., 2010; Pollack et al., 2015; Singelton et al., 2019). However, this notion was not replicated in individuals with very severe BN and BED symptomology (mean score on symptom intensity of EDs 4.4) (Pollack et al., 2015). This might indicate that ED symptomology is a better explanatory variable for QoL in individuals with extreme ED pathology, or potentially, that symptoms of depression and symptom intensity of EDs to a larger extent coincides in explaining QoL in this population. Lastly, the differences in instruments used to measure QoL, and similarities with other psychological comorbid conditions could also contribute to explain some of the differences for symptoms of depression as an explanatory variable for QoL between populations (Grenon et al., 2010; Pollack et al., 2015; Singleton et al., 2019).

Some studies on women with BN and BED indicate that well-being and learning to cope with the disease may be just as important as remission from the symptoms of the ED (Bratland-Sanda et al., 2019; de Vos, et al., 2017; Hudson et al., 2007; Kessler et al., 2013; Masheb & Grilo, 2004; Pettersen et al., 2018). Although CBT, PED-t and lifestyle modification treatments have been found to reduced symptoms of depression, clinicians might find it beneficial to further assess and address comorbid symptoms of depression in treatment of BN and BED in an attempt to further improve QoL in populations with EDs (Mathisen et al., 2018; NICE, 2017; Singelton et al., 2019).

5.2 Level of physical activity and quality of life in women with BN and BED

Level of PA was significantly correlated with QoL, and was identified as a significant explanatory variable for QoL in the CBT group at pre-therapy, but not at post-therapy. For the complete sample and PED-t level of PA was not significantly correlated with QoL at pre- or post-therapy. There exists discrepancies on how level of PA relates to QoL (da Silva et al., 2009; Grimmett et al., 2011; Lustyk et al., 2014; Mond et al., 2005; Pinto Pereira, Geoffroy & Power, 2014; Rejeski & Mihalko, 2001; Trojanowski & Fischer, 2018; Vagetti et al., 2004; Wu et al., 2017) The finding from the CBT group at pre-therapy aligns with some findings from the general population identifying level of PA as a significant explanatory variable for QoL (da Silva et al., 2009; Grimmett et al., 2011; Rejeski & Mihalko, 2001; Wu et al., 2017). However, the finding contradicts previous findings on the relationship between PA behavior, ED behavior and QoL, indicating no explanatory power of PA in a community sample of women, nor amongst healthy college students (Mond et al., 2005; Trojanowski & Fischer, 2018).

Several potential factors may contribute to explaining the difference in the strength of level of PA as an explanatory variable for QoL in the current study, compared to previous research. First, objective methods were used to describe the level of PA in this sample, while previous studies often have applied subjective methods for measures of level of PA. Objective measures are generally considered more reliable, compared to subjective methods when describing actual PA behavior. Subjective measures of PA are vulnerable to several biases. These biases can reduce the reliability and validity of the measure, which in turn may lead to discrepancies in findings of the level of PA from subjective measures (Prince et al., 2008). Therefore, it is possible that some of the differences in level of PA as an explanatory variable for QoL can be attributed to differences in measuring instruments (Anderssen, 2009; Mond et al., 2005; Prince et al., 2008; Trojanowski & Fischer, 2018). Second, the current sample consisted of women with BN and BED, while similar studies have been performed on community- and college-populations. Although, these studies have accounted for symptom intensity of EDs there might still be significant variations between a healthy- and clinically ill population. Lastly, the level of PA was not found to be significant in the CBT-group at post-therapy, it is plausible that some of the changes in significance of level of PA as an explanatory

variable for QoL can be explained by individuals dropping out of the study from pre- to post-therapy.

Findings from post-therapy aligns with previous findings on the relationships between PA behavior, ED behavior and QoL, which reveals no associations, neither in a community sample of women with EDs, nor amongst healthy college students (Mond et al., 2004; Trojanowski & Fischer, 2018). Our sample experienced reductions in both, symptoms of depression and symptom intensity of EDs from pre- to post-therapy. Due to these reductions our sample can be considered healthier in terms of symptoms of depression and symptom intensity EDs. Consequently, we might expect our findings regarding level of PA in a larger extent to coincide with normative values. As a result, the current study aligns with previous research proposing that eating pathology and symptoms of depression may function as mediators in the relationship between level of PA and QoL (Mond et al., 2004; Pinto et al., 2014).

Neither motivation for PA, frequency of PA or PA behavior has previously been found to be a significant explanatory variable for QoL in women with BN and BED (Mond et al., 2004). Although not significant, studies have found that performing PA to improve physical appearance or relieve feelings of guilt to be strongly associated with ED pathology and reduced QoL in the general population and in individuals with EDs (Mond et al., 2005; Trojanowski and Fischer, 2018). On the other hand, performing PA for enjoyment or mood improvement was associated with lower levels of ED disturbances and improved QoL in the same populations (Mond et al., 2005; Trojanowski and Fischer, 2018). These findings were further supported by findings from the PED-t trial, where reduction in ED symptomatology also resulted in a reduction in dysfunctional exercise (i.e. motives for exercise), but no significant change in objectively measured level of physical activity from pre- to post therapy (Mathisen et al., 2018). Hence, it appears that the actual amount of PA may be less important compared to the motives for PA when explaining QoL in women with BN and BED. This implies that a qualitative understanding of PA may be better suited to assess QoL in this population. (Bratland-Sanda et al., 2019). Further longitudinal research is required to evaluate and understand the potential contribution of PA to EDs and QoL.

5.3 Symptom intensity of eating disorders and quality of life in women with BN and BED

Although significantly correlated to QoL, symptom intensity of eating disorders as an explanatory variable did not offer a significant unique contribution to the unique variance in QoL in the complete sample, PED-t separately or CBT separately, at neither at pre- or post-therapy.

There have been discrepancies in findings on how symptom intensity of EDs relates to QoL (Bamford & Sly, 2010; DeJong et al., 2013; de la Rie et al., 2005; Latner et al., 2013; Padierna et al., 2000; Pollack et al. 2015) The findings at post-therapy aligns with some previous findings also failing to identify symptom intensity of EDs as an explanatory variable for QoL in women with severe BN and BED (Pollack et al. 2015). However, these findings contradict some previous studies which have identified symptom intensity of EDs as a significant explanatory variable for QoL in BN and BED (Bamford & Sly, 2010; de la Rie et al., 2005; Latner et al., 2013; Padierna et al., 2000). Symptom intensity of EDs has been found to account for 9 % of the unique variance in QoL in women with BN and BED (Bamford & Sly 2010). Most of the studies that have identified symptom intensity of EDs as a significant explanatory variable of QoL in BN and BED have not accounted for the potential influence from comorbid psychiatric conditions (DeJong et al., 2013; de la Rie et al. 2005; Bamford & Sly, 2010; Latner et al., 2013). A study including both symptom intensity of EDs and symptoms of depression, found symptoms of depression to account for more of the variance observed in both mental and physical domains of QoL in women with EDs (Padierna et al., 2000). Further, Studies on healthy college students indicate that when controlling for the effects of depression, the association between symptom intensity of EDs and QoL is reduced, leaving symptoms of depression as the central contributor to QoL (Trojanowski and Fischer, 2018). These findings align with results in the current thesis and may suggest that symptoms of depression accounts for some of the variance in QoL previously thought to be explained by symptom intensity of EDs.

The subscale of EDE-q measuring body shape concern, seems to be the more important explanatory variable for QoL in a healthy population sample (Trojanowski and Fischer, 2018). This finding suggests that individuals without diagnosed EDs may still experience

body image concerns, increasing their risk of impaired mental health and development of EDs (Stice & Shaw, 2002). Interestingly, the differences in measurements of body shape concern, eating concerns and -restrictions may be the main difference between healthy individuals and individuals with EDs. In EDs subscales measuring eating concern and –restrictions often have scores of clinical severities and may be more influential on impairment on QoL in an ED-population compared to healthy individuals, while shape and weight concerns seem to be more associated with QoL in the healthy population (de la Rie et al., 2005; DeJong et al., 2013; Padierna et al., 2000; Pollack et al., 2015; Trojanowski and Fischer, 2018). These findings provide support for the claim that sociocultural processes may foster body dissatisfaction, which in turn increases the risk of a bulimic pathology. An increased focus on body image disturbances might enhance prevention and treatment interventions (Stice & Shaw 2002).

5.4 Limitations

5.4.1 Sample and representativity

There are certain circumstances regarding the sample and its representativity that ought to be addressed.

The form of recruitment, inclusion criteria and treatment forms based on PA and dietary therapy utilized in the PED-t trial may attract certain demographics of women, increasing the risk of certain selection bias (Heckman, 1979). This study may have appealed to younger women, women hoping to receive PED-t as form of treatment and women situated in the eastern part of Norway. Therefore, it is plausible that these women are different from other women diagnosed with BN and BED. In addition, it should be noted that it was a substantial drop-out from pre- to post-therapy (29.8 %), most notably in the CBT group. The individuals that dropped out from pre- to post-therapy exhibited, in general lower levels of PA and elevated levels of symptoms of depression pre-test. This can potentially have reduced the explanatory power of level of PA on QoL and increased the explanatory power of symptoms of depression, especially in the CBT group from pre- to post-therapy.

The current findings are only applicable to women with BN and BED included in our sample. This implies that the results only provide an indication of the explanatory role of

depressive symptoms, level of physical activity and symptom intensity, for QoL in young women with BN and BED situated in eastern Norway.

5.4.2 Constructs and construct overlap

Quality of life is a complex construct, affected by a number of social, psychological and environmental factors. This thesis focused on factors, identified in the literature, as being important explanatory variables of QoL. Another qualifier was that data regarding these factors was available from the PED-t trial. It is likely that several personal factors and/or comorbid diagnoses in addition to depressive symptoms, level of PA and symptom intensity of EDs also are important explanatory variables for QoL in women with BN and BED.

Finally, there seems to exist a construct overlap between depression and anxiety (Singleton et al., 2019). Although symptoms of depression have been shown to provide unique contributions to the variance in QoL in women with BN and BED, we cannot exclude the possibility that including anxiety in the regression model could have affected the explanatory power of symptoms of depression for variance in QoL.

5.4.3 Questionnaires

There exist several limitations to using subjective measures in the form of questionnaires. All questionnaires were anonymous, but registered with ID-numbers, this means that the questionnaire can be traced back to the participant by the researchers, which may contribute to some women answering what they assume to be socially accepted, thereby increasing the risk of social bias.

Further, the participants interpretation of the questions may not have been in accordance with the actual intention of the questions. Some of the questionnaires contain questions where participants are asked to recollect and describe previously performed behaviors, as such the validity of the information is challenged by recall bias (Sedgwick, 2012).

On the other hand, some of the included questionnaires concern sensitive topics (depressive symptoms, symptom intensity of EDs and QoL). Participants may experience a higher sense of anonymity from questionnaires compared to interviews, this may in turn motivate participants to answer more truthfully.

Accounting for these limitations, the questionnaires utilized in the PED-t trial have been reviewed as valid and reliable for measures of depression, symptom intensity in EDs and QoL (Adler & Fagley, 2005; Beck et al., 1961; Friberg et al., 2013; Grilo et al., 2001; Luce & Crowther, 1999; Smarr & Keefer, 2011; APA, 2013).

5.4.4 Level of physical activity

Accelerometers (ActiGraph GT3x and GT3x+, Actigraph, LCC, Pensacola, Florida, USA) are considered as a precise instrument for obtaining objective measures of PA because they provide a good overview of the actual levels of PA in a population (Anderssen, 2009). However, accelerometers are not sensitive to contributions from activities such as cycling, strength training and heavy lifting using upper- and/or lower extremities. Also, accelerometers are not waterproof and can therefore not evaluate potential contributions from water activities to the total level of PA, thereby reducing the reliability in registrations of total levels of PA.

Furthermore, there exists a risk that some participants might change their level of physical activity. This phenomenon is called the “Hawthorne effect” and may be particularly related to behavioral changes (Svartdal, 2019). Carrying activity monitors have been shown to induce elevated levels of physical activity. However, the potential effects are likely to be similar amongst all participants and comparable to findings from other studies using accelerometers.

To conclude, most of the literature examining the role of level of PA on QoL in women with BN and BED have been obtained through subjective measures, this makes the objective measures utilized in this thesis an interesting addition.

5.4.5 Statistical analysis

Firstly, multiple regression does not aim to imply causality, therefore this thesis is unable to determine whether the model tested reveals explanatory variables or moderators of QoL, or if QoL works as a moderator on depressive symptoms, level of physical activity and symptom intensity of EDs. To explore the nature of causality in these relationships, prospective longitudinal studies investigating the succession of the variables are required.

Secondly, this thesis utilized a manual approach to variable selection. Independent variables for the regression model were selected based on findings from the literature and

expert knowledge. In addition, objective measures of level of PA is an interesting addition to examining the relationship between PA behavior and QoL in women with BN and BED. This can be considered a strength with this thesis because it reduces the chances of identifying potentially false explanatory variables (Burnham & Anderson, 2002; Harrel in Andersen, 2003; Miller, 2002). When utilizing automatic processes in statistics, regression models can falsely identify explanatory variables as significant (Burnham & Anderson, 2002; Harrel in Andersen, 2003; Miller, 2002). Not using automatic processes can be considered a weakness as it increases the risk of human error. The inclusion of explanatory variables could be biased, and one may potentially fail to identify variables that are important for explaining the variance in the dependent variable (Burnham & Anderson, 2002; Harrel in Andersen, 2003; Miller, 2002). In an attempt to minimize the effect of these potential limitations, bivariate screening was performed. By only including variables that were significantly correlated with QoL in the bivariate correlation we increased the explanatory power of the regression model. This process was repeated for all groups, at all times in all analysis.

Finally, in listwise exclusion a case is dropped from an analysis if it contains a missing value in at least one of the specified variables. This means that the analysis only is run on cases which have a complete set of data, increasing the reliability and validity when comparing effects from pre- to post-therapy. The current analysis used casewise exclusion. This means that the statistical procedure includes cases that could contain some missing data. Although this procedure cannot include a specific variable when it has a missing value, the case can still be included when analyzing other variables with non-missing values. Both pre- and post-therapy results were already available before we conducted the analysis, therefore we were aware of the drop-out rates (29.8 %) from pre- to post-therapy. As a result of this we opted for casewise exclusion over listwise exclusion, to reduce the loss of statistical power from pre- to post-therapy. However, choosing casewise exclusion came at a cost as it reduced our ability to compare the potential effects of treatment.

5.5 Summary of discussion: symptoms of depression, level of physical activity, symptom intensity of eating disorders and quality of life

The current study has replicated previous findings on elevated levels of symptoms of depression, symptom intensity of EDs and reduced QoL in BN and BED compared to normative levels in the general population. We found symptoms of depression as an important explanatory variable and potential mediator for QoL in women with BN and BED (de la Rie et al., 2005; Faulconbirdge et al., 2013; Grenon et al., 2010; Mond et al., 2004; Padierna et al., 2000; Singelton et al., 2019). Depression has been shown to further debilitate several areas of QoL that are important for daily functioning in women with BN and BED. Therefore, clinicians might find it beneficial to assess and address comorbid symptoms of depression in treatment of BN and BED (Bratland-Sanda et al., 2019; de Vos, et al., 2017; Hudson et al., 2007; Kessler et al., 2013; Masheb & Grilo, 2004; Pettersen et al., 2018).

We found level of PA to be a significant explanatory variable for QoL in the CBT group at pre-therapy, but not in any other analysis. This relationship is found in healthy controls, but is yet to be identified in individuals with EDs (Grimmett et al., 2011; Lustyk et al., 2014; Mond et al., 2005; Pinto et al.; Trojanowski & Fischer, 2018; Vagetti et al., 2004; Wu et al., 2017). Our findings contribute to the assumption that the relationship between level of PA and QoL is mediated by symptoms of depression and symptom intensity of EDs (Mond et al., 2005; Trojanowski & Fischer, 2018). Motivation for PA may be a more accurate explanatory variable for QoL, compared to actual PA behavior in women with BN and BED (Mathisen et al., 2018).

Symptom intensity of EDs was not identified as a significant explanatory variable for QoL in our sample. Some studies have identified symptom intensity of EDs as a significant explanatory variable for QoL, but when accounting for symptoms of depression the explanatory power of symptom intensity of EDs is reduced (Bamford & Sly, 2010; DeJong et al., 2013; de la Rie et al., 2005; Latner et al., 2013; Padierna et al., 2000; Pollack et al. 2015). The increased strength in correlation between symptoms of depression and symptom intensity of EDs from pre- to post therapy indicates that these variables more closely related in explaining the variance in QoL at post-test.

Sociocultural processes may be implicated in fostering body dissatisfaction (Padierna et al., 2000; Pollack et al., 2015; Stice & Shaw 2002; Trojanowski and Fischer, 2018).

6 CONCLUSIONS

This study has evaluated the explanatory role of symptoms of depression, level of physical activity and symptom intensity of eating disorders on quality of life in women with bulimia nervosa and binge eating disorder. Various combinations of symptoms of depression, level of physical activity and symptom intensity was tested in a regression model. The results of the regression analysis showed that the included variables had moderate predictive power of QoL in women with BN and BED, partially confirming the hypothesis. This finding indicates that further exploration of potential explanatory variables to QoL in BN and BED is required if we are we are to acquire a more comprehensive understanding of variables that affect QoL in women with BN and BED.

Level of PA was identified as a significant explanatory variable for QoL in the CBT group pre-therapy. Discrepancies in findings may be accounted for due to the usage of objective measures of level of PA in the current thesis compared to subjective measures in similar populations. If we are to determine the usability of objective measures of level of PA on QoL in women with BN and BED further studies are required. In comparison to the actual level of PA, motivation for PA has been proposed to provide a more comprehensive understanding of the dysfunctional relationship between PA and EDs. Future research could therefore benefit from utilizing motivation for PA as an explanatory variable for QoL in women with BN and BED. Our findings contribute to the assumption that the relationship between level of PA and QoL is mediated by symptoms of depression and symptom intensity of EDs.

Our research clearly illustrates that symptoms of depression have a negative impact on QoL. At the same time, it raises the question of how depression and ED pathology coincides in explaining QoL. It seems likely that depression accounts for some of the variance in QoL that was previously assumed to originate from ED pathology. As a result of this, it is plausible that symptoms of depression and ED-pathology function as mediators for QoL in this population. This underscore the need to assess and address symptoms of depression when treating women with BN and BED. Focusing on alleviating symptoms of depression as well as symptoms of EDs in treatment of BN and BED could lead to elevated levels of QoL. Studies have shown that women with BN and BED may identify focus on well-being and learning to live with the disease as equally important as

remission from the symptoms of EDs itself. Therefore, the utilization of QoL as an outcome measure in treatment of BN and BED could have substantial clinical implications.

Future studies could potentially benefit from utilizing disease specific measurements of QoL, because they may provide a more detailed view to which dimensions of QoL that are impaired, making them easier to target and treat. This could in turn make positive or negative changes in treatment easier to spot, and thereby making treatment and interventions easier to evaluate both on the level of the individual and as merit of treatment.

To conclude, prospective longitudinal studies are required if we are to increase our understanding of the temporal nature of the relationship between depression, PA, EDs and QoL.

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8 APPENDIX

APPENDIX I: BECK'S DEPRESSION INVENTORY (BDI-IA)

APPENDIX II: EATING DISORDER EXAMINATION QUESTIONNAIRE (EDE-Q)

APPENDIX III: QUALITY OF LIFE (QoL), SATISFACTION WITH LIFE SCALE
(SWLS)

APPENDIX IV: CONSENT ON PARTICIPATION

APPENDIX V: APPROVAL LETTER FROM THE REGIONAL COMMITTEES FOR
MEDICAL RESEARCH ETHICS

APPENDIX I: BECK'S DEPRESSION INVENTORY (BDI-IA)

Beck's Depression Inventory

Navn: _____ Alder: _____ Kjønn: _____

Nedenfor finner du en rekke setninger inndelt i grupper. Les alle setningene innenfor hver gruppe nøye. Deretter velger du den setningen i hver gruppe som best beskriver hvordan du har **følt deg den siste uka, i dag inkludert**. Sett så en ring rundt tallet utenfor setningen du har valgt.

Skulle formuleringen være uklar, kan du sette et spørsmålstegn i marginen, men sett likevel en ring rundt tallet foran den setningen du tross alt synes passer best. Velg kun en setning i hver gruppe.

-
1. 0 Jeg føler meg ikke trist.
1 Jeg er lei meg eller føler meg trist.
2 Jeg er lei meg eller trist hele tiden og klarer ikke å komme ut av denne tilstand.
3 Jeg er så trist eller ulykkelig at jeg ikke holder det ut.
 2. 0 Jeg er ikke særlig pessimistisk eller motløs overfor fremtiden.
1 Jeg føler meg motløs overfor fremtiden.
2 Jeg føler at jeg ikke har noe å se frem til.
3 Jeg føler at fremtiden er håpløs og at forholdene ikke kan bedre seg.
 3. 0 Jeg føler meg ikke som et mislykket menneske.
1 Jeg føler at jeg har mislykkes mer enn andre mennesker.
2 Når jeg ser tilbake på livet mitt, ser jeg ikke annet enn mislykkethet.
3 Jeg føler at jeg har mislykkes fullstendig som menneske.
 4. 0 Jeg får like mye tilfredsstillelse ut av ting som før.
1 Jeg nyter ikke ting på samme måte som før.
2 Jeg får ikke ordentlig tilfredsstillelse ut av noe lenger.
3 Jeg er misfornøyd eller kjeder meg med alt.

5. 0 Jeg føler meg ikke særlig skyldbetyngt.
1 Jeg føler meg skyldbetyngt en god del av tiden.
2 Jeg føler meg temmelig skyldbetyngt mesteparten av tiden.
3 Jeg føler meg skyldbetyngt hele tiden.
6. 0 Jeg har ikke følelsen av å bli straffet.
1 Jeg føler at jeg kan bli straffet.
2 Jeg forventer å bli straffet.
3 Jeg føler at jeg blir straffet.
7. 0 Jeg føler meg ikke skuffet over meg selv.
1 Jeg er skuffet over meg selv.
2 Jeg avskyr meg selv.
3 Jeg hater meg selv.
8. 0 Jeg føler ikke at jeg er noe dårligere enn andre.
1 Jeg kritiserer meg selv for mine svakheter eller feilgrep.
2 Jeg bebreider meg selv hele tiden for mine feil eller mangler.
3 Jeg gir meg selv skylden for alt galt som skjer.
9. 0 Jeg har ikke tanker om å ta livet mitt.
1 Jeg har tanker om å ta livet mitt, men jeg vil ikke omsette dem i handling
2 Jeg ønsker å ta livet mitt.
3 Jeg ville ta livet mitt om jeg fikk sjansen til det.
10. 0 Jeg gråter ikke mer enn vanlig.
1 Jeg gråter mer nå enn jeg gjorde før.
2 Jeg gråter hele tiden nå.
3 Jeg pleide å kunne gråte, men nå kan jeg ikke gråte selv om jeg gjerne vil.

11. 0 Jeg er ikke mer irritert nå enn ellers.
1 Jeg blir lettere ergerlig eller irritert enn før.
2 Jeg føler meg irritert hele tiden nå.
3 Jeg blir ikke irritert i det hele tatt over ting, som pleide å irritere meg
12. 0 Jeg har ikke mistet interessen for andre mennesker.
1 Jeg er mindre interessert i andre mennesker enn jeg pleide å være.
2 Jeg har mistet det meste av min interesse for andre mennesker.
3 Jeg har mistet all interesse for andre mennesker.
13. 0 Jeg tar avgjørelser omtrent like lett som jeg alltid har gjort.
1 Jeg forsøker å utsette det å ta avgjørelser mer enn tidligere.
2 Jeg har større vanskeligheter med å ta avgjørelser enn før.
3 Jeg klarer ikke å ta avgjørelser i det hele tatt lenger.
14. 0 Jeg føler ikke at jeg ser dårligere ut enn jeg pleide å gjøre.
1 Jeg er bekymret for at jeg ser gammel eller lite tiltrekkende ut.
2 Jeg føler at det er varige forandringer i mitt utseende som får meg til å se lite tiltrekkende ut.
3 Jeg tror at jeg ser stygg ut.
15. 0 Jeg kan arbeide omtrent like godt som før.
1 Det kreves en ekstra anstrengelse for å ta fatt på noe.
2 Jeg må presse meg selv meget hardt for å gjøre noe.
3 Jeg klarer ikke å gjøre noe arbeid i det hele tatt.
16. 0 Jeg sover like godt som ellers.
1 Jeg sover ikke så godt som før.
2 Jeg våkner 1-2 timer tidligere enn ellers og har vanskelig for å sovne igjen.
3 Jeg våkner flere timer tidligere enn jeg pleide og får ikke sove igjen.
17. 0 Jeg blir ikke fortere trett enn ellers.
1 Jeg blir fortere trett enn før.
2 Nesten alt jeg gjør, blir jeg trett av.
3 Jeg er for trett til å gjøre noe som helst.
18. 0 Matlysten min er ikke dårligere enn ellers.
1 Matlysten min er ikke så god som den var før.
2 Matlysten min er mye dårligere nå.
3 Jeg har ikke matlyst i det hele tatt lenger.
19. 0 Jeg har ikke gått ned meget i vekt, om i det hele tatt noe.
1 Jeg har i den senere tid tatt av mer enn 2 kg.
2 Jeg har tatt av mer enn 4 kg.
3 Jeg har tatt av mer enn 6 kg.
20. Jeg prøver bevisst å gå ned i vekt ved å spise mindre:
0 Ja
1 Nei
21. 0 Jeg er ikke mer bekymret for helsen min enn vanlig.
1 Jeg er bekymret over fysiske plager som verking og smerter; eller urolig mage; eller forstoppelse.
2 Jeg er meget bekymret over mine fysiske plager og det er vanskelig å tenke på stort annet.
3 Jeg er så bekymret over mine fysiske plager at jeg ikke klarer å tenke på noe annet.
22. 0 Jeg har ikke merket noen forandring i mine seksuelle interesser i det siste.
1 Jeg er mindre interessert i sex enn jeg var før.
2 Jeg er mye mindre interessert i sex nå.
3 Jeg har helt mistet interessen for sex.

APPENDIX II: EATING DISORDER EXAMINATION QUESTIONNAIRE (EDE-Q)

DATO: _____

ID NUM: _____

Instruksjoner: Dette spørreskjema handler kun om de siste fire ukene (28 dager). Les hvert spørsmål nøye. Svar på alle spørsmålene.

Spørsmål 1 til 12: Tegn en sirkel rundt det tallet til høyre som du synes passer best. Husk at spørsmålene kun handler om de siste fire ukene (28 dagene).

	På hvor mange av de siste 28 dagene ...	Ingen dager	1-5 dager	6-12 dager	13-15 dager	16-22 dager	23-27 dager	Alle dager
1	Har du bevisst <u>prøvd</u> å begrense mengden mat du spiser for å påvirke din figur eller vekt (uavhengig av om du har klart det eller ikke)?	0	1	2	3	4	5	6
2	Har du i lengre perioder (8 våkne timer eller mer) ikke spist noe i det hele tatt for å påvirke din figur eller vekt?	0	1	2	3	4	5	6
3	Har du <u>prøvd</u> å utelukke noen typer mat du liker, for å påvirke din figur eller vekt (uavhengig av om du har klart det eller ikke)?	0	1	2	3	4	5	6
4	Har du <u>prøvd</u> å følge bestemte regler for hva eller hvordan du spiser (f.eks. en kalorigrense) for å påvirke din figur eller vekt (uavhengig av om du har klart det eller ikke)?	0	1	2	3	4	5	6
5	Har du hatt et klart ønske om å ha <u>tom</u> mage for å påvirke din figur eller vekt?	0	1	2	3	4	5	6
6	Har du hatt et klart ønske om å ha en <u>helt flat</u> mage?	0	1	2	3	4	5	6
7	Har du opplevd at tanker om <u>mat, spising eller kalorier</u> har gjort det veldig vanskelig å konsentrere deg om ting du er interessert i (f.eks. å arbeide, følge en samtale eller lese)?	0	1	2	3	4	5	6
8	Har du opplevd at tanker om <u>figur eller vekt</u> har gjort det veldig vanskelig å konsentrere deg om ting du er interessert i (f.eks. å arbeide, følge en samtale eller lese)?	0	1	2	3	4	5	6
9	Har du hatt en klar frykt for å miste kontroll over <u>spisingen</u> din?	0	1	2	3	4	5	6
10	Har du hatt en klar frykt for at du kan <u>gå opp</u> i vekt?	0	1	2	3	4	5	6
11	Har du følt deg <u>tykk</u> ?	0	1	2	3	4	5	6
12	Har du hatt et sterkt ønske om å <u>gå ned</u> i vekt?	0	1	2	3	4	5	6

DATO: _____

ID NUM: _____

Spørsmål 13 til 18: Fyll inn passende antall i boksene til høyre. Husk at spørsmålene kun handler om de siste fire ukene (28 dagene).

I LØPET AV DE SISTE FIRE UKENE (28 DAGENE)...	
13 ... hvor mange ganger har du spist det andre ville betraktet som en <u>uvanlig stor mengde mat</u> (omstendighetene tatt i betraktning)?
14 ...ved hvor mange av disse episodene hadde du en følelse av å ha mistet kontrollen over spisingen din (mens du spiste)?
15 I løpet av de siste 28 dagene, hvor mange <u>DAGER</u> har slike episoder med overspising forekommet (dvs. der du har spist uvanlig store mengder mat <u>og</u> hatt en følelse av å miste kontrollen mens du spiste)?
16 I løpet av de siste 28 dagene, hvor mange <u>ganger</u> har du kastet opp for å kontrollere din figur eller vekt?
17 I løpet av de siste 28 dagene, hvor mange <u>ganger</u> har du brukt avføringsmidler for å kontrollere din figur eller vekt?
18 I løpet av de siste 28 dagene, hvor mange <u>ganger</u> har du følt deg drevet eller tvunget til å trene for å kontrollere din vekt, figur eller fettmengde, eller for å forbrenne kalorier?

Spørsmål 19 til 21: Tegn en sirkel rundt det tallet som du synes passer best. Vær oppmerksom på at i disse spørsmålene brukes begrepet "overspisingsepisode" om å spise det andre ville synes var en uvanlig stor mengde mat i den situasjonen du var i, samtidig med en følelse av å ha mistet kontroll over spisingen.

19 I løpet av de siste 28 dagene, hvor mange dager har du spist i hemmelighet (i skjul)? ...tell ikke med overspisingsepisoder.	Ingen dager	1-5 dager	6-12 dager	13-15 dager	16-22 dager	23-27 dager	Alle dager
	0	1	2	3	4	5	6
20 Hvor mange av de gangene du har spist, har du hatt skyldfølelse (følt at du har gjort noe galt) fordi det kan påvirke din figur eller vekt? ...tell ikke med overspisingsepisoder.	Ingen av gangene	Noen få ganger	Færre enn halvparten	Halvparten	Mer enn halvparten	De fleste gangene	Hver gang
	0	1	2	3	4	5	6
21 I løpet av de siste 28 dagene, hvor bekymret har du vært for at andre mennesker ser deg spise? ...tell ikke med overspisingsepisoder.	Ikke i det hele tatt		Litt		Ganske mye		Veldig mye
	0	1	2	3	4	5	6

DATO: _____

ID NUM: _____

Spørsmål 22 til 28: Tegn en sirkel rundt det tallet til høyre som du synes passer best. Husk at spørsmålene kun handler om de siste fire ukene (28 dagene).

I LØPET AV DE SISTE 28 DAGENE.....	Ikke i de hele tatt	Litt	Ganske mye	Veldig mye			
22 Har <u>vekten</u> din påvirket hvordan du tenker om (bedømmer) deg selv som person?	0	1	2	3	4	5	6
23 Har <u>figuren</u> din påvirket hvordan du tenker om (bedømmer) deg selv som person?	0	1	2	3	4	5	6
24 Hvor opprørt ville du bli hvis du ble bedt om å veie deg en gang i uken (ikke mer, ikke mindre) de neste fire ukene?	0	1	2	3	4	5	6
25 Hvor misfornøyd har du vært med <u>vekten</u> din?	0	1	2	3	4	5	6
26 Hvor misfornøyd har du vært med <u>figuren</u> din?	0	1	2	3	4	5	6
27 Hvor mye ubehag har du følt ved å se kroppen din (f.eks. når du ser figuren din i speilet, reflektert i et butikkvindu, ved klesskift, eller når du bader eller dusjer)?	0	1	2	3	4	5	6
28 Hvor mye ubehag har du følt ved at <u>andre</u> ser figuren din (f.eks. i offentlige omklede rom, når du svømmer, eller når du har på deg trange klær)?	0	1	2	3	4	5	6

Sett et kryss (x) i kolonnen som best beskriver hvordan dine spisevaner, trening eller følelser knyttet til din spising, figur eller vekt har påvirket livet ditt i løpet av DE SISTE 28 DAGER. Takk.

	I løpet av de siste 28 dagene, i hvilken grad har dine spisevaner, trening, eller følelser knyttet til din spising, figur eller vekt....	Ikke i det hele tatt	Litt	En god del	Mye
1 gjort det vanskelig å konsentrere deg?				
2 gjort at du har følt deg kritisk til deg selv?				
3	... hindret deg i å gå ut sammen med andre?				
4	... påvirket din prestasjon i jobb eller utdanning? (hvis aktuelt)				
5	... gjort deg glemsk?				
6 påvirket din evne til å ta beslutninger i hverdagen?				
7	... skapt vansker ved måltider med familie eller venner?				
8 gjort deg opprørt?				
9 gjort at du har skammet deg over deg selv?				
10 gjort det vanskelig å spise ute med andre?				
11 gitt deg skyldfølelse?				
12	...vanskeliggjort eller hindret deg i å gjøre ting du pleide å ha glede av?				
13	... gjort deg distrè/åndsfraværende?				
14	... fått deg til å føle deg mislykket?				
15	...hatt negativ innvirkning på ditt forhold til andre?				
16	... gjort deg bekymret?				

TAKK!

APPENDIX III: QUALITY OF LIFE (QoL), SATISFACTION WITH LIFE SCALE (SWLS)

Livskvalitet

Vis hvor godt eller dårlig hver av de fem påstandene om livet som stemmer for deg (Sett ett kryss for hvert spørsmål).

	Stemmer dårlig					Stemmer helt	
	1	2	3	4	5	6	7
1. På de fleste måter er livet mitt nær idealet mitt	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Mine livsforhold er utmerkede	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Jeg er tilfreds med livet mitt	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Så langt har jeg fått de viktige tingene jeg ønsker i livet	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Hvis jeg kunne leve livet på nytt, ville jeg nesten ikke forandret på noe	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Diener

	<i>Meget dårlig</i>	<i>Dårlig</i>	<i>Verken god eller dårlig</i>	<i>God</i>	<i>Meget god</i>
1. Hvordan vurderer du livskvaliteten din?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Hvor tilfreds er du med helsen din?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

WHO

Tenk deg en trapp eller stige der nederste trinn er 0 og øverste trinn er 10. Toppen står for livet på sitt beste slik du ser det og 0 livet på sitt verste. På hvilket trinn i en slik stige eller trapp står du i slik du ser livet ditt nå for tiden?

Ladder

APPENDIX IV: APPROVAL LETTER FROM THE REGIONAL COMMITTEES FOR MEDICAL
RESEARCH ETHICS

Region: REK sør-øst	Saksbehandler: Silje U. Lauvrak	Telefon: 22845520	Vår dato: 16.12.2013	Vår referanse: 2013/1871/REK sør-øst D
			Deres dato: 18.11.2013	Deres referanse:

Vår referanse må oppgis ved alle henvendelser

Til Jorunn Sundgot-Borgen

2013/1871 Behandling av spiseforstyrrelser: - en randomisert, kontrollert prospektiv studie

Vi viser til tilbakemelding fra prosjektleder, mottatt 18.11.2013, i forbindelse med ovennevnte søknad. Tilbakemeldingen ble behandlet av komiteens leder på delegert fullmakt.

Forskningsansvarlig: Norges Idrettshøgskole

Prosjektleder: Jorunn Sundgot-Borgen

Prosjektomtale

Kontrollerte behandlingsstudier, samt oversiktsartikler, viser at kognitiv terapi har et godt kunnskapsgrunnlag og er et førstevalg i behandling av bulimi, uspesifikke spiseforstyrrelser og overspisingslidelse. Søkers forskningsgruppe har i tidligere studier vist at terapeutisk ledet fysisk aktivitet reduserte bulimisyntomer like godt som kognitiv terapi, men at også kostrådgivning hadde effekt. Dette kan bety at kostrådgivning pluss fysisk aktivitet kan ha en additiv effekt som kan være like god eller bedre enn den man ser ved kognitiv terapi. Formålet med den omsøkte studien er å teste ut effekten av tre ulike behandlingsformer: 1) kognitiv terapi, 2) fysisk aktivitet og kostveiledning og 3) kontrollgruppe med behandling som vanlig hos fastlege. Det skal inkluderes 105 kvinner i alderen 18-35 år, og det skal gjøres en rekke tester som måler fysisk aktivitet, samt DXA-målinger av beinmineraltetthet, fettprosent og fettfri kroppsvekt. Studien skal måle effektendringer over 36 måneder og ta utgangspunkt i symptomendringer, brukertilfredshet og helsekostnader.

Saksgang

Søknaden ble første gang behandlet i møtet 23.10.13, hvor komiteen utsatte vedtak i saken.

Slik komiteen oppfattet søknaden, er kognitiv terapi antatt å være mest effektiv for pasienter med spiseforstyrrelser. Komiteen var derfor bekymret for om pasienter som ikke ble inkludert i denne armen, ble fratatt best mulig behandling, og ba prosjektleder redegjøre for om det var etisk forsvarlig å la en gruppe deltakere gå i tre år uten å få kognitiv terapi.

Prosjektleders tilbakemelding ble mottatt 18.11.2013.

Komiteens vurdering

Når det gjelder spiseforstyrrelser, er det god dokumentasjon på at kognitiv terapi er effektiv. I en randomisert studie skal kontrollgruppen vanligvis få beste behandling, dersom en slik finnes. I dette tilfellet vil imidlertid den realistiske kontrollgruppen være deltakere som får behandling via fastlege, siden de fleste ikke har tilgang til kognitiv terapi. Prosjektleder argumenterer godt for at alle de tre behandlingsalternativene (kognitiv terapi, fysisk aktivitet og kostveiledning, og behandling som vanlig hos fastlege) er vist å ha effekt. På bakgrunn av prosjektleders tilbakemelding mener komiteen at prosjektets design er etisk forsvarlig.

Komiteen anser beredskapen i prosjektet som tilfredsstillende ivaretatt. Dersom det fremkommer at en deltaker har en aktiv suicidalproblematikk, kontaktes psykiatrisk legevakt. Det vil også være en stopp-prosedyre for deltakere som ved studiestart har BMI <19 og som taper seg mer enn 2 kg. Tiltakene som gjøres dersom noen deltakere opplever ubehag ved å bli filmet under gruppeterapien er også tilfredsstillende.

Etter en helhetlig vurdering har komiteen kommet til at den godkjenner at prosjektet kan gjennomføres som beskrevet i søknad og protokoll.

Vedtak

Med hjemmel i helseforskningsloven § 9 jf. 33 godkjenner komiteen at prosjektet gjennomføres.

Godkjenningen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknad, protokoll, tilbakemelding fra prosjektleder og de bestemmelser som følger av helseforskningsloven med forskrifter.

Tillatelsen gjelder til 31.12.2017. Av dokumentasjonshensyn skal opplysningene likevel bevares inntil 31.12.2022. Opplysningene skal lagres aidentifisert, dvs. atskilt i en nøkkel- og en opplysningsfil. Opplysningene skal deretter slettes eller anonymiseres, senest innen et halvt år fra denne dato.

Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder for «Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse og omsorgssektoren».

Dersom det skal gjøres vesentlige endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden, må prosjektleder sende endringsmelding til REK.

Prosjektet skal sende sluttmelding på eget skjema, senest et halvt år etter prosjektslutt.

Du kan klage på komiteens vedtak, jf. forvaltningslovens § 28 flg. Klagen sendes til REK sør-øst D. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK sør-øst D, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Vi ber om at alle henvendelser sendes inn på korrekt skjema via vår saksportal:

<http://helseforskning.etikkom.no>. Dersom det ikke finnes passende skjema kan henvendelsen rettes på e-post til: post@helseforskning.etikkom.no.

Vennligst oppgi vårt referansenummer i korrespondansen.

Med vennlig hilsen

Finn Wisløff
Professor em. dr. med.
Leder

Silje U. Lauvrak
Rådgiver

Kopi til: turid.sjostedt@nih.no; postmottak@nih.no

APPENDIX V: CONSENT ON PARTICIPATION

Forespørsel om deltakelse i forskningsprosjektet

Behandling av spiseforstyrrelser – en kontrollert studie

Bakgrunn og hensikt

Dette er et spørsmål til deg om å delta i en forskningsstudie for å teste ut effekten av to ulike behandlingsformer for spiseforstyrrelsene bulimi og overspisingslidelse. Studien finansieres av Norske Kvinners Sanitetsforening, og gjennomføres som et doktorgradsprosjekt ved Norges Idrettshøgskole, i et samarbeide med Modum Bad og Universitetet i Tromsø –Norges arktiske universitet.

Hva innebærer studien?

I denne studien skal vi ha med kvinner som er mellom 18 og 40 år som har de nevnte spiseforstyrrelsene. Hvis du melder deg til studien deltar først i et telefonintervju der prosjektledelsen vurderer om du kan passe inn i studien. Gjør du det, vil vi be deg om å fylle inn et spørreskjema (evnt ringes opp for klarerings intervju), og dernest kontakte din fastlege/en lege for å få en bekreftelse på at legen mener at du kan være med i studien. Dersom det er i orden, vil du bli trukket ut til å delta i en av to grupper med enten; 1) kognitiv terapi, eller 2) fysisk aktivitet og kostveiledning. Behandlingen er gratis, foregår i grupper på 5-8 personer, varer i 16 uker med totalt 20 stk treff à 90 min med gruppe og veiledere pr uke, og foregår hovedsakelig på Norges idrettshøgskole i Oslo. Du vil jevnlig gjennom denne perioden, samt ved oppfølging 6, 12, og 24 mnd. etter behandlingsslutt, svare på spørreskjema, gjennomføre fysiske aktivitetstester (styrke og kondisjon). I tillegg vil det bli tatt blodprøve (i uke 0, uke 8 og uke 17 av studien), og du vil også bli veid ukentlig i behandlingsperioden og ved hver av de nevnte oppfølginger (selvfølgelig uten noe av de andre deltakerne tilstede). En DXA (røntgenscanning) gjøres før behandlingsstart og ved oppfølginger. I den kognitive terapigruppen filmes gruppemøtene, dette kan periodesvis også gjøres i treningsgruppen. Filmopptaket vil kun bli vist til terapeutene slik at de kan vurdere resultatene fra terapitimene. I alle behandlingsgruppene vil det gis hjemmearbeidsoppgaver i behandlingsperioden. Disse vil i omfang tilsvare ca. 1-2 timer pr uke og der du skal beskrive kosthold, trening og eventuell oppkast, og i treningsgruppen også gjøre egentrening etter instruksjoner.

Mulige fordeler og ulemper

Som deltager får du umiddelbart tilgang til et 16 ukers behandlingsprogram med godt utdannede terapeuter (ernæringsfysiolog, psykiater, aktivitets- og helseterapeuter). Røntgenscan av deg før og etter de 16 studieukene innebærer at du ligger rolig på en benk mens en maskin sakte skanner over kroppen din. Dette kan ikke kjønes fysisk. Blodprøvene kan for noen være ubehagelig, men vi vil gjøre det som er mulig for å redusere eventuelt ubehag. De som fordeles til treningsgruppen vil ut fra 3 økter pr uke med en intensitet opp mot maksimalt, i perioder oppleve høy puls, svette og melkesyre, men samtidig kunne oppnå bedre fysisk form.

Hva skjer med prøvene og informasjonen om deg?

Prøvene tatt av deg og informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene og prøvene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger og prøver gjennom en navneliste.

Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Det gjøres ingen koblinger mot andre private eller offentlige befolkningsregistre.

Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Frivillig deltakelse

Det er frivillig å delta i studien. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få konsekvenser for eventuell videre behandling. Dersom du senere ønsker å trekke deg eller om har spørsmål til studien, kan du kontakte professor Jorunn Sundgot-Borgen (jorunn.sundgot-borgen@nih.no tlf: 922 41 745) eller doktorgradsstipendiat Therese F. Mathisen (t.f.mathusen@nih.no, tlf 95 75 28 18).

Studien er for øvrig godkjent av Regional Komite for Medisinsk og Helsefaglig Forskning

Ytterligere informasjon om studien finnes i kapittel A – utdypende forklaring av hva studien innebærer.

Ytterligere informasjon om biobank, personvern og forsikring finnes i kapittel B – Personvern, biobank, økonomi og forsikring.

Samtykkeerklæring følger etter kapittel B.

Kapittel A- utdypende forklaring av hva studien innebærer

- **Kriterier for deltakelse**

Vi søker kvinnelige deltagere som har bulimi nervosa eller overspisinglidelse. Kriterier for inklusjon er videre; en alder mellom 18-40 år, BMI mellom 17,5 – 35, og bosted innen Oslo-omegn område (inklusjon krever ukentlig deltakelse ved Norges Idrettshøyskole). Personer som ikke kvalifiserer til deltakelse, er aktive/konkurrerende idrettsutøvere, personer som allerede er under aktiv behandling med kognitiv terapi eller har vært så de siste 2 årene, alvorlige tilleggsdiagnoser (slik som alvorlig depresjon, personlighetsforstyrrelse suicidalproblematikk, post traumatisk stress lidelse, ruslidelser, tvangslidelse, eller ulike angstlidelser), og gravide.
- **Bakgrunnsinformasjon om studien**

Flertallet av mennesker med bulimi og overspisinglidelse i befolkningen søker ikke hjelp, og for de som gjør dette, tar det ofte 4-5 år før profesjonell hjelp søkes. Grunnene til det er ofte en feilaktig opplevelse av kontroll over mat, kropp og vekt, samt skam og skyldfølelse. Kognitiv terapi er den foretrukne behandlingsform i dag, men likevel er det 20-30 % pasienter som får et dårlig sykdomsforløp og ikke greier å nyttiggjøre seg kognitiv terapi. Det er viktig å utvikle et forskningsbasert behandlingstilbud til kvinner som ikke responderer på de etablerte kunnskapsbaserte terapiformer, fordi det kan redusere risiko for et dårlig sykdomsforløp med tilhørende dårlig livskvalitet og funksjonsnivå. En tidligere studie (Sundgot-Borgen et al. 2002) har vist at terapeutisk ledet fysisk aktivitet/trening, som ikke er konkurransepreget, reduserer symptomer ved bulimi og i samme grad som ved kognitiv terapi. Vi ønsker å undersøke effekten av et nytt, designet behandlingstilbud bestående av veiledet fysisk aktivitet og kostholdsopplæring for kvinner med spiseforstyrrelsen bulimia nervosa eller overspisinglidelse.
- **Undersøkelser, blodprøver og annet den inkluderte må gjennom**

Det vil tas stilling til om du kvalifiserer til deltakelse i studien gjennom et innledende telefonintervju, spørsmålsskjema og skriftlig erklæring fra egen fastlege. Før studien starter, og etter de 16 behandlingssukene svarer du på spørsmålsskjema delvis via intervju og delvis via egenutfylling. Du møter også til styrke- og kondisjonstester ved NIH både før, midtvegs og etter studieperioden. Blodprøver planlegges gjennomført før, undervegs og etter behandlingssukene. Etter behandlingssukene vil du kontaktes for gjentatte tester ved 6, 12 og 24 måneder etter behandling.
- **Tidsskjema – hva skjer og når skjer det?**

Vi går i gang med pretester i mars 2014 og vil fortløpende sette i gang behandlingsgruppene så raskt vi har antall deltagere for å fylle de to behandlingsgruppene. Rekrutteringen fortsetter inntil vi har totalt 150 personer gjennom våre tester og behandlingssopplegg. Siste etter-tester vil derfor antas å være ferdige i 2017).
- **Mulige fordeler**

Som deltager får du umiddelbart tilgang til et 16 ukers behandlingsprogram med godt utdannede terapeuter (ernæringsfysiolog, psykiater, aktivitets- og helseterapeuter). Du vil møte erfaren psykolog med et godt dokumentert terapiopplegg i den kognitive terapigruppen, mens du som deltager i aktivitets- og kostholdsgruppen møter godt utdannede og erfarne treningsinstruktører, og får optimal veiledning for et normalt og sunt kosthold og effektiv trening.

- **Mulige bivirkninger**
Ingen kjente.
- **Mulige ubehag/ulemper**
Ved fysisk aktivitet er det alltid en risiko for belastningsskader, akutte skader eller uhell. Vårt opplegg utgjør ingen større fare enn normal egen aktivitet og atferd, og vil i større grad forebygge skader gjennom balansert og dokumentert fornuftig totalbelastning. All deltagelse, og spesielt kognitiv behandling, kan føles psykologisk belastende i perioder, men anses som en nødvendighet for å bryte med uheldig atferd og tankemønstre.
- **Eventuell kompensasjon til og dekning av utgifter for deltakere**
Ingen. Deltagere tilbys et gratis behandlingsopplegg over 16 uker og langvarig oppfølging via gjentatte tester opp til 24 mnd etter avsluttet behandlingsperiode. Utgifter relaterer til nødvendig utstyr (for eksempel joggesko, trenings-bh) eller transport dekkes personlig av den enkelte deltager.

Kapittel B - Personvern, biobank, økonomi og forsikring

Personvern

Opplysninger som registreres om deg, er fødselsdato, vekt, høyde, DEXA-resultater (kroppssammensetning), styrke- og kondisjonsresultater, videoopptak fra kognitiv behandlings gruppemøter, blodprøvesvar på ernæringsstatus, hormonstatus og benomsetning, og scorerresultater på de ulike psykologiske tester som distribueres og gjennomføres via spørreskjema og intervju.

Norges Idrettshøgskole ved administrerende direktør er databehandlingsansvarlig.

Biobank

Blodprøvene som blir tatt vil bli lagret i en forskningsbiobank ved Norges Idrettshøgskole. Hvis du sier ja til å delta i studien, gir du også samtykke til at det biologiske materialet og analyseresultater inngår i biobanken. Jorunn Sundgot-Borgen er ansvarshavende for forskningsbiobanken. Blodprøvene som tas, ønskes analysert for følgende markører: serum ferritin, total kolesterol, LDL, HDL, triglyserider, Apo A, Apo B, vitamin D, folat, leptin, insulin CTX-1 and PTH, østrogen, progesteron, TSH, T3, T4, FSH, LH, and cortisol. Dette er markører for din ernæringsstatus og hormonbalanse, som kan svare på forskningsspørsmål omkring din fysiske helse. Det finnes pr i dag liten kunnskap om hvordan spiseforstyrrelser som overspising og bulimi kan påvirke slike helsevariabler, og vi ønsker derfor å studere dette nærmere. Prøvene kan også gi oss svar på om, og hvor raskt, slike helsevariabler lar seg påvirke gjennom et behandlingsforløp.

Retten til innsyn og sletting av opplysninger om deg og sletting av prøver

Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigeret eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet alle innsamlede prøver og opplysninger, med mindre opplysningene allerede er avidentifisert og inngått i analyser eller brukt i vitenskapelige publikasjoner.

Økonomi og Norske Kvinners Sanitetsforenings rolle

Studien og biobanken er finansiert gjennom forskningsmidler fra Norske Kvinners Sanitetsforening og Universitetet i Tromsø.

Sanitetskvinnene er en frivillig organisasjon med 50.000 medlemmer som arbeider for å skape et trygt og inkluderende samfunn. Organisasjonen har som formål å bidra til et trygt og inkluderende samfunn ved å aktivisere medlemmer til frivillig innsats innenfor helse- og sosialområdet. N.K.S. har som ambisjon å være landets ledende organisasjon knyttet til utvikling av kvinners livsvilkår, og vi ønsker å posisjonere oss som den foretrukne organisasjonen for de som er opptatt av nettopp kvinners livsvilkår. Norske Kvinners Sanitetsforening er livssynsøytral og partipolitisk uavhengig.

Forsikring

Deltaker i prosjektet er forsikret dersom det skulle oppstå skade eller komplikasjoner som følge av deltakelse i forskningsprosjektet. NIH er en statlig institusjon og er således selvassurandør. Dette innebærer at det er NIH som dekker en eventuell erstatning og ikke et forsikringsselskap. For skade på mennesker som oppstår under medisinske forsøk, gjelder også pasientskadelovens regler

Informasjon om utfallet av studien

Som deltager vil du få tilgang til resultatene fra studien når disse er klare for publisering. Offentlig publisering vil skje gjennom artikler i anerkjente, internasjonale tidsskrifter, og dernest via omtale i media.

Samtykke til deltakelse i studien

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)