DISSERTATION FROM THE
NORWEGIAN SCHOOL OF
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2018

Therese Fostervold Mathisen

A randomized controlled trial of physical exercise- and dietary therapy versus cognitive behavior therapy:

Treatment effects for women with bulimia nervosa or binge eating disorder

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Norwegian Women's Public Health Association

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"*If we could give every individual the right amount of nourishment and exercise, not too little and not too much, we would have found the safest way to health.*"

- Hippocrates

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Therese Fostervold Mathisen

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List of papers

This dissertation is based on the following original research papers, which are referred to in the text by their Roman numerals:

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III. Mathisen, Therese Fostervold; Bratland-Sanda, Solfrid; Rosenvinge, Jan H; Friborg, Oddgeir; Vrabel, Kari-Anne; Pettersen, Gunn; Sundgot-Borgen, Jorunn. *Treatment effects on compulsive exercise and physical activity in eating disorders.* [submitted]

IV. Mathisen, Therese Fostervold; Rosenvinge, Jan H; Pettersen, Gunn; Friborg, Oddgeir; Vrabel, Kari-Anne; Bratland-Sanda, Solfrid; Sundgot-Borgen, Jorunn. *Eating disorders can be treated with physical exercise and dietary therapy. A randomized controlled trial with 12 months follow-up.* [submitted]

Summary

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. Less than half of the persons with bulimia nervosa (BN) or binge eating disorder (BED) are detected and offered treatment for their ED in primary care. Besides low detection rate; low mental health literacy, and long waitlists for special care are important causes to this scenario. Cognitive behavior therapy (CBT) is recognized as the preferred evidence based treatment option for BN and BED, still more than 60% do not fully abstain from symptoms.

There is a need to explore new treatment options that circumvent the challenges with low treatment access and poor remission rate. Evidence suggest that regular physical activity effectively prevents and treats physical- and mental morbidity and mortality, contributing to improvements in quality of life. Physical activity is however, rarely incorporated in treatment of EDs out of fear of exacerbating the compulsive and excessive nature of exercise in patients for compensatory or affect regulation purposes.

Objectives: To evaluate the effect of a new treatment method for women with BN or BED, combining guided physical exercise and dietary therapy (PED-t), being offered as group therapy. The novel treatment method was compared to the effect of cognitive behavior therapy (CBT), and a waitlist control group. The first paper describes the rationale for, and the specific study protocol from the PED-t trial. The second paper describes the physical fitness in women with BN or BED more thoroughly than previously in the literature. In the third paper we investigated the effect from PED-t or CBT on compulsive exercise and level of physical activity. In the fourth paper we investigated the effect from PED-t or CBT on remission from ED, ED-symptomology, and measures of mood and quality of life**.**

Methods: During 2014-2016 totally 187 women with BN or BED, aged 18-40 and with BMI 17.5-35 were enrolled in this RCT, and allocated to PED-t (n=82) or CBT (n=82), or temporarily placed in a waitlist control group (n=23). Effect from 16 weeks of treatment by either CBT or PED-t, or being in control group, was evaluated and compared at baseline (T1), post-test (T2) and follow-up periods (6 months, T3, and 12 months, T4). Outcomes were blood pressure, cardiorespiratory fitness (CRF), muscle strength (1RM), physical activity, body composition, compulsive exercise (CE), remission from diagnosis, and alleviation of ED-symptoms (by EDE-

q) and comorbidity. Measures were by cardiopulmonary exercise testing, 1RM strength tests, DXA, objective registration of physical activity, and questionnaires.

Results: In total 156 met for baseline screening, of whom 103 were diagnosed with BN and 53 with BED. Overall, participants with BN or BED displayed adequate physical fitness; however, a high number had high blood pressure, low CRF and unfavorable body composition. The number of randomized participants (n=164) that met for therapy was 149, of whom 112 completed treatment (32% drop out). Dropouts and completers were different by a lower mean (CI_{95}) score for depression amongst completers (-3.08 $_{-5.95, -0.21}$, g=0.39, p=0.035), and significantly more from CBT were lost to follow-up at T3 and T4 compared to PED-t. About 40-70% of all participants scored above clinical cut-off in the compulsive exercise test (CET) at baseline. CBT and PED-t were equally effective in reducing compulsive exercise after 16 weeks of treatment ($P < 0.01$, Hedges $g \sim 0.4$), with sustained long-term effects (T3-T4). The proportion of participants that complied with the official recommendation for physical activity (~47%) neither changed following treatment, nor emerged different between the therapy arms. After treatment mean EDE-q global score improved more in the PED-t group compared to the CBT group (-0.66, [CI_{99} -1.23, -0.1], g=0.52, p <0.003) and to the control group (-1.15, [CI_{99} -1.97, -0.34], g=1.00, p<0.001), whereas CBT did not differ from the control group (-0.49 [CI_{99}-1.32, 0.34], g=0.48, p=0.12). Numbers in full- or partial remission were higher in PED-t (29.0% and 19.7%) and CBT (12.4% and 16.7%) compared to control (0.1% and 5.6%), p<0.004. Both therapies resulted in significant improvement in life quality, but mood rating only improved in PED-t with short-lived effect. Long-term effects (T3-T4) from therapies were equally successful in remission rates, alleviation from ED-symptoms and improvements in quality of life.

Conclusions: The finding of a high number with impaired physical fitness calls for inclusion of physical fitness evaluation in routine clinical examinations, and for guided physical activity and dietary therapy in the treatment of BN and BED. Both indirect (CBT) and direct (PED-t) approaches may be successful in reducing CE with sustained long-term effect. Neither approaches raised the level of physical activity or compliance with official recommendations for physical activity, hence a need to increase mean physical activity towards healthy levels remains unsolved. The therapeutic effect from PED-t was comparable to the current preferred therapy (CBT), hence it may be an alternative pathway to recovery from BN and BED. A high availability of professionals within exercise medicine and dietetics may attract new segments of ED patients and circumvent the poor access to mental health services.

Sammendrag (Summary in Norwegian)

Bakgrunn: Spiseforstyrrelser utgjør en av verdens ti mest vanlige alders- og kjønns justerte sykdomsbyrder som medfører redusert livskvalitet, og det rammer kvinner spesielt. Mindre enn halvparten av alle personer med bulimia nervosa (BN) eller overspisingslidelse (BED) blir diagnostisert og tilbudt behandling via primær helsetjenesten. Foruten lav oppdagelses rate, er lav mental helse kunnskap og lange ventelister i spesialisthelsetjenesten av de viktigste årsaker til dette. Kognitiv atferdsterapi (CBT) er den mest anbefalte vitenskapsbaserte behandlingsmetode for BN og BED, men likevel er det mer enn 60% som ikke responderer tilfredsstillende.
Det er et opplagt behov for å utforske flere alternativer til behandling, som kan omgå utfordringene med begrenset behandlingstilbud og –behandlingseffekt. Fysisk aktivitet er effektiv i å forebygge og behandle fysiske og psykiske lidelser, og bidrar også til å øke livskvaliteten. Fysisk aktivitet inkluderes derimot sjeldent i behandling av spiseforstyrrelser, i frykt for å provosere den tvangsmessige og overdrevne treningen, hvilket ofte er å finne hos disse pasientene, som en kompensering for overspisingen, eller som affekt regulering.
Hensikt: Å evaluere effekten av en ny behandlingsmetode for kvinner med BN eller BED, hvor veiledet trening- og kostholds terapi (PED-t) kombineres og tilbys som gruppeterapi. Denne nye metoden ble sammenlignet med CBT og en venteliste kontroll gruppe. Første artikkel presenterer rasjonale for, og metoden i denne studien. Den andre artikkelen presenterer den fysiske helsetilstanden hos kvinner med BN eller BED, og med en grundigere beskrivelse enn hva som tidligere er gjort. Arbeidet i den tredje artikkelen utforsket effekten fra PED-t eller CBT på tvangsmessig trening og nivå av fysisk aktivitet. Arbeidet i den fjerde artikkelen utforsket effekten av PED-t eller CBT på tilfriskning fra diagnose, symptomer for spiseforstyrrelse, og resultater relatert til humør og livskvalitet.
Metode: Mellom 2014-2016 ble totalt 187 kvinner med BN eller BED, i alderen 18-40 år, og med BMI mellom 17.5-35, inkludert i denne randomiserte, kontrollerte studien. Deltagerne ble tilfeldig fordelt i CBT (n=78 stk) eller PED-t (n=78 stk) for behandling, eller midlertidig satt i en venteliste kontroll gruppe (n=23 stk). Effekten fra 16 ukers behandling med enten CBT eller PED-t, eller å være i kontroll gruppe, ble evaluert og sammenlignet før behandling (T1), etter behandling (T2), og ved oppfølginger 6 mnd (T3) og 12 mnd (T4). Resultater som ble evaluert, var blodtrykk, kondisjon, maksimal styrke, nivå av fysisk aktivitet, kroppssammensetning, forekomst- og grad av tvangsmessig trening, tilfriskning fra diagnose, og reduksjon av symptomer på spiseforstyrrelser (ved EDE-q) og av samsykelighet. Målemetoder var kardiorespiratorisk

aktivitetstest, maksimal dynamisk styrke, DXA, objektive aktivitetsregistreringer, og spørreskjemaer.

Resultater: Totalt møtte 156 stk til kartleggingen før behandlingsstart, hvorav 103 ble diagnostisert med BN og 53 stk med BED. Generelt var kvinnene med BN eller BED ved normal fysisk form og helsetilstand, men vi avdekket også et betydelig antall med høyt blodtrykk, lav kardiorespiratorisk form og ugunstig kroppssammensetning. Antallet av de randomiserte deltagere (n=164) som møtte til behandling var 149 stk, hvorav 112 fullførte behandling (totalt 32% frafall). De som fullførte behandling hadde en lavere grad av depresjon enn de som falt fra (-3.08 $_{-5\text{-}95,\ -0\text{-}21}$, g=0.39, p=0.035), og gjennom oppfølgingsperioden (T3-T4) falt det signifikant flere fra i CBT-gruppen sammenlignet med PED-t gruppen. Rundt 40-70% av alle deltagerne scoret over klinisk grense for tvangsmessig trening før behandling. CBT og PED-t var tilsvarende effektive i å redusere tvangsmessig trening ($P < 0.01$, Hedges $g \sim 0.4$), og med langvarig effekt (T3-T4). Antallet deltagere som klarte å etterfølge anbefalingen om fysisk aktivitet (~47%) var ikke endret etter behandling eller i oppfølgingsperiode, og heller ikke ulik mellom gruppene. Total EDE-q poengscore ble mer forbedret etter behandling i PED-t enn i CBT (-0.66, [CI_{99} -1.23, -0.1], g=0.52, p <0.003) og mer enn i kontroll gruppen (-1.15, [CI_{99} -1.97, -0.34], g=1.00, p<0.001), mens deltagerne i CBT ikke skilte seg fra kontroll gruppen (-0.49 [CI_{99}-1.32, 0.34], g=0.48, p=0.12). Etter behandling var antallet som var i full- eller delvis tilfriskning fra diagnose høyere i PED-t (29% og 19.7%) og CBT (12.4% and 16.7%) i forhold til kontroll gruppen (0.1% and 5.6%), p<0.004. Begge terapiformer gav bedring i livskvalitet, men kun PED-t oppnådde en midlertidig bedring i humør. Langtids effekten på tilfriskning fra diagnose, reduksjon i symptomer på spiseforstyrrelse, og forbedring i livskvalitet var like god i CBT og PED-t.

Konklusjon: Våre funn viste at en høy andel av de med BN eller BED har redusert fysisk form og –helse, hvilket tilsier at evaluering av fysisk helse må inn i ordinær klinisk kartlegging. Fysisk aktivitet og kostholds veiledning bør også innføres i behandling av BN og BED. Både CBT og PED-t kan være vellykkede behandlings metoder for å redusere tvangsmessig trening, med langvarig opprettholdt effekt. Ingen av behandlingsmetodene økte nivå av fysisk aktivitet eller andel som etterfulgte anbefalingen for fysisk aktivitet, hvilket betyr at behovet for å øke det generelle aktivitetsnivå foreløpig er uløst. Den terapeutiske effekten av PED-t eller CBT var tilsvarende gode, hvilket viser til at PED-t kan være en alternativ behandlingsmetode for BN og BED. En høy tilgjengelighet av profesjonelle treningsterapeuter og ernæringsfysiologer kan være med på å tiltrekke seg en nye segmenter av personer med spiseforstyrrelser, og også omgå utfordringen med begrenset tilgang til behandling for de med mentale lidelser.

Abbreviations

AN	Anorexia Nervosa
APA	American Psychiatric Association
BED	Binge Eating Disorder
BDI	Beck Depression Inventory
BMD	Bone Mineral Density
BN	Bulimia Nervosa
BMI	Body Mass Index
CBT	Cognitive Behavior Therapy
CBT-BN	Cognitive Behavior Therapy for Bulimia Nervosa
CBT-E	Cognitive Behavior Therapy enhanced model
CE	Compulsive Exercise
CET	Compulsive Exercise Test
CI	Clinical Impairment
CIA	Clinical Impairment Assessment
CPET	Cardiopulmonary Exercise Test
CRF	Cardiorespiratory Fitness
DSM-5	Diagnostic and Statistical Manual of Mental Disorders, version 5
ED	Eating Disorder
EDE-q	Eating Disorder Examination questionnaire
GP	General Practitioner (medical doctor)
NCD	Non-communicable diseases
NSSS	Norwegian School of Sport Sciences
OSFED	Other Specified Feeding and Eating Disorders
PED-t	Physical Exercise- and Dietary therapy

QoL	Quality of Life
RCT	Randomized Controlled Trial
RM	Repetition maximum
RMR	Resting Metabolic Rate
SWLS	Satisfaction with Life Scale
VAT	Visceral Adipose Tissue

Nomenclature

Interpretation of concepts in this thesis:

Biopsychosocial medicine	a comprehensive, integrative framework for understanding human development, health, and functioning, based on the perspective that "*humans are inherently biopsychosocial organisms in which the biological, psychological, and social dimensions are inextricably intertwined*"(1)
Cardiorespiratory fitness	the ability of the circulatory and respiratory systems to supply oxygen to skeletal muscle during sustained physical activity(2)
Compulsive exercise	A condition characterized by an association with weight and shape concerns, and persistent continuation in order to mitigate the experience of extreme guilt or negative affect when unable to exercise, and avoid the perceived negative consequences of stopping(3)
Dysfunctional exercise	term in this thesis for the dysfunctional exercise motives or –routines practiced by persons with EDs, to cope with negative affect, stress, or as a compensatory method after binge eating
Exercise	physical activity that is planned, structured, and repetitive and has as a final or an intermediate objective to improve or maintain physical fitness(4)
Excessive exercise	physical exercise impounding time from other important/normal activities, occurs at inappropriate times or settings, or being conducted despite injuries or other health issues(5)

Mental health	A state of well-being in which the individual realizes his or her own abilities, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to his or her community"(6)
Non-communicable diseases	non-infectious diseases of chronic character with slow progression, causing 63% of all annual deaths, hence being the leading cause of death world wide. There are four main types of NCD: cardiovascular diseases, cancer, chronic respiratory diseases and diabetes(7)
Physical activity	any bodily movement produced by skeletal muscles that result in energy expenditure. The activity can be occupational, sports, conditioning, household, or other activity(4)
Physical fitness	a set of attributes (either health- or skill related) one have or achieve that relates to the ability to perform physical activity (i.e. cardiorespiratory fitness, muscle strength and -endurance, body composition, flexibility)(4)
Physical health	in this context interpret as the result from anthropometric measures, and general medical screening (e.g. *blood pressure, resting heart rate, plasma lipid- and glucose levels*) indicating the physical status in rest.

Introduction

In medicine, the main aim is to maintain or restore health by prevention and treatment of illness. In ancient medicine, there was a belief that an imbalance of four cardinal liquids caused illness(8). The four bodily liquids: yellow bile, black bile, blood and mucus, assured optimal health if balanced, with the liquids representing the liver, spleen, heart and brain(8). Proper foods and regular physical activity was held as the foundation for good physical and mental health, and as such, prevention and treatment of illness had a holistic approach(9). During the end of the 19th century, the theoretic concepts in medicine turned from the humoral pathologic understanding of health, towards the cellular pathologic understanding(10), and as such, a more reductionistic, dualistic understanding of health evolved(11). Illness was now proposed to have its causes in cellular mechanisms, and with the modern, scientific based medicine, knowledge and technology advanced. Nonetheless, modern medicine then also appeared more divided, with somatic health issues approached and treated differently from how one approaches mental health issues(11, 12). Despite an apparent culmination with a paradigmatic change in the 1970's(13), introducing the biopsychosocial medical concept(11), modern medicine still appear divided, and the understanding of illness through biopsychosocial theories is rather person dependent than mainstream(14), and further challenged by the lack of methodology to capture the concept in science(13). Hence, mental illness is commonly treated with psychological techniques, not necessarily considering lifestyle and somatic health for successful outcome, nor evaluating such approaches as ways of dealing with the primary illness. Such practice largely fails to address the high prevalence of physical comorbidity, and a reduced life expectancy of 15-20 years in persons with severe mental illnesses compared to the general population(15, 16). Not only do we have evidence to suggest that regular physical activity effectively prevents and treats physical morbidity and mortality(17-19), but also that it improves mental- and physical life quality(20, 21). Hence, by incorporating a more comprehensive treatment of mental illnesses, there is potential to increase treatment efficiency and long-term outcome.

Mental illness affects more than a third of the European population in any given 12-month period(22), and is held as one of the leading causes of disability(23). Low treatment rates, delayed treatment provision and inadequate treatment(22, 24-26) might be due to low mental health literacy and poor treatment access(23, 24, 27, 28). To overcome the challenges with high prevalence of mental illnesses, there is a need to reduce barriers for treatment seeking behavior,

and to improve treatment access and -efficiency(25). Addressing such requirements demands investigation of new treatment approaches and new ways of treatment delivery. Any successful result does not necessarily have to overcome existing offers in efficiency, as even small effects might add important contribution to the selectable alternatives(24).

The aim of this thesis is to test the effect of a new and comprehensive treatment approach for a class of mental illnesses which currently relates to unsatisfactory expectations in treatment outcome (29); eating disorders. This new therapy aims at treating bulimia nervosa (BN) and binge eating disorder (BED), concurrently by addressing physical fitness.

Eating disorders

Eating disorders (EDs) are mental disorders characterized by irregular eating habits and severe distress or concern about body weight or shape(5). It is 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 (23). EDs carries the potential for serious, secondary negative effects on mental and physical health, and social functioning(30-32). The disorders typically have peak occurrence in mid- to late adolescence, still can arise both during childhood and adult life, and are more common in females than males(5, 30, 32-38). According to the American Psychiatric Association (APA), there are four diagnostic groups of EDs; anorexia nervosa (AN), bulimia nervosa (BN), binge eating disorder (BED), and other specified or unspecified feeding and eating disorders (OSFED)(5).

The prevalence of EDs is either expressed by point prevalence or lifetime prevalence, in which the former identifies those who currently meet the criteria for an ED, and the latter the ones that have ever met criteria for an ED. The lifetime prevalence of EDs amongst women in the western society is estimated to 5-13%, with a prevalence of AN and BN of 1-4% and 1-2%, respectively (33, 39-41). The lifetime prevalence of the newly added diagnosis BED(5), is estimated to 1-4%, while corresponding prevalence of OSFED is about 2-3%(33, 39, 40). The incidence of EDs is estimated to have been stable the last three decades, and a few reports on a higher incidence rate are assumed to be a result of changes in diagnostic criteria and higher detection rates(33, 41, 42). As such, newly defined diagnosis (e.g. BN from 1979 and BED from 2013) are found with increased incidence rate during the first following years of definition(43). The last revised diagnostic criteria for EDs in 2013(5), implied a change in which higher numbers with disordered

eating behavior met the criteria for AN and BN(39, 40). Further, with the introduction of the new diagnosis BED, less were left diagnosed with OSFED(40).

For the further purpose of this thesis, due to the focus of the RCT on which this thesis rest, only BN and BED in females will be presented and discussed.

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

BN and BED both involve regular episodes with binge eating, i.e. consumption of large amounts of food in distinct time (often defined within two hours), with a feeling of loss of control, and finally typically followed by a feeling of disgust, guilt or shame(5). With BN the binge eating episodes most often are followed by compensatory behavior (i.e. purging like self-induced vomiting, use of diuretics and laxatives, fasting, and driven exercise), still two sub diagnosis separate BN as purging BN and non-purging BN(5). Purging are not practiced by persons with a BED diagnosis (*for more on specific diagnostic criteria, see textboxes*), at least not as frequently as described in the BN diagnostic criterion(5). BED is further distinctive from BN and other EDs by a presentation later into adolescence, and by having a more equal appearance in females and males (5, 35-39). There have been suggestions for introducing sub classes of BED, due to the heterogeneity in comorbidity and pre-ED-history(44). One such suggestion relates to the order of binge eating- or dieting before BED onset. Findings suggest that those with a history of dieting before the onset of the binge eating disorder, are older when binge eating starts. On the contrary, those who binge eat before onset of diagnosis, seems to be younger, have higher prevalence of psychopathologic comorbidity and an earlier onset of overweight and of diagnosis(45-47). However, due to inconsistency in such findings, there is uncertainty of the specific risk factors that might relate to BED or different sub-classes of BED(44, 48), and more research on etiology and profile descriptions are needed(44). Finally, although not defined in the diagnostic criteria of BED, the overvaluation of body weight and shape in defining self-worth, found in diagnostic criteria of BN, is often also seen in females with BED(5, 37, 38, 49, 50).

Binge eating in BN and BED

Binge eating is the cardinal symptom in the diagnosis of BN and BED, yet there are discrepancy on how to best define and capture the behavior per se, in terms of importance for and prediction of diagnosis distinction, prognosis, treatment approach and – response(51).

Text boxes: *DSM-5 diagnostic criteria of bulimia nervosa and binge eating disorder(5)*

Bulimia nervosa (BN)

I. Recurrent episodes of binge eating* with a feeling of lack of control during eating

II. Recurrent inappropriate compensatory behavior (*e.g. self-induced vomiting, misuse of laxatives, fasting, or excessive exercise*) in order to prevent weight gain

III. The binge eating episodes and compensatory behavior both occur on average, at least once per week for three months

IV. Self-evaluation is unduly influenced by body weight and shape

V. The disturbance does not occur exclusively during episodes of anorexia nervosa

**A binge is defined as eating an amount of food that is definitely larger than most would eat, within a relatively short amount of time, usually a span of 2 hours or less.*

Binge eating disorder (BED)

I. Recurrent episodes of binge eating* with a feeling of lack of control during eating

II. The binge eating episodes occur on average, at least once per week for three months

III. Binge eating episodes are associated with three or more of the following:

-eating much more rapidly than normal

-eating until uncomfortably full

-eating large amounts of food when not feeling physically hungry

-eating alone because of being embarrassed by how much one is eating

-feeling disgusted with oneself, depressed, or very guilty after overeating

IV. Marked distress regarding binge eating

V. Absence of regular compensatory behavior

**See parallel textbox for definition.*

Two approaches to understand binge eating, is the recognition of *subjective* binge eating and of *objective* binge eating (51, 52). While the latter has been conceptualized in the diagnosis of BN and BED (see text box 1), the former relates to the individuals own perception of the episode, and do not take volume of food or timeframe in to account. Both interpretations involve the feeling of lack of control, and affect the individual with distress, anxiety and disgust, hence suggested as equitable alternatives for diagnostic criteria(51).

Regarding **volume**, the objective binge episode is still dependent on a subjective interpretation; with the definition rather diffuse (i.e. "an amount of food that is definitely larger than most people would eat during a similar period of time and under similar circumstances"). This might be the reason why the diagnostic question regarding number of binge episodes is the behavioral

items that shows greatest difference between the diagnostic EDE-interview and the diagnostic EDE-q self-report(53-56). In terms of energy contents, studies have found objective binge episodes to range from 3000 kcal to 7000 kcal (51). In regards to the **timeframe**, about 85.5% of binge episodes are found to be within 2 hours, however the range is from 19 minutes to one day(51). The "**lack of control** while binge eating" is an important diagnostic claim, emphasizing the difference of giving into cravings deliberately and of losing control of the situation due to a strong urge for symptom relief. However, it is hard to interpret the concept of "lack of control", hence suggesting additional questions like: 1) "*Could you have stopped eating once you had started?*", and 2) "*Could you have prevented the episode from occurring?*"(5).

The food consumed during a binge can be both healthy and **unhealthy foods**, but most typically the latter, i.e. high in sugars and/or fat(5, 57). Foods high in proteins are less likely to be part of a binge meal, as proteins are satiating and effortful to chew, hence hindering the fast and large food consumption typical in a binge(58). In persons with BN, where purging succeeds the binge, food items often have a soft consistency and/or includes large amounts of fluids to facilitate vomiting.

The binge can occur **at any time** during the day, but very often during the afternoon and late evening(57). The episode typically occur at home and **alone,** hidden from others(5). While the urge to binge can be **spontaneous triggered** during a planned meal, or due to negative affect; e.g. boredom, loneliness, frustration, or as an immediate response to mood or emotions, the urge to binge can be controlled for a short time, until the situation allows the individual to give in to the cue(5). A binge episode can also be a **planned event**(5), and serve as a reward or relief after a stressful effort, and if desired food is not available, the urge can be put at hold while actively attaining such(51).

Purging in BN

The use of different purging methods in BN, can be a way of **dealing with stress** and anxiety, still mainly a way of **compensating** for the high energy intake during binge eating(5, 59). Different purging methods are use of diuretics and laxatives, fasting periods and skipping meals, use of drugs that are claimed to manipulate metabolism, however; most frequently reported are **self-induced vomiting** and **excessive exercise**(5, 60-62). The overall effect from purging methods as compensatory methods are generally minor regarding energy balance(63), probably being one of the main reasons why persons with BN often remain weight stable or slowly gain weight(35, 64-66). Diuretics do not affect metabolism, but result in temporary acute weigh

reduction due to loss of body fluids through increased urination. Laxatives has the corresponding acute, but temporary effect on weight loss, by facilitating faster feces removal. However, there is no overall effect on energy balance, as feces are only left-overs *after* digestion and absorption of nutrients. The effect on energy balance from excessive exercise is easily outbalanced by consumption of equal or even more energy from energy dense foods during binges. The same explanation complies to use of metabolism enhancing drugs. Provoked vomiting is not any more effective to outbalance the overconsumption of energy, as gastric emptying is an ongoing process, initiating digestive processes in gut system during eating. Only foods still remaining in the gastric bladder can be purged with the self-induced vomiting. An overall positive net balance after binge eating followed by self-induced vomiting has been reported (63).

Understanding the binge eating behavior in BN and BED

With the behavioral feature model described in cognitive behavioral theory, Fairburn aims to explain the maintaining features of binge eating in BN(52, 67, 68) (*figure 1*). A corresponding explanation for binge eating in BED has been proposed(37). The model points towards the upholding reason for binge eating, i.e. an overvaluation of an ideal bodyweight and shape. Such valuation results in dieting procedures, which in most circumstances will end up in a binge eating episode due to hunger, cravings, stress, or exposure to forbidden foods. The distress and guilt following the binge eating episodes reinforce the original idea, i.e. the need to control body weight and shape, thereby driving focus towards another dieting regime, spinning the wheel further. Different from persons with BED; those with BN will practice compensatory behavior in an attempt to control body weight with recurrent episodes of binge eating.

A second explanation of binge eating, and especially related to BED, is a sudden increase of negative affect and tension, or rapid decrease of positive affect, which is handled with an immediate breakdown of emotion and impulse regulation by binge eating(37). Emotion dysregulation is found in substance-abuse disorders, where neuroimaging have shown diminished activation in emotion processing regions in response to stress, and an increased activation in regions associated with cravings(69). Cravings, being triggered by a dopaminergic release, activates reward-related brain regions, finally increasing the reward-seeking behavior(69). These mechanisms are suggested in food addiction, a condition observed in about 42-57% of persons with BED(69). Highly palatable foods appear to stimulate the mesolimbic dopamine system, in a similar way as addictive substances, hence triggering hedonically pleasurable effects that changes

the reward-related neural systems(69). A dysfunction in reward related processes, either being hypo-sensitiveness to substances and therefor in need of an higher-than-normal dose (binge eating) to achieve the reward response, or being hypersensitive to the triggers and therefor experiencing a higher reward sensation than normal, causes an elevated reward sensitivity to the cue(69). Furthermore, impulsivity, a common comorbidity in BED(35, 70), refers to the likelihood of responding to stimuli in an unplanned manner, with little regards for negative consequences. Persons with impulsivity are likely to engage in behavior that rewards in the short-term (e.g. binge eating), despite being detrimental in the long-term (e.g. health problems). In food addiction, negative urgency; i.e. the tendency to act impulsively while experiencing negative mood states, closely resembles such impulsivity(69), and food related impulsivity have been found in BED(70).

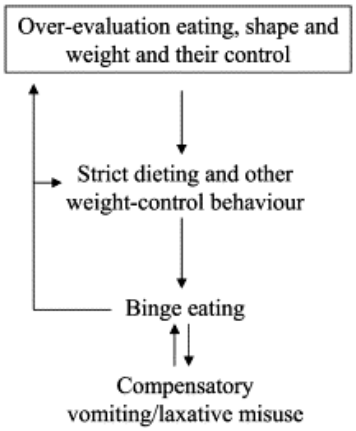

Figure 1: The cognitive behavioral model, illustrating the maintenance of BN. The overvaluation of the importance of body weight and shape for self-esteem and –acceptance initiates dietary regimes resulting in cravings and hunger, ultimately ending up in a binge eating episode. The guilt following the episode reinforces the desire to control diet and body weight, starting the cycle all over again. By time, some resort to compensatory behavior in attempt to control energy balance.

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Risk factors for BN and BED

The risk of having an ED is a product of biological, psychological and sociocultural influences (5, 33, 36, 71). The sociocultural presence of idealization of thinness (typically in the modern Westernized society) have been proposed as essential for any BN behavior and features to occur(36, 43, 72), still debatable due to poor methodology or support of documentation(36). Anyhow, the exposure to such sociocultural phenomenon, results only in a few that internalize the thinness ideal, and in even less, this results in an ED like BN. As such, an underlying vulnerability (e.g. biological causes) must be present to make any such exposure a risk factor for BN(30, 36). This interaction pinpoints an important interaction of genetics and environment. The internalization of the thinness ideal, giving rise to increased body dissatisfaction and dieting behavior, with or without elevated body weight, increases the risk of disordered eating behavior and eating disorders in genetic vulnerable individuals(30, 36). Supporting the theory of genetic predisposition, are findings of familial aggregation of EDs like BN and BED, and twin- and adoptions studies (36, 73, 74). For the future, genome-wide association studies, in which there is a search for single nucleotide polymorphisms in the entire genome, are believed to give better understanding of hereditability of eating disorders and related behavior. Recently, a genome-wide locus has been identified for AN(75). But at present time, the small sample sizes in such studies, besides a preliminary priority of AN-research in such genome studies, are probably the main reasons why specific genes for BN or BED are not yet identified(30, 71, 76).

Moderators of the effect from environmental factors as risk factors for EDs (i.e. the pressure for thinness), are personality traits. These traits are also of inherited character, with up to 50% explained by genetics(77). From longitudinal research, personality traits like negative emotionality, perfectionism, and impulsivity have been found to prospectively predict the risk for ED-symptoms(30). The negative emotionality represents trait-based disposition for unpleasant emotions like stress and anxiety, which are found to predict the development of eating pathology (i.e. drive for thinness, bulimic symptoms), full-threshold EDs, and bulimic syndromes. Perfectionism means high personal standards and an overly critical evaluation of oneself, and with concurrent occurrence of e.g. body dissatisfaction or low self-esteem, the risk of bulimic behavior and development of an ED increases(30, 41). The findings of impulsivity as a risk factor for EDs have been mixed, but points towards a role when expressed as negative urgency (i.e. engage in rash actions when stressed) in explaining the likelihood of binge eating- and purging behavior(30).

Other important factors that emerges as correlates in development of EDs, are neurocognitive elements and molecular deficits(30). The former relates to the ability of cognitive flexibility and inhibitory control. Cognitive flexibility, i.e. the ability to shift between multiple tasks, have been found reduced in relation to BN, and deficits in inhibitory control (i.e. suppressing/over-riding an automatic response in favor of a less automatic one) are most consistently observed in EDs involving binge eating- and purging behavior. Molecular deficits as explanation for risk of EDs, rely on the theory of specific genes contributing to the presence of EDs. As such, the genome-wide association studies are assumed to give improved knowledge in the future(30).

Eventually, traumatic episodes, difficulties in psychosocial functioning, or harsh environments during childhood and adolescents, can result in coping strategies like the dieting-, bingeing- and purging behavior found in EDs, with or without overvaluation on the need to control body weight and – figure(5, 41, 44).

Comorbidity with BN and BED

Rate of psychiatric comorbidity is high in females with BN and BED, with reduced quality of life, functional impairment and enhanced mortality (5, 31-33, 35, 38, 78-81). The reason for high level of comorbidity is not known, but evidence exists for genetic factors (35). Another explanation relates to the age of onset for the ED, where early onset relates to more severe psychopathology, which may impair personality development(82).

The most common psychiatric comorbidities are mood and anxiety disorders, with depression, social phobia, obsessive-compulsive disorder and generalized anxiety disorder the most prevalent ones(5, 31-33, 39, 83-85). More specifically up to 70% of all with BN presents with mood disorders, while borderline disorders, avoidant or obsessive compulsive disorder are very common, and about 20% has concurrent substance abuse(39, 81). In BED about 1/3 has anxiety disorder, 29% has personality disorders (most typically avoidant, borderline or obsessive-compulsive) and a comparable number to BN has substance abuse disorder (39, 86).

Previous findings suggest that amongst persons with BN, less had personality disorder if having high BMI compared to low BMI, with the corresponding finding for age(81). Further; being recruited for treatment, or from an outpatient sample, is associated with higher probability of having personality disorders compared to inpatient samples(81). These findings underline the importance for right choice of, and intensity of, treatment of EDs, as such comorbidity are found

to worsen recovery prognosis from EDs, impair long-term treatment outcome from EDs, and also to increase risk of dropout(84, 87-89).

Physical comorbidity in BN

Physical comorbidity in BN relates primarily to medical local and systemic effects from purging behavior. Local effects are seen in the tissue affected by the choice of purging behavior. Self-induced vomiting might lead to parotid gland enlargement, inflammation and tears of the esophagus, erosion of the dentin and enamel, persistent gastric acid reflux, and dysphagia(31). Long-term or chronic use of laxatives on the other hand, might lead to dysfunction of the colon and of the anus sphincter muscles, with increased risk of hemorrhoids, haematochezia and rectal prolapse(31). The systemic effects are electrolyte- and acid-base imbalance caused by the purging of fluids and minerals, with self-induced vomiting, diuretics- or laxative abuse. The most common abnormalities are metabolic alkalosis and hypokalemia, which might cause life-threatening cardiac arrhythmias(31). Furthermore, the chaotic nature of eating behavior, compensatory behavior and weigh fluctuations in BN can give rise to profound effects in metabolism and physical health. In fact, having BN is associated with increased risk of diabetes-2, cardiovascular illness and metabolic syndrome (33, 90-92)

Physical comorbidity in BED

With BED, physical comorbidity mostly relates to the medical health effects of obesity, a condition typical for most in this diagnostic group (35, 65). From cross-sectional studies, the conditions most often associated with BED, are hypertension, gastrointestinal conditions, arthritis and chronic neck/back pain, dyspnea and sleep problems, and asthma(32, 78, 83). Further, females with BED more often have menstrual dysfunction, infertility, delivery of higher birth weight babies, and long labor duration(78). When controlling for BMI, the pain conditions, gastrointestinal conditions, sleep problems, and early menarche still persists as important associations to BED. From longitudinal studies, findings suggest that persons with BED diagnosis are more likely to develop new diagnosis of dyslipidemia, hypertension, diabetes and/or metabolic syndrome (33, 78, 90, 92).

Quality of life and functional impairment in BN and BED

Persons with EDs report impaired quality of life (QoL) and subjective well-being compared to healthy controls(80, 93-95) , and even more impaired than persons with other severe mental- or physical illnesses(94). Having BN is found to impair most domains of QoL and especially social-life domains(5, 95), while persons with BED more typically report functional impairment(5). Indeed, compared to weight matched obese individuals, persons with BED have greater functional impairment, lower QoL, more subjective distress, and greater psychiatric comorbidity(5). Underlining this difference, and possibly offering an explanation of such, might be that it is not so much the volume of food consumed during a binge episode that causes the QoL impairment, rather the "loss of control"(94).

According to the WHO(6), mental health is defined as:

> "A state of well-being in which the individual realizes his or her own abilities, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to his or her community"

Psychological well-being is about living a good life with purpose and meaning, optimal functioning and self-realization(96). The concept of well-being is divided into psychological, emotional and social well-being, with the former related to aspects like self-acceptance, autonomy, personal growth and positive relationships with others, while the emotional aspect relates to happiness and positive affect, and the social aspect relates to contribution, integration and coherence(97). As such, well-being is much about satisfaction with life; a subjective, judgmental process involving a comparison of ones perceived life circumstances with a self-imposed standard(98).

Although most persons with BN or BED never seek profession help for their ED (35, 42, 99, 100), they often consult health care due to other health issues and because of the debilitating effect their condition has on their QoL (35, 65, 100). As a matter of fact, while treatment of EDs is about symptom relief and remission from the specific diagnosis, persons with EDs more often rate personal well-being important rather than remission from ED behavior(96). When asking persons recovered from EDs about the most important achievements from treatment, the following were among the most importantly rated: positive relationships with others, self-

acceptance, personal growth, and self-adaptability (resilience), but also improved body evaluation, social contribution, purpose and meaning in life, and improved physical functioning(96). Hence, it seems reasonable to requests evaluation of effect on QoL from ED-treatments, as the traditional, exclusive report on ED symptom change or remission do not appear adequate(96). One suggestion for such improved outcome definition was proposed by de Vos et al in 2017(96), to compliment the remission criteria as previously suggested(101):

> "The ability to adapt and to self-manage in the face of social, physical and emotional challenges with an overall tendency towards growth in psychological well-being and adequate symptom remission"

As reliance on only one single instrument for evaluation of QoL can be misleading, there is suggestion of incorporation of both subjective and objective measures, preferable one generic and one disease-specific(93, 94). As such, the potential to capture the specific impairments caused by the ED improves(102). Specifically, body weight concern, shape concern and binge eating behavior have been found to cause specific clinical impairment in persons with BN or BED(102).

Dysfunctional exercise motives in BN and BED

Dysfunctional motives or routines for exercise (hereafter mentioned as "dysfunctional exercise") are described for about 20-40% of those with BN (103-105), and are related to higher psychopathology, worse treatment outcome, and higher risk of relapse(3, 103, 106). This phenomenon serves as coping strategies for compulsivity, anxiety and stress, still even more relevant in BN is the role as a compensatory method to control body weight(5, 104, 106-110). In diagnosis of BED no criteria exists for " overvaluation of controlling body weight or figure", nor does it mention routinely use of compensatory behavior(5). Furthermore, as the binge eating is a way to cope with emotions and anxiety(5), this dysfunctional exercise has not yet been described for BED. Still, there are findings indicating high concerns about body weight, figure and appearance in patients with BED(49, 50), and as such, dysfunctional exercise might be relevant.

Nevertheless, complicating the understanding and evaluation of the phenomenon, is the lack of consensus on how to define and capture dysfunctional exercise in BN (3, 59, 107, 109, 111, 112). Definitions varies with emphasize on either qualitative- or quantitative elements, and with the use of terms such as; compulsive-, excessive-, driven-, or obligatory exercise, and exercise addiction

or -dependence (59, 112). Complicating the use of "excessive exercise", as used in the diagnostic criteria of BN(5), is the lack of unity on how to capture the excessiveness. While the official recommendations for physical activity helps us define the least acceptable level of physical activity(113), no definition exists for any upper, healthy level of physical activity. Hence, suggestions from the APA highlights elements of priority, time and settings (i.e. interfering with the activities of a normal life; occurs at inappropriate times or settings; continues despite injury or illness)(5).

In contrast to the diagnostic *quantitative* description of exercise in BN (excessive or driven)(5), there are findings pointing towards a more important *qualitative* aspect of dysfunctional exercise in BN. These findings suggest exercise in BN to be of a compulsive character (59, 107, 111, 112, 114), with features like the feeling of anxiety and depression if unable to exercise, using exercise as permission to eat, exercising to cope with emotions, maintenance of rigid exercise regimens, and prioritizing exercise before other important activities. Importantly, compulsive exercise, more than excessive exercise, relates to impairment in QoL(94).

With poor consensus on how to best capture the dysfunctional exercise, few reports exists on how this phenomenon responds to treatment. Compulsive exercise (CE) is assumed to be reflected with excessive exercise, still no reliable evidence exist for such linkage, as most reports are based on interviews and self-reports. Such methods are known to be highly biased, and less trustworthy(115, 116). CBT addresses compensatory exercise, but there is little specific evidence supporting whether CBT is effective in alleviating CE. Since CBT does not specifically address exercise routines other than driven exercise for compensatory reasons, there are recommendations on the development of new or adjuvant interventions to CBT, to deal with dysfunctional exercise(37). As an alternative, reestablishing practical experience with healthy exercise, along with theoretical understanding of exercise physiology, might induce a more positive attitude towards exercise(117). However, the fear of exaggerating the compulsiveness and any excessiveness, are the main reasons for a reluctance of allowing physical activity in treatment of EDs(117-119). Only one previous publication reports on CE after adding structured physical activity of low impact to treatment of EDs(120). Here, the exercise intervention proved effective in reducing dysfunctional attitudes towards exercise. However, it is unknown whether structured physical exercise interventions alter CE behavior in a longer-term, whether progressive exercise is comparable feasible, and whether interventions emphasizing physical activity

simultaneously raise the actual, objective measured level of physical activity in patients with BN or BED.

Physical activity and –fitness in BN and BED

The increase in morbidity and mortality caused by physical inactivity is so substantial that it is considered the fourth leading cause of death worldwide (121, 122). Health issues related to inactivity may be even more pronounced in patients, yet, physical health, -activity and -fitness in persons with EDs is often inadequately addressed by the treatment services(117). One reason may be insufficient knowledge of the physical health in those with BN and BED, still, lifestyle, like diet and exercising, may affect physical fitness in many ways and cause profound changes, ultimately affecting total morbidity and mortality(2, 123, 124). Nevertheless, besides self-reports or interviews on physical activity level, widespread use of body mass index (BMI) as health- and bodyweight indicator, and a few, but conflicting reports on bone mineral density (BMD), there is scant information on physical fitness in individuals with BN or BED.

Level of physical activity in BN and BED

Evidence for an excessive nature of exercise in EDs was suggested based on the interviews by Davis et al in 1997, reporting up to 80% doing excessive exercise(105). Here, excessiveness was defined by exercising more than 60 minutes per day for at least six days a week, not less than one month. Additionally, the patients had to describe the exercise as obsessive, driven or out of control(105). This definition of excessiveness (i.e. in quantitative terms) are certainly debatable, and it is more reasonable to suggest it capture the qualitative aspects of dysfunctional exercise, like compulsiveness(59, 125). Anyhow, later publications seems to support the findings of excessiveness as a common feature in about 20-40% of persons with BN, still all rely on interviews(103, 104). Self-reports of physical activity has previously been found to be biased in the general population, by overestimating the actual levels(115). By introducing objective measures for evaluation of physical activity in persons with BN, the discrepancy between self-report on physical activity and objectively measured physical activity was confirmed(116). Still, rather than over-reporting the actual level of physical activity, persons with EDs tend to underestimate, and the objective devices revealed higher levels of physical activity compared with healthy controls(116). Albeit, with a general population described as physical inactive, not capable to comply with the minimal recommendation for physical activity(126-128), the latter finding might not necessary imply any excessiveness. Perhaps does the quantitative definition of

excessiveness not serve any clinical importance or meaning, and would rather improve with a rationalistic understanding of the excessiveness. As such, the definition of excessiveness by the APA sounds reasonable: *physical exercise impounding time from other important/normal activities, occurring at inappropriate times or settings, or being conducted despite injuries or other health issues*(5). Still, the compulsiveness is held as the probably best differentiator between healthy exercise and the dysfunctional exercise found in EDs, suggesting volume of exercise to be of a less clinical meaningful information(125). The current understanding of compulsive exercise, based on the definition of compulsive as "*an insistent urge to perform an action (here: exercise) to relieve the anxiety stemming from a fear of perceived negative consequences if not being performed*"(freely rendered from DSM-5)(5), is formulated as (3);

> "A condition characterized by an association with weight and shape concerns, and persistent continuation in order to mitigate the experience of extreme guilt or negative affect when unable to exercise, and avoid the perceived negative consequences of stopping"

Physical activity in BN serves the role as a affect regulator and as a compensatory behavior for body weight regulation(5, 106). The type of activity preferred by persons with BN is predominantly of aerobic character(116, 129). With the nature of such activity, being continuous with intensity of movement, heart rate and rate of respiration dependent on preferred intensity, it is reasonable to suggest this as an effective way for affect regulation. Additionally, with a high drive for thinness (30, 130, 131), aerobic activity (i.e. high acute energy consumption, low stimuli for muscle growth) is probably the preferred mode of exercise to deal with body weight regulation.

Interviews and self-reports from samples with BED show that persons with BED are less physical active than healthy control persons and obese persons without BED(132-135). With regards to persons with BED, there is good reasons to assume low levels of physical activity, due to high rates of obesity, the absence of compensatory behavior in diagnostic criteria, and the use of binge eating per se as affect- or emotion regulator.

Physical fitness

Physical health and -fitness is a product of genetics and lifestyle (136, 137). Cardiorespiratory fitness (CRF), being one of the elements in physical fitness, is suggested to be the most important indicators of physical health and mortality (2, 123), with predictive power for mortality rating above traditional measures like BMI, smoking, blood pressure and plasma lipid levels(2). CRF refers to the circulatory and respiratory systems ability to supply oxygen to skeletal muscle during sustained physical activity(2), and the optimal measure for CRF is maximal oxygen uptake(136). The few studies that report on CRF in persons with BN, indicate both inferior and comparable fitness(138, 139) relative to normative values(140). No reports on CRF exists for persons with BED, other than substitute tests like the 6 minutes' walk test(132, 134, 141), in which single measures from screening procedures lack standard comparatives for interpretation, hence regarded more suitable to track changes by time(142). The results from 6 minutes' walk test in persons with BED reveal comparable results to non-BED obese persons, but inferior compared to healthy non-obese population(134).

Further; muscular fitness reduce the risk of metabolic syndrome (143), relate to self-reported health (144), lower weight and abdominal fat mass gain, and reduce risk of illness and total mortality in different populations (145). Reports on muscular fitness in populations with BN or BED are rare, but one study found muscular strength in women with longstanding BN to be comparable to healthy controls(138).

Body composition and physical health

Physical health and risk of non-communicable diseases (NCD) are often evaluated from anthropometric measures, and body mass index (BMI) is a widely used measure for body weight evaluation in adults(146, 147). Normal BMI values have been found for people with BN(35, 148), and overweight and obesity have been associated with BED(135, 149, 150). Still, findings of higher prevalence of overweight and obesity in persons with BN during the period 2000-2010, and an increase in lifetime obesity in all diagnosis of EDs, points towards a change in BW categories(35, 64-66, 151). In this regard, there are reports on prevalence of overweight and obesity being higher than 70% among persons diagnosed with BN or BED (35, 65). Nonetheless, body composition, rather than body weight categorization, is more important in evaluating the risk of physical health complications(152). With regards to the disturbed pattern of eating, and additionally the purging in BN, there is potential for morbid changes in metabolism, hence also in

body composition. However, detailed information on body composition (total fat mass, regional body fat storage, lean body mass, visceral adipose tissue, and BMD) is largely missing in descriptions of persons with BN and BED.

Women with BN in the lower and upper BMI categories have been shown to have lower and higher body fat percentage, respectively, compared with healthy controls(148). More importantly, the specific distribution of fat has important health implications. There is evidence that visceral adipose tissue (VAT), more than subcutaneous fat, strongly associates to increased morbidity; with findings of impaired insulin sensitivity, high levels of triglycerides and cholesterol, and secretion of inflammatory signal-substances (153-160). However, the regional body fat storage has previously not been evaluated in persons with BN or BED, except one study; reporting increased VAT in women with BN or BED compared to healthy controls(161).

With regards to bone mineral density (BMD), evidence state that physical activity, nutritional components of the diet, and body weight interacts with the genetic disposition for BMD(162). Low BMD is repeatedly found in AN(163, 164), and assumed to be the result of energy- and nutrient restriction and low bodyweight, or the loss of body weight per se (165, 166). Findings on BMD in BN have been equivocal, but when low bone mass has been identified, mainly spine bone mass is affected (163, 164, 166, 167). In women with BED no information on BMD is reported.

In summary, we do not know much about the physical health and fitness in people with BN or BED, still dieting, bingeing and purging behavior, and routines for-, or lack of routines of, physical activity imply a potential for severe physical impairment. Furthermore, to better understand the effect from BN or BED per se, controlling for a history of AN seems necessary(148, 168). Individuals with EDs may undergo diagnostic cross-over, hence a pre-history of AN may occur in individuals with current diagnosis of BN or BED(5). Diagnosis of AN involves high risk of profound negative effects on bone mineral density and body composition due to the low body weight and/or energy- and nutrient deficient diet(169). Although most effects are reversible, some effects or characteristics may persist after remission from, or change of, diagnosis(168, 170).

Treatment of BN and BED

Less than half of the persons with BN or BED are detected and offered treatment for their ED in primary care(25, 35, 65, 171-174), and less than 7% of persons with BN and 20% of persons with BED receive professional psychiatric care for their ED(25, 35, 42, 99, 173). Besides low detection rate; low mental health literacy (25, 173, 175, 176) and long waitlists for special care (25, 26, 177-180) are important causes to this scenario.

Successful therapy can be ascribed the approach and technique used for treatment, the modality of treatment, the personality, experience and knowledge of the therapist, and special elements in the therapeutic process. Amongst the many therapy options suggested for BN and BED are behavior therapy, multidisciplinary therapy, interpersonal psychotherapy, dialectical-behavior therapy, psychodynamic therapy, pharmacotherapy, hypnosis(181), and weight loss therapy(29, 182, 183). Still, family-based therapy, CBT, and interpersonal psychotherapy have proved most effective(29, 183), with CBT repeatedly argued as the preferred evidence based treatment offer for BN(29, 184-187) and more often also for BED(37, 184-186, 188). One prominent feature of CBT, is the rapid effect in remission compared to other optimal treatment options, still with comparable outcomes in the long-term(25, 189-191).

Cognitive behavior therapy (CBT) as preferred therapy for BN and BED

The foundation for CBT is the CBT-behavioral model (figure 1), hence a three phased therapy progress; each with focus related to the specific variables in the model. The CBT-model illustrating the behavioral elements of BN (or BED), brings clear implications for successful treatment. If treatment is to have long-lasting impact, it needs to address the extreme dieting, the over-evaluation of shape- and weight, and the tendency to eat in response to adverse events and negative moods(52, 191). Hence, CBT aims to de-emphasize the need to control body weight and -shape to uphold self-esteem and self-worth, by stimulus control procedures and by challenging the cognitive beliefs adhered to justification of such a need(52). While emphasizing the necessity of achieving an early behavioral change to successive continue to the next phase in treatment and ultimately achieve successful treatment outcome, the CBT favor the cognitive restructuring as the crucial element for long-term success(52, 191).

The treatment is originally designed for individual therapy, but also encouraged for group therapy(52, 192). There are 20 treatment sessions covering the same number of weeks, and is structured by three progressive treatment stages, and a final stage of summary. First stage

involves an intensive 4 week period with twice-weekly appointments. Here, the aim is to engage the patient in treatment and change, finding a personalized formulation, and to introduce two potent procedures; i.e. in-session weighing and regular meals(52). Stage two involves weekly sessions with review of progress, identification of barriers to change, and modification of formulation if needed. Stage three is the main body of treatment and addresses the mechanisms maintaining the patients' ED. The final stage three focuses on the future and how to maintain progress and minimize risk of relapse.

An improved version of CBT, CBT-enhanced (CBT-E) adds new strategies to address the psychopathology in EDs, mainly by putting more emphasize in engagement, modifications on the overvaluation of controlling body weight and figure, and how to deal with setbacks(68). An additional advantage with CBT-E, is the potential to treat a trans-diagnostic sample with ED's(68). A broad version of CBT-E additionally takes four different traits into account (i.e. clinical perfectionism, low self-esteem, and interpersonal problems) due to their obstructing influence on treatment outcome(193). Fairburn proposed; both the underlying cognitive disruption's; causing and upholding the illness, and the behavioral elements, are mostly similar in the range of ED diagnosis, hence this treatment can provide good outcomes for most EDs(68). CBT-E perform comparable to the original CBT for EDs, still improves outcomes in more treatment-resistant patients with the specific targeted traits (194, 195).

Group psychotherapy for increased efficiency in treatment delivery

The traditional psychotherapy, with one-to-one counseling, is highly ineffective taking into account the limited access to qualified therapists, and the high demand for help (22, 25, 179, 180). Because self-help groups have proved effective as treatment(25, 183, 187, 196, 197), a stepped care model has been suggested(197, 198), in which persons with EDs are offered the least intensive and most cost-effective therapy options at first try. A next step would be to suggest therapist led group therapy, which have proved comparable effective to individual therapy (24, 192, 199-201). In a recent meta-analysis (year 2017), group therapy for EDs were more than 5 times likely to result in behavior abstinence compared to waitlist controls, and comparable effective to individual therapy(200). Concurrently, group therapy improved psychopathology like depression and self-concept, still by small effect sizes compared to control group (200).

Additional advantages to a more effective treatment delivery and at lower cost, group therapy may provide cohesiveness; promoting engagement, initiative and motivation, improving

relationship skills, reducing risk of isolation, while also offering a supportive environment (200, 202-204).

To efficiently deliver group psychotherapy, also nonprofessionals or health-students can be trained to run the groups(24, 25, 198). As such, one might overcome the challenge of the restricted availability of professional therapists(24). Optimal treatment outcome, i.e. remission rate of 31-50% amongst completers of therapy, have previously been found with individual therapy ran by CBT-trained non-psychiatrist in primary care(205, 206), and with group therapy ran by master students(25).

Treatment effects on comorbid conditions in BN and BED

The co-existence of other psychiatric disorders may complicate treatment of the ED, due to interference of illnesses(207, 208), due to increased risk of dropout (87, 88), or insufficient focus on alleviating the ED-symptoms. Additionally, common features in ED and personality disorders, like self-devaluation, low mood, anxiety, and poor self-insight into behavioral or cognitive dysfunctional patterns, may complicate treatment response, if ED and personality disorder reinforce the severity of each other(209).

The treatment of the ED is likely to concurrently improve comorbidity like mood and anxiety disturbances (5).Furthermore, CBT-BN and CBT-E has proved effective on improving QoL in persons with ED, with individual therapy apparently more successful than group therapy (210). Still, effect sizes after CBT is larger for the ED-symptoms per se, compared to the effect for QoL. This probably relates to the specific design of CBT for EDs; specifically addressing ED-behavior, while effects in QoL plausible are secondary effects to remission from the ED (210). Hence, there are weak evidence for the most efficient treatment approach capable of both addressing ED ánd the impaired QoL, with the latter relating to both generic and disease specific impairment. Such knowledge and information do not only appear important for the affected individual, but can also support decision-making in domains such as healthcare (211).

Despite the knowledge of impaired physical health and increased morbidity in patients with severe mental illness(15, 16), there seems to be poor routines on screening, evaluating and consulting on physical health and fitness during psychiatric care (16, 212-214). Hence, knowledge on effects from such treatments on physical health is poor, still most probably neglectable if no efforts on directly addressing such challenges exists with the typical psychiatric practice.

Elements in successful therapies for BN and BED

While CBT is held as the preferred option of available treatments for BN and BED(184, 186, 187), considerably few responds to this type of treatment, typically leaving about 50-70% in need of other treatment offers due to poor CBT-response(29, 177, 215). Treatment of EDs is in general challenging due to a relative high number of drop outs (177, 205, 216, 217), -non-responders (189, 216) and relapsing individuals (218). High rate of comorbidity is one complicating reason for the poor treatment efficiency (208, 209, 219). Identification of variables affecting or predicting treatment outcome can aid to tailor the optimal treatment or required therapy elements, before treatment- and motivation fatigue pervade, and to confine high costs with extended treatment.

Amongst variables identified to predict poor treatment outcome or high dropout rate in treatment of BN and BED, are baseline depression (208, 216, 220), poor social adjustment (216), impulsivity (216), personality disorders(87), poor motivation(208, 219), and history of obesity (191, 220). Concurrently, high baseline self-esteem, and high weight- and shape concern have all been found to predict a more favorable result(221). Still, more frequently suggested as favorable elements, are early change in ED symptoms during treatment, and therapeutic alliance(208, 222, 223).

With the knowledge on the importance for early treatment response (i.e. alleviation ED-symptoms), the early phase of CBT is dedicated to break cycles of dieting(52). Dieting reinforces the binge eating episodes, hence, the CBT-technique to break this cycle, is to (re-)introduce regular meals. The success criteria for treatment effect from CBT is proposed to be both normalizing eating patterns and arenas of affect regulation, and changing the cognitive beliefs acting as maintaining mechanisms for the behavioral patterns(52, 191, 224). However, the need to target cognitive restructuring in treatment has been questioned, with normalization of the eating pattern held as the most effective treatment element, and with cognitive restructuring as subsequent, secondary effects to this behavioral change (225). In support of this theory, are findings of no additional benefit from full CBT treatment compared to its separate components (29, 226). Hence, contrary to the original idea, findings seem to suggest the behavioral changes are of higher, or at least comparable-, importance for optimal treatment outcome, and that directly addressing cognitive elements is of less importance, or at least only one way to improve from this illnesses(225-227). Further supporting this, is the finding of relational interventions (i.e. empathy, understanding and warmth, involvement and collaboration) and structural interventions

(i.e. agenda-setting, homework assignment, pacing the session and summarizing) being more effective strategies, than cognitive interventions(227). Here, relational intervention motivates the client for investment, collaboration and change, while the behavioral intervention may result in actual symptom change, finally resulting in changes in cognitive mechanisms(227).

Relational interventions embrace the concept of "therapeutic alliance"; defined as "*collaborative relationship that develops between patients and their therapists, where there are shared goals and agreement and willingness from both parties to engage in the tasks that need to be done in order for therapy to progress*"(228, 229), involving three shared components; goals, tasks and bond. The therapeutic alliance is associated to treatment outcome for a range of psychiatric disorders, but in treatment of BN and BED, its role is rather vague(230). In fact, rather than assuming that therapeutic alliance creates an atmosphere and initiative for early and sustained behavioral change, and hence; more positive treatment outcome, it seems to be the other way around (222, 227, 229). Early change in eating concern and eating restriction have not only been found to predict final improvements in EDE-q, but also to bring about a stronger therapeutic working alliance midway in treatment(229). This finding was supported in a recent meta-analysis (222) Here, early change in ED symptoms and therapeutic alliance were found to interact as outcome predictors in a range of psychiatric treatments, still; in CBT and behavioral therapy for ED, early change was found to precede alliance, finally together resulting in improved treatment outcome (222).

Therapeutic alliance and early change aside; behavioral treatment have mixed findings in treatment outcome compared to psychoeducation (191, 226). Perhaps by emphasizing bona fide interventions(226, 231), while concurrently ensuring optimal relational intervention, the behavioral therapies may improve. In fact, treatments resting on conceptual models are suggested to be most efficient in treatment of ED (226), which implies a need for a specific description, structure and order of treatment modules, techniques based on theoretical rationale, and trained therapists, to be successful.

Summary of therapy options for BN and BED

There is obvious a need to explore other evidence based treatment offers, that matches the needs defined; i.e. lowering the barriers for treatment seeking behavior, a treatment-option motivating the patient to approach help and comply with the treatment, efficient treatment delivery to handle the waitlist challenge, treatment that considers the high comorbidity in ED, and evaluation from treatment encompassing more than simply evaluating remission from diagnostic

criteria. Still perhaps most importantly; a wider treatment offer, to match the needs of more individuals. In this respect, WHO has pointed out "best buy interventions" as desirable approaches, i.e. interventions being highly cost effective, feasible, affordable and appropriate to implement within the local health system(25, 232). This further implicates capacity of the health system to deliver a given intervention to the targeted population, technical complexity of the intervention (e.g. level of training that might be required) and acceptability based on cultural, religious and social norms(25).

When designing treatment for EDs, and evaluating treatment effects, several aspects needs to be considered. Essentially, the suitability of a treatment in regards to match complexity of comorbidity needs to be considered(207). If treatment does not have the flexibility to meet complex needs, or are not assumed to match a specific need of treatment attention, proper screening before treatment initiation is needed, to avoid prolonged expensive and unsuccessful therapy. New treatments could ensure optimal results by relying on success criteria from existing offers, like efforts on achieving therapeutic alliance, early change, and addressing mental and physical comorbidity. Furthermore, behavioral focus, relying on structural methods with or without conceptual models, might substantiate such success criteria, more than psychoeducation and cognitive focus per se.

Proposing a new, behavioral therapy for BN and BED

With regard to the suggested essential criteria for successful therapy for ED, and with respect to the suggestion for "best buy interventions"(25, 232), physical activity and dietary consultation have the potential to succeed. Physical activity and nutrition are amongst the core interests of persons with ED's, and by being social acceptable and desirable interests, there is potential to lower barrier before treatment seeking is initiated, and further to motivate to comply with treatment. Conceptual models for the mental health effect from physical activity have been proposed previously (see figure 2), arguing for potential successful effects, while constructive and progressive dietary consultation directly promotes early change in eating routines, and are also found to enhance outcomes from established treatment modules (233, 234).

Physical activity as treatment for ED

During the last decades, evidence for positive effects from physical activity on preventing or treating mental health issues, has been provided (21, 235). Although not always providing

explanations for causal relationship, positive relation between physical activity and quality of life (236, 237), cognitive function(237, 238), self-concept, self-perception, self-esteem, self-efficacy and body image (235, 238-242) in children, adolescents, adults and older people have been identified. Furthermore, there is good evidence for positive effects from physical activity in preventing and treating depression (21, 235, 243, 244), and for reducing trait anxiety or to alleviate symptoms in anxiety disorders (235, 244). Physical activity is socially accepted and desirable, reflects the interests of persons with EDs (i.e. controlling body weight and figure), is found to reduce cravings for binge eating(245, 246), incorporates clear guidelines for immediate initiation (early change), and allows for social interaction; hence – in summary, physical activity matches most of the criteria for successful treatment for EDs.

With increased awareness of the low levels of physical activity(247), high physical comorbidity and total mortality with severe mental illnesses(21), more efforts are put into finding motivational strategies to help patients with such challenges to increase their level of physical activity (20, 248, 249). However, until recently; there have been no suggestion for structured use of physical activity in treating EDs (21, 250). Instead, a reluctance for recommendation and implementation of physical activity during treatment has long been a fact(114, 117, 118). This may be due to unawareness of the impaired physical health in EDs like BN and BED, maybe due to an over concern for the very clear physical clinical severity in AN, with following consequences of being underweight and undernourished. Still most probably do the reluctance for physical activity in treatment of BN relate to the fear of exaggerating the characteristics of excessive and/or compulsive physical activity (103-105). Anyhow, recently clinicians and scientists have requested more attention to the potential positive role of physical activity in treatment of EDs(114, 118, 251), and suggestions on guidelines for such implementations have been presented (117, 252).

Proposed mechanisms from physical activity on mental health

A proposed conceptual model for effects from physical activity on mental health suggests the effects to be explained by neurobiological, psychosocial and behavioral mechanisms, all being moderated by the nature of the physical activity (figure 2).

The **neurobiological mechanisms** are proposed to be a product of structural and functional changes of the central nervous system. The suggested structural (*e.g. increased vascularization surrounding the neurons in the central nervous system, and changes in structure of brain cortical regions*) and functional changes (*e.g. activation of cytokines or other stimulating hormones or factors*), together with

neurobiological changes (*e.g. effects from neurotransmitter systems and endogenous opioids on wellbeing*) are not well proven or understood, and are only tentative explanations from theories based on observations and from animal studies(240). The **psychosocial mechanisms** contributes to increased wellbeing, by having physical activity improving psychosocial elements (*e.g. social connectedness, autonomy, self-acceptance, and environmental mastery*). However, importantly is proper instructions through physical education or guidance, to avoid the opposite effects like decreased perception of competence and global self-esteem.

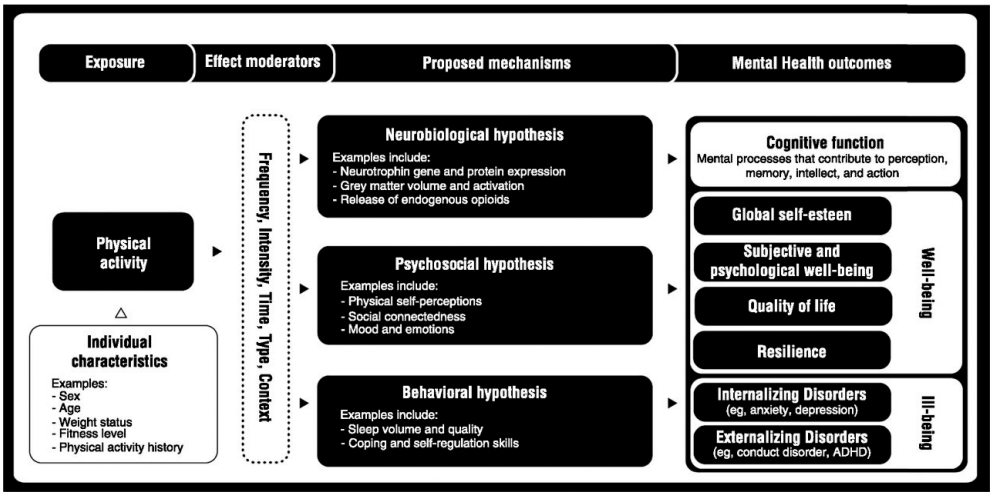

Figure 2: A suggested conceptual model for the effects from physical activity on mental health outcomes in young people.

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The **behavioral mechanism** relates to how physical activity can change relevant behavior; e.g. increase coping and self-regulation, hence finally improve mental health(240). The model found interim weak evidence for the neurobiological- and behavioral mechanisms, but available evidence to support the psychosocial mechanisms (*e.g. improved self-confidence, appearance self-perceptions and self-esteem*). Hence, with regard to risk factors for EDs (30, 33, 36), meaningful effects from regular physical activity in preventing, but also treating EDs, are provided.

Present knowledge on the effect of physical activity in treatment of EDs

Compelling evidence of successful implementation of guided physical activity during treatment of EDs exists, where the interventions neither did interfere with desirable weight gain in underweight persons, nor did result in negative treatment outcome (135, 246, 251, 253-255). Indeed, the feared negative association between physical activity and prognosis of treatment outcome from an ED, seems to be mediated from an original pathological motivation for exercise, rather than the exercise per se (114).

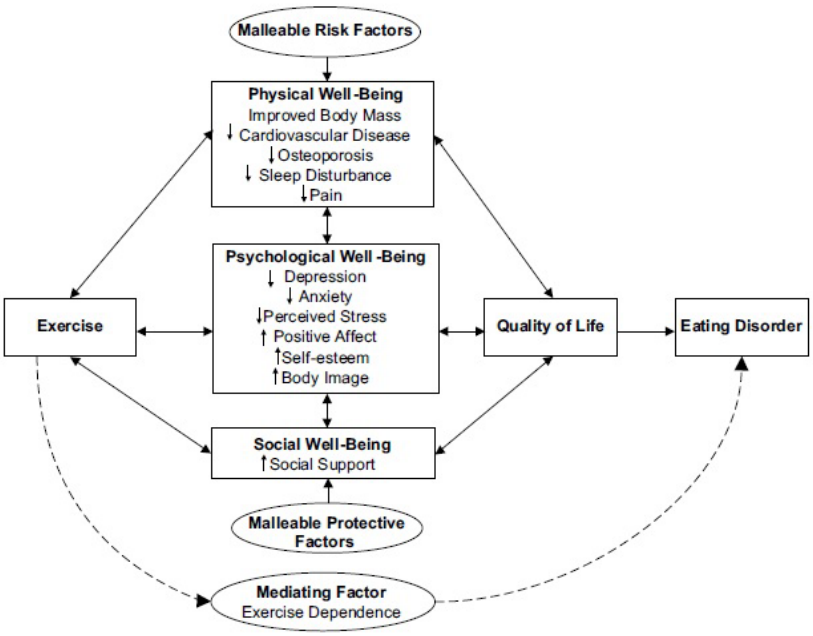

Figure 3: Conceptual figure on how exercise can prevent or treat EDs, with potential for reciprocal effects, by Hausenblas et al (114).

Reprinted with permission. From: Hausenblas HA, Cook BJ, Chittester NI. Can Exercise Treat Eating Disorders? Exercise and Sport Sciences Reviews. 2008;36(1):43-7.
http://journals.lww.com/acsm-essr/Abstract/2008/01000/Can_Exercise_Treat_Eating_Disorders_.9.aspx

The many potential positive effects in which physical activity contribute in preventing and treating EDs are intriguing, with many of the effects acting reciprocal (see figure 3). Nevertheless, few attempts exists to prove the efficacy of physical activity in treatment of ED's (Tabell 1). Challenging the interpretation of results from most of the current studies examining the effect from physical activity as single form therapy, are the lack of active treatment comparatives, no reports on remission, or no long term follow up. Nevertheless, physical activity have proved

comparable effective to CBT post-treatment in reducing cognitive elements of the ED and in reducing binge eating and purging, and superior to CBT at 18 month follow up(139).

When combining physical activity to usual psychological ED-treatment, several advantageous effects have been revealed, with the current findings suggesting effects on psychological- and social wellbeing most important (figure 3)(114). The effects relates to improvements in general ED-psychopathology (135, 239, 254-256) and in QoL(239, 254, 255), less exercise rigidity and compulsiveness(120, 255, 257), and reduced anxiety(245).

Table 1: Physical activity interventions in participants with BN or BED, as isolated treatment for BN or BED. Arranged according to year of publication.

Research group	Year	Diag-nosis	Age M(SD)	N/ sex (drop out)	Intervention	Duration (follow up)	Findings
Levine, Marcus, & Moulton (258)	1996	BED	36,6 (6,5)	77 ♀	Walking program (1000 kcal/week) or control group	24 weeks	Walking group reduced BE.
Sundgot-Borgen, Rosenvinge, Bahr, & Schneider (139)	2002	BN	~22 (3)	64 ♀ (5)	CBT, DT, PA (running in groups 1h/week) or control	16 weeks (6 & 18 months)	BE, purging, EDI-DT , EDI-BD: PA=CBT post-treatment, PA>CBT>DT 18mnths follow-up
McIver, O'Halloran, & McGartland (245)	2009	BED	40 (10,6)	71 ♀ (21)	Yoga group (60 min/week) or waitlist	12 weeks (3 months)	Yoga group reduced BES-score
Schlegel, Hartmann, Fuchs & Zeeck(255)	2015	ED	25	50 ♀ (14)	Exercise + psychotherapy or psychotherapy	13 weeks	Exercise ↓CES Both ↓EDE-q No Δ in BW, PA, EDI-BD or EDI-DT

NOTE: BED, Binge eating disorder; BN, Bulimia Nervosa; ED, eating disorders; N, number of participants; ♀, females; BE; Binge eating, CBT, cognitive behavior therapy; PA, physical activity; BES, Binge Eating Scale; DT, dietary therapy; CES, commitment to exercise scale; Δ, change; EDI- DT; EDI Drive for Thinness, EDI-BD; EDI body dissatisfaction.

Physical activity also brings about a positive attitude towards foods or eating (120, 246, 256). As such, it contributes in improving body weight regulation, by aiding in weight reduction in

overweight persons with ED(259), but also in improving rate of weight gain in underweight persons with ED(120). With mainly low impact activity in these interventions (e.g. yoga, walking, stretching, resistance exercise with low load), the effect on physiological aspects have been minor, still, there have been reports on improvements of physical fitness/performance or body weight(135, 239, 246, 251).

Appetite regulation by regular physical activity

Not addressed in the conceptualizing figure for effects from physical activity on risk of ED (figure 4), is the general improved appetite- and satiety regulation with increased levels of physical activity. These effects may explain the positive results from exercise interventions on appetite control(120) and reduction of binge eating(246, 256) in EDs. An early study of free-living, healthy men with different occupational activities, revealed a linear increase in ad libitum energy intake with increased energy expenditure at work, hence a relative stable body weight (figure 4) (260). The observations also revealed that the opposite situation was not correlated when energy expenditure was low, hence a tendency for weight gain due to the lack of correlated regulation of appetite and energy balance(260). Hence a J-shaped curve best describes the continuum of energy intake from energy expenditure. This implies that physical inactive individuals, living in societies and cultures where food is abundant, will not experience any optimal appetite regulation, and easily overconsume energy. This relationship between energy consumption and energy intake have also been confirmed in more recent studies(261, 262).

Appetite is controlled by several processes that signals hunger, satiation, and satiety. These processes are regulated by episodic- and tonic signals, with the former influenced by e.g. meal-size, and –frequency, and the latter stem from body tissues and cellular metabolism(261). While these homeostatic regulations interact with non-homeostatic regulations, like food hedonic and behavioral traits, physical activity have the potential to adjust both processes(261). The homeostatic processes may be influenced by physical activity due to adjustment of body composition and its effect on postprandial peptides, while the non-homeostatic processes involves reduced hedonic wanting for high-fat food (261-263). However, the mechanisms are not well understood, and there might be moderating effects like sex, obesity and exercise modality(263-265). Furthermore, while being physical active seems to aid in long term body weight regulation in both sexes, the overall effect on body weight regulation is variable, with biological variations in the regulating mechanisms of appetite and satiety causing individual different results(263).

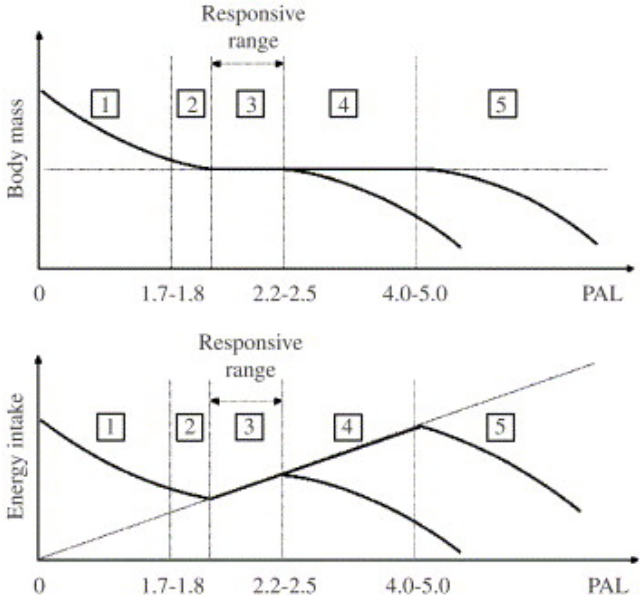

Figure 4: The relationship between energy expenditure and energy intake. *zone 1*: decrease in PAL and increase in sedentariness does not induce compensatory reduction in food intake and leads to increase in body mass; *zone 2*: introduction of acute physical activity on a short-term basis suppresses food intake, due to mobilization of stored fuels, and leads to decrease in body mass; *zone 3 (responsive range)*: moderate to intense physical activity performed regularly and on a long-term basis by lean individuals increases food intake accordingly and maintains body mass; obese individuals, due to their excess energy storage, do not show significant changes in food intake; the PAL level in the general population has an upper limit around 2.2–2.5 (*zone 4*), and in highly trained subjects around 4.0–5.0 (*zone 5*). Above these values, the human body is not capable to cover the high-energy expenditure, and loss of body mass occurs as a consequence.

Reprinted from Clinical Nutrition, 24/6, Katarina Melzer,Bengt Kayser,Wim H.M. Saris,Claude Pichard, Effects of physical activity on food intake, 885-895, Copyright 2018, with permission from Elsevier. Originally from: Mayer J, Roy P, Mitra K. Relation between caloric intake, body weight, and physical work: studies in an industrial male population in West Bengal. Am J Clin Nutr 1956; 4(2):169 – 75. 51

Dietary consultation as treatment for ED

Dietary consultants are found preferable professionals to most likely be consulted by persons with BN in initial help seeking behavior(175, 176), and their profession is also highly respected in treatment teams and clinics for ED treatment(224, 266). An important and crucial part of the CBT-program, is to establish stable eating routines during the first four weeks of treatment(67). Implementation of sufficient number of meals, regularity in meal consumption, and sufficient volume of food consumed, are assumed to be highly important to recess binge eating and purging episodes(224). Nevertheless, dietary consultation alone is not assumed to be adequate for

long-term successful treatment, as it does not directly target the cognitive perpetuating elements(52, 224, 266).

Contrary to the assumption of superiority of CBT to dietary counseling, are theories emphasizing the similarities between successful elements of CBT and ordinary practice of dietary counseling(267). Three theories are proposed as explanatory rationales for the effect from dietary consultation in treatment of EDs(267). The "*theory of restriction*" advocate the energy deficiency after restriction of food intake as the main cause for the symptomatic behavior in EDs. With restricted energy intake comes hunger, and with hunger comes cravings, finally resulting in a binge eating with or without compensatory behavior (267). The second theory "*negative affect regulation*" propose the learned positive experience of temporary relief from negative stress by binge eating, while the third theory propose purging episodes as a way of *physically reducing the level of uncomfortable stress*. Purging will result in energy deficiency, a cue for hunger and craving, increasing the risk of a new cycle of binge eating and purging (267).

While CBT mainly rests on the first two theories proposed, dietary consultation will do much the same. Dietary consultations typically focus on normalizing eating patterns, reducing restrictiveness and breaking myths about food, and on increasing knowledge and reliance on food diversity and sufficient energy, to maintain or even increase health outcome(266, 268, 269). Additionally, dietary consultation is much about (re)learning to recognize feelings of hunger and satiety, and as such to be able to recognize other cues to (binge)eat, to be able to take control over the eating behavior.

Present knowledge on the effect of dietary consultation in treatment of EDs

Findings on the effect from dietary consultation as treatment for BN or BED are inconclusive. Important distinctions between successful interventions(267, 270, 271) and less successful interventions(139, 234, 272) are apparently the duration of each therapy session and the content of the therapy (table 2). While focus on rapid weight loss and/or kcal-restriction seems less favorable for cessation of binge eating behavior and remission from diagnosis in BN (272), focus on health promoting diets and increased knowledge on food quality, awareness of hunger and satiety signals and of reason for craving cues, have proved more successful (267, 271). Such findings harmonize with the three theories of binge eating and how dietary consultation may aid in improvements (267). In treatment of BED, engagement for promoting body weight loss has induced interventions with very low kcal diets (VLCD). While considerable weight loss has been achieved during intervention(273, 274), most regain during follow up(273-276). Few of the

VLCD-trials measure outcomes that are related to diagnostic evaluation, still some suggest improvements (e.g. reduced binge eating frequency)(274, 276, 277), while other suggest risk of full blown diagnosis in diagnostic sub-threshold individuals after VLCD(277).

Detailed descriptions of progress, content and duration of successful dietary consultation interventions has been requested (278), and comparison to active treatment (preferable evidence based successful treatments) are needed to suggest any successful treatment effect from dietary counseling.

Table 2: Dietary therapy for BN or BED, with comparison group, reporting on treatment outcomes relevant for diagnosis. Arranged according to year of publication.

Research group	Year	Diagnosis	Age M(SD)	N/ sex (drop out)	Intervention	Duration (follow up)	Findings
Dalvitt-McPhillips(271)	1984	BN	-	20♀	Nutrient dense diet (NDD) or placebo diet (*diet as usual*)	8 weeks (2 years)	NDD ceased BE
Laessle, Beumont, Butow et al(267)	1991	BN	23,8 (3,8)	55♀ (7)	Stress management (SM) or nutritional counselling (NC)	3 months (6 & 12 months)	NC>SM in ↓BE: 50-60-56% NC 27-25-33% SM. SM>NC in psychopathology
Beumont, Russel, Touyz et al(270)	1997	BN	24 (5)	67♀ (18)	Dietary therapy (1h/week) with or without medication	8 weeks (12 wk FU)	Both interventions ↓BE and purging Superiority with medication lost at FU.
Grilo & Masheb(272)	2005	BED	46.3 (9.0)	90 ♀♂ (20)	CBT-gsh or BWL-gsh or control	12 weeks	CBT (58%)> BWL (18%) & C (13%) in remission
Burton & Stice(279)	2006	BN (+OSFED)	21 (5,3)	85♀ (16)	Diet-restriction (DR) (6 sessions) or waitlist (WL)	8 weeks (3 months)	DR = ↓BE & BWL Remission: DR (16%)>WL: (2%) (FU: 35% > 10%)

NOTE: BED, binge eating disorder; BN, bulimia nervosa; N, numbers of participants; FU, follow up; ♀, females; ♂, males; BE, binge eating; CBT-gsh, Cognitive behavior therapy group self-help format; BWL-gsh, body weight loss group self-help format; NDD, nutrient dense diet; CT, cognitive therapy; CNT, cognitive-nutritional therapy; SM, stress management; NC, nutritional counselling; WL, waitlist; DR, diet restriction; BWL, body weight loss; FU, follow up.

The addition of dietary consultation, or physical activity, to ordinary CBT have proved more beneficial than the effect from each separately (233, 234, 259, 280). Often combination of two or more treatment methods has the potential to amplify the treatment effect (281), and as such; the combination of methods that separately do not achieve satisfactory results, can give rise to successful outcome. While most such combination therapies find amplified effects(234, 259, 280, 282), some do not(233, 283) (table 3).

Nevertheless, in the request for a wider treatment availability, other disciplines besides psychotherapy need to be evaluated. Hence, a combination of treatment approaches involving psychotherapy do not circumvent the challenge with access to qualified and evidence based treatment.

Dietary counseling remain an important part of treatment in multidisciplinary teams and in the preferred evidence based treatment of EDs; CBT. It has been found crucial for successful effect from the consecutive psychotherapy in CBT (52), and to amplify treatment effects from psychotherapy(234, 280, 282). Concurrently; physical activity efficiently improves or treats mental health issues (21, 235, 238-242) relevant for comorbidity and psychopathology in EDs, hence; carries potentials for effects in treatment of EDs (figure 3 & 4) (114). Albeit, there has been no attempt so far, to combine guided, progressive physical activity and dietary therapy as treatment for EDs, and to compare the effects to evidence based treatment and control condition.

Table 3: Combination therapies for BN or BED, combining physical activity, dietary counseling and/or psychotherapy, and with comparison group. Arranged according to year of publication.

Research group	Year	Diagnosis	Age M(SD)	N/ sex (drop out n)	Intervention	Duration (follow up)	Findings
Pendleton Goodrick, Poston et al(259)	2001	BED	45	88 ♀ (4)	CBT with or without maintenance or CBT + physical activity with or without maintenance	4 months + 6 months maintenance (6mnd FU)	Maintenance amplify treatment effect. Physical activity amplify treat.effect
Hsu, Rand, Sullivan et al(234)	2001	BN	24,5 (6,4)	100 (27)♀	CT (60 min) or NT (60 min) or CNT (120 min) 2 times*2 weeks, 1time*12 weeks	14 weeks	CNT≥CT≥NT. Remission: 52% CNT, 35% CT, 17% NT,
Painot, Jotterand, Kammer et al(233)	2001	BED	42 (2)	62♀ (2)	CBT or CBT-DT	12 weeks	No additional effect from DT on psychopathology
Fossati, Amati, Poinot et al(280)	2004	BED	40 (5)	63♀ (2)	CBT or CBT-DT or CBT-DT-PA	12 weeks	All improves in ED CBT-DT-PA improves more in mood & BWL
de Zwaan, Mitchell, Musell et al(274)	2005	BED	39.3	71 ♀	VLCD or VLCD+CBT	24 weeks (1, 6 & 12 months)	Both ↓BE & BWL BWL regain in FU
Brambilla, Samek, Company et al(282)	2009	BED	46(9)*	35♀ (5)	CBT+Med1&2+DT(1) or CBT+Med1+DT(2) or CBT+NT(3)	6 months	Only 1 & 2 improves in psychopathology
Grilo, Masheb, Wilson et al(283)	2011	BED	45 (10)	125♀♂ (39)	CBT vs BWL vs CBT-BWL	24 weeks (12 months)	BWL = CBT in ↓BE No additional effect from combination

NOTE: BED, binge eating disorder; BN, bulimia nervosa; N, numbers of participants; FU, follow up; ♀, females; ♂, males; CT; cognitive therapy NT; nutrition therapy CNT; cognitive & nutrition therapy; Med; medication; BE, binge eating; DT, dietary therapy; PA, physical activity; CBT, cognitive behavior therapy; WL, waitlist; BWL, body weight loss

Aims of the thesis

The overall aim of this PhD thesis was to evaluate the effect of a new treatment method for women with BN or BED, combining guided physical exercise and dietary therapy (PED-t), being offered as group therapy. The novel treatment method is compared to the effect of CBT and a waitlist control group. The specific aims of the separate papers were the following:

1. To describe the rationale for, and the specific study protocol from, the PED-t trial **(Paper I)**
2. To describe the physical fitness in women with BN or BED more thoroughly than previously described in the literature. We aimed to describe the physical fitness with a wider range of variables and with the use of objective measures, to compare the findings to normative or recommended values, and to evaluate the effect of a previous diagnosis of AN on physical fitness **(Paper II)**
3. To investigate the acute and long-term effect from PED-t or CBT on compulsive exercise and level of physical activity **(Paper III)**
4. To investigate the acute and long-term treatment effect from PED-t or CBT on remission from ED, ED symptomology, and measures of mood and life quality **(Paper IV)**

Methods

This thesis and the four papers which it is based on, are the first quantitative official results from the PED-t trial. The PED-t trial was designed to evaluate the effect of a new treatment method for BN and BED, specially designed by the research team in which the PhD candidate belongs.

Study design

This trial was designed with 20 therapy sessions covering a period a 16 weeks, in which participants received either CBT or physical exercise- and dietary treatment (PED-t) in groups of 5-8 participants, each arranged at the Norwegian School of Sport Sciences (NSSS).

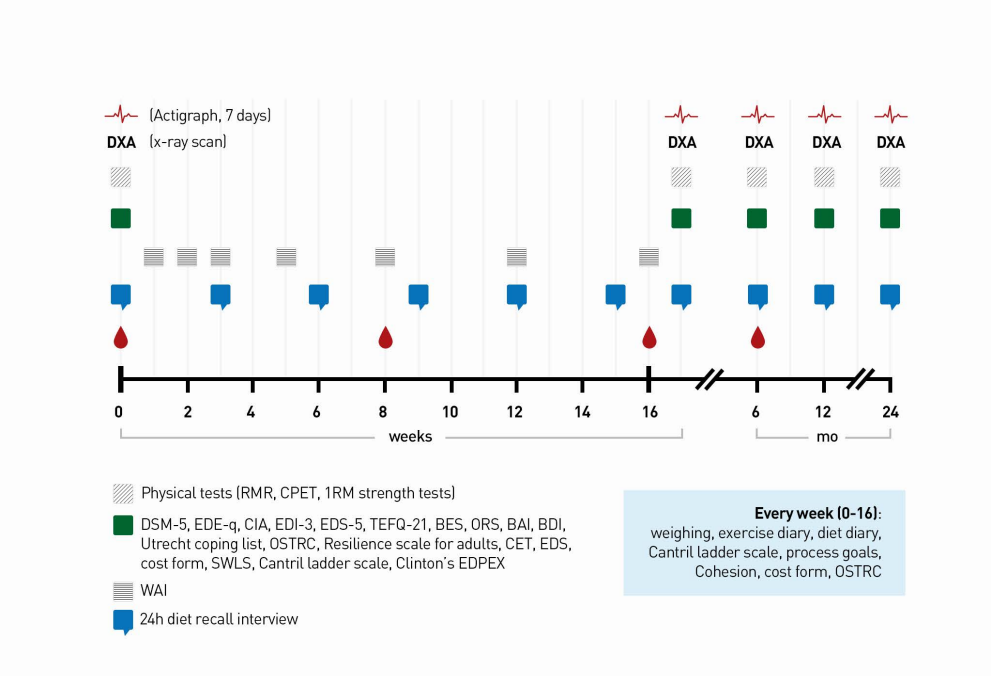

Figure 5: Overview of study design, with baseline measures before treatment initiation (week 0), a total of 16 weeks of treatment, followed by post-treatment evaluation at week 17. Thereafter follow up measures; 6 months, 12 months and 24 months after end of treatment. Each time point with measures includes the identical battery of evaluations, illustrated by the coloured boxes. The different coloured boxes includes different set of tests, and each test are explained in abbreviated form in the figure, and in details in the text.

Treatment effects were compared by measuring within-group changes from baseline to post-treatment periods, and between-group differences at post-treatment periods. Outcome variables were measured five times: baseline measure (T1) held 1-2 weeks before treatment initiation, post-treatment (T2) held 1-2 weeks after last treatment , and 6-, 12- and 24 months post-treatment (T3 – T5) (Figure 5). Additionally, temporary outcomes and process evaluation were measured by self-reported questionnaires after each treatment session.

For the purpose of this thesis, only selected outcomes from T1-T4, relevant for the issues raised in the four papers, are described in details; others only briefly mentioned.

Recruitment

Females with BN or BED were recruited for participation, by distribution of information through GP's, and through articles and advertisement in magazines, websites of the ED patient organizations, newspapers, national TV, social media, and posters. Interested were encouraged to make contact by email or phone. The investigator re-contacted interested by phone call to inform about the project purpose, and to screen for participation using inclusion and exclusion criteria by general interview, and by using the Mini International Neuropsychiatric Interview screening(284) and the Eating Disorder Examination (EDE-q)(5, 54, 285) (Fig. 6). After the screening interview, eligible persons had a written information and informed consent emailed, and were asked to sign them and bring them at the first visit to NSSS (baseline measures).

Included participants had diagnosis finally confirmed during baseline measures (T1) based on repeated self-reported information by the EDE-q, and by written self-reported behavior according to DSM-5 diagnostic criteria, finally confirmed by clinical assessment by project fellow worker, experienced in ED treatment.

Inclusion and exclusion criteria

Inclusion criteria for treatment participation were being female aged between 18–40 years, a BMI in the range of 17.5–35, a DSM-5 diagnosis of BN or BED with duration of at least 3 months, and with mild to severe symptoms (minimum one episode per week of compensatory behaviors or binge eating, respectively)(5).

Women not eligible were those who were or planned to become pregnant during the treatment period and those who were competitive athletes. Also excluded were those who had a concurrent

severe symptom or personality disorder in need of other treatment options. To prevent effect diffusions we also excluded individuals who had received CBT for ED during the last two years before the trial.

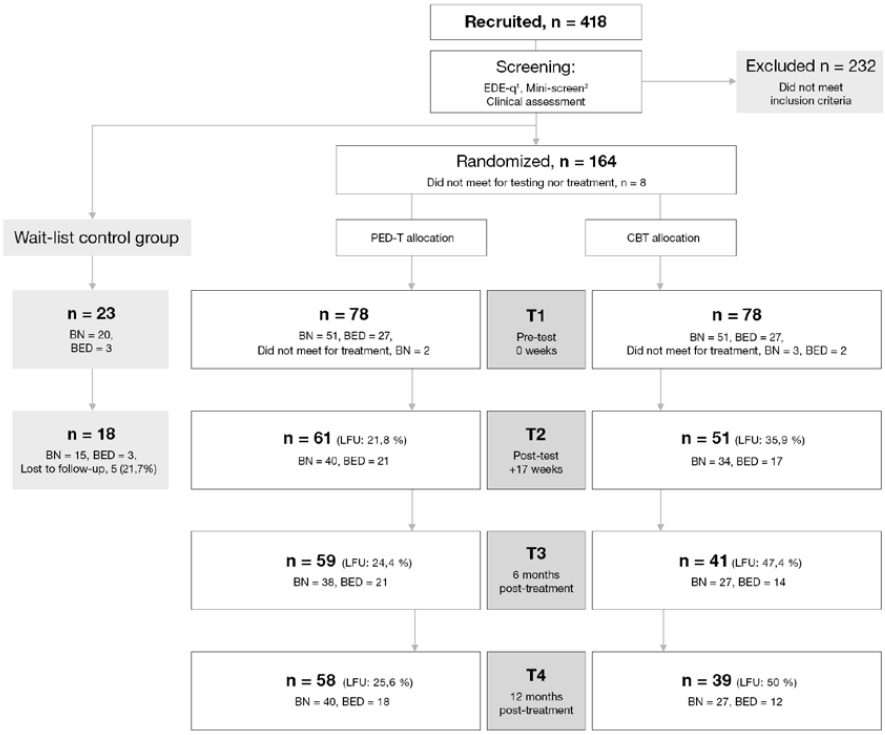

Figure 6: Screening and randomization for treatment, or waiting for randomization to treatment (control group), and attendance at the evaluation times (T1-T4). *Notes:* EDE-q, Eating Disorder Examination questionnaire; BN, bulimia nervosa; BED, binge eating disorder; LFU, lost to follow up; [1]Fairburn et al 2008 (286); [2]Shenan et al(284).

Reasons for only including females, were the low ratio of males-to-females in occurrence of ED, and as such to ensure optimal group climate and coherence with a group therapy format. Age was limited in range due to practical reasons; i.e. a lower limit of legal age (18 years) and an upper limit of age to ensure optimal group climate and coherence (limiting range of age). BMI was limited in range, not only to ensure group coherence, but also to avoid risk of harmful effects from a non-individual adjusted exercise routine if randomized to PED-t.

Furthermore, reason for excluding pregnant females is obvious reasons; i.e. to avoid harmful effects from exercise if randomized to PED-t, and any harmful effects from the testing procedures (DXA, maximal efforts in CRF and strength tests). Competitive athletes were excluded due to the nature of the treatment program, i.e. not individual adjusted according to competitive needs; neither in diet nor exercise.

Signed informed consents

Final inclusion was based on four written and signed declarations, i.e., the informed consent by the woman to take part in the trial and the assessment procedures herein, a declaration of mutual secrecy about personal information revealed in the group treatment sessions, an informed consent regarding videotaping of treatment sessions, and a signed consent from their GP that they were medically fit to participate. These documents were returned personally upon the first visit to the treatment- and test facilities (NSSS).

Randomization

We enrolled participants for randomization to treatment groups semiannually for totally 6 seasons (2014-2016), and participants were randomized by block size of eight to receive either CBT or PED-t treatment. The block size was used to reflect the ideal size of treatment groups, ensuring an even distribution of participants in each treatment condition. The randomization list was created by independent colleague not engaged in the trial at www.randomizer.org in 2014, and organized in numbered, concealed envelopes delivered to the Head of Office at Department of Sports Medicine at the Norwegian School of Sports Sciences (also not engaged in this trial). A list of participants, being screened and ready for randomization, was delivered semiannual to the Head of Office for group allocations. The group allocation was then communicated to participants by email *after* the baseline measures in front of treatment initiation.

Researchers and test personnel in the study were blind with regard to group allocation, but due to the nature of the two treatment procedures, therapists and participants are obviously not blinded to the treatment allocation. The participants were informed about their group allocation after completing the baseline measures.

A control group was represented by participants placed on a waitlist (i.e. not randomized) during recruitment- and treatment periods. Reasons for being placed in the waitlist control group were:

being recruited after the semiannual randomization and treatment initiation, choosing to wait due to personal reasons, or not able/willing to attend the treatment due to distance to the treatment facilities, still willing to serve as a control.

Ethics

The study has been approved by the Norwegian Regional Committee for Medical and Health Research Ethics the 16th of December 2013 (ID: 2013/1871) and prospectively registered in Clinical Trials the 17th of February 2014 (ID: NCT02079935) (*see appendices*). All included participants, and their general practitioners, signed informed consents before treatment initiation, in addition to signing declaration of confidentiality with respect to the group treatments, and informed consent about being videotaped during treatment (only for the purpose of treatment-per-manual evaluation by the scientific team) (*see appendices*).

Safety procedure

We planned for a stop-procedure during treatment if included subjects displayed a worsening of ED symptoms (e.g. a BMI < 17.0 and/or rapid and significant weight loss of more than 3 kg from normal weight), severe depression, or if severe osteoporosis was identified among those randomized to PED-t. Individuals excluded for any of these reasons would be medically evaluated for admittance to health care services. However, we did not find it necessary to apply such procedures, as none of the included participants displayed any of the described situations.

If participants reported not to have been eating properly before exercise sessions in the PED-t groups, or if feeling ill, we did not allow the participant to participate in the exercise session that day. During the pre- and post-tests, if participants reported severe purging or restrictive eating in the days before, no physical tests were performed. A defibrillator was available in the lab where physical tests were held, and a medical health care team was available next house if help was needed.

Test procedure and outcome measures

Each participant were invited for one single test day during each of the testing periods (T1-T5), and up to six participants were measured each day. Participants were instructed to meet fasting and to arrive by passive transportation to the laboratories at the NSSS during 07.30AM -

10.00AM. The test procedure was the following: DXA, RMR, blood sample, breakfast pause with questionnaires, clinical assessment interview, dietary recall interview, CPET and 1RM strength tests.

Body composition and bone mineral density

Participants were weighed in their underwear and height was measured with a fixed stadiometer (Seca scale, Mod: 8777021094, S/N: 5877248124885). A **d**ual-**e**nergy **x**-ray **a**bsorptiometry (Lunar iDXA, GE Healthcare, enCORE Software, Version 14.10.022) performing a three site scan (lumbar L2-L4, femoral neck, −trochanter and –shaft [proximal femur], and whole body scan) was used to measure body composition (fat mass, body fat percentage [%BF], visceral adipose tissue [VAT], lean body mass, android-gynoid fat mass ratio [AG-ratio], bone mineral content, and bone mineral density [BMD]). All measures were performed and analyzed according to guidelines(287).

Resting metabolic rate

Immediately following the DXA-scan, resting metabolic rate was measured by indirect calorimetry. No further details of RMR measures are presented herein, as these outcomes are not part of this thesis.

Hormonal- and nutritional status evaluation

Blood samples were collected by qualified lab personnel and stored frozen at NSSS for future analyzes in a certified lab. Samples were drawn at T1, week 8 of treatment, T2 and T3. Due to financial shortcomings, the blood samples were kept frozen at the time for this dissertation, and therefore details about procedures are not included.

Cardiorespiratory fitness and muscle strength

Cardio pulmonary exercise test (CPET)

One to three hours after completing DXA and consuming their personal breakfast, lung function, maximal voluntary ventilation, resting blood pressure and maximal oxygen uptake were measured. The results from the two former are not presented in this thesis; hence not further explained herein.

Resting blood pressure was measured twice according to a standardized protocol(288) with an automatic blood pressure device (Spot Vital Signs LXi; Welch Allyn, Skaneateles Falls, NY, USA). The average recordings were used.

CRF was measured by performing cardiopulmonary exercise test (CPET) on a treadmill (ELG 90/200 Sports; Woodway, Weil am Rhein, Germany) with an incremental modified Balke protocol until exhaustion(289). The CPET started with three minutes steady-state measurements and habituation to the treadmill at 4% inclination and a walking speed of 4.5 km/h. The protocol instructed a constant uphill walking speed of 5 km/h and progressively increased inclination by 3% every minute; up to 15 %. If the participant was still able to continue, the speed increased by 1.0 km/h until the participant reached exhaustion. Gas exchange and minute ventilation (VE) were measured continuously, breath-by breath, while breathing into a Hans Rudolph two-way breathing mask (2700 series; Hans Rudolph Inc, Kansas City, USA), connected to an OxyconPro analyzer (Jaeger, Würtzburg, Germany). A capillary blood sample was taken one minute after test termination and analyzed immediately in a 1500 Sport lactate analyzer (YSI Incorporated, Yellow Springs Instruments Company, Ohio, USA).

Respiratory exchange ratio (RER) ≥ 1.10 and lactate concentration ≥7.0 mmol/L were used to approve a valid VO_2max(289). If any of these measures were missing, a Borg scale rating ≥17 was used to support approval of valid test result(290, 291).

Maximal muscle strength (one repetition maximum, 1RM)

Maximal strength tests followed the CPET in the following order: squats in machine, bench press, and seated cable row. All of the three 1RM-tests were performed according to predefined performance criteria, and initiated with standardized warm up sets of 10 – 8 – 6 – 4 repetitions. The 1RM was determined during 1-4 following attempts separated by two minutes rest, in which the loads were increased by 1.5 – 10 kg until failure.

Physical activity

Sedentary time and physical activity were objectively measured for seven consecutive days using the ActiGraph accelerometer (ActiGraph GT3x and GT3x+, Actigraph, LCC, Pensacola, Florida, USA) placed on their right hip. It was only removed for water activity and night-time sleep. All accelerometers extract data from the vertical axis in 60-second epochs with 30 Hertz sampling rate. Non-wear time was determined as continuous zero count epochs lasting at least 60 minutes

(allowing for two exceptions). Wear days were deemed valid if worn for at least 600 minutes/day, and a minimum of two valid days. Intensity-specific PA were derived using the Troiano cut-points(127), and continuous bouts of moderate-to-vigorous physical activity (MVPA) were determined by summing minutes of at least moderate intensity that were a part of a bout of MVPA minutes lasting at least 10 minutes (allowing for two drops in intensity before terminating the bout).

Questionnaires

Standardized instruments with good psychometric quality and high clinical utility were included during test-periods and treatment weeks, respectively (figure 5). Questionnaires from treatment weeks were answered directly after each treatment session, still being in the group setting and concurrently with the weigh in procedure in both treatment groups. Questionnaires from test-periods were answered at the test day, during the breakfast pause, while resting in a group meeting room.

Questionnaires for test periods

During the test day for each of the test periods (T1-T5) a printed sample with all the following questionnaires were answered by self-report. Questionnaires not relevant for this thesis and its publications are only listed, while those used for publications are here presented in details:

- A diagnostic questionnaire according to the **DSM-5 diagnostic criteria** for BN and BED (*composed by our research team*)(5) (**Paper II-IV**)
- **Questionnaire about personal** menstrual history, training experience, history of eating disorders, history of treatment, current occupation, living- and family situation, current use of medications, and information on any additional treatment received during follow up (*composed by our research team*). (**Paper II-IV**)
- **Eating disorder examination questionnaire, EDE-q** (286) (**Paper II-IV**)

  The EDE-q 6.0 (Cronbach's $\alpha = 0.87$, T1 current study) validly assesses the frequency and severity of ED features to produce ED diagnoses according to the DSM-5(5, 54-56, 285, 286). Apart from a global score, four subscales measure eating restraint (ER), eating concern (EC), shape concern (SC), and weight concern (WC). Mean (SD) global score for a

Norwegian cohort of healthy female controls is 1.25 (1.10), while corresponding national clinical cut-off for probable BN and BED are 2·62, and 2·63, respectively(292).

- **Compulsive exercise test, CET**(293, 294) (**Paper III**)

  CET assesses the core features of compulsive exercise in EDs, i.e. continuance (e.g. continue to exercise despite injuries or illness), affect regulation (exercise brings about negative or positive reinforcement), weight and shape driven exercise (e.g. exercise to burn calories, or to reduce body weight), and exercise rigidity (repetitive exercise routines) (Cronbach's $\alpha = 0.84$ based on T1). CET is a 24-item instrument scored on a 5-point Likert scale (0 = never true, 5 = always true), and evaluated with five different subscale mean scores (avoidance and rule driven behavior, weight control exercise, mood improvement, lack of exercise enjoyment, and exercise rigidity), and a global score summing the means of subscales (score range 0-30). CET has proved good internal consistency and content validity, in healthy samples and in adults with ED, with a suggested global cut-off score of 15, where higher scores indicate more compulsivity (293, 294).

- **Beck's depression inventory, BDI-Ia** (295) (**Paper IV**)

  The BDI-Ia (Cronbach's $\alpha = 0.86$, based on T1) measures current (past two weeks) self-reported symptoms of depression(296). It consists of 21 items scored with a 4-point Likert scale ranging from 0 (not at all) to 3 (extreme). Total score range is 0-62, and a cut-off score of ≥21 is suggested to detect a clinically significant episode of major depression (295).

- **Satisfaction with life scale, SWLS** (297) (**Paper IV**)

  SWLS is a short 5-item scale measuring contentment with life, scored with a 5-point Likert scale ranging from 1 (never true) to 7 (always true) (Cronbach's $\alpha = 0.89$, based on T1). The total score is summarized and evaluated in 6 sub-categories: Very high score (Highly satisfied) (30-35 points), high score (25-29 points), average score (20-24 points), Slightly below average (15-19 points), dissatisfied (10-14 points), extremely dissatisfied (5-9 points). An age-matched mean normative value from a Norwegian cross sectional health investigation is 26.3 (298).

- **Clinical Impairment (CIA 3.0)** (299) (**Paper IV**)

  The CIA 3.0 (Cronbach's α = 0.90, T1 current study) is a self-report instrument to measure personal, social, and cognitive impairment due to the ED (299). The CIA consists of 16 items scored on a 4-point Likert scale ranging from 0 (not at all) to 3 (a lot) during the past 28 days. Within the 0-48 total score range 16 has been suggested as a clinical cut-off score (299), while mean (SD) normative values from gender-matched, healthy Norwegian sample was 6.4 (7.5) (300).

- **Working Alliance Inventory** (301) (**Paper IV**)

  The WAI-short form is a 12-item scale, scored with a 7-point Likert scale, and measures clients perception of alliance with therapist (301) (Cronbach's α = 0.90, week 1 in treatment in current study). It captures the patient's perception of the help offered by the therapist, by measuring the feeling of being liked and understood, the feeling of a common consensus on the goal of the treatment, and whether the patient believes the therapy will be helpful.

Other questionnaires from test periods, but not used in the included papers: Eating disorder Inventory, EDI-3 (302), Three factor eating questionnaire, version 21, TFEQ-12 (303), Binge Eating Scale, BES(304), Outcome Rating Scale, ORS (305), Cost form (reports of individual costs related to the attendance for the testing situation, *composed by our research team*), Expectations and Experiences of Treatment in Eating Disorders, EDPEX(306), Oslo Sports Trauma Research Center's questionnaire for health and injuries(307), Exercise dependence scale, EDS (308) Cantril Ladders' scale for Quality of Life (309), Beck anxiety inventory, BAI (310), Eating disorder scale No. 5, EDS-5 (311), Utrecht coping list (312), Resilience scale for adults (313)

Qualitative approaches, i.e. in-depth interviews, to give insights into ED-patients' perspectives and satisfaction with treatment (314), and physical therapists experiences of competence in treatment of BN and BED, were planned and completed during 2015-2018 (315).

Questionnaires in treatment weeks

In addition to a self-reported weekly overview of physical activity routines in both treatment groups, the PED-t group kept a detailed training diary recording compliance and intensity for the interventional exercise routines. A process evaluation form, asking for ED behavior, weight and shape concern (questions from EDE-q), life quality satisfaction by Ladder scale(309) and

experience with group cohesion (316) were answered directly after each treatment session. So were also a cost form (reports of individual costs related to the attendance for the testing situation, *composed by our research team*), Oslo Sports Trauma Research Center's questionnaire for health and injuries(307), Working Alliance Inventory and the "Coerciveness" subscale from the "Therapeutic Factor Inventory" scale(316, 317).

Energy balance and nutritional intake

Food- energy- and nutrient intake were recorded in both treatment groups through repeated 24-h dietary-recall interviews (T1, week 3, 6, 9, 12, 16, T2-T5). Body weight change was measured weekly throughout treatment, in addition to weigh-in during testing days. Further details are not given, as these results are not included in papers in this thesis.

Clinical assessment

All participants were assessed by interview according to the DSM5 diagnostic criteria by experienced clinical therapist during each test-period. Interviews were either conducted face-to-face during the test-day, or by telephone one of the first days following the testing.

Treatment protocols

The physical exercise and the dietary therapy (PED-t)

The PED-t is a treatment method particularly designed for BN and BED by our research group. The therapy adheres to recent guidelines developed from systematic reviews to successfully use therapist guided physical exercise in ED-treatment (252), recommendations for a minimal training volume to accomplish a health benefit (113, 318), the Nordic and Norwegian recommendations on dietary and nutritional composition (318), and sports nutrition as promoted through international consensuses (319, 320). The intervention aimed to (re)establish healthy eating and exercise routines, to change body ideals by focusing on the body's functionality rather than body appearance, and to provide knowledge about the harmful metabolic effects of shifts between dieting and non-dieting periods with corresponding fluctuations in body weight. Besides information on general nutrition, education about harmful effects of unhealthy dieting- and exercise behavior was given, while emphasizing how basic and sports related nutritional needs may be implemented and balanced. One responsible dietitian and two vicarious dietitians held the

dietary therapy, while in total seven physical trainers were engaged in the physical exercise team during 2014-2016. Per treatment group, three physical trainers and one dietician conducted the intervention, all being specialists in physical exercise and dietetics, holding a bachelor- or master degree in dietetics, or in exercise medicine.

A detailed treatment manual, *The PED-t treatment manual*, were made before the trial initiation, and may be available at request.

Physical exercise

The weekly exercise program in PED-t aimed to establish a healthy volume of physical activities, emphasizing the training principles of progression and load variation. The exercise program consisted of three weekly exercise sessions, each of 40–60 min' duration. Two sessions were resistance exercise, of which one was supervised. The third exercise session consisted of unsupervised pyramid interval running, involving shifts between intensive work periods and active rest-periods with progressive duration (from one minute work period to four minutes of work). In addition to the weekly exercise sessions, participants were encouraged to comply with the recommendations for physical activity (113, 318).

There are three main reasons for presenting resistance training to the participants. The arguments relate to the cognitive nature of ED's, still also targeting physical/metabolic complications either suspected or found to be related to the BN or BED behavior. First, regular resistance exercise may improve metabolism and bone mineral density, and increase muscular mass and strength (113, 321-323). Change in body composition further increases the potential for improvement in energy metabolism, weight control and metabolic status (321, 324). Second, the repeated bouts of supervised resistance exercise, involving technical guiding/corrections while lifting may improve body posture and awareness(325). Third, strength training involves easily coordinated movements, which may increase the likelihood of positive experience of mastery and weekly progression in performance. These bodily experiences during and after a period with exercise training, have potential to improve body image, self-perception, affect regulation and feeling of coping(326-330). Intensive work periods, followed by active recovery periods, as practiced with interval training may improve physical fitness more effectively compared to the extended exercise regimen often seen in ED (331-334).

The physical strength-training program intended to improve maximal strength and muscle hypertrophy. It was divided into five micro cycles with both linear and daily variation in training

load(335). Linear progression involves increased intensity and reduction of training volume over a period of time, with the objective to increase maximal strength. Each week consisted of one supervised heavy load, and one unsupervised medium load session. In the former, the absolute loading increased progressively during the 16 weeks (corresponding to 10RM during first weeks and 2RM towards the end of the training period), while in the medium load session, relative load was kept constant at 10RM (table 4). The exercises in the resistance exercise program were squats in smith-machine, lunges with dumbbells, seated dumbbell shoulder press, bench press, latissimus pulldown and seated row in cable machine (*see appendices*).

Table 4: Overview of the exercise module of the PED-t treatment arm. Resistance load is given as number of repetition maximum (RM).

		Supervised exercise	Unsupervised exercise	
Week	**Microcycle**	**Resistance exercise**	**Interval running**	**Resistance exercise**
1-3	1	10RM	Pyramid interval	10RM
4-7	2	8RM	Pyramid interval	10RM
8-11	3	6RM	Pyramid interval	10RM
12-14	4	4RM	Pyramid interval	10RM
15-16	5	2RM	Pyramid interval	10RM

The intensity and work periods in the interval running program, followed a traditional pyramid structure performed with progressive interval periods and active rest periods, and then repeated in reverse. After a 10 min warm up, the interval periods were initiated by the first work period of 1 min and a 30 s active rest period (lower intensity), followed by the next work periods of 2 and 3 min and their corresponding rest periods of 60 and 90 s respectively. During the last six weeks, an extra interval period added to the program with 4 min of work and 2 min of active rest (*see appendices*).

During the mid-period (week 8–11) a supervised fourth, weekly group exercise session was introduced, leading the participants to do both the resistance exercise sessions unsupervised. The intention of introducing the participants to the fourth, additional exercise sessions was to inspire them to find a variety of training modalities that can improve physical fitness and promote training joy and motivation. Further, the intention with the group sessions was also to make them more experienced in exercising together with others, supervised by an instructor. The four sessions were Total body Resistance eXercise (TRX) suspension training or Cat slide exercise, one boot camp session, one indoor cycling class, and one combat inspired session.

Dietary therapy

The dietary therapy consisted of three modules (table 5), aiming to re-establish healthy dietary routines through weekly lectures, and on discussions related to the weekly topics and the experiences by the participants. For insight into main topics covered in the lectures, see table 5.

Table 5: Overview of the content of the dietary module of the PED-t treatment arm.

Module	Therapy session	Targets	Main content
1	1 – 5	Dietary routines & structure	Meal frequency and portion size Eating situation/milieu Exercise theory Repetition and summary
2	6-17	Nutritional knowledge & practical skills	Energy needs Daily routines Nutrients Nutritional labels Impulsive food shopping Exercise theory Sports nutrition Repetition and summary
3	18-20	Summary of future plans	Reflections, repetition and summary Presenting a personal plan for the future (exercise, diet, daily routines)

Between every session, the participants registered the meals they were consuming (pen and paper), and worked on individual tasks related to dietary routines (increase number of meals per day, increase volume of food in each meal, improve the composition of the meal etc.).

The cognitive behavioral therapy (CBT)

The manual-based CBT followed a group format, and rests on a transdiagnostic model positing generic core ED-characteristics across ED-diagnoses) (195). The therapy ran through four stages (table 6); 1) engagement and behavioral change, 2) monitoring and evaluating progress, 3) addressing the core pathology of ED, and 4) relapse prevention.

Table 6: Overview of the cognitive behavior therapy (CBT) module

Stages	Therapy session	Targets	Main content
1	1-4	Engagement, preparation and early behavior change	Educate about the nature of CBT and how the therapist and the participants work together Engage the participants in the treatment. Develop a case formulation for each participant. Strategies to take control over the behavioral symptoms of BN and BED
2	5-6	Monitoring and evaluating progress and barriers to change	A detailed review of progress so far, and to identify barriers to change
3	7-16	Modifying the core pathology of ED	Reduce the over-evaluation of weight and shape Address extreme dieting, binge eating, and purging
4	17-20	Consolidating change and relapse prevention	Secure that progress is maintained after treatment end

Participants in CBT received no exercise guidelines other than encouragement to comply with a healthy lifestyle. However, if needed, exercise used as a compensatory behavior was addressed. In

total five therapists were engaged in respective CBT treatment groups, and all were trained and coordinated by one, responsible therapist. All sessions were videotaped and coded according to a CBT manual adherence form (336).

Statistics

Power calculation

Analysis of covariance (ANCOVA) was used to raise statistical power. The effect size of the covariates was set to R2 = 25%, alpha = .05 and 1-beta = .80. The CBT treatment effect for EDs using the Eating Disorder Examination Questionnaire is about d = 1.30(195). A small change (d = 0.30) in the wait-list condition requires 14 subjects in each group (total N = 28), but since the difference between the PED-t and CBT treatment conditions was of primary interest a non-inferiority margin of d = 0.45 was considered as clinically relevant (337). This required a sample size of 62 + 62 subjects, increasing to 72 + 72 when adjusted for the group therapy factor (intra-class correlation = .05, design factor 1.16).

Data were processed differently for each paper due to the nature of the research question, results and corresponding analysis. Details are presented below, and related to the different papers. The first paper is a protocol description, and therefor includes no statistics or calculations.

Paper II

For evaluation of the physiological variables where mean values of norms and recommendations were attainable, and with reference to the more descriptive purpose of this study, a liberal 99% confidence interval was created, to enable statistical comparisons.

Multiple linear regressions were calculated separately for BN and BED to identify models to explain %BF, VAT and bone mineral density in spine and in proximal femur, respectively. Excluded from the models were variables that were statistically non-significant in the bivariate correlations.

Inspection of the scatter plot of VAT and %BF indicated a distinct bend in the curve at roughly the same location as previously reported in a piecewise regression model (i.e., at 38.8% BF)(338). We therefore performed a similar analysis, and searched empirically for the cutoff point that maximized *R*-squared (explained variance) in our study. The piecewise regression model was

specified as $f(VAT) = b_0 + b_1 BF\% + b_2 BF\%_{high}$. $BF\%_{high}$ was coded as

$\begin{Bmatrix} BF\% \; if \; BF\% \geq 0 \\ 0 \; if \; BF\% < 0 \end{Bmatrix}$, 0 representing the centered BF% value around the chosen cutoff.

Excluded from analysis were participants if errors occurred in the registration of physical parameters, and 30 participants in presentation on history of body weight fluctuations, due to missing self-reports.

Participants with a history of AN were compared to those with no such history by analysis of variance and Mann-Whitney U test. Due to multiple comparisons, a Bonferroni correction (p = .05/17 tests) was used to reduce the family-wise error rate and p-values < 0.003 were interpret as significant. Standardized mean differences were calculated as Hedge's g (339). These effect sizes were interpreted as small, moderate or large if larger than 0.2, 0.5 or 0.8, respectively. Excluded from analysis were 19 participants due to missing information on history of AN.

Paper III and IV

All analyses were conducted in SPSS version 24 (IBM, Armonk, NY). Linear mixed regression models were built to estimate the between-group differences (PED-t vs. CBT) and the within-group changes (baseline vs. any of the three posttest measures). This analysis yields relatively unbiased estimates despite drop out, given that data are missing completely at random or missing at random(340). Moreover, it can be safely used without conducting beforehand multiple imputations(340). Standard errors were estimated with the restricted maximum likelihood function, and type III *F*-tests were preferred. Dependency in the outcome data was accounted for by including a random intercept factor. The fixed factors were: *Group* (0-PEDt, 1-CBT) representing the overall treatment difference, *Time* (repeated measures) representing change across measurements, and the *Group*×*Time* interaction in order to detect treatment differences at certain time points only. The between-group analyses used the baseline values as a covariate, which improves the statistical power of these tests(341). Differences between the treatment arms were examined with planned comparisons at each time point (least square difference tests). The within-group analyses included all four measurements in the *Time* factor. Due to the number of tests, differences with *p*-values < .01 were considered as significant, and outcome data are presented as estimated means including 99% confidence intervals.

A comparable statistical approach was used for the dichotomous outcome variables, replacing the analysis with a generalized linear model using a binominal distribution and logit link function (reference category coded 0). Degrees of freedom were computed using Satterthwaite approximation.

Standardized Hedge's *g* effect-sizes were calculated as a ratio of the estimated means (extracted from the mixed models) and the observed pooled standard deviations (SD). Values around 0.2, 0.5 and 0.8 were interpreted as weak, medium and strong effect sizes, respectively, according to Hedge and Olkin (339).

Analyses of dropout and lost to follow up for the two separate follow up tests, were examined with conventional tests (e.g., *t*-, chi-square- or Fischer's tests). Differences with *P*-value less than 5% were accepted in these analysis.

Results

Out of totally 419 women who responded to the recruitment during the treatment period 2014-2016, 48 were temporarily placed on a waitlist throughout the recruitment- and treatment period. Of these waitlist participants, 23 responded positively to serve as control group participants. In total, 164 qualified for inclusion consecutively throughout the recruitment period, and were allocated to the two treatment groups. All participants were invited for baseline measures before being familiarized to the group allocation. Totally eight out of the 164 randomized women did not respond after the first communication, hence; they did not attend baseline measures, nor were they included in their allocated groups. After familiarization to treatment groups, two women with BN in PED-t, and three women with BN in CBT did not respond to any further communication. Additionally, two women with BED in the CBT group were excluded due to BMI above the inclusion criteria, disclosed during the baseline measure. As such, 76 of the 78 allocated women in PED-t, and 73 women in CBT, initiated treatment (*figure 6, p.37*). All attending participants are presented in table 7. No differences were observed between the treatment groups and the control condition ($p>0.11$).

Table 7: Demographics of participants at baseline. All variables are presented as mean (SD) and numbers (%), except number of binging- and purging episodes (median and min./max. values).

	PED-t (n=76)	CBT (n=73)	Control (n=23)
Age, years	28.2 (6.2)	27.7 (5.3)	26.5 (5.6)
Illness duration, years	13.0 (7.5)	12.1 (6.7)	10.6 (7.4)
Body weight, kg	71.7 (16.0)	71.4 (14.4)	67.2 (14.1)
BMI, $kg \times m^{-2}$	25.3 (5.1)	25.5 (4.7)	24.1 (4.9)
EDE-q global score	3.7 (0.8)	3.7 (0.9)	3.8 (0.9)
Binge eating episodes, *n*	10.0 (0 / 75)	9.0 (0 / 50)	10.0 (3 / 49)
Purging episodes, *n*	6.0 (0 / 95)	4.3 (0 / 29)	5.0 (0 / 30)
Bulimia nervosa, *n* (%)	49 (64.5)	48 (65.8)	20 (87.0)
Binge eating disorder, *n* (%)	27 (35.5)	25 (34.2)	3 (13.0)

The PED-t trial protocol: The effect of physical exercise- and dietary therapy compared with cognitive behavior therapy in treatment of bulimia nervosa and binge eating disorder (*Paper I)*

The protocol paper contain no results, but gives a short introduction to the rationale for the trial, the design of the trial, the methods used, and a description of the treatment programs, with short discussion on possible implication from the findings. As such, most of the information given, is presented in more detail in the introduction and method section of this thesis.

Body composition and physical fitness in women with bulimia nervosa or binge-eating disorder (*Paper II)*

Overall, females with BN (n=103) were comparable to normative or recommended levels in physical fitness, whereas females with BED (n=53) had lower cardiorespiratory fitness (CRF), and higher levels of BMI, body fat percentage, and VAT compared with norms or recommendations. History of AN was reflected by overall lower scores for physical fitness compared to those with no history of AN, irrespective of current diagnosis.

Mean [SD] level of physical activity (*counts per minute*) were higher amongst females with BN (457.2 [163.2], CI 99%: 409.3, 505.0) and BED (433.5 [163.2], CI 99%: 367.1, 493.9), compared to a national healthy cohort of comparable age span and sex (349.0 [141.0]). Furthermore, more females with BN or BED were complying with the official recommendations for physical activity (i.e. 150 min×wk^{-1}) compared with the national cohort (46.9%, 43.2% and 28.5%, respectively). Concurrently, mean time in sedentary behavior was ~ 10 hours×day^{-1} (BN: 10.02 [1.01], CI 99%: 9.7, 10.3), and BED: 9.99 [1.00], CI 99%: 9.6, 10.4), with the corresponding result in the national cohort being 9.12 (0.06) hours×day^{-1}.

About 28% of females with BN or BED had increased blood pressure or were hypertensive, and a considerable high number of the participants (20% of females with BN; mean value for females with BED) had CRF below previous suggested lower healthy threshold (i.e. <35.1 ml×kg^{-1}×day^{-1}).

In females with BN, mean body fat percentage was 30.2 (8.2), CI 99%: 28.1, 32.3, and 39.5 (8.6), CI 99%: 36.3, 42.7 in females with BED. Amongst these, 37.9% with BN and 75.5% with BED had body fat percentage above suggested healthy threshold. Despite that BMI was successful in identifying the majority with an unhealthy high bodyweight and -composition, 12% of all participants were found with masked obesity (i.e. normal BMI values; <25, still high body fat percentage; ≥33%). Furthermore, the traditional anthropometric measure evaluating body fat distribution, like waist-to-hip ratio, or in this scenario; the analogue android-to-gynoid body fat ratio by DXA, missed out about 1/3 with high levels of VAT (i.e. >300g).

Low bone mineral density was identified in three (2.9%) females with BN and six (11.3%) females with BED.

By inspection of the relation between total body fat percentage and VAT accumulation, we found a sudden acceleration of VAT accumulation close to the suggested healthy threshold for total body fat percentage (figure 7).

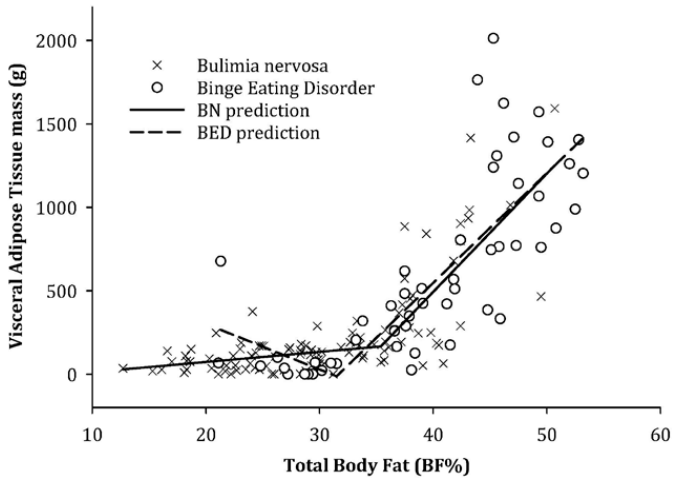

Figure 7: The non-linear relationship between visceral adipose tissue (VAT, g) and percentage total body fat (BF%) according to a piecewise regression model with separate slopes and BF% cutoff levels for bulimia nervosa and binge eating disorder, respectively. There is a cut-off for body fat% of 35.7% in BN, where BF% predicted 44.3% of VAT below cut-off, and 63.9% above cutoff. For participants with BED, the BF% cut-off was at 31.9%, where BF% predicted 56.4% of VAT below cut-off, and 64.1% above cut-off.

Multiple regression analysis identified variables related to physical activity as significant in explaining the variation of fitness outcomes. Overall, 65.9 - 67.2% of variation of body fat percentage, 51.2 - 68.2% of variation of VAT, and in females with BN 28.8 - 45.0% of variation in local BMD were alternately explained by the following variables: BMI, time spent in MVPA, CRF, lean body mass, and absolute muscle strength.

Finally, a history of AN was not a significant variable in our multiple regression analysis explaining body fat percentage, VAT or BMD. However, by comparing fitness outcomes in participants according to history of AN (irrespective of current diagnosis), we found such history in most cases to coincide with significantly lower results, with medium to strong effect sizes.

The effect of treatment on compulsive exercise and physical activity in eating disorders (*Paper III*)

We found both treatment options successful in reducing CET-score after treatment, with long-term effects. Only PED-t had a significant reduction in the numbers scoring above CE cut-off after treatment, with sustained effect during follow up (figure 8). Nevertheless, there were no differences between groups; neither in reduction of total CET-score, nor in reduction of the numbers scoring above CE cut-off. Additionally, neither treatment resulted in any changes in levels of physical activity, or in numbers complying with the recommendations for physical activity.

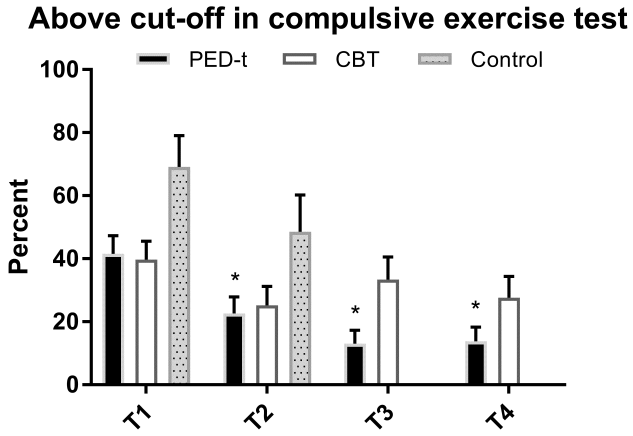

Figure 8: Estimated proportion (SE) of subjects scoring above the cut-off score defining compulsive exercise, across time and the treatment arms. ** Significant change from baseline, p<0.002.*

The within-group changes in CET after treatment (T2) were significant both in PED-t: (-1.29, CI 99%: -2.07, -0.52, g=0.49, p<0.001) and CBT (-1.08, CI 99%: -1.91, -0.26, g=0.41, p<0.001), while no change was seen within control group (-0.54, CI 99%: -1.99, 0.89, g=0.16, p=0.33). There were no between-groups differences at T2, neither between therapy groups (p=0.69), nor between each therapy group and the control group (p>0.09). During follow up, both therapy groups maintained their improvements from baseline in total CET score (g>0.44, p<0.007).

Concurrently with the improvement in mean total CET score after treatment, there was a reduction in the numbers scoring above CE cut-off in PED-t (p<0.002). No such change was

seen in CBT or control group (p>0.02), still there were no between-group differences at any time (p>0.015).

Of totally five CET subscales, only scorings in "weight control exercise" and "avoidance and rule driven behavior" improved significantly in therapy groups after treatment. For scoring in "weight control exercise" participants in PED-t improved by -0.75 (CI 99%: -1.05, -0.46, g=0.57, p<0.001) and participants in CBT by -0.38 (CI 99%: -0.69, -0.06, g=0.33, p=0.002), while there was no significant change in scorings in the control group (-0.35, CI 99%: -0.89, -0.19, g=0.30, p=0.1). This improvement from baseline was sustained in PED-t at T3 and T4 (p<0.001), and at T4 in CBT (p<0.001). For "avoidance and rule driven behavior" participants in PED-t improved by -0.50 (CI 99%: -0.80, -0.20, g=0.28, p<0.001) and participants in CBT improved by -0.38 (CI 99%: -0.70, -0.06, g=0.24, p=0.003), while there was no significant change in the scoring in the control group (-0.16, CI 99%: -0.72, 0.41, g=0.11, p=0.5). Improvements from baseline were sustained in both therapy groups at T3 and T4 (p<0.005).

There were no between-groups differences in any subscale at any time, neither between therapy groups (T2-T4, p>0.02), nor between each therapy group and the control group (T2, p>0.02).

We found no changes in total levels of physical activity (counts per minute) after treatment, neither in PED-t (19.02, CI 99 %:-43.85, 81.88, g=0.17, p=0.4) nor in CBT (-15.77, CI 99%: -84.90, 53.36, g=0.09, p=0.6). There were similar findings during follow up; with no change from baseline in neither group (p>0.08), and no between-groups differences at any time (p>0.011). Corresponding to these findings, there were no change in numbers complying with the official recommendations for physical activity after treatment (p>0.5) or during follow up (p>0.18), neither were there any between-groups differences (p>0.5).

Eating disorders can be treated with physical exercise and dietary therapy. A randomized controlled trial with 12 months follow-up (*Paper IV)*

Totally 149 of the 164 randomized participants initiated treatment, of whom 112 completed the treatment period. No differences were found between dropouts and completers; except a lower mean score for depression among those who completed treatment (-3.08 $_{-5.95, -0.21}$, g=0.39, p=0.035). During follow-up periods (T3-T4) more from the CBT group were lost to follow up, compared to the PED-t group (p<0.006) (figure 6).

The initial treatment effects from PED-t were overall stronger compared to CBT, but equally effective in the long-term, both outperforming the waitlist control group. The initial improvement in global EDE-q score (T2) was better in PED-t compared to CBT (-0.66, CI 99%: -1.23, -0.09, g=0.52, p=0.003) and compared to control (-1.15, CI 99%: -1.97, -0.34, g=1.00, p<0.001) (figure 9). No other between-group differences was found (p>0.05), and both therapy groups had positive long-term effect (T3-T4), with sustained improvement in global EDE-q-score compared to baseline (p<0.001).

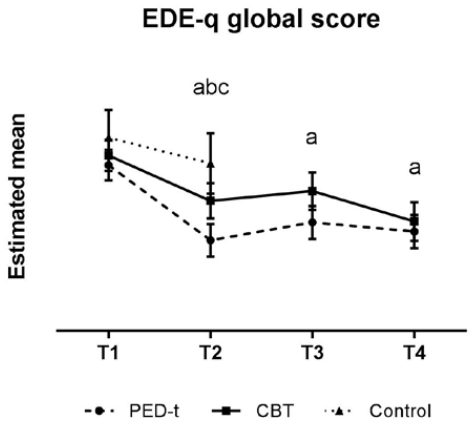

Figure 9: EDE-Q estimated mean global score (CI 99%) in each group from baseline (T1) to post-treatment (T2) and follow ups (T3 and T4). *NOTE: PED-t, physical exercise and dietary therapy; CBT, cognitive behavior therapy; EDE-q, eating disorder examination questionnaire; T1, baseline measure; T2, post-treatment; T3, 6 months follow up post treatment; T4, 12 months follow up post treatment; [a] significant change from baseline in each of the therapy groups, p<0·001; [b] significant difference between therapy groups (p=0·003); [c] significant difference between PED-t and control (p<0·001).*

Only therapy groups improved in EDE-q subscales after treatment, with no change in the control group. There were few differences between groups, but PED-t improved more than the control group after treatment in EDE-q "eating restriction scale" (-1.25, CI 99%: -2.14, -0.36, g=0.82, p<0.001), and in "eating concern scale" (-1.49, CI 99%: -2.39, -0.60, g=1.10, p<0.001). Additionally, PED-t improved more in EDE-q "body weight concern" compared to CBT after treatment (-0.77, CI 99%: -1.41, -0.14, g=0.54, p=0.002), but the differences vanished during follow up (p>0.06).

The numbers in full remission from diagnosis after treatment was significantly increased in PED-t with sustained results during follow up (figure 10), while the numbers in remission in CBT was increased after treatment and continued to increase towards last follow up. No differences emerged between therapy groups, but participants in therapy groups improved more than those in the control group (p<0.004).

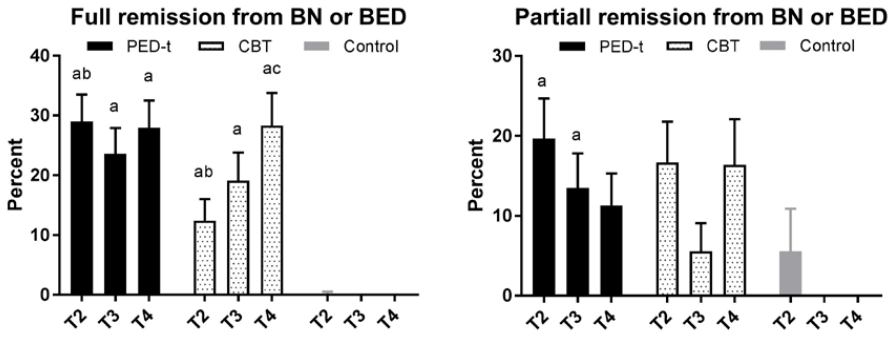

Figure 10: Estimated mean (SE) percent in each group in full remission (left) and partial remission (right) at post-treatment (T2) and follow ups (T3, T4). Note: PED-t, physical exercise and dietary therapy; CBT, cognitive behavior therapy; T2, post-treatment; T3, 6-month post-treatment; T4, 12-month post-treatment; [a] significant change from baseline, p<0·005; [b] significantly different to control group, p<0·004; [c] significant change from T2, p=0·007.

Both therapy groups had medium to strong effects in improvement from ED-related impairment (CIA) and in subjective well-being (SWLS) after treatment, with sustained improvements from baseline during follow up. Except a faster and better improvement in CIA in PED-t compared to CBT after treatment (-6·13, CI 99%: -11·89, -0·37, g=0.49, p=0.006), no other between-groups differences were found during follow up.

Only participants in PED-t improved their rating for manifestation of depression after treatment with strong effect size (-6.79, CI 99%: -9.79, -3.78, g=0.89, p<0.001) and with medium effect size at T3 (-5.12, CI 99%: -8.18, -2.06, g=0.64, p<0.001) compared to baseline, but with no further effect at T4 (p>0.05). This improvement was significantly better than the effect in CBT at T2 (-3.13, CI 99%: -9.08, 2.82, g=0.36, p=0.006), still; with no difference to control group (p>0.17), and with no further differences to CBT at follow up's (T3-T4) (p>0.09).

We found no effect from therapeutic alliance (WAI) on none of the between-group outcomes, other than a positive effect in favor of PED-t group compared to CBT on improvements of manifestation of depression when early WAI-scoring in therapy was average (T2 mean difference: -4.8, CI_{99}: -8.9, -0.6, p=0·003) or high (T2 mean difference: -8·6, CI_{99}: -13.9, -3.2, p<0·001, and T3 mean difference: -7·3, CI_{99}: -13.1, -1.6, p=0·001).

Discussion

This thesis aimed to explore the effects from a new treatment approach for women with BN or BED. Effects were evaluated by rates of remission after treatment and during follow up 6- and 12 months post-treatment, and by its effects on selected outcomes of psychopathology and comorbidity. Results were compared to the current preferred evidence based treatment offer (CBT) and a control group. Additionally, we aimed to describe physical fitness in persons with BN or BED, and as such, contribute with information for evaluation of necessary elements in treatment, to be able to comprehensively address their mental and physical health and fitness.

The following paragraphs shortly discuss the findings from the three empirical works in this thesis, before an overall, general discussion is given.

Body composition and physical fitness in women with bulimia nervosa or binge-eating disorder (Paper II)

Implications from our findings in paper II are a need for more advanced health screening procedure, and to address physical fitness and -activity in treatment of BN and BED. Due to the distinctive behavior, psychopathology and comorbidity in BN and BED, we hypothesized to find impaired physical health and fitness in women with these disorders. The results from our screening supported our hypothesis, and identified a high number of women with BN or BED with physical health impairments.

Our findings on a considerable number with high BF%, high VAT, increased blood pressure and/or low CRF, implies an increased risk for NCD's(7). This is health information rarely examined or reported in treatment or treatment trials, and accordingly not properly or routinely addressed during treatment. Importantly, we found variables associated with regular physical activity (CRF, MVPA, lean body mass and muscle strength) to explain variability in VAT in participants with BED, and variability of BF% and BMD in participants with BN. Interventions with physical activity could favorably influence these health variables; preferably physical activity with moderate to high intensity activities(113, 342, 343). While treatment of BN rarely includes the use of exercise, at least not structured and progressive, treatment of BED is often concerned about the need to reduce obesity in addition to treating the ED (135, 187, 344). As such, there

are evaluations of therapies with use of physical activity in treatment of BED (*e.g. table 1, p.27 and table 3, p.26*), but most such interventions are about low-intensity activity like walking programs or yoga (245, 258, 259, 280). Accordingly, there is a need to evaluate the feasibility of-, and health impact from, exercise programs designed with progression and/or decent intensity and volume, both in persons with BN and in those with BED. By addressing physical activity during treatment, the patient may achieve an understanding of its clinical importance. The treatment period offers as such, an ideal situation to be educated on-, and to get to practice healthy- and reasonable exercise routines.

Intriguing in light of the diagnostic differences and previous descriptions of persons with BED as being physically inactive (132-135), was our finding of no difference between females with BN and BED in levels of physical activity (*results not explicitly addressed in publication, however identifiable by confidence interval*). The total level of physical activity in females with BN or with BED were higher than in a comparative, national cohort. This finding matches well with descriptions of females with BN using physical activity as a compensatory method in their over-concern about control of body weight. However, this finding do also echoes previous findings of a comparable concern for bodyweight and –figure in females with BED (49, 50), suggesting a comparable drive in females with BED for exercise to control bodyweight. Whether this finding applies to a wider sample of persons with BED, or BN, remains to be proved. Confining the generalizability of our findings are the limited BMI-criteria for inclusion, and in referral to the recruitment purposes (i.e. participation in a new treatment program offering physical activity as part of one of the treatment modules); assuming that we may have recruited participants highly motivated for physical activity. The argument relating to recruitment purposes, do also raise the question whether our sample was of general better physical fitness than women with BN or BED who chose not to respond to such exercise based therapy offers.

The failure to find a history of AN to explain any of the physical fitness variables evaluated in our multiple regression analysis, contradict previous findings (163, 165, 168). A likely confounder is the fact that history of AN was registered by self-reports, and not by clinical and structured diagnostic interview. Further, we did not control for the duration of AN, or age for onset, information that may largely explain the presence or absence of physical consequences(5, 168). However, pointing towards persistent effects from previous AN, were our findings of differences between those in our sample (BN + BED) with self-reported history of AN and those without such self-reported history (*table 6 in paper II*). Implication from this information, is increased

awareness of the likeliness of low BMD in persons with BN or BED and a history of AN, compared to those with no such history. This finding do also imply that those with no history of AN are more likely have higher levels of body fat percentage and VAT compared to those with a history of AN.

Finally, more advanced screening technology is implicated as none of the standard field anthropometric measures; like BMI or waist-to-hip measures, successfully identified all those with impaired body composition. We propose the use of DXA in routine screening, or if in need of priorities; at least considering those with low levels of MVPA physical activity, low muscle strength or little experience with resistance exercise. Ordering DXA is a recommended procedure when there are reasons to assume low BMD, still we argue for this low-risk x-ray screening method also when in need of a more comprehensive body composition evaluation. Additionally, the use of CPET is recommended as standard screening in the clinics, due to the firmly established association between CRF and risk of cardiovascular disease and of mortality (2). Our results suggest the need for standard screening with CPET when identifying BN or BED. Previous findings have revealed an increased risk of diabetes type-2, metabolic syndrome and cardiovascular illnesses in persons with BN and BED, which goes in line with our anthropometric- and CRF findings. This calls for new guidelines in screening and treatment of persons with BN or BED(184); with increased concern and attention towards physical health and fitness.

The effect of treatment on compulsive exercise and physical activity in eating disorders (Paper III)

The comparable effect on reduction of CE from two different therapy modalities, both designed to, and successful at treating the primary illness (the ED), indicate a primary effect from diagnostic remission on the CE. Supporting this suggestion, is a previous finding of a mediating role of dysfunctional exercise between the exercise behavior and the negative outcome of such behavior; an ED(345). If the dysfunctional exercise exists as a consequence of the motive of controlling body weight, it is reasonable to suggest that remission from ED diagnosis (alleviation of the overvaluation of controlling body weight) itself will reduce dysfunctional exercise (here; compulsive exercise).

Of importance; we found support to the notion of a suggested "exercise paradox", which conceivably aids to clarify the confusion on how to best describe or capture dysfunctional exercise in BN (and BED). Here, the motives for exercise are dysfunctional, indicating a high drive for physical activity, but the actual level of physical activity may not necessarily be high or excessive. Indeed, we found mean total CET-score comparable to a previous finding with similar patient sample(293), and about 40-70% in our sample had CE-score above suggested clinical cut-off. However, in regard to actual levels of physical activity, less than 47% complied with the *minimal* recommendations for health promoting aerobic physical activity(113), thus finding no reason to suggest the presences of any excessive exercise in this outpatient sample of women with BN or BED. Supporting the assumption on primarily a dysfunctional *motive* for exercise, are our results on a significant reduction in the "exercise for body weight regulation" scale (i.e. "I exercise to burn calories and lose weight") after treatment, and a comparable reduction in "rule driven exercise" (i.e. "I feel extreme guilty if I miss an exercise session"). Concurrently, the level of physical activity remained unchanged. The dysfunctional motives for exercise, reflecting a guilt-related drive and obligation towards exercise, originating from a desire to control body weight, may be strong in maintaining the illness. Not following up on the intention to exercise, may bring about a strong disgrace and feeling of incompetence and low self-efficacy, increasing the likelihood for binge eating as a relief from negative affect. This impetus for continuance of illness may be resolved by psychoeducation; in which its dysfunctionality is addressed. Additionally, we have proved that another pathway to alleviation from such dysfunctional cognitions may be through a practical oriented therapy. Focus on improved performance, and the introduction to a progressive exercise regime, that requires recovery days, may have reduced the reliance on (excessive) exercise for appearance improvement, hence breaking the obsessive relation to exercise.

While participants in CBT were encouraged to comply with a healthy lifestyle, and those in PED-t were educated on the benefits of regular physical activity, less than half of our participants complied with the *minimal* recommendations for physical activity, with no change over time. Still, rather than finding the lack of change in physical activity an unsuccessful result; it may be regarded as a therapeutic successful effect in reducing obligation towards exercise. In PED-t, aiming to increase overall level of physical activity, a therapeutic valuation of quality in exercise, rather than quantity, and the emphasis on recovery for health and for performance improvements, may have given reasons to ease on any driven exercise. After years with over-

concern about the need to exercise, this may finally have brought good reasons to worry less about volume of exercise, hence also total levels of physical activity.

In comparison to the control group, neither of our therapy groups had better improvements in total CET score, hence indicating no effect from treatment. However, with the significant improvement within both treatment arms, not found in control group, and a sustained gradual improvement during follow up in treatment groups (medium effect sizes), we suggest a likely effect from treatment. The apparent lack of effect from treatment may also be caused by a potential low statistical power, with a rather small control group, and dropout during treatment-control period.

The findings from this paper provide information to the inconsistency in the literature on how to best capture the phenomenon of dysfunctional exercise in BN and BED. We further have provided evidence for successful treatment effects on this cognitive symptom, following ED-treatment and remission from diagnosis, and that different therapy modalities may lead to such symptom improvement.

Eating disorders can be treated with physical exercise and dietary therapy. A randomized controlled trial with 12 months follow-up (Paper IV)

The rates of remission from PED-t and CBT both aligns with previous findings from CBT-treatment of BN or BED; i.e. 20-50% remits from diagnosis (29, 225, 346), with one year follow up remission rate at 27-28% (219).

The fact that PED-t was equally successful to CBT as therapy for BN and BED, could be that both therapies are designed to promote early symptom change, an effect previously found significant for successful treatment outcome(189, 190, 223, 229), also serving as the strongest argument for CBT compared to other psychotherapies(189, 190). Intriguing, we found a stronger or more rapid effect from PED-t in most outcomes (either significant, or with a tendency) with CBT catching up during follow up.

The significant between-group difference in EDE-q global score after treatment, was mainly brought about by a strong effect from PED-t on the subscales "eating concern" and "eating restriction". The superior, immediate effect on these subscales after treatment may relate both

directly and indirectly to the content in the PED-t program. Directly, the dietary therapy, running throughout the whole therapy period, gives participants more time to deal with their dietary concerns and to achieve confidence with their dietary choices compared to CBT, hence promoting early change and sustained focus in dietary routines. Indirectly, the weekly training program may have made the changes in dietary practice more acceptable, a finding previously emphasized when underweight persons with ED gained about 40% more in bodyweight compared to control, by implementing exercise to standard treatment (120). The exercise module may have introduced other arenas for emotional regulation (*figure 2, p.25*), and it may have changed focus from body weight control towards function and coping. Further, the regular exercise may have improved sensation of appetite and satiety (*figure 4, p.29*), and through the exercise and dietary educational elements, PED-t may have increased knowledge and willingness to change dietary practice in line with the health- and performance enhancing focus in the exercise module.

The success criteria from CBT comes from a convenient therapy model, which targets early change in symptoms, then successively addresses maintaining mechanisms, i.e. cognitive beliefs about self-valuation, to ensure sustained treatment effect (52, 191, 224). An early change promote increased therapeutic alliance, hence ensuring an improved chance for successful outcome (222). The PED-t therapy rests on a conceptual model for effect on mental health, and relies on a structured intervention with specific description for progression and methods. The dietary and exercise modules were both designed to ensure fast experience of results and progress, hence reinforcing motivation to continue the changing progress. Similarities in the structure of both therapies are striking, still so are also the differences in content and focus of the respective therapy modules.

General discussion

The scenario for this thesis was the knowledge of low treatment seeking behavior amongst persons with BN or BED, poor treatment access and efficiency, and inadequate treatment success from current evidence based therapies.

The new therapy was comparable to the effect from CBT and to the remission rates reported previously in the literature(219, 225).

Hence, two rather different therapy modalities, one emphasizing psychotherapy, the other being a behavioral orientated therapy, brought about comparable treatment effects. Accordingly, two likely explanations emerges as suggestions for their successes. One is; the therapies shares some common therapeutic element of crucial importance, the other is; the causes to the illness can be addressed by rather different approaches, still bring about the same effect(226).

Common therapeutic elements in CBT and PED-t

Like CBT, PED-t addresses eating behavior early in treatment. In the theory of CBT-BN, the importance of targeting eating behavior is advocated, before advancement in therapy with subsequent focus of the upholding cognitions(52). Hence, the crucial "early response" to treatment(208, 223, 347) seems to rely on successful behavioral changes in dieting and eating routines. In CBT participants are challenged to introduce regular eating and practice real-time monitoring of eating and relevant thoughts and behavior(348). PED-t relies on a progressive approach; in which basic, overall challenges in diet first are approached (i.e. meal frequency, meal size, promoting a healthy eating milieu) through education, discussions and goal settings. Aiming for the same achievements (i.e. regular eating and normalization of meal size), there are only small differences in therapeutic techniques between the treatment arms. However, as CBT moves forward by focusing on cognitive elements during the next part of therapy; PED-t continues with increased focus on these behavioral changes with advancement into details of nutrition, foods and meals. Accordingly, the first weeks in therapy in PED-t is much about the same elements found in CBT, both opting for an early change. This "early change" in symptoms has previously been found to promote optimal therapeutic alliance (229), which further enhances the chances for good treatment outcome(222).

Essential to the CBT theory is the proposed "core psychopathology" (i.e. overvaluation of the need to control body weight and figure) acting like a triggering, provocative, and upholding element to the illness (*figure 1, p.7*)(52). However, challenging this theory is the suggestion that the core psychopathology is an *effect* from the dieting behavior, and not the other way around(225). In support of this, are findings where the most frequently reported trigger of the progress into an ED is dieting. Concurrently, the level of dietary restraint do not necessarily relates to this dieting behavior(225, 349). Hence, if successful therapy is about addressing the cause of the illness, the *dieting behavior* should be the target, and secondary effects (e.g. psychopathology) may improve because of the behavioral change(225). Intriguing, only PED-t

improved significantly more than control group in "eating restriction" and "eating concern" after treatment, with no significant difference between CBT and control (*figure 3 in paper IV*). In addition, "body weight concern" improved more in PED-t compared to CBT after treatment. Hence, findings suggest a stronger effect on diagnostic relevant psychopathology after behavioral therapy, compared to treatment emphasizing psychoeducation.

Furthermore, the intention with the advancement of CBT (CBT-enhanced) was to address unsatisfactory treatment outcomes with the original therapy-module, by targeting additional psychopathology assumed to interfere with the treatment response(348). Still, with the extra efforts directed towards psychopathology, the overall remission rates have not improved considerably (29, 187, 225). In addition, with findings on no superior effect from the total CBT-module compared to its components(29, 226), the first one, i.e. the behavioral module seems to be the most essential element in CBT therapy of BN and BED.

Another similarity between CBT and PED-t, is the use of homework assignment. While CBT therapy requested participants to write a dietary diary, rendering both food intake and the emotions and thoughts related thereto, participants in PED-t had different homework tasks throughout therapy, related to the weekly focus in therapy. Regardless of exact tasks asked for in the homework assignment, the engagement of participants for practicing coping and the responsibility for personal progress, are probably the effect accounted for by the homework, an element previously suggested to promote good outcome from therapy(226, 350).

Overall, if some unique element in therapy is to be hold accountable for successful outcome in therapy of BN and BED; the focus towards early behavioral change appears most likely the common successful detail in PED-t and CBT. Here, regular meals of appropriate size and composition is most prominent, while secondary effects are moderation of cravings, binge eating and purging, and finally successful improvements in psychopathology. Hence, focus on behavioral change, early progress and use of homework assignment seems to be important success criteria.

Different therapeutic elements in CBT and PED-t

In contrast to the theory of one unique, successful therapy element, is the suggestion that psychopathology may be addressed by rather different approaches, still bring about the same treatment effect. While theory of CBT holds the psychoeducation (i.e. addressing specific psychopathology) as crucial for long-term effect from therapy, the "common factors model"

suggests otherwise (226, 351). The "common factors model" proposes three common therapeutic ingredients as essential elements for successful change in any therapy. These therapeutic ingredients includes; 1) achievement of good therapeutic alliance, 2) towards the client; suggesting a rationalistic explanation to the problem, and then finally; 3) using therapeutic techniques aligning with the clients perception of the problem(226). Hence, rather than holding CBT psychotherapy as a unique modality for ED-therapy, it may simply stand as one way to achieve change and remission (here; psychoeducation). Thus, PED-t offers an alternative way to remission, partly by improving dietary routines, and increasing knowledge and practical skills related to diet, and partly by "acting and experiencing rather than talking" (here;. the experience of coping and progress through physical activity, and dietary related tasks).

The diagnostic criteria in BN and BED mainly revolves about the dysfunctional eating behavior, and while the criteria of an overvaluation of the importance on controlling body weight and figure is specific for diagnosis of BN, it is prevalent also in persons with BED (5, 37, 38, 49, 50). In CBT the overvaluation of controlling body weight and figure is held as the core psychopathology, causing the other features (like dietary restraint, weight control behavior and preoccupation with thoughts on weight and eating)(348). Thus, treatment revolves much about challenging these thoughts and reflections, finding new domains for self-evaluations, increasing food flexibility and finding new ways to deal with intense mood(348). Rather than generating a milieu and opportunity to directly address and challenge such unconscious or automatic reflections and actions, the PED-t offers an indirect approach to achieve the same result. By relying on the proposed mechanisms from physical activity om mental health(*figure 2, p.25*)(240), finding them reflected in the proposed mechanisms from physical activity in preventing or treating EDs (*figure 3, p.26*) (114), PED-t offers new ways to recovery from BN and BED. Hence, two different therapy modalities brings about the same effect(226).

Therapy to improve mastery, physical self-concept and global self esteem

Importantly, low self-esteem seems to be a common underlying psychologic feature for BN and BED, and it is repeatedly reinforced by the unsuccessful dieting routines ending up in binges. Hence, by helping the client change evaluation of self-worth; from control of food intake and body weight, towards other aspects and qualities of one self, important changes in psychopathology may be achieved. Such changes in self-evaluation may be achieved in different ways, e.g. by talking about it (CBT) or by action (PED-t). CBT opts to reflect on the "core psychopathology", and challenge its value. In therapy, unhelpful thoughts and behavior are

directly addressed, educated on, discussed and challenged. Participants are helped by sorting the irrational thoughts, behavior and reactions, and by being required to self-monitor, and finally by finding new domains for self-evaluation. On the other hand, PED-t actively creates arenas for mastery and positive experience by letting practical skills act on self-efficacy and self-confidence. By further appraising these progresses in therapy; these experiences may manifest as new elements for the self-esteem. The professional guidance and a structured progressive exercise program, facilitates a potential for early progress and exercise results (e.g. improved technique, improved strength, improved stamina). Thus, the experience of achieving results after behavioral efforts (i.e. routinely exercising, and complying with a prescribed program), may certainly affect self-efficacy. The group condition do bring up a competitive arena interfering with the focus- and potentially reducing the effect of treatment. However, by addressing such challenges; striving for focus on solidarity, using the arena to empower each other and to keep focus on own efforts and progress, a social connectedness might rather enforce the therapeutic process(235). With improved performance and by relating exercise to function rather than body weight- and figure regulation, an increase in mastery and coping has the potential to improve the physical self-concept, the self-perception and body image. (235, 240-242). These experiences through exercise participation have the potential to affect global self-esteem, subjective well-being and overall quality of life(132, 235).

> *Moving focus from how I look towards the experience of having a body that is well functioning is very rewarding. I imagined that I would lose weight, and that was my goal when I enrolled in the treatment program. But now; realizing the fact that I am pleased even though I did not lose weight and that I see the value of changing my thoughts about food and exercise, tells me it was a success.*

Quotation, female with BED in the PED-t group(314)

Our findings on improvements on rating of depression in the PED-t group matches previous findings from other population samples, evaluating the effect of physical activity on depression(21, 235, 243, 244). This improvement was not achieved in CBT, and vanished in the PED-t group towards last follow up (T4). This finding may be due to a low prevalence of depression, as severe depression was an exclusion criterion to the study. Still, it is intriguing to see such a difference between therapies after treatment, when in fact many participants in CBT also chose to do regular exercise. It is inviting to speculate whether the difference may be explained

by the structural component and focus in PED-t, in which a detailed training program, expectations on adherence to the program, follow up each week, experience of mastery, and constructive feedback and motivation from experienced exercise therapists, were elements to help bring about such a different effect.

Therapy to cope with emotions, impulsivity and negative affect

Dietary restriction typically works well until some unforeseen or uncontrollable incident changes emotional state and mood (i.e. causing negative affect, stress or anxiety), which is often coped with by binge eating. This reaction (the binge eating) distracts uncomfortable thoughts and feelings, but do also bring about initial relief (37, 69).

CBT focuses towards such circumstances (i.e. the restriction and the binge eating to cope with negative affect), by identifying triggers and suggesting alternative pathways for coping, and finally assigning homework related to these mechanisms (i.e. by self-monitoring, and by identifying the triggers and try new coping strategies).

Exercise offers a physical arena to cope with stress, impulsivity, and affect regulation (*figure 2, p.25 and figure 3, p.26*)(235, 240, 244). The mechanisms for stress-coping and affect regulation may be the exercise induced physical responses (i.e. increased pulse, rush-out sensation of anxiety and tension, followed by a relaxing feeling), and the psychological responses (i.e. breaking circuits of negative thoughts and getting away from dysfunctional thoughts, putting focus towards practical doing, experience of self-efficacy and mastery). Additionally, exercising offers an arena to practice self-regulation and develop coping skills. One thing is to learn to cope with the social interaction, another thing is be able to concentrate on internal bodily processes by becoming more aware of bodily function and to master the coordination of technique and movement.

As such, directly (CBT) or indirectly (PED-t) addressing dysfunctional coping actions, and concurrently offering new and more desirable strategies to handle discomfort and stress, may be comparable successful.

Therapy to regulate appetite and cravings

According to the three theories suggested to explain the effect from dietary consultation in treatment of EDs, the behavior in BN and BED may be alleviated by (1) breaking the vicious cycle of energy restriction causing cravings, by identifying stressful events cuing the (2) binge

eating or (3) purging, and finding new ways to deal with such negative affect. CBT works these problems around much by self-monitoring in real-time, and by introducing regular eating.

The participants in the PED-t were challenged to re-introduce regular meals with appropriate meal size early in treatment, and were also encouraged to compose meals with proper serving of proteins and fiber-rich carbohydrates to promote satiety. With the concurrent instructions on regular physical activity, and encouragement to comply with the exercise program, the successful treatment effects may be ascribed the elimination of energy restriction and the introduction of more desirable affect regulation (i.e. the physical activity). Supportive to these suggestions, are the superior treatment effect on EDE-q eating restriction and -eating concern. The introduction of regular physical activity further have the potential to improve appetite and satiety regulation (*figure 4, p.29*)(261, 262). Hence; when participants were re-learning to eat healthy and increased their regular physical activity, they may have experienced a reduced food craving and improved appetite regulation.

The participants reported that the treatment had contributed to a more healthy way of thinking on food. They had learnt that when exercising, they needed energy refilling the same day, and described that they were no longer afraid to eat and that food no longer was experienced as 'a bad thing'. Consequently, they experienced a decrease in the need to keep strict dietary rules and less stress if such rules were broken.

Quoting experiences from participants in PED-t(314)

For now, there are no good suggestions on what kind of exercise, or what kind of intensity, would prove most efficient in treating EDs (246). However, previous studies have found important improvements by low impact aerobic activity (*table 1, p.27 and table 2, p.31*)(246), and we serve an argument for high impact activity and resistance training, with support from a recent meta-analysis on the effect from resistance exercise for depression (352). This indicates effects from a range of physical activities, and may suggest that targeting reasonable goals for physical activity, following a measurable progress, and being helped to realize the achievements, mediates the important treatment outcomes like increased self-efficacy, mastery, and improved physical self-concept(114). Whether the regular physical activity also causes improvements in mood and primary illness by neurobiological effects(240), remains to be proved.

Limitations

The overall validity of the present findings relates to multiple roles, the inclusion and exclusion criteria for participation, the implementation of the treatment, and the testing procedures.

Chiefly, the role of the PhD-candidate (TFM) needs proper disclosure due to her involvement in planning of the trial, in designing the PED-t, in trial- and testing logistics, in doing the dietary therapy in the PED-t, arranging the testing procedures, in statistical analysis, and in writing the manuscripts. Due to financial and practical shortcomings, there were small choices for other implementation; however, there have been several practical solutions to deal with the challenges of impartiality and biases. During planning, the project group were concerned about aspects that potentially could interfere with therapy effects, like number of therapy sessions, duration of therapy sessions and manual-allegiance. Representatives from both therapies were involved to ensure that the original, evidence based protocol of CBT would be feasible, and that the PED-t was adapted to match these predefined criteria (i.e. therapy structure). With no former experience or knowledge of CBT and its content or techniques, the PED-t was designed to best match the necessary and successful elements from exercise and dietary consultation, still following the same structure as CBT. Hence, a former CBT protocol for group therapy(353) served as a guide for such structural design. Further, while TFM did most screening interviews and listed the eligible participants by consecutively assigned id-numbers, an independent colleague created the randomization list, and another independent colleague assigned participants by concealed allocation according to the id-number list. As such, TFM had no role in allocation of participants, or no chance to influence this procedure. The group-related logistics during treatment was kept within each arm/group, handled by each therapist respectively. With respect to testing procedures, each participant had their appointment adjusted to match their individual time schedule, still within the frames given for optimal screenings (i.e. within the weeks planned and booked for testing, and with early attendance for the given day, and with the predefined order of testing). Hence, biased results are less relevant here. The role of TFM during testing, was most about logistics and communication, and minor about practical implementation. Thus, the only chance for impact on individual test outcomes would be the presence of TFM per se. In trying to deal with this, TFM aimed to act equal towards all participants in welcoming, informing and guiding them through the testing day, and otherwise not being physically present during each of the testing situations. During the therapy period, TFM was holding the dietary therapy while also arranging the overall logistics of groups in both arms. As such, it could be that information

attained from progress in each intervention arm, could motivate for extra efforts in the PED-t group. However, staying to a predefined manual and already eager to prove the potential efficacy from the new therapy, there is little room for any other extra effort. The same argument relates to the CBT therapists, who all were eager to attain optimal results, both in regards to the health of each participant, and in regards to the scientific purposes of the trial. Finally, the role by TFM in doing all analysis and in interpreting and communicating the results is clearly questionable. While coding of all questionnaires to SPSS files (data analytical programs) were either automatic (registration of physical activities by Aktigraph) or performed by blinded and trial-independent personnel (questionnaires), TFM ran all the analysis, and was the first to describe the findings in the separate manuscripts. However, a project-fellow was responsible for composing the statistical models, and all in the project group were offered open access to the statistical files. Further, for the relevant papers, there were authors with interests pertaining to each of the treatment interventions, hence an opportunity for all to argue otherwise if not accepting the interpretation of results. TFM recognize the challenges with her mixed roles, still hope most find these explanations and disclosures sufficiently acceptable.

Internal validity

The internal validity of our findings may be threatened by the repeated testing, in which participants gets familiar with the questionnaires or instruments, and accordingly responds to them based on knowledge on, or familiarity to, the outcome they measure. The repeated testing with the reflection this demands by the participants, may in itself change behavior or cognitions, hence result in changes not ascribed from therapy. A less appropriate or true response may further have been generated by the relation to therapists and test crew, all being present during testing situations. Consequently, participants may have felt an obligation or need to respond more favorable than pertinent, to please the therapists and crew. We also included a rather high number of questionnaires, which may have resulted in fatigue, hence having participants not responding sincerely and reflected. To deal with these challenges, we made sure the participants were given enough time for the questionnaire session, and further made them aware of the scientific significance of their response; encouraging them to take their time and read the questions thoroughly. Additionally, each participant was offered appropriate personal space during questionnaire session, and each were given an envelope in which the questionnaires could be returned closed and concealed to safeguard their anonymity. As such, there is small chances that this situation would affect participants from each therapy-group different, but rather a

question about the general influence from questionnaire fatigue. However, such fatigue effects are at least likely to be evenly distributed across the treatment arms.

Other aspects of the testing situation, relates to the "Hawthorne effect", and may especially relate to behavioral changes. While carrying physical activity sensors (Aktigraphs), there is a risk some would change their level of physical activity, as carrying activity monitors often induce motivated improvements in levels of physical activity. However, the effect must be assumed to be similar amongst all participants, and also in cohort studies to which we compared our outcomes. As such, comparisons with normative levels (paper II) and between treatment- or diagnostic groups (paper II and IV) are justified.

Most of our psychometric instruments were self-reported questionnaires, and information on body weight history, AN-history, and history of treatments, were all by self-report in questionnaires or by the screening interview. As such the validity of this information is challenged by recall bias and the fact that previous diagnostic history is not confirmed through clinical interviews. We attempted to address this issue by clinical assessment to confirm the information given, still recall-information must be interpret with caution.

Importantly, we noticed a skewed attrition rate, with more participants in CBT being lost to follow up (*figure 6, p.37*). Participants lost during follow up periods are often assumed to be those with less favorable outcomes, hence, reflecting a more favorable outcome from intervention with only responders left in the group. Suggestions have also been the contrary; those lost to follow up (LFU) are responders, while those meeting to follow up reflect a need for more treatment (215). We assume the skewed attrition rate may be due to the nature of test-battery, where participants from CBT probably felt less motivated to repeat the physical fitness tests with no exercise intervention after all. Neither phone calls, detailed explanations, repeated reminders, nor captivating with gift cards, did change this scenario. These LFU's did not respond to electronic questionnaires either, hence there was an unwillingness to respond to any request for follow up measure. This skewed number of participants from each group, attending follow up measures, is probably one of the more serious threats to the validity of our results. Hence especially the long.-term effects must be interpreted with caution. Nevertheless, we did not find any differences between those who met and those who were LFU; neither in respect to baseline measures, nor with respect to results from the prior test period before being LFU. These results indicate no systematic differences between LFU and attending participants, still with the clearly skewed LFU

rates between therapy arms, it's reasonable to assume some systematic difference. Accordingly, the long-term results from this trial, must be interpret with some caution.

Of further importance to the internal validity, is the question on therapy fidelity. If therapies are not ran by the model prescription, we do no longer compare distinct therapies, rather effect from random treatment. This is of additional serious concern, as therapy not adhering to protocols are found less effective than bona fide models(226, 231). There have been four different therapists in the CBT group during the treatment period 2014-2016, which for certain brings up the question on treatment individuality, and CBT-loyalty and – knowledge. However, one experienced psychologist trained all therapists, to make sure there was similarity in implementation of the therapy, and fidelity to protocol. The loyalty to manual in the PED-t is also timely to question, as different group climate and challenges therein may bring about difficulties in following the protocol. We did plan for per-protocol evaluation, by videotaping therapy sessions. Unfortunately, currently these have not yet been evaluated.

This trial recruited participants for a RCT with two different therapy options, still the news were about the new therapy; PED-t. It is reasonable to assume some were disappointed for not being allocated to this new therapy, a suggestion justified by the mean duration of illness in participants, and the fact that a considerable high number reported a history of previous treatment attempts (*not reported in results*). It may be assumed that some of the CBT-participants therefor got motivated to do action on their own, initiating new exercise routines. We assume the uniqueness in our exercise-treatment design, -delivery and approach are not easy to imitate by personal training routine. However; by having such imitations of therapy content, differences between treatment outcomes may be diluted, or outcome from treatment groups may approach each other, due to similarities in interventions.

In regards to the issue on expectations to receive the new therapy, those assigned to CBT may have been demotivated for treatment, disappointed on not having the chance to experience the new therapy. We were aware of this potential situation, and were striving to make sure all knew CBT is the current preferred therapy. We further noticed that disappointed or joyful responses after randomization went in both directions; i.e. there were both disappointed and happy participants in CBT as well as in PED-t. Therefore, we find it reasonable to suggest this effect was evenly distributed, and would at least not be the cause for differences between groups in outcomes.

External validity

Due to the group design of this trial, and the lack of competence and resources to follow up on specific individual needs, we excluded participants with severe comorbidity. Persons with BN or BED are found with high rates of comorbidity, and this is further found to complicate treatment (84, 87, 89). Hence, the results from this trial may not be valid for other with more severe complexity in comorbidity. With that being said, with the high occurrence of mood- and anxiety disorders amongst persons with BN and BED, we did not exclude all, but by evaluation of severity. A further challenge for generalization of results, are the BMI-criteria, which especially for those with BED restricted access to participation. A higher BMI may relate to other comorbidity or underlying causes of illness, and these persons may therefore respond differently to such therapy modality. Obviously, results must be interpreted with caution in regards to whom these effects applies to, and further studies must follow to evaluate the suitable recipient of this particular therapy (i.e. PED-t). One example from such previous evaluation and following customization, is the advancement of CBT to "CBT-enhanced" to match more severe psychological clinical features (348). Related to the issue of for whom this therapy might be beneficial for, is the suitability for this kind of therapy (PED-t) in other environmental conditions. Whether this new therapy is suitable for institutions with inpatients, for primary health care with outpatients, or in general training facilities, remains to be evaluated.

The experimental situation have the potential to create a special attitude, motivation and responsibility by the participant, which could be in contrast to routine treatment. The participant joins with curiosity and optimism, and feels uttermost responsible to comply with treatment because the results might bring importance for fellow(wo)men. Such obligation and motivation is harder to create if being faced with a definitely need for treatment, with small choices of therapy alternatives, no comprehensive follow-up test procedure or evaluation, and with no impact for others than one self. However, while many participants uttered their engagement for helping fellowmen by contributing in this trial, they finally found their participation being about a personal project after all. We hope a wider selection of therapy options in clinical practice may improve motivation and hope for more when facing need for treatment. Still, we do acknowledge the potential for more advantageous results due to the setting; i.e. being in a scientific trial.

Motivational aspects do also relate to the readiness and willingness for change and treatment. With this outpatient treatment, participants responded to recruitment by free will, being offered two specific variants of treatments. This contrasts to the situation in which a clinician suggests or

imposes treatment, and therapy modality is not clarified or free of choice. Verifying a high motivation for treatment in our trial, is a rather high attendance rate to treatments (i.e. ≥75%), despite no financial elements (neither personal expenditures for therapy, nor reward for compliance).

Having four different therapists semi-annually engaged to run the CBT therapy, is in contrast to one therapist in the dietary therapy module in PED-t, only occasionally substituted due to practical reasons. This raises the question on whether especially the PED-t treatment may be generalized with other therapists running the module. However; despite being experienced in dietary consultations, the therapist was neither experienced in running group treatment, nor in treating EDs. As such, any experienced dietitian would potentially be successful in running such therapy, by following the protocol. Further of importance, the dietary therapy was only half of the therapy given in PED-t, the other being exercise therapy. Here, totally seven different therapists were engaged throughout the three years with trials, and as such moderated the individual or personal therapist effect. Hence, we have reasons to believe that any experienced therapist, holding a master level of exercise physiology or in dietetics, following the prescribed manual and receiving a decent level of training, could perform equally well to the personnel in the current trial.

Statistical validity

Each of the papers in this thesis provides a large number of statistical analyses due to the use of several questionnaires, repeated tests over a period of time, and due to multiple comparisons within- and between groups. These multiple tests brings about a timely question related to type-1 error. We recognized this issue in paper II, but found the multiple comparisons proper, due to the explorative nature of that paper. Regarding paper III and IV, we strictly evaluated and adjusted the number of variables and outcomes to deal with the issue of multiple comparisons. However, the main question on changes in CE demanded several tests, due to the number of subscales, and finally the number of follow-ups. Hence, we accommodated this challenge by stricter demands on specificity; i.e. lowering the p-value.

We calculated a need of 144 participants in treatment (72+72) to be able to detect a difference in the main outcome, i.e. EDE-q global score. Adjusting the numbers randomized (78+78) to the actual numbers starting treatment (76+72, *figure 6, p.37*) we are still within the calculated need of participants. However, due to a rather high dropout rate, the numbers left after treatment were

much smaller (61+51), and even smaller towards last follow-ups. Hence, we are running a risk to ignore true differences between groups, by not retaining the power needed. Anyhow, with respect to the non-inferiority design of this study, and the fact that the few differences that appeared between groups were in favor of PED-t, we found comparable effects from the two treatments at quest, and with better outcomes than the control group. Hence, a decent high effect from treatments seems to overcome the challenge of possibly being underpowered, arguing for a comparable successful effect from PED-t.

Construct validity

The expectations to the performance of the new treatment (PED-t) may have especially motivated the crew for efforts towards this group, hence generating a more favorable outcome than ascribed from the therapy modality per se (*the Rosenthal effect)*. Reducing the impact of this issue, is the assumption that all therapists were motivated to create the best outcome in their groups. Confirming this assumption is reports from the project leader on highly motivated therapists; both experienced CBT therapists eager to prove the efficiency of CBT, and "novice" PED-t therapists eager to put their highly held therapy to test. Anyhow, while individual traits amongst the different therapists may influence or even set the therapeutic outcome (354), we find no reason to believe there were any systematic order in such variability.

Conclusion

We have evaluated the effect of a new group-therapy for women with BN or BED, combining guided physical exercise and dietary therapy (PED-t), and compared the effects to the currently preferred therapy (CBT), and a waitlist control group. We have also given a thorough evaluation of the physical fitness in women with BED or BN with objective and validated technology.

II. Overall, participants with BN or BED displayed adequate physical fitness; however, a high number had high blood pressure, low CRF and unfavorable body composition. Participants with history of AN were found with lower values for body composition compared to those with no AN-history. The finding calls for inclusion of physical fitness evaluation in routine clinical examinations, and for guided physical activity and dietary recommendations in the treatment of BN or BED.

III. Both indirect (CBT) and direct (PED-t) approaches may be viable in reducing CE with sustained long-term effect, but neither approaches raised the level of physical activity or compliance with official recommendations for physical activity.

IV. Combining physical exercise and dietary therapy (PED-t) may be an alternative pathway to recovery from BN or BED to the currently preferred evidence based therapy (CBT). Known initial effects from CBT were found, but the initial effects from PED-t were stronger. Nevertheless, both treatments alleviated core ED symptoms and provided a significant increased numbers of participants in remission, and improved subjective wellbeing after treatment and during follow ups. Hence, both treatments were comparable successful therapies.

Implications from findings and future perspectives

We have reasons to believe PED-t has the potential to lower the barrier towards treatment consideration, and further to increase motivation for treatment completion, by relying on the core interests of persons with ED, and with elements having high social acceptability. The therapists, on which this therapy relies on, are highly available, increasing the chances for early treatment initiation promptly when motivation for change is high. Additionally, we found the group format successful, hence capable in helping more persons per time, which further adds efficiency to this therapy. The comparable effect from this new therapy to the currently preferred CBT makes PED-t a reasonable alternative, possibly attracting new segments from the pool of ED patients in the general populations, as well as making the PED-t relevant to those patients not responding to other psychological therapies. Our findings further add to previous experiences with the use of physical activity in treatment of BN or BED, by reporting no negative effects that could interfere with the treatment of the EDs. Hence, these previous experiences, and our results; finding no negative impact on CE or excessive exercise, encourages the use of physical activity in routine treatment of BN and BED.

Feedback from several participants from both intervention arms indicates a need for a less abrupt end of treatment(314). Despite the inclusion of review, evaluation and preparation for termination of therapy several weeks ahead, many expressed the feeling of a sudden ending. Thus, to prevent such negative experiences, potentially threatening progress for remission and increasing the risk for relapse; the effect from short, recurrent therapy-boosters should be considered.

Despite addressing the positive health implications from adhering to the recommendations for physical activity, neither of the therapies were successful at increasing such compliance. Thus, there may be a need to find other motivational strategies to succeed with such objectives.

Finally, we acknowledge the limitation of this study, partly by a favorable condition; being an experimental scene with presumably highly motivated participants. The generalizability is questionable, hence requiring replication with other samples and in other settings. Satisfactory power in any such replication, by accommodating the risk for a rather high dropout, would further benefit the interpretation of our findings

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Papers and Appendices

Paper I

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STUDY PROTOCOL Open Access

The PED-t trial protocol: The effect of physical exercise –and dietary therapy compared with cognitive behavior therapy in treatment of bulimia nervosa and binge eating disorder

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Abstract

Background: Sufferers from bulimia nervosa (BN) and binge eating disorder (BED) underestimate the severity risk of their illness and, therefore, postpone seeking professional help for years. Moreover, less than one in five actually seek professional help and only 50% respond to current treatments, such as cognitive behavioral therapy (CBT). The impetus for the present trial is to explore a novel combination treatment approach adapted from physical exercise- and dietary therapy (PED-t). The therapeutic underpinnings of these separate treatment components are well-known, but their combination to treat BN and BED have never been previously tested. The purpose of this paper is to provide the rationale for this new treatment approach and to outline the specific methods and procedures.

Methods: The PED-t trial uses a prospective randomized controlled design. It allocates women between 18 and 40 years (BMI range 17.5–35.0) to groups consisting of 5–8 members who receive either CBT or PED-t for 16 weeks. Excess participants are allocated to a waiting list control group condition. All participants are assessed at baseline, post-treatment, 6, 12 and 24 months' post-follow-up, respectively, and monitored for changes in biological, psychological and therapy process variables. The primary outcome relates to the ED symptom severity, while secondary outcomes relates to treatment effects on physical health, treatment satisfaction, therapeutic alliance, and cost-effectiveness. We aim to disseminate the results in high-impact journals, preferable open access, and at international conferences.

Discussion: We expect that the new treatment will perform equal to CBT in terms of behavioral and psychological symptoms, but better in terms of reducing somatic symptoms and complications. We also expect that the new treatment will improve physical fitness and thereby, quality of life. Hence, the new treatment will add to the portfolio of evidence-based therapies and thereby provide a good treatment alternative for females with BN and BED.

Trial registration: Prospectively registered in REC the 16th of December 2013 with the identifier number 2013/1871, and in Clinical Trials the 17th of February 2014 with the identifier number NCT02079935.

Keywords: Eating disorders, RCT, Physical exercise, Dietary therapy, CBT, Treatment outcome, Physical fitness, Bone mineral density, Resistance exercise

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Background

The present paper reports on an ongoing, new treatment for bulimia nervosa (BN) and binge eating disorders (BED). Binge eating disrupts normal eating patterns and introduces vicious circles of fasting and binging that causes a chaotic energy intake. Also, binge eating causes an energy surplus, which those with BN compensate for by purging, *eg.* vomiting, using laxatives, diuretics, or enemas, misusing medications or exercising in an extreme or rigid manner, all which can change body metabolism. It is noteworthy that such changes may also be the result of physical inactivity, which is frequently observed particularly among sufferers from BED.

Binge eating and compensatory behaviors can raise the medical severity of BN and BED by means of hypokalemia, that may elicit inter-current infections as well as cardiac complications, diseases or arrest, or it may affect glucose, insulin and lipid levels that increases the risk of type-2 diabetes [1–5]. A combination of rigid exercising and eating may over time inflict chronic low energy availability and raise the risk for low bone mineral density, and ultimately osteoporosis [6, 7]. The non-medical severity comprises personal and familial burdens. A slightly raised standardized mortality rate is due to both medical and non-medical burdens [8–10]. According to a recent systematic review, the societal health care costs range from €888–18,283 for BN and €1762–2902 for BED [8–10].

Most sufferers do not acknowledge the clinical severity and the medical and non-medical risks of eating disorders (ED), as 80–94% of people with BN and BED never seek professional help or delay it 4–5 years [11–15]. Effective treatment of BN and BED is considerably hampered by this incongruence, which may be circumvented by offering treatment options outside the contexts of traditional health services or improving access to such options. Among those who do enter treatment, a protracted course of illness is typically seen among every third patient [16]. Important reasons are early drop-out due to a failure to engage patients into treatment and lack of rapid symptom changes or symptom coping, thereby lowering patients' motivation and self-efficacy [17].

In most treatment guidelines, cognitive-behavioral therapy (CBT) is regarded as the treatment-of-choice for BN [18]. Clinical targets in CBT include weakening the strength of core beliefs about low self-worth and compensatory beliefs about the need to control food intake, body weight and shape. Use of stimulus-control procedures to reduce the frequency of disordered eating, *ie.* bingeing and/or purging [19] is also central. Studies, systematic reviews and meta-analyses show promising effects of CBT for BED, and intermediate effects for BN, but the methodological quality of studies is low to moderate [20–22] even when often observed comorbid conditions are incorporated in the treatment [23–25]. New treatment approaches are called for because up to 50% of patients do not respond to CBT, even when the therapy is especially designed for ED [26].

Guided physical exercise (PE) may facilitate regulation of negative emotions [27], yet guided PE is rarely used in clinics [28] due to a fear of reinforcing the excessive exercise used to compensate for bingeing. A previous randomized controlled trial has shown that guided PE is as effective as CBT in alleviating BN symptoms [29]. The present study aims to replicate and expand on these findings.

Dietary therapy (DT) and counseling alone to correct the chaotic eating pattern has unclear empirical support [5, 30], but one review indicate some support to a possible *additive* effects of DT with CBT [31]. The present trial is the first one to examine the additive effects of DT and PE (PED-t) compared to CBT alone, and using a group therapy format.

Therapeutic alliance is an important moderator (or even mediator) of treatment effects in general; however, for EDs its impact is less understood [18, 32, 33]. High treatment expectations and installment of hope seems to predict treatment alliance in anorexia nervosa, but the relationship is uncertain for BN and BED [34]. Recent literature reviews have shown inconsistent findings across ED diagnoses, treatments, patient age groups and time (*eg.* early, mid or late) of assessment [31, 35, 36]. We hence included measures of alliance and group climate after every CBT and PED-t session to study the temporal order between these factors and response in both treatment arms [31].

Hypotheses and predictions

This trial will test six hypotheses:

1) Comparison of treatment arms: a) PED-t and CBT have comparable effects in terms of less symptoms of eating pathology, b) both perform better than a wait-list control group in reducing binge eating and/or purging, and c) both improve dietary intake.
2) Compared with CBT, the PED-t intervention produces a more rapid treatment response.
3) By improving physical strength and endurance, body composition, bone mass, and the nutritional and hormonal status, PED-t will surpass CBT in reducing the number and severity of medical complications.
4) Positive early changes in therapeutic alliance scores and group cohesiveness partly mediate effects of PED-t and CBT.
5) PED-t surpasses CBT in terms of a lower dropout rate and higher patient satisfaction with treatment.
6) The direct treatment costs are comparable for PED-t and CBT, but the indirect costs of PED-t are expected to be lower.

We predict that the PED-t combination will serve as an effective treatment method for BN and BED because the preoccupations of exercise and diets are transformed away from being ED-symptoms and toward functional coping and self-regulative activities. We also predict that the treatment effect of PED-t will be rapid and strong, defined according to a systematic review and meta-analysis [37], and the best empirically derived predictors of sustained remission at 6 and 12 months follow-up [38, 39] *ie*. as a 25% reduction in depression scores and ≤3 binge eating episodes a week during the first four weeks of treatment. Given that our novel treatment (PED-t) targets clinical features that occupy the sufferers' minds, we expect a high level of treatment engagement, motivation and compliance. Such accomplishments may facilitate a stronger therapeutic alliance [40].

Methods and design

This randomized controlled trial includes three groups: participants are randomized to either the CBT or the PED-t treatment group, while participants having to wait represent the control group condition. After 16–20 weeks, these are randomized to either treatment arm. The treatments are delivered to groups consisting of 5–8 participants. It includes 20 therapy sessions stretching across 16 weeks. All outcome variables are measured five times: pre, post, 6, 12 and 24 months (Fig. 1). Mediator/moderator data (*ie*. therapy process variables) are collected after each treatment session, which yields excellent statistical power for conducting growth curve modeling, nuanced mediation or moderation analyses.

Treatment groups run through 2014–2016. The last follow up assessment is scheduled in December 2018. A detailed treatment manual for the new treatment method (PED-t) can be provided upon request. All treatment sessions are arranged at the Norwegian School of Sport Sciences in Oslo, Norway (NSSS).

Inclusion and exclusion criteria

Included are women aged 18–40 years with a BMI in the range of 17.5–35, a DSM-5 diagnosis of BN or BED with duration of at least 3 months, and with mild to severe symptoms (minimum one episode per week of compensatory behaviors or binge eating, respectively) [41]. A signed letter from the women's general practitioner (GP) confirming their suitability for the study is required for final enrollment.

Women not eligible are those who are or plan to become pregnant during the study period and those who are competitive athletes. Also excluded are those with a concurrent severe axis I and/or axis II mental disorder obviously in need of other treatments options not focusing on the ED. To prevent effect diffusions we also excluded individuals who have received CBT for ED during the last two years before the trial.

Recruitment

Study- and contact information is distributed through GP's, magazines and websites of the ED patient

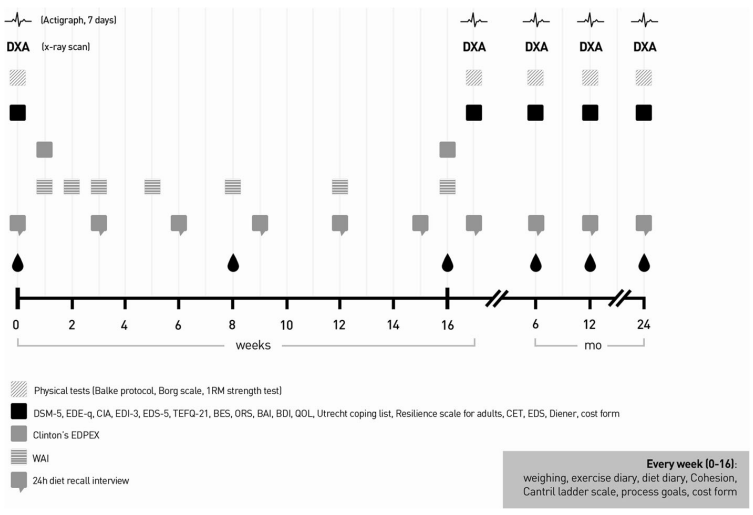

Fig. 1 Overview of measures and measurement points. Abbreviations are explained by full name in Table 4

organizations, newspaper ads, national TV, social media, and posters.

Individuals calling by phone are informed about the project purpose, and for those who pass the inclusion criteria, a diagnostic screening is conducted using the Mini-International Neuropsychiatric Interview screening [42] and the Eating Disorder Examination (EDE-q) [41, 43, 44] (Fig. 2). Final inclusion is based on three written and signed declarations, *ie,* the informed consent by the woman to take part in the trial and the assessment procedures herein, a declaration of mutual secrecy about personal information revealed in the group treatment sessions, and a signed consent from their GP that they are medically fit to participate. These documents are returned personally upon the first visit to the NSSS.

Randomization

The participants complete the baseline measures before randomization. We use block randomization of size eight (https://www.randomizer.org/) to ensure equal sized treatment arms. A project-independent fellow worker allocated eligible participants to either treatment arm according to a concealed randomization list. Researchers and test personnel in the study are blind with regard to group allocation, but due to the nature of the two treatment procedures, therapists and participants are obviously not blinded to the treatment allocation. The participants are informed about their group allocation after completing the baseline measures.

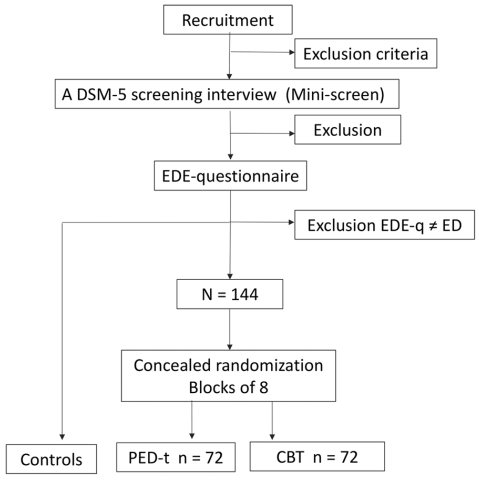

Fig. 2 Recruitment, screening and randomization of participants

Safety procedures

A stop-procedure is activated if included subjects display a worsening of ED symptoms (eg. a BMI < 17.0 and/or rapid and significant weight loss of more than 3 kg from normal weight), severe depression or if severe osteoporosis is identified among those randomized to PED-t. Individuals excluded for any of these reasons are medically evaluated for admittance to health care services. Further: if participants report not to have been eating properly before exercise sessions in the PED-t groups, or if feeling ill, we tell the participant not to participate in the physical test or the exercise session that day. During the pre- and post-tests, if participants reports severe purging or restrictive eating in the days before, no physical tests will be performed. A defibrillator is available in the lab where physical tests are held, and a medical health care team is available next house if help is needed.

Statistical power and analyses

Analysis of covariance (ANCOVA) is used to raise statistical power. The effect size of the covariates is set to R^2 = 25%, alpha = .05 and 1-beta = .80. The CBT treatment effect for EDs using the Eating Disorder Examination Questionnaire is about d = 1.30 [45]. A small change (d = 0.30) in the wait-list condition requires 14 subjects in each group (total N = 28), but since the difference between the PED-t and CBT treatment conditions is of primary interest a non-inferiority margin of d = 0.45 is considered as clinically relevant [46]. This requires a sample size of 62 + 62 subjects, increasing to 72 + 72 when adjusting for the group therapy factor (intra-class correlation = .05, design factor 1.16). The longitudinal data will be analyzed using multilevel regression models to accommodate for dependency in the repeated data within subjects and within groups. The maximum likelihood procedure uses all information available, thus, handling dropout well. Multiple imputation will be used to impute missing values. Follow-up data is analyzed with mixed model regression to estimate correct between-group treatment effects adjusted for within-group variance components related to patients and groups. Moderator variables will be included to analyze whether any treatment effects are modified by variables as motivation, therapist alliance or group cohesiveness. If treatment arms do not differ in outcome, combined latent class growth curve modeling will be conducted to analyze reasons for individual differences at startup and in the rate of change across time.

Interventions

The physical exercise and the dietary therapy (PED-t)

Physical exercise The PED-t is a treatment method particularly designed for BN and BED by our research

group, and adheres to recent guidelines developed from systematic reviews to successfully use therapist guided physical exercise [47], and recommendations for a minimal training volume to accomplish a health benefit [48–51].

The intervention aims to (re)establish healthy eating and exercise routines, to change body ideals by focusing on the body's functionality rather than body appearance and to provide knowledge about the harmful metabolic effects of swings between dieting and food craving. Education about harmful effects of unhealthy behavior is given and how basic and sports related nutritional needs may be balanced.

Three physical trainers and three dieticians conduct the intervention, all holding a master degree in sport sciences and having about three years of practice with supervised exercise. To qualify as a PED-t therapist the physical trainers hold a bachelor's degree in physical exercise and health or exercise medicine.

The weekly training program in PED-t aims to establish a healthy volume of physical activities, emphasizing the training principles of progression and variation. The exercise program consists of three weekly exercise sessions, each of 40–60 min' duration. Two sessions are resistance exercise of which one is supervised. The third exercise session consists of unsupervised pyramid interval running, involving shifts between intensive work-periods and active rest-periods with progressive duration (from one minute work period to 4 min of work period).

There are three reasons to focus on giving the participants experience with resistance exercise. First, regular resistance exercise may improve metabolism and bone mineral density, and increase muscular mass and strength [49, 52–54]. Change in body composition further increases the potential for improvement in energy metabolism, weight control and metabolic status [52, 55]. Second, the repeated bouts of supervised resistance exercise, involving technical guiding/corrections while lifting may improve body posture and awareness. Third, strength training involves easily coordinated movements, which may increase the likelihood of positive experience of mastery and weekly progression in performance. These bodily experiences during and after a period with exercise training, have potential to improve body image, self-perception, affect regulation and feeling of coping [56–60]. Intensive work periods, followed by active recovery periods, as practiced with interval training may improve cardiovascular health more effectively and with a lower risk compared to the extended exercise regimen often seen in ED [49, 61–64].

The physical strength-training program intends to improve maximal strength and growth. It is divided into five microcycles with both linear and daily variation in training load [65]. Linear progression involves increased intensity and reduction of training volume over a period of time, with the objective to increase maximal strength. Each week consists of one supervised heavy load, and one unsupervised medium load session. In the former, the number of repetition maximum (RM) increases progressively during the 16 weeks, while in the medium load session, relative load is kept constant at 10RM.

The exercises in the resistance exercise program are squats in smith-machine, lunges with dumbbells, seated dumbbell shoulder press, bench press, latissimus pulldown and seated row in cable machine. The intensity and work periods in the interval running program, follows a traditional pyramid structure performed with progressive interval periods and active rest periods, and then repeated in reverse. After a 10 min warm up, the interval periods are initiated by the first work period of 1 min and a 30 s active rest period (lower intensity), followed by the next work periods of 2 and 3 min and their corresponding rest periods of 60 and 90 s respectively. During the last six weeks, an extra interval period adds to the program with 4 min of work and 2 min of active rest (Table 1).

During the mid-period (week 8–11) a supervised fourth, weekly group exercise session is introduced, leading the participants to do both the resistance exercise sessions unsupervised. The intention of introducing the participants to the fourth, additional exercise sessions is to inspire them to find a variety of training modalities that can improve physical fitness and promote training joy. Further, the intention with the group sessions is also to make them more experienced in exercising together with others, supervised by an instructor. The four sessions are Total body Resistance eXercise (TRX), suspension training or Cat slide exercise, one boot camp session, one indoor cycling class, and one combat inspired session.

Dietary therapy The dietary therapy consists of three modules (Table 2), aiming to re-establish healthy dietary routines through weekly lectures, and on discussions related to the weekly topics and the experiences by the participants. Between every session, the participants register the meals they are consuming (pen and paper), and work on individual tasks related to dietary routines (increase number of meals per day, increase volume of food in each meal, improve the composition of the meal etc.).

The cognitive behavioral therapy (CBT)

Our manual-based CBT has a group format, and rests on the transdiagnostic model of generic core ED-pathology across ED-diagnoses [45]. The treatment runs through four stages (Table 3). All sessions are videotaped

Table 1 Overview of the exercise module of the PED-t treatment arm

		SUPERVISED EXERCISE	UNSUPERVISED EXERCISE	
Week	Microcycle	Resistance exercise	Interval running	Resistance exercise
1–3	1	10 RM	Pyramid interval	10 RM
4–7	2	8 RM	Pyramid interval	10 RM
8–11	3	6 RM	Pyramid interval	10 RM
12–14	4	4 RM	Pyramid interval	10 RM
15–16	5	2 RM	Pyramid interval	10 RM

Resistance load is given as number of repetition maximum (RM)

and coded according to a CBT manual adherence form [66]. Psychologists who are experienced with CBT and EDs run the CBT treatment.

Measures and variables

Standardized instruments with good psychometric quality and high clinical utility are included throughout. Count variables measure physical injury and illness [67], and the number of participants meeting DSM-5 criteria for BN or BED [41], respectively. Psychological measures comprise both positive and negative clinical features (Table 4). Since variables of the same measurement domain (*eg.*, eating pathology) will likely be highly multicolinear, these variables will not be combined in the same regression analysis.

Biological measures acknowledged as gold standard methods for assessing physical fitness as well as body composition and bone health [68–70] are used. They comprise changes in blood pressure, serum ferritin, total, high, and low cholesterol, respectively, triglycerides, Apo A, Apo B, vitamin D, folic acid, leptin, insulin CTX-1 and PTH, estradiol, progesterone, TSH, T3, T4, FSH, LH, and cortisol. Also included are objective measures of physical activity (ActigrapgGT3X) [71], a cardio pulmonary exercise test (CPET) to screen for aerobic physical fitness (an incremental modified Balke protocol and Borg Scale) [72–74], muscular strength (1RM test on three selected events -squats, bench press, seated row) [69], resting metabolic rate, bone mineral density (BMD), body fat and lean body weight. Body composition is measured using **d**ual-**e**nergy **x**-ray **a**bsorptiometry (DXA) (Lunar iDXA, GE Healthcare, enCORE Software, Version 14.10.022) performing a three site scan (lumbar L2-L4, femoral neck, –trochanter and –shaft, and whole body scan) and analysis procedure according to the guidelines for best practice [75]. Physical tests and DXA-measurements are conducted in the lab at the NSSS, and blood samples are collected by qualified lab personnel and stored frozen until analyzed in a certified lab.

Reasons for physical exercise is measured using the Exercise Dependence Scale [76], and the Compulsive Exercise Test [77]. Throughout the 20 weeks of the physical and dietary therapy, program a training diary records intensity, type of training, and time. Dietary intake and energy/nutrient status is measured through a

Table 2 Overview of the content of the dietary module of the PED-t treatment arm

Module	Therapy session	Targets	Main content
1	1–5	Dietary routines & structure	Meal frequency
			Portion size
			Eating situation
			Exercise theory
			Repetition and summary
2	6–17	Nutritional knowledge & practical skills	Energy needs
			Daily routines
			Nutrients
			Nutritional labels
			Impulsive food shopping
			Exercise theory
			Sports nutrition
			Repetition and summary
3	18–20	Summary of future plans	Reflections, repetition and summary
			Presenting a personal plan for the future (exercise, diet, daily routines)

Table 3 Overview of the cognitive behavior therapy (CBT) module

Stages	Therapy session	Targets	Main content
1	1–4	Engagement, preparation and early behavior change	Educate about the nature of CBT and how the therapist and the participants work together
			Engage the participants in the treatment.
			Develop a case formulation for each participant.
			Strategies to take control over the behavioral symptoms of BN and BED
2	5–6	Monitoring and evaluating progress and barriers to change	A detailed review of progress so far, and to identify barriers to change
3	7–16	Modifying the core pathology of ED	Reduce the over-evaluation of weight and shape
			Address extreme dieting, binge eating, and purging
4	17–20	Consolidating change and relapse prevention	Secure that progress is maintained after treatment end

24-h diet-recall interview (pre, week 3, 6, 9, 12, 16 and post), weight change (pre/post and separate weekly weigh-ins). Blood samples are taken in week 0, 8, and 17, respectively.

Patient satisfaction is measured using the "Expectations and experiences of ED-treatment" scale [78]. Qualitative approaches, such as in-depth interviews, may give additional insights into ED-patients' perspectives and satisfaction with treatment [79, 80]. Therefore, a sufficient number of participants to meet data saturation criteria [81] are qualitatively interviewed about a) the immediate overall satisfaction with particular therapy sessions, the therapy process and outcomes, b) the recovery process; and c) the extent to which participants experience long-term treatment benefits. Interview data are analyzed in four steps within the framework of systematic text condensation [81]. Direct and indirect costs associated with treatment and follow-up are recorded prospectively.

Mediator variables comprise the "Working Alliance Inventory" [82] and the "Coerciveness" subscale from the "Therapeutic Factor Inventory" scale [83], both showing good psychometric qualities [84, 85].

Participants not continuing in the study will be compared to those who do continue by examining for differences in the pretest outcome measures.

Discussion

Support to our hypotheses and predictions will provide a platform for enlarging the portfolio of evidence-supported treatments for BN and BED. Enlarging this portfolio is a major achievement given the complex nature of these disorders. An important additional task is to examine which patient, treatment or common therapeutic factors that facilitate a stronger response to cognitive behavioral treatment versus dietary/physical therapy. By bringing ahead knowledge of who responds best to which kind of treatment, we may offer help to a larger proportion of sufferers of ED.

The present trial also offers a possibility of exploring generic therapeutic mechanisms, *eg.* therapeutic alliance, group cohesion or experience of universality among group members facilitating treatment effects. For EDs the impact of such mechanisms in CBT treatment is less understood [18, 31–33, 35, 36] in particular with respect to BN and BED [34], and for obvious reasons completely unknown with respect to the novel physical exercise and dietary treatment program. The exploring of the impact of such mechanisms imply a search for the mediation effects and when such effects occur during the course of treatment. This knowledge may pave the way for future research into the effects of treatment modules, the succession of modules and the possibility of shortening the treatment length without cutting down on treatment intensity.

In principle, as effective treatments can be unaffordable and intolerable, it is essential to capture the patient satisfaction aspects. The limited number of studies of patients' satisfaction with treatment have used biased retrospective recalls of treatment modalities rather than methods [11, 86, 87]. In contrast, we use prospective quantitative and qualitative measures to study how satisfaction might be

Table 4 Overview of the psychological measures in the PED-t trial

Eating Disorder Examination-Questionnaire (EDE-q) [95]	Binge Eating Scale (BES) [96]
Clinical Impairment Assessment (CIA) [95]	Beck Anxiety Inventory (BAI) [97]
Eating Disorder Inventory-3 (EDI-3) [98]	Three-Factor Eating Questionnaire (TFEQ-21) [99]
Eating Disturbance Scale (EDS) [100]	Beck Depression Inventory (BDI) [101]
Subjective well-being scale [102]	Cantril's Ladder Scale [103]
Utrecht Coping List [104]	Resilience Scale for Adults [105]
Outcome Rating Scale (ORS) [106]	Oslo Sports Trauma Research Center questionnaire on health problems (OSTRC) [67]

associated with pretreatment expectations, treatment elements, or generic factors in the two treatment arms.

The level of actual knowledge about the costs and benefits of treatments does not meet health authorities' need to control the health budgets. A recent review located only one CBT study on EDs, also flawed by retrospective recall of direct costs only [8]. The present trial adds to the basis of knowledge by prospective recording of direct and indirect illness-related costs.

In recent years, dissemination has been highly at focus with respect to CBT [88], showing that CBT can be delivered by health professionals other than heavily trained and payed psychologists and psychiatrists. An affordable and tolerable new program with an equal or better effect than CBT would represent major societal benefits in the sense that the PED-t can be delivered by new groups of professionals, *eg*. exercise therapists and registered dietitians, hence a possibility of reaching out to new segments of those sufferers who are reluctant to seek help through the health care services.

However, a concern can be raised about treatment effectiveness, *ie*. how well the PED-t might perform in clinical settings. Two deviations from such settings should be mentioned, i.e. the failure to offer booster sessions to consolidate changes during treatment, and to exclude severe comorbid conditions frequently found among patients with BN and BED [89–93], notably anxiety, depression, personality disorders, and active substance abuse. Regrettably, on the other hand, a long waiting time before starting treatment would actually mirror real life clinical settings. The impact of such waiting time on drop-out rates from treatment does, however not seem relevant here as such impact is relevant mostly for patients with severe comorbid conditions [94].

Abbreviations

ANCOVA: analysis of covariance; BAI: Beck Anxiety Inventory; BDI: Beck Depression Inventory; BED: Binge eating disorder; BES: Binge Eating Scale; BMD: bone mineral density; BMI: body mass index; BN: Bulimia nervosa; CBT: cognitive behavioral therapy; CIA: clinical impairment assessment; CTX-1: carboxy-terminal collagen crosslinks; DSM-5: diagnostic and statistical manual of mental disorders, 5th edition; DT: dietary therapy; DXA: dual-energy x-ray absorptiometry; ED: eating disorders; EDE-q: Eating Disorder Questionnaire; EDI-3: Eating Disorder Inventory, version 3; EDS: Eating Disturbance Scale; FSH: follicle-stimulating hormone; GP: general practitioner; LH: luteinizing hormone; NSSS: Norwegian School of Sport Sciences; ORS: Outcome Rating Scale; OSTRC: Oslo Sport Trauma Research Center questionnaire on health problems; PE: physical exercise; PED-t: Physical exercise and dietary therapy; PTH: Parathyroid hormone; RM: repetition maximum; T3: triiodothyronine; T4: thyroxine; TFEQ-21: Three Factor Eating Questionnaire, 21 items version; TSH: thyroxine stimulating hormone

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Availability of data and materials

Data sharing is not applicable to this article as no datasets were generated or analysed.
The Project group monitor the data gathering and filing process continuously. Data are handled and stored according to guidelines given by the Norwegian Regional Committees for Medical and Health Research Ethics. All data are de-identified. The identification numbers are stored electronically and separate from the clinical data. The list that maps ID numbers to the personal information will be erased when the project is finished, thus completely anonymizing the data during the current study. Data will for the future be held within the project group.

Authors' contributions

This study is a multidisciplinary cooperation between experts in exercise medicine from the NSSS and the University College of Southeast Norway, and experts in nutrition from Oslo University Hospital and experts in psychology, CBT and methodology from the UiT- The Arctic University of Norway, and from the treatment and research institution Modum Bad. Dr. JSB provided the original research idea, and is responsible for project planning and -running together with ph.d.-student TFM, drs. GP, JR, and OF. Testing and running of the treatments are handled by the ph.d.-student (PED-T) and drs. TS and KV (CBT), supported by research assistants. Qualitative data are collected by another ph.d.-student (MB). Drs. GP and OF are chief responsible for the qualitative and quantitative data analyses, respectively. The ph.d. student TFM, drs. SBS and MS are responsible for planning and implementation of the physical exercise –and the dietary program. Ph.d student MB and dr. RW have contributed in the qualitative aspects of the study. JSB, JR and TFM wrote the main manuscript, OF managed the statistical description, TFM, SBS, TS, KV, and MS described the interventions and methods in the manuscript, MB, RW and GP contributed with the description of the qualitative aspects in the manuscripts, and all authors have approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

Not applicable.

Ethics approval and consent to participate

The trial is approved by the Norwegian Regional Committee for medical and health research ethics identifier: 2013/1871 the 23rd of October 2013, and prospectively registered in Clinical Trials identifier: NCT02079935 the 17th of February 2014. All participants sign an informed consent delivered at the first visit on NSSS.

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ORIGINAL ARTICLE

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Body composition and physical fitness in women with bulimia nervosa or binge-eating disorder

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Abstract

Objective: Knowledge about physical fitness in women with bulimia nervosa (BN) or binge-eating disorder (BED) is sparse. Previous studies have measured physical activity largely through self-report, and physical fitness variables are mainly restricted to body mass index (BMI) and bone mineral density. We expanded the current knowledge in these groups by including a wider range of physical fitness indicators and objective measures of physical activity, assessed the influence of a history of anorexia nervosa (AN), and evaluated predictive variables for physical fitness.

Method: Physical activity, blood pressure, cardiorespiratory fitness (CRF), muscle strength, body composition, and bone mineral density were measured in 156 women with BN or BED, with mean (*SD*) age 28.4 years (5.7) and BMI 25.3 (4.8) kg m^{-2}.

Results: Level of physical activity was higher than normative levels, still <50% met the official physical activity recommendation. Fitness in women with BN were on an average comparable with recommendations or normative levels, while women with BED had lower CRF and higher BMI, VAT, and body fat percentage. We found 10–12% with masked obesity. A history of AN did not predict current physical fitness, still values for current body composition were lower when comparing those with history of AN to those with no such history.

Discussion: Overall, participants with BN or BED displayed adequate physical fitness; however, a high number had unfavorable CRF and body composition. This finding calls for inclusion of physical fitness in routine clinical examinations and guided physical activity and dietary recommendations in the treatment of BN and BED.

KEYWORDS

binge-eating disorder, bulimia nervosa, cardiorespiratory fitness, eating disorders, muscle strength, physical activity, physical fitness

Trial Registration: Prospectively registered in REC the 16th of December 2013 with the identifier number 2013/1871, and in Clinical Trials the 17th of February 2014 with the identifier number NCT02079935.

1 | INTRODUCTION

Lifestyle behaviors like diet and exercising may affect physical fitness in many ways and cause profound changes, ultimately affecting total morbidity and mortality (Mendis, 2014; Myers et al., 2015; Ross, et al., 2016). Besides body mass index (BMI) and bone mineral density, information on physical fitness (i.e., physical activity level, blood pressure, cardiorespiratory fitness [CRF], muscle strength, total body composition, and body fat distribution) in individuals with binge-eating disorder (BED) or bulimia nervosa (BN) is scant. As such, physical fitness is rarely considered in treatment, leaving this population at an increased risk for physical comorbidity.

Individuals with BED have been described as sedentary (Hrabosky, White, Masheb, & Grilo, 2007; Vancampfort et al., 2015), whereas the opposite has been the case for those with BN. In patients with BN, the level of physical activity may even be higher than in the general population (Bratland-Sanda et al., 2010a; Davis et al., 1997), and in about 20–30% of female patients, physical activity may be highly excessive and compulsive in nature (Dalle Grave, Calugi, & Marchesini, 2008; Davis et al., 1997; Haskell et al., 2007; Shroff et al., 2006).

CRF is closely related to physical activity and suggested as one of the most important indicators of physical fitness and mortality (Myers et al., 2015; Ross et al., 2016). The few studies that have examined CRF among women with BN (Bratland-Sanda, et al. 2010b; Sundgot-Borgen, Rosenvinge, Bahr, & Schneider, 2002) indicate both inferior and comparable fitness relative to normative values (Edvardsen, Hansen, Holme, Dyrstad, & Anderssen, 2013). CRF has not previously been reported for individuals with BED. Furthermore, in the general population, muscular strength has been positively correlated with self-reported health (Payne, Gledhill, Katzmarzyk, Jamnik, & Ferguson, 2000), optimal body composition, and metabolic regulation (Artero et al., 2012; Bakker et al., 2017). Little is known about muscular strength in women with BN or BED, apart from one study of female inpatients with longstanding BN (Bratland-Sanda et al., 2010b), which reported levels of muscular strength comparable with healthy controls.

Normal BMI values have been found for BN (Hudson, Hiripi, Pope, & Kessler, 2007; Probst et al., 2004), and overweight and obesity have been associated with BED (Bulik & Reichborn-Kjennerud, 2003; Vancampfort et al., 2013; Wilfley, Wilson, & Agras, 2003). However, an increase in lifetime obesity within all eating disorder (ED) diagnoses (Bulik, Marcus, Zerwas, Levine, & La Via, 2012; Villarejo et al., 2012) may account for findings of a 70% prevalence of overweight and obesity in patients with BN or BED (Hudson, Hiripi, Pope, & Kessler, 2007; Kessler et al., 2013). Nonetheless, body composition, more than body weight categorization, seems to be important in evaluating the risk of physical health complications (Hamer, O'Donovan, Stensel, & Stamatakis, 2017). Evaluations of body composition need information, which has been largely missing in the ED literature, notably with respect to fat mass, regional body fat storage, lean body mass, visceral adipose tissue (VAT), and bone mineral density. Women with BN in the lower and upper BMI categories have been shown to have lower and higher body fat percentage (%BF), respectively, compared with healthy controls (Probst et al., 2004). Moreover, increased VAT is reported among weight-restored females with anorexia nervosa (AN) (Iketani, Kiriike, Nagata, & Yamagami, 1999) as well as among women with BN or BED (Ludescher et al., 2009). Findings on bone mineral density in BN have been equivocal, whereas information on bone mineral density in women with BED is sparse (Robinson, Aldridge, Clark, Misra, & Micali, 2016; Solmi et al., 2016).

A history of AN may be decisive on findings of current body weight, body composition, and bone mineral density. Hence, when evaluating the interrelationship between BN or BED, body weight and composition, history of AN might be important to consider. A few studies addressing this interrelationship have shown that a history of AN is an important determinant of current body weight and variables of body composition in persons with current diagnosis of BN compared with those with no history of AN (Naessén, Carlström, Glant, Jacobsson, & Hirschberg, 2006; Robinson et al., 2016; Vaz, Guisado, & Peñas-Lledó, 2003). Moreover, how different EDs relate to level of physical activity, physical fitness, and body composition is hampered by the fact that only a limited number of health variables are examined and with various methods. In particular, the wide use of subjective and self-report measures is a consistent source of underestimation of CRF and physical activity among individuals with ED (Bratland-Sanda et al., 2010a; Soundy, Taylor, Faulkner, & Rowlands, 2007).

The present study aims to provide extensive information about objectively measured physical fitness (physical activity level, blood pressure, CRF, muscle strength, body weight history and current body weight, body composition, and bone mineral density) among women with BN or BED and to describe the results relative to normative or recommended levels. We also compare individuals according to a history of AN, regardless of current ED diagnosis. We hypothesize that persons with BN or BED have impaired physical fitness as compared with normative or recommended values and that values for body composition and bone mineral density are lower in women with a history of AN compared with those with no history of AN.

2 | METHOD

For the purpose of the present study, 156 female participants were included. They represented the full eligible sample recruited for a randomized controlled trial to investigate whether a new physical exercise and dietary therapy treatment program may reduce symptoms of BN and BED equally to cognitive behavioral therapy (Mathisen et al., 2017). Figure 1 provides an overview of the recruitment and screening procedures. Responders to recruitment were considered for inclusion if they were between 18 and 40 years of age, had a BMI range between 17.5 and 35, a Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) diagnosis of BN or BED with mild-to-severe symptoms. Diagnosis was based on information from Eating Disorder Examination Questionnaire 6.0 (EDE-Q), self-reported behavior according to DSM-5 diagnostic criteria (printed form), and finally confirmed by clinical assessment. A final inclusion required signed confirmation from the participant and their general practitioner. Women who were currently pregnant, a competitive athlete, had a concurrent severe

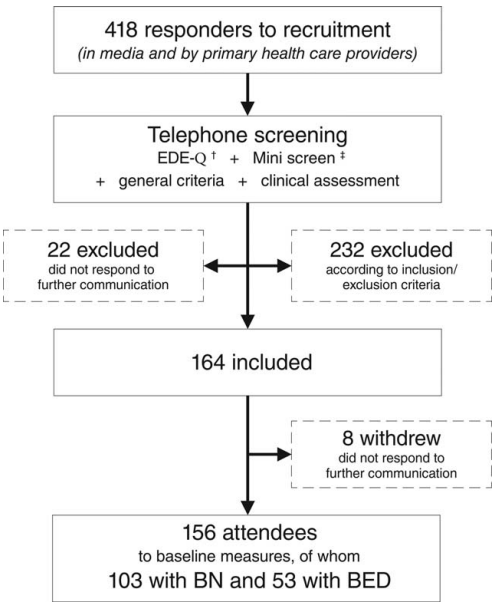

FIGURE 1 Flow chart of inclusion of participants to the present study based on who were recruited for participation in the original RCT studying the effects of cognitive behavior therapy (CBT) versus a physical exercise and dietary therapy treatment program (PED-t) (Mathisen et al., 2017). *Note*. †Fairburn et al. (2008), ‡Sheehan et al. (1997)

symptom or personality disorder in need of other treatment options, and those who had received cognitive behavior therapy for ED for the last two years before the study were excluded. All participants attending the assessment at baseline before the commencement of the mentioned treatment are included in the present descriptive study. The study has been approved by the Norwegian Regional Committee for Medical and Health Research Ethics (ID: 2013/1871) and registered in Clinical Trials (ID: NCT02079935).

2.1 | Physical activity, CRF, and muscle strength

Sedentary time and physical activity were objectively measured for 7 consecutive days using the ActiGraph accelerometer (ActiGraph GT3x and GT3x+; Actigraph, LCC, Pensacola, FL) placed on their right hip. It was only removed for water activity and night-time sleep. All accelerometers extract data from the vertical axis in 60-s epochs with 30 Hz sampling rate. Nonwear time was determined as continuous zero-count epochs lasting at least 60 min (allowing for two exceptions). Wear days were deemed valid if worn for at least 600 min/day and a minimum of two valid days. Intensity-specific physical activities were derived using the Troiano cut-points (Troiano et al., 2008), and continuous bouts of moderate-to-vigorous physical activity (MVPA) were determined by summing the time (in min) of at least moderate intensity that was a part of a bout of MVPA minutes lasting at least 10 min (allowing for two drops in intensity before terminating the bout).

All participants were instructed to fast and to travel using passive transportation to the laboratories at the Norwegian School of Sport Sciences from 7:30 to 10:00 a.m. Resting blood pressure was measured twice according to a standardized protocol (Mancia et al., 2013) with an automatic blood pressure device (Spot Vital Signs LXi; Welch Allyn, Skaneateles Falls, NY). The average recordings were used.

One to three hours after the participants completed the body composition measurement and ate breakfast, their CRF was measured by performing a cardiopulmonary exercise test on a treadmill (ELG 90/200 Sports; Woodway, Weil am Rhein, Germany) with an incremental modified Balke protocol until exhaustion (Edvardsen, Hem, & Anderssen, 2014). Gas exchange was measured using a breath-by-breath gas analysis system (OxyconPro analyzer; Jaeger, Würtzburg, Germany) with a Hans Rudolph two-way breathing mask (2700 series; Hans Rudolph, Kansas City, KS). Measures of respiratory exchange ratio (RER) $\geq$ 1.10, and lactate concentration $\geq$ 7.0 mmol/L measured 1 min after test termination and analyzed immediately in a 1500-Sport-lactate analyzer (YSI, Yellow Springs Instruments, Yellow Springs, OH), were required to ensure a valid measure of maximal oxygen uptake (VO_{2max}) (Edvardsen et al., 2013). A Borg scale rating $\geq$ 17 was additionally required to approve the test result (Borg, 1982; Haff & Dumke, 2012).

Maximal strength tests (one repetition maximum, 1RM) followed the cardiopulmonary exercise test in the following order: squats in machine, bench press, and seated cable row. These three tests were performed according to predefined performance criteria and initiated with standardized warm-up sets of 10–8–6–4 repetitions.

2.2 | Body composition and bone mineral density

Participants were weighed in their underwear, and their height was measured with a fixed stadiometer (Seca scale, Mod: 8777021094, S/N: 5877248124885, Seca Deutschland, Hamburg, Germany). A dual-energy X-ray absorptiometry (Lunar iDXA, enCORE Software, version 14.10.022; GE Healthcare, Madison, WI) performing a three-site scan (lumbar area [L2-L4]; femoral neck, trochanter, and shaft [proximal femur]; whole body) was used to measure body composition (fat mass, %BF, lean body mass, VAT, android-to-gynoid fat mass ratio [AG ratio], bone mineral content, and bone mineral density). All data were analyzed according to the guidelines (Nana, Slater, Stewart, & Burke, 2015). Recommended %BF for premenopausal females was set at $<$33%, based on an evaluation of previous studies (Imboden et al., 2017a; Okorodudu et al., 2010). By combining BMI and %BF information, we defined a woman as having "masked obesity" if BMI $<$ 25 and %BF $\geq$ 33%.

2.3 | Questionnaires and retrospective information

All participants completed the EDE-Q (Fairburn, 2009) and provided information on ED-history, body weight fluctuation, and menstrual history (Mathisen et al., 2017). The EDE-Q cutoff scores 2.62 and 2.63 have been identified as valid in identifying BN and BED, respectively, among Norwegian adults (Rø, Reas, & Stedal, 2015).

TABLE 1 Characteristics of participants with BN or BED related to age and illness history

variable	BN		BED	
	n	*M* (*SD*)	*n*	*M* (*SD*)
Age (years)	103	27.8 (5.5)	53	29.5 (6.1)
Duration of illness (years)	103	11.9 (6.6)	53	13.5 (8.1)
EDE-Q, global score	102	3.8 (.9)	53	3.6 (.9)
Previous history of AN, *n* (%)	32 (36.0%)		5 (10.4%)	

2.4 | Reference measures

For comparative reasons, we included the recommended or normative levels for physiological fitness in Section 3, all presented consecutively with corresponding references.

2.5 | Statistical analyses

All data were analyzed with SPSS version 24 (IBM, Armonk, NY). The results were presented as mean (standard deviation [*SD*]) unless otherwise stated. For evaluation of the physiological variables mean values of norms and recommendations were added when attainable, and with reference to the more descriptive purpose of this study, a liberal 99% confidence interval was used to enable statistical comparisons.

Multiple linear regressions were calculated separately for BN and BED to identify models to predict %BF, VAT, and bone mineral density in the spine and proximal femur, respectively. Excluded from the models were variables that were statistically nonsignificant in the bivariate correlations.

Inspection of the scatter plot of VAT and %BF indicated a distinct bend in the curve at roughly the same location as previously reported in a piecewise regression model (i.e., at 38.8% BF) (Bosch et al., 2015). We therefore performed a similar analysis and searched empirically for the cutoff point that maximized R^2 (explained variance) in our study. The piecewise regression model was specified as $f(\text{VAT}) = b_0 + b_1\text{BF\%} + b_2\text{BF\%}_{\text{high}}$. $\text{BF\%}_{\text{high}}$ was coded as $\left\{ \begin{matrix} \text{BF\% if BF\%} \geq 0 \\ 0 \text{ if BF\%} < 0 \end{matrix} \right\}$, 0 representing the centered BF% value around the chosen cutoff.

The results from participants who had errors in the registration of physical parameters, and from 30 participants in the presentation on history of body weight fluctuations (due to missing self-reports), were excluded from the respective and relevant analysis.

Participants with a history of AN were compared with those with no such history by analysis of variance and Mann–Whitney *U* test. Due to multiple comparisons, a Bonferroni correction ($p = .05/17$ tests) was used to reduce the family-wise error rate and *p* values <.003 were considered statistically significant. Standardized mean differences were calculated as Hedge's *g* (Hedge & Olkin, 1985). These effect sizes were interpreted as small, moderate, or large if larger than .2, .5, or .8, respectively. The results of 19 participants were excluded from the analysis because of missing information on history of AN.

3 | RESULTS

The mean (*SD*) age and BMI for all included were 28.4 (5.7) years and 25.3 (4.8) kg/m^2, respectively. The characteristics of included participants are presented in Table 1 according to diagnosis.

3.1 | Physical activity, CRF, and muscle strength

Less than half of the participants with BN or BED complied with recommendations for physical activity, whereas one third of the participants in each of the diagnostic groups had high levels of physical activity (i.e., ≥30 continuous minutes of MVPA) (Table 2). Increased blood pressure was found among 24.7% and 28.0% of participants with BN and BED, respectively, of whom seven (6.9%) participants with BN and three (6.0%) participants with BED were classified as hypertensive for either systolic or diastolic blood pressure. The mean CRF among participants with BED, and the CRF in 20% of participants with BN, was below the previously suggested healthy threshold of 35.1 mL kg^{-1} min^{-1} (Aspenes et al., 2011).

3.2 | Body composition and bone mineral density

The majority of participants with BN had normal weight, whereas the majority of participants with BED were overweight or obese (Table 3). Moreover, 12 (12%) participants with BN and 5 (9.4%) participants with BED had masked obesity.

The mean BF% and mean VAT were below recommended upper thresholds in participants with BN, but above such thresholds in participants with BED (Table 4). Overall, the AG ratio correlated well with VAT in both samples. However, a small variation in VAT was observed with AG ratio < 1.0, whereas there was a strong, correlational increase in VAT with AG ratio > 1.0.

Among participants with BN, BMI (β = 1.76, 95% confidence interval, CI, [1.46, 2.07]) and MVPA (in 10-min increments) (β = −.75, 95% CI [−1.21, −0.30]) accounted for 65.9% of the %BF variation ($F[2,78] = 78.19$, $p < .001$). With respect to BED, BMI alone accounted for 67.2% of the variation in %BF (β = 1.39, 95% CI [1.12, 1.66]) ($F[1,51] = 107.6$, $p < .001$).

For participants with BN, BMI alone accounted for 51.2% of the variation in VAT (β = 59.72, 95% CI [48.26, 71.19]) ($F[1,100] = 106.8$, $p < .001$). By contrast, 68.2% of the variation in VAT among participants with BED was accounted for by BMI (β = 80.24, 95% CI [63.23, 97.26]) and CRF (β = −0.34, 95% CI [−0.51, −0.16]) ($F[3,49] = 55.7$, $p < .001$).

The piecewise regression models with %BF as the predictor and VAT as the outcome showed a maximum R^2 using BF% cutoff values of 35.7% and 31.9% BF for BN and BED, respectively (Figure 2). The first linear part predicted 44.3% and 56.4% of variation, respectively, whereas the additional modeling of the steeper increase in VAT after the cutoff points predicted an additional 19.6% and 8.1%, respectively ($p < .001$ for all). For BN, the β coefficients were 6.1 ($p = .07$) and 64.9 ($p < .001$), thus yielding an increase of 71 g VAT per unit change in BF% after the BF% cutoff point (35.7%). For BED, the β coefficients were −27.3 ($p = .24$) and 93.1 ($p < .001$), thus yielding

TABLE 2 Physical fitness in participants with BN or BED, and healthy normative (no) or recommended (re) levels

Physiologic variable	BN		BED		Normative (no)/ recommended (re)
	n	*M* (*SD*) [CI]	*n*	*M* (*SD*) [CI]	
Physical activity level per day, counts per min	81	457.2 (163.2) [409.3, 505.0]	44	433.5 (153.4) [367.1, 493.9]	349.0 (141.0) (no)[a]
Average time spent in moderate to vigorous activity, min/day	81	24.4 (19.8) [18.6, 30.2]	44	23.0 (20.3) [15.3, 31.9]	15.0 (.8) (no)[a]/21.4 (re)[a]
Physically active according to recommendations, *n* (%)	81	38 (46.9%)	44	19 (43.2%)	28.5% (CI: 24.1, 32.9) (no)[a]
Average sedentary time per day (min/day)	81	601.2 (60.7) [583.4, 618.9]	44	599.8 (60.1) [574.7, 624.2]	547.0 (4.0) (no)[a]
Systolic blood pressure (mmHg)	101	118.3 (12.7) [115.0, 121.6]	50	121.9 (10.4) [118.0, 125.9]	120–129 (re)[b]
High normal systolic blood pressure, *n* (%)	13 (12.9%)		9 (18.0%)		130–139 (re)[b]
Diastolic blood pressure (mmHg)	101	75.6 (7.6) [73.6, 77.6]	50	78.4 (6.9) [75.8, 81.1]	80–84 (re)[b]
High normal diastolic blood pressure, *n* (%)	6 (5.9%)		7 (14.0%)		85–89 (re)[b]
Maximal oxygen uptake (L min^{-1})	100	2.65 (.45) [2.53, 2.76]	52	2.73 (.49) [2.54, 2.91]	2.60 (.44) (no)[c]
Maximal oxygen uptake (mL BW^{-1} min^{-1})	100	40.7 (6.8) [38.9, 42.5]	52	34.6 (8.1) [31.6, 37.6]	40.0 (7.3) (no)[c]
Maximal oxygen uptake (mL LBM^{-1} min^{-1})	100	60.5 (7.7) [58.4, 62.5]	52	58.5 (8.9) [55.2, 61.8]	54.7 (8.6) (no)[c]
Squat, 1RM (kg)	96	65.4 (19.2)	46	61.4 (17.6)	
Squat, relative 1RM (kg BW^{-1})	96	1.00 (.31)	46	.79 (.25)	
Bench press, 1RM (kg)	96	37.8 (10.1)	49	37.6 (9.5)	
Bench press, relative 1RM (kg BW^{-1})	96	.58 (0.16) [.54, .62]	49	.47 (.13) [.42, .53]	.39 (.08) (no)[d]
Seated row, 1RM (kg)	96	33.6 (8.2)	46	34.6 (5.9)	
Seated row, relative 1RM (kg BW^{-1})	96	.51 (.13)	46	.44 (.09)	

Note. LBM = lean body mass; 1RM = one repetition maximum. 99% Confidence intervals (CI) are presented for variables with recommended or normative values, for comparisons.
[a]Hansen et al. (2015).
[b]Mancia et al. (2013).
[c]Edvardsen et al. (2013) (mean values of age group 20–29 and 30–39).
[d]Brown et al. (1998) (mean values of age group 20–29 and 30–39).

an increase of 65.8 g VAT per unit change in BF% after the BF% cut-off point (31.9%).

Three (2.9%) participants with BN and six (11.3%) participants with BED had spine Z-scores corresponding to low bone mineral density, and one participant with BN had a spine T-score corresponding to a diagnosis of osteoporosis. Furthermore, one participant with BN and one participant with BED had proximal femur Z-scores corresponding to low bone mineral density. Results for bone mineral density are presented in Table 5.

Among participants with BN, BMI ($\beta = 0.015$, 95% CI [0.007, 0.023]) and lean body mass ($\beta = 0.007$, 95% CI [0.002, 0.012]) accounted for 28.8% of spine bone mineral density variations [$F(2,99) = 21.4$, $p < .001$]. No significant determinants were detected for participants with BED.

For BN, BMI ($\beta = .02$, 95% CI [.02, .03]) and 1RM squat ($\beta = .002$, 95% CI [.001, .003]) accounted for 45.0% of variance in proximal femur bone mineral density [$F(2,93) = 39.8$, $p < .001$]. No variables were related to femur bone mineral density among participants with BED.

3.3 | History of AN

Overall, participants with a history of AN had lower values on variables related to body composition compared with those with no history of AN, with effect size >.6 (Table 6).

TABLE 3 Body mass index (BMI) and body fat percentage (%BF) in participants with BN or BED

	BN ($n = 103$)		BED ($n = 53$)	
BMI class	**% Of participants**	**%BF M (*SD*)**	**% Of participants**	**%BF M (*SD*)**
Underweight (BMI < 18.5)	5.8	18.7 (2.5)	—	—
Normal weight (BMI 18.5–24.9)	61.2	27.4 (6.2)	28.3	31.2 (5.5)
Overweight (BMI 25–29.9)	28.2	36.2 (6.0)	30.2	37.1 (7.0)
Obese (BMI ≥ 30)	4.9	44.5 (4.4)	41.5	46.9 (4.4)
%BF ≥ 33%, *n* (%)	39 (37.9%)		40 (75.5%)	

4 | DISCUSSION

Overall, results from this study showed that women with BN or BED were more physically active than a national healthy cohort of a comparable age span and sex, still less than half of the participants with BN or BED met the official minimal recommendations for physical activity. Furthermore, women with BN were comparable with the healthy population in physical fitness, whereas women with BED scored lower on maximal oxygen uptake and higher on BMI, BF%, and VAT than the normative or recommended levels. Despite overall average normal findings on physical fitness, we identified high numbers of women with BN or BED with unfavorable CRF and body composition and up to 12% had masked obesity. Furthermore, after comparing participants with history of AN to those with no such history, we found that the former had generally lower values on physical fitness variables.

4.1 | Physical activity, CRF, and muscle strength

The finding of a higher level of physical activity and time spent in MVPA in both diagnostic groups, compared with a national cohort study (Hansen et al., 2015), replicated a previous finding, being the first to report on physical activity in patients with ED using objective measures (Bratland-Sanda et al., 2010a). The finding from the current study was mainly because of higher volume of continuous time spent in MVPA per day. Nevertheless, the recommendation relates to a minimum of physical activity. The fact that less than half of the participants in this study complied with the recommended weekly MVPA (Haskell et al., 2007), and spent about 10 hr being sedentary, makes it fair to hypothesize that such a sedentary lifestyle among women with BN and BED increases the risk of medical comorbidity (Myers et al., 2015; Warburton, Nicol, & Bredin, 2006).

TABLE 4 Anthropometrics and body composition in participants with BN or BED, and normative (no) or recommended (re) levels

	BN		BED		
Soft body tissue variables	***n***	***M* (*SD*) [CI]**	***n***	***M* (*SD*) [CI]**	**Normative (no)/ Recommended (re)**
Body weight (kg)	103	66.2 (11.8)	53	81.4 (15.5)	
Height (cm)	103	167.6 (6.5)	53	168.1 (6.7)	
BMI (kg m^{-2})	103	23.5 (3.6) [22.6, 24.4]	53	28.8 (5.1) [26.9, 30.7]	18.5–24.9 (re)[a]
Total adult BW difference[b] (kg)	86	23.4 (12.8)	40	33.4 (21.3)	
Lean body mass (kg)	102	43.8 (5.4) [42.5, 45.3]	53	45.8 (8.5) [44.4, 48.8]	43.3 (6.45) (no)[e]
Fat mass (kg)	102	19.9 (8.5)	53	32.3 (12.3)	
Body fat percent (%)	102	30.2 (8.2) [28.1, 32.3]	53	39.5 (8.6) [36.3, 42.7]	<33% (re)[d] 34% (9.75) (no)[f]
VAT (g)	102	225.8 (293.9) [149.4, 302.2]	53	606.2 (545.5) [405.4, 806.2]	300.0 (300.0) (no)[c]
AG ratio	102	.73 (.24) [.67, .79]	53	.92 (.20) [.85, .99]	.36 (.14)[d]

Note. BW = body weight; VAT = visceral adipose tissue; AG-ratio = ratio of android-to-gynoid fat tissue percentage. 99% Confidence intervals (CI) are presented for variables with recommended or normative values, for comparisons.
[a]World Health Organization (1995).
[b]Adult total body weight difference is the difference between the lowest and the highest body weight after 18 years of age.
[c]Bosch et al. (2015), normative values based on interpretation of results.
[d]Imboden et al. (2017a), mean values of age group 20–29 and 30–39.
[e]Imboden et al. (2017b), mean values of age group 20–29 and 30–39.
[f]Okorodudu et al. (2010).

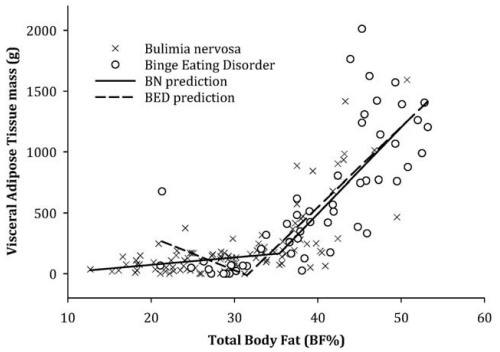

FIGURE 2 The non-linear relationship between visceral adipose tissue (VAT, g) and percentage total body fat (BF%) according to a piecewise regression model with separate slopes and BF% cutoff levels for bulimia nervosa and binge-eating disorder, respectively

The mean blood pressure values were within the normal range (Mancia et al., 2013), but about one third of participants with BN and BED, respectively, had increased blood pressure or hypertension, indicating an increased risk of cardiovascular disease (Mancia et al., 2013).

The mean CRF scores (VO_{2max}) for participants with BN were comparable to normative values (Edvardsen et al., 2013), but approximately 20% scored below the previous identified healthy threshold (Aspenes et al., 2011), and for the BED group, the mean score was below this threshold. Previous studies have found CRF to be a more important predictor for mortality than any other lifestyle factor (Ross et al., 2016). The low VO_{2max} in participants with BED raises concern about the long-term health risk in this specific subsample.

Normative values for muscular strength are only available for one of the tested exercises. Both groups in the present study were above such normative values (Brown & Miller, 1998), probably because very few were underweight and at risk for atrophy and myopathy, often found in patients with AN (McLoughlin et al., 1998; Nicholls, Wells, Singhal, & Stanhope, 2002).

Our findings on high numbers of participants not complying with the minimal recommendation for physical activity, having high blood pressure, and a low CRF among participants with BN or BED raise concern about their morbidity.

4.2 | Body composition and bone mineral density

The mean %BF, when sorted by BMI categories in participants with BN, was comparable with a previous report (Probst et al., 2004). Despite the mean BMI and %BF being within a healthy range, a large proportion of the participants with BN or BED was overweight or obese. BMI served as a good indicator of body composition in our sample. However, the fact that 12% (BN) and 9.4% (BED) had masked obesity replicated previous findings. Here, a BMI $\geq$ 30 corresponded well with morbid body composition, but a BMI $<$ 30 did not always correspond well with %BF or cardiometabolic health (Bratland-Sanda, Martinsen, & Sundgot-Borgen, 2012; Swainson, Batterham, Tsakirides, Rutherford, & Hind, 2017; Tomiyama, Hunger, Nguyen-Cuu, & Wells, 2016). Hence, the customary practice of using BMI as a health indicator for individuals with ED may be questioned.

VAT is associated with a range of risk factors for lifestyle-related diseases, such as insulin sensitivity and triglyceride and cholesterol levels (Bi et al., 2015; Rothney et al., 2013; Sasai et al., 2015). Eighteen (17.5%) participants with BN and 33 (62.3%) participants with BED had VAT levels above a previous suggested normative, healthy level of 300 g (Bosch et al., 2015). In this respect, BMI was the most important determinant for VAT in participants with BN, accounting for 51.2% of the variation, and with the addition of CRF for participants with BED, 68.2% of variation in VAT was accounted for. Previous studies suggest an unfavorable metabolic profile with increased VAT levels and with low VO_{2max}, separately (Aspenes et al., 2011; Ross et al., 2016). In our multiple linear regression models for VAT levels, CRF was negatively related to VAT in participants with BED. Moreover, low CRF has previously been associated with high VAT accumulation in men (Arsenault et al., 2007), and we found such associations among 50% of those having BN and low VO_{2max}, and among all but two of those with BED and low VO_{2max}.

We found a sudden bend in the curve between VAT and %BF when assessed by exploratory observation. A previous study reported a bend at 38.8%BF using a piecewise regression model (Bosch et al., 2015). We

TABLE 5 Bone mineral content and density in participants with BN or BED, with recommended *Z*-scores for comparisons

	BN		BED		
Bone health variables	***n***	***M* (*SD*) [CI]**	***n***	***M* (*SD*) [CI]**	**Recommended**
Total bone mineral content (g)	102	2483.3 (331.2)	53	2581.3 (314.5)	
Total bone mineral density (g cm^{-2})	102	1.197 (0.109)	53	1.236 (0.086)	
Total bone mineral density, *Z*-score	102	1.1 (.9) [.87, 1.34]	53	0.9 (.9) [.59, 1.21]	$>-2.0^a$
Bone mineral density spine, (g cm^{-2})	102	1.182 (0.148)	53	1.215 (0.113)	
Bone mineral density spine, *Z*-score	102	−0.2 (1.1) [−.42, .13]	53	−0.3 (1.0) [−.71, .03]	$>-2.0^a$
Bone mineral density femur (g cm^{-2})	102	1.020 (0.131)	53	1.044 (0.105)	
Bone mineral density femur, *Z*-score	102	.14 (.94) [−.11, .38]	53	.03 (.84) [−.28, .34]	$>-2.0^a$

Note. [a]ISCD (2015), World Health Organization (2004). For comparison, 99% confidence intervals (CI) are presented for variables with recommended or normative mean values available.

TABLE 6 Characteristics for participants with or without a history of anorexia nervosa (AN) (irrespective of current diagnosis)

Characteristics and body composition variables	Previous AN		No previous AN			
	N	*M* (*SD*)	*n*	*M* (*SD*)	*p*	Hedge's *g*
Age for illness onset (years)	37	15.2 (3.1)	100	16.3 (4.6)	.28	−.26
Duration of illness (years)	37	12.0 (6.5)	100	13.0 (7.6)	.49	−.14
Total adult BW difference[a] (kg)	28	21.7 (8.0)	80	28.2 (16.3)	.17	−.44
Adult lowest BW (kg)	31	49.7 (9.9)	88	55.9 (10.9)	.005	−.58
Adult highest BW (kg)	30	71.0 (9.9)	83	83.5 (17.9)	.001	−.77
Current BW (kg)	37	62.2 (10.4)	100	75.1 (14.7)	.000	−.94
Height (cm)	37	167.5 (5.9)	100	167.7 (6.5)	.91	−.03
BMI (kg m^{-2})	37	22.1 (3.4)	100	26.7 (4.7)	.000	−1.05
Physical activity level per day (counts per min)	27	465.5 (176.8)	87	424.5 (166.9)	.08	.24
Maximal oxygen uptake (mL min^{-1})	36	2586.5 (540.7)	97	2731.8 (427.8)	.11	−.32
Maximal oxygen uptake (mL BW^{-1} min^{-1})	36	42.0 (8.1)	97	37.5 (7.4)	.005	.59
Fat mass (kg)	36	17.4 (8.3)	100	26.8 (11.4)	.000	−.88
Lean body mass (kg)	36	42.4 (5.4)	100	45.6 (5.5)	.003	−.58
Body fat percent (%)	36	28.0 (9.1)	100	35.7 (8.9)	.000	−.86
VAT (g)	36	173.8 (219.5)	100	441.9 (465.3)	.002	−.65
Total bone mineral density (g cm^{-2})	36	1.163 (0.106)	100	1.226 (0.943)	.001	−.63
Bone mineral density spine (g cm^{-2})	36	1.136 (0.141)	100	1.216 (0.130)	.002	−.60
Bone mineral density femur, (g cm^{-2})	36	0.986 (0.125)	100	1.045 (0.118)	.01	−.49
Current diagnosis of BN, *n* (%)[b]	32 (86.5%)		57 (57%)		—	
Current diagnosis of BED, *n* (%)[b]	5 (13.5%)		43 (43%)		—	

Note. BN = bulimia nervosa; BED = binge-eating disorder; BW = body weight; BMI = body mass index; BMD = bone mineral density; VAT = visceral adipose tissue.
[a]Adult total BW difference is the difference between the lowest and the highest BW after 18 years of age.
[b]Number with BN or BED significant different between those with and without history of AN, $p = .001$.

found cutoff areas for the relationship between VAT and %BF to be close to this previously identified threshold in both participants with BN and with BED (35.7% and 31.9%, respectively). Noticeably, these cutoffs were both close to the %BF we evaluated as the upper threshold for a healthy body composition (i.e., 33%), thus supplementing the literature of body composition on evaluation of a healthy %BF.

The waist-to-hip ratio, or the AG ratio, is used as indication of VAT accumulation. In our sample, an AG ratio <1.0 presented with small variation in VAT, but with a strong, correlational increase in VAT when >1.0. This might imply that the mean AG ratios observed in our sample were within a healthy range, even when being above a previously suggested normative level (Imboden et al., 2017a). Moreover, among the participants with BN and BED, 15% and 42%, respectively, had an AG ratio >1, and all but two of these had VAT levels above normative levels. Still, about one third of those with high VAT was not identified by an AG ratio >1.0. This implies that the AG ratio, or an extension to this, the use of waist-to-hip ratio, is not successful at identifying all at risk for metabolic impairment observed with high VAT levels.

Surprisingly, low bone mineral density seemed to be more frequent in participants with BED compared with those with BN. The literature is unclear on the role of BED on bone mineral density; however, high body weight and low restrictiveness in eating behavior are assumed to protect bone mass (Goebel, Schweiger, Krüger, Fichter, 1999). Additionally, we found fewer participants with history of AN among those with BED compared with those with BN, a condition known to cause low bone mineral density (Robinson et al., 2016; Singhal et al., 2018). However, irrespective of diagnosis, low scores in spine BMD were the most prevalent site-specific finding, replicating previous studies on bone mineral density among individuals with BN (Naessén et al., 2006; Newton, Freeman, Hannan, & Cowen, 1993; Robinson et al., 2016; Solmi et al., 2016). For participants with BN, variables related to physical fitness (lean body mass and squat strength), together with BMI, were found to account for variations in bone mineral density. In contrast to previous findings (Robinson et al., 2016), history of AN has no effect on bone mineral density, yet the importance of our finding is difficult to evaluate because of the lack of information about the onset or the duration of AN.

Even if BMI proved an important variable in most of our multiple linear regression analysis, it did not successfully identify all with impaired fitness and masked up to 12% with morbid body composition.

The results of our analysis further highlighted the role of CRF and muscle strength for optimal body composition (i.e., to constrain %BF and VAT levels and improve bone mineral density).

4.3 | History of AN

We found differences in body composition when evaluating the participants according to history of AN and irrespective of current diagnosis. Hence, our findings support previous suggestion that those with a history of AN seem to preserve some of the restrictive behavior after remission or transition into other ED diagnosis (Vaz et al., 2003).

4.4 | Limitations

The use of participants recruited from the general population increases the generalizability, as studies based on treatment-seeking patients or in-treatment populations only reflect the minor proportion that ever seek help. Furthermore, the use of objectively based high-technology devices for physical health and activity measures increases the credibility and validity of the findings.

The present findings may not apply to markedly obese women with BN or BED because the participants were recruited from an RCT using BMI >35 as an exclusion criterion. In addition, the findings may not necessarily apply to males. This is important considering the sex distribution being more even with BED diagnosis (Hudson et al., 2007). Furthermore, a lack of objective information about weight history and a history of various ED diagnoses, notably AN, may raise a risk of underreporting, but it is expected to be negligible. Measuring VAT by magnetic resonance imaging and computed tomography would have yielded even more accurate data than the use of DXA, but high intercorrelations across these methods (Mohammad et al., 2017; Neeland, Grundy, Li, Adams-Huet, & Vega, 2016; Reinhardt, Piaggi, DeMers, Trinidad, & Krakoff, 2017) indicate differences of negligible clinical significance (Neeland et al., 2016). Additionally, inclusion of an age- and BMI-matched healthy control group would strengthen the conclusions about eating disorders and physical fitness as measured in the current study. However, as the intention of this article was to describe the physical fitness status of those with BN or BED approaching treatment, we consider the comparisons to normative or recommended levels as a sufficient first step.

5 | CONCLUSIONS AND CLINICAL IMPLICATIONS

Overall, the women with BN or BED displayed adequate physical fitness. Nevertheless, the need for clinical attention to increase physical activity and CRF was justified, as a proportion of these women, notably those with BED, had impaired physical fitness and complied poorly with the recommendation for physical activity. Evaluation of physical fitness with the traditional BMI or waist-to-hip ratio (AG ratio in our work) did not well identify all with impaired physical fitness and left a high proportion with unidentified high VAT and up to 12% with masked obesity. Furthermore, CRF, lean body mass, muscle strength, and time in MVPA were all central determinants of VAT and %BF. These findings call for inclusion of physical fitness in routine clinical examinations and the need to integrate rather than restrict guided and facilitated physical activity and dietary recommendations in the treatment of women with BN or BED. Furthermore, with reference to the high correlation of CRF and physical fitness (Myers et al., 2015; Ross et al., 2016), and findings of improved correlation between regional fat storage and physical health, rather than BMI and physical helath, (Hamer et al., 2017), our results suggest that cardiopulmonary exercise testing and DXA can be ideally included in routine examination and screening of persons with EDs.

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CONFLICT OF INTEREST

The authors indicate no conflict of interest.

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Paper III

TREATMENT EFFECTS ON COMPULSIVE EXERCISE AND PHYSICAL ACTIVITY IN EATING DISORDERS.

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ABSTRACT

PURPOSE: Physical exercise is part of the symptom spectrum of eating disorders, including bulimia nervosa (BN) and binge eating disorder (BED). The presence of excessive physical activity, or having a high desire for physical activity (PA), complicates treatment outcome, hence PA is rarely included in the treatment of BN and BED. The present study examined

short- and long-term changes in the level of compulsive exercise and actual PA in women with BN or BED. **METHODS**: Totally 187 women with BN or BED, aged 18-40 years, with BMI 17.5-35, were recruited to an outpatient randomized controlled therapy trial. Physical exercise and dietary therapy (PED-t), cognitive behaviour therapy (CBT), or temporarily placed on a waiting list as control group, were offered for 16 weeks, with 6- and 12 months follow-up. Outcomes were self-reported compulsive exercise (CE) and objectively measured PA, analysed by linear mixed regression models. **RESULTS**: CBT and PED-t were equally effective in reducing CE ($P < 0.01$, Hedges $g \sim 0.4$). In PED-t, there was a significant reduction of numbers scoring above cut-off rating for CE; otherwise, no between-group differences emerged. The proportion of participants complying with the official recommendation for PA neither changed following treatment, nor emerged different between the treatment arms. **CONCLUSION:** Despite no difference to the control group, both therapies were successful at reducing CE after treatment, with a maintained effect during follow up. The numbers complying with the recommendation for physical activity were stable during this study, and no change in total physical activity was found. Presence and intensity of CE decline with treatment, but a need to increase physical activity towards healthy levels remains unsolved.

TRIAL REGISTRATION: Approved by the Norwegian Regional Committee for Medical and Health Research Ethics (ID: 2013/1871, 16th of December 2013); registered in Clinical Trials (ID: NCT02079935, 17th of February 2014).

KEY WORDS: Excessive exercise, driven exercise, MVPA, bulimia nervosa, binge-eating disorder, cognitive behaviour therapy

PLAIN ENGLISH SUMMARY

Physical activity is part of the symptom spectrum of eating disorders, and persons with these disorders are often described as being excessively physical active or having high desire for physical activity. This symptom is related to worse treatment outcome and higher risk of relapse. Worrying about a provocative effect, physical activity is often restricted, or not included, in treatment of eating disorders. Concurrently, persons with bulimia nervosa (BN) and binge-eating disorders (BED) are found with impaired physical health, hence; physical activity would be a desirable intervention.

We studied the effect on this symptom and PA by use of a new therapy for women with BN or BED (physical activity and dietary therapy, PED-t), or by the highly recommended cognitive behaviour therapy (CBT). We found comparable improvements on compulsive exercise (CE) from both therapies. PED-t did not result in any provocative effect on volumes of exercise, and both therapies revealed stable levels of physical activity and symptom improvement during treatment and follow-up.

Less than 50% of women with BN or BED comply with the minimal recommendation for physical activity, hence, there is an unsolved need to find methods to take hold of this insufficient level of healthy physical activity.

BACKGROUND

Regular physical activity may improve mental and physical health [1, 2], and for this reason, regular physical activity is encouraged as a first or concurrent intervention for a range of physical- and mental illnesses [3]. However, in the treatment of eating disorders (EDs) physical activity has often been restricted or not encouraged [4-6], because of its excessive and compulsive nature found in about 20-80% of patients with EDs [7-10]. Physical exercise is part of the symptom spectrum of eating disorders like bulimia nervosa (BN), described in

the diagnostic description as “excessive and recurrent”[11], while several studies [7-9] indicate that the compulsive aspects of their exercise is a more prominent clinical feature which comprises many facets. Compulsive exercise (CE) includes the maintenance of rigid exercise regimens, exercising despite physical injuries, prioritizing exercise before other important activities, feelings of anxiety if unable to exercise, or rigidly imposing exercise regimens before meals, or as a compensation for binge eating [12, 13]. The purpose of CE is to compensate for energy surplus due to binge eating, but may also serve to regulate negative affects that may appear as a result of the ED [9]. Contrary to BN, a diagnosis of BED does not include an "overvaluation of controlling body weight or figure" [11]. However, along with the high prevalence of obesity in BED [14, 15], these persons may still present with concerns about body weight, figure and appearance [16] that may trigger CE.

Physical inactivity is frequently reported among persons with BED [14, 17, 18]. For BN, the mixed findings with respect to whether persons are highly active or insufficient active, may be due to methodological differences across studies [14, 19, 20]. In general, and compared to the official recommendation for physical activity by the American College of Sport Medicine [21], insufficient activity levels have been reported in BN when using objective measures of activity [14, 20].

Hence, there seems to be an exercise paradox, with findings of insufficient actual levels of physical activity in BN and BED, still with dysfunctional attitudes and cognitions related to exercise indicating high levels of physical activity [7-9].

Cognitive behavioural therapy (CBT) is the preferred treatment approach for BN and BED [22]. Here, stimulus-control techniques are used to normalize eating patterns, and a focus on changing underlying cognitions serves the purpose of undermining the psychological,

maintaining factors for the ED. CBT also addresses compensatory exercise, but there is little specific evidence supporting whether CBT is effective in alleviating CE.

Re-establishing practical experience with healthy exercise, along with theoretical understanding of exercise physiology, might induce a more positive attitude towards exercise [4]. Some studies [17, 23-27] report on interventions adding structured physical exercise to treatment of BN or BED, but only one has reported on effects on attitudes towards exercise [28]. Here, the exercise intervention with a supervised and varied exercise program characterized by low impact activity, proved effective in reducing dysfunctional attitudes towards exercise. However, it is unknown whether structured physical exercise interventions alter CE behaviour in a longer-term, and whether such interventions simultaneously raise the objective level of physical activity in persons with BN or BED.

This paper reports on the short- and long-term effects of a 16-week outpatient treatment-intervention with **p**hysical **e**xercise- and **d**ietary **t**herapy (PED-t) or CBT on compulsive exercise and objectively measured physical activity in women with BN or BED [29]. We hypothesize: 1) both treatments show reductions in CE at post-test and at follow-up compared to baseline, 2) the differences between the treatments (PED-t versus CBT) are non-significant or non-substantial at post-test and at follow-up, 3) both treatments perform better than the waiting-list control condition at post-test, and 4) compared to CBT, PED-t results in a higher level of physical activity, compatible with the official recommendation by the American College of Sport Medicine.

METHODS

Participants

Female participants with BN or BED were recruited for a randomized controlled trial (RCT), investigating the effect of a new outpatient group treatment program; the PED-t, comparing

outcomes to group-CBT and a waiting list control group [29]. Participants were recruited through general practitioners (GP's), articles and advertisement in magazines and newspapers, websites of the ED patient organizations, national TV, social media and posters. Inclusion criteria were age 18-40, BMI range 17.5-35, and a DSM-5 diagnosis of BN or BED. Diagnoses were ascertained by the questionnaire version of the Eating Disorder Examination (EDE-q) [30], by self-reported behavior according to DSM-5 diagnostic criteria, and finally confirmed by clinical assessment (Figure. 1). A final inclusion required written informed consent from the participants and their GP. Exclusion criteria were currently being pregnant, being a competitive athlete, having a concurrent severe symptom- or personality disorder in need of other treatment options, as well as having received CBT for ED the last two years prior to the study.

In total, 187 of recruited women were eligible for inclusion, of which 23 temporarily were allocated to a waitlist control group. An independent fellow co-worker assisted in creating a randomization list (from www.randomizer.org) with block size of eight, and in allocating the 164 recruited participants to treatment groups by a concealed allocation. Totally 156 of the randomized participants met for baseline measures, and then successively received information on group allocation and initiated treatment. Of included participants, 103 were diagnosed with BN and 53 were diagnosed with BED. In the waitlist control group, 20 were diagnosed with BN and three with BED.

Insert figure 1 about here.

Design

The experimental design was mixed factorial as it included a between-group factor with three levels (PED-t, CBT and control), and a within-group factor with four levels (repeated assessments at baseline, post-test after 16 weeks of treatment, and two follow-ups at six and 12 months post-treatment).

Outcomes

Questionnaires

All participants completed the EDE-q (Cronbach's α = 0.87) [30], which comprises 18 items scored 0-6 to measure the presence (12 items) and the frequency (6 items) of core ED-characteristics. Cut-off scores 2.62 and 2.63 were used, which have proved valid in identifying BN and BED among Norwegian female adults [31].

Additionally, all participants completed the Compulsive Exercise Test (CET) [32] (Cronbach's α = 0.84). CET assesses the core features of compulsive exercise in EDs, i.e. continuance (e.g. continue to exercise despite injuries or illness), affect regulation (exercise brings about negative or positive reinforcement), weight and shape driven exercise (e.g. exercise to burn calories, or to reduce body weight), and exercise rigidity (repetitive exercise routines). CET is a 24-item instrument scored on a 5-point Likert scale (0 = never true, 5 = always true), and evaluated with five different subscale mean scores (avoidance and rule driven behaviour, weight control exercise, mood improvement, lack of exercise enjoyment, and exercise rigidity), and a global score summing the means of subscales (score range 0-30). CET has proved good internal consistency and content validity, in healthy samples and in adults with ED, with a suggested global cut-off score of 15, where higher scores indicate more compulsivity [13, 32].

Physical activity

Level of physical activity (counts/minute, CPM) were objectively measured for seven consecutive days using the ActiGraph accelerometer (ActiGraph GT3x and GT3x+, Actigraph, LCC, Pensacola, Florida, USA) placed on their right hip. Details on data recording, extraction and variable definition have been presented previously [14]. Numbers of participants measuring physical activity for T1-T4 are presented in figure 1. Reasons for not

giving information on physical activity were; not sufficient numbers of days with registration, technical errors in separate devices, not willing to carry the device, and devices lost in mailing process.

Treatment programs

Physical exercise- and dietary therapy (PED-t)

The PED-t is a group treatment particularly designed for BN and BED by our research group, combining guided physical exercise- and dietary therapy. The exercise treatment includes theoretical sessions on exercise physiology and exercise principles, encourages to comply with the recommendations for physical activity (i.e. 150 min×week) [21], and adheres to recent guidelines developed from systematic reviews to successfully use therapist guided physical exercise [33]. The treatment offers 20 therapy sessions covering 16 weeks, with 1-2 weekly supervised resistance exercise session combined with a dietary therapy, and two weekly unsupervised exercise sessions (one resistance exercise and one session with high intensity interval training, respectively).

Cognitive behaviour therapy (CBT)

The manual-based CBT follows a group format, and rests on a trans diagnostic model positing generic core ED-characteristics across ED-diagnoses [34]. The CBT-treatment consists of 1-2 weekly therapy sessions (20 in total) over 16 weeks of therapy. The therapy runs through four stages; 1) engagement and behavioural change, 2) monitoring and evaluating progress, 3) addressing the core pathology of ED, and 4) relapse prevention. Participants received no exercise guidelines other than encouragement to comply with a healthy lifestyle. However, if needed, exercise used as a compensatory behaviour was addressed.

Details of the PED-t and the CBT programs have been published elsewhere [29].

Control group

All control group subjects fulfilled the inclusion criteria of the study. Some controls were waiting for treatment initiation, while others withdrew from treatment before it had started due to reasons irrelevant for the purpose of the study. Such reasons were living too far from treatment facilities, moving before treatment initiation and work/study obligations not combinable with weekly study participation. Controls completed questionnaires at baseline (T1) and the first follow-up (T2), but no data were generated at the remaining follow-ups, as all were offered immediate treatment after waitlist period (i.e. after 16 weeks). No outcome from physical activity was available for this group.

Statistics

All analyses were conducted in SPSS version 24 (IBM, Armonk, NY). Linear mixed regression models were built to estimate the between-group differences (PED-t vs. CBT) and the within-group changes (baseline vs. any of the three posttest measures). This analysis yields relatively unbiased estimates despite drop out given that data are missing completely at random or missing at random. Moreover, it can be safely used without conducting beforehand multiple imputations [35]. Standard errors were estimated with the restricted maximum likelihood function, and type III *F*-tests were preferred. Dependency in the outcome data was accounted for by including a random intercept factor. The fixed factors were: *Group* (0-PEDt, 1-CBT) representing the overall treatment difference, *Time* (repeated measures) representing change across measurements, and the *Group*×*Time* interaction in order to detect treatment differences at certain time points only. The between-group analyses used the baseline values as a covariate, which improves the statistical power of these tests [36]. Differences between the treatment arms were examined with planned comparisons at each time point (least square difference tests). The within-group analyses included all four measurements in the *Time*

factor. Due to the number of tests, differences with *p*-values < .01 were considered as significant, and outcome data are presented as estimated means including 99% confidence intervals. Standardized Hedge's *g* effect-sizes were calculated as a ratio of the estimated means (extracted from the mixed models) and the observed pooled standard deviations (SD). Values around 0.2, 0.5 and 0.8 were interpreted as weak, medium and strong effect sizes, respectively, according to Hedge and Olkin [37].

A comparable statistical approach was used for the dichotomous outcome variables, replacing the analysis with a generalized linear model using a binominal distribution and logit link function (reference category coded 0). Degrees of freedom were computed using Satterthwaite approximation.

Analyses of dropout and loss to follow up for the two separate follow up tests, were examined with conventional tests (e.g., *t*-, chi-square- or Fischer's tests). Differences with *P*-value less than 5% were accepted in these analysis.

RESULTS

In total 17 (21.8%) participants in PED-t, 27 (35.9%) participants in CBT and five (21.7%) in the control group dropped out during the treatment period. Dropouts were less physical active than completers were (g=0.44, $P = 0.04$), and fewer among dropouts complied with the recommendations for physical activity (P=0.036). Compared to the PED-t group, more in the CBT group was lost to follow up at T3 (P=0.026) and T4 (P=0.002). Additionally, those lost to follow up at T4 were less physically active at baseline compared to the completers at T4.

No differences were found between treatment groups and control participants at T1 for age, illness duration, EDE-q global score, or diagnosis ($P > 0.05$) (Table 1). The attendance rate to

therapy in PED-t was 81% and 75% in CBT. In PED-t the adherence rate to exercise sessions (supervised+unsupervised) was 69.8% for resistance exercise, and 56.7% for interval training.

Table 1: Baseline demographic and clinical information (mean (SD) or in n/percent) on participants in the PED-t, CBT and control group, respectively.

Group	PED-t	CBT	Control
Age, *years*	28.2 (6.2)	27.7 (5.3)	26.5 (5.6)
Illness duration, *years*	12.9 (7.5)	12.1 (6.7)	10.6 (7.4)
EDE-q global score	3.7 (0.8)	3.7 (1.0)	3.8 (1.0)
BN, *n (%)*	49 (64.5)	48 (65.8)	20 (87.0)
BED, *n (%)*	27 (35.5)	25 (34.2)	3 (13.0)

NOTES: PED-t, Physical Exercise and Dietary Therapy; CBT, Cognitive Behavior Therapy; EDE-q, Eating Disorder Examination Questionnaire; BN, Bulimia nervosa; BED, Binge-eating disorder.

Changes in compulsive exercise

Within group changes

Both treatment groups had a significantly reduced total CET score after treatment and at follow up compared with baseline. Effect sizes were medium in PED-t and weak to medium in CBT (Table 2). Furthermore, both treatment groups were scoring lower on "CET avoidance and rule driven behaviour" (small effects in both groups) and on "CET exercise for weight control" (small to medium effects) after treatment and at follow up. There were no significant changes in the control group in CET total score or any of the CET subscales ($P > 0.1$). After treatment and during follow-up, fewer participants in PED-t scored above the clinical cut-off for CET total-score (Figure 2). There were no significant change in numbers above CET clinical cut-off in CBT and control group ($P \geq 0.01$).

Between group differences

CET total score, subscale scores, and numbers above CET clinical cut-off were not different between any of the three groups at any time ($P > 0.01$) (Table 2 and Figure 2).

Insert table 2 about here.

Insert figure 2 about here.

Level of physical activity (CPM)

Within group changes

Neither mean total physical activity (CPM) nor MVPA changed from baseline to any of the three post-tests in any group ($P > 0.08$ and $P > 0.2$, respectively) (Figure 3). In PED-t the numbers complying with the recommendation for physical activity varied between 45.4% - 56.4%, but with no significant change by time ($P > 0.2$). The corresponding results for CBT were 42.4 - 53.9%, also with no significant change by time ($P > 0.5$).

Between group differences

No differences between groups appeared for total physical activity (CPM) ($P > 0.01$) nor MVPA ($P > 0.06$) (Figure 3). No significant differences in the proportion complying with the recommendation for physical activity were observed between the groups ($P > 0.05$).

Insert figure 3 about here.

DISCUSSION

This study investigated effects of a 16-week outpatient treatment-intervention with PED-t or CBT on compulsive exercise (CE) and objectively measured physical activity in women with BN or BED. As hypothesized, we found both treatment interventions successful in reducing CE. The positive changes were comparable in the two treatment groups, with non-significant

or non-substantial differences. Contrary to our hypothesis, neither of the treatments were better than the waiting-list control condition. This comparison was only available at the first post-test, and limited by a small number of control participants. Our final hypothesis was not supported either, as those participating in the PED-t treatment arm did not achieve a higher level of physical activity compared to the CBT participants.

Since CBT does not specifically address exercise routines other than driven exercise for compensatory reasons, there are recommendations on the development of new or adjuvant interventions to CBT, to deal with dysfunctional exercise attitudes [38]. Hence, our finding, that CBT showed reduction in the compulsive nature of physical activity, is encouraging because there has been little specific evidence for such an effect from CBT in the literature. Since the PED-t also efficiently reduced CE, and in particular the subscales "exercise for weight control" and "avoidance and rule driven exercise", and had continuous reduction in numbers scoring above CE cut-off, PED-t stands out as a promising new pathway to reduce CE. This finding also serves to argue against any reluctance towards addressing PE in the clinic. The finding of improvements on "exercise for weight control" in particular, contradicts clinically based arguments for not incorporating physical exercise in the treatment of persons with ED's. Exercising for weight control has been suggested to be the most frequent motive for exercise, and reason for excessive exercise in BN [39], and a feature negatively affecting treatment outcome [40]. Additional benefits of inclusion of physical activity to treatment of EDs can be to improve the poor physical health reported in females with BN and BED (19) and to improve the overall quality of life [2].

The CET total- and subscale scores in both treatment groups were lower than previously found in an inpatient sample with dispersion of diagnoses [8], but comparable to a previous finding predominately among patients with BN and BED [32]. However, with reference to this latter comparable study, we found a higher mean score in the subscale "mood

improvement" and lower mean score on "lack of exercise enjoyment", which did not change by time. It is reasonable to suggest that our participants were highly motivated for physical exercise, having responded to treatment recruitment offering physical exercise. Additionally, our results on these subscales reflects positive aspects of exercise, and it is of interest that our sample is able to experience exercise as positive, regardless of illness severity.

The lack of a significant difference between the treatment arms and the wait list control group may relate to the rather low sample size in control group (n =23), thus considerably reducing the statistical power of our comparisons. Further, with no control group during follow up, interpretation of the long-term effect is uncertain; still, both treatments appeared to maintain their effects during the follow up period. Overall, the present findings on reduction in CE in both intervention groups, suggest that comparable long-term effects are achieved through rather different therapeutic pathways and approaches.

Level of physical exercise

We did not find any support for the previous findings that females with BN practice high volumes of exercise [10]. In total, only 46% were complying with the *minimal* recommendation for MVPA at baseline, concurrently, 40.8% was above the clinical cut-off for total CET score, with high scorings not necessarily coinciding. This confirms the "exercise paradox", namely that dysfunctional attitudes and cognitions related to exercise are high, whereas the actual levels of physical activity is insufficient.

A failure to identify the reasons and motives why persons with ED patients exercise (e.g. exercise to burn calories and lose weight), may miss out important aspect of the nature of EDs, which in return could compromise the prospect of a favourable treatment outcome [33, 40]. Guidelines for using physical activity to treat ED amplify the need to change negative attitudes towards exercise and the exercise-related psychopathology [33]. However, these

guidelines do not include recommendations on how to increase physical activity among persons with EDs who are inactive or active below the level of health benefits. Despite having a special focus of regularly supervised exercise sessions and education on the health benefits of sufficient overall physical activity in PED-t, we were unable to increase the level physical activity compatible with the official recommendation by the American College of Sport Medicine [21]. Importantly though, these findings help undermine any fear of exaggerating exercise volumes if addressing exercise behaviour and cognitions in the treatment of females with BN or BED.

Strengths and limitations

High generalizability by recruiting participants with BN or BED from the general population is tempered by excluding mental disorder comorbidity. Combining psychological measures of motives for physical exercise and objective measures of exercise made it possible to study different facets of dysfunctional exercise. Objective measures of physical activity may reduce the risk of errors from self-reports [20]. However, it may also increase the risk of under-reporting the impact of static movement and weight lifting activities [41], which were practiced during the PED-t treatment condition. The interpretation of findings are hampered by a high dropout rate, notably among CBT participants who were not so physically active, and by the fact that control group data were not available at all measure points.

Conclusion

Both indirect (CBT) and direct (PED-t) approaches may be viable in reducing CE in the long-term, but neither approaches raised the level of physical activity and compliance with official recommendations for physical activity.

ABBREVIATIONS

BN – bulimia nervosa

BED – binge-eating disorder

CBT – cognitive behaviour therapy

CE – compulsive exercise

CET – compulsive exercise test

CPM – counts per minute

ED – eating disorder

EDE-q – eating disorder examination questionnaire

MVPA – moderate to vigorous (intensity) physical activity

PA – physical activity

PED-t – physical activity and dietary therapy

T1 – baseline measure (Time 1)

T2 – post-test (Time 2)

T3 – follow up 6 months (Time 3)

T4 - follow up 12 months (Time 4)

DECLARATIONS

Ethical approval

The study has been approved by the Norwegian Regional Committee for Medical and Health Research Ethics (ID: 2013/1871) and registered in Clinical Trials (ID: NCT02079935).

Consents

All participants, and additionally their general practitioners (GP), had to signed informed consent before participation.

Data sharing

The datasets generated and analysed during the current study are not publicly available, but may be available from the corresponding author on reasonable request.

Competing interests

No conflicts are to be declared. The results from the present study do not constitute endorsement by ACSM, and the results of the study are presented clearly, honestly, and without fabrication, falsification, or inappropriate data manipulation.

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None of the funding or supporting institutions had any role in the design of the study, in collection, analysis, or interpretation of data, or in writing the manuscript.

Author contribution

TFM was responsible for logistics in the trial, ran the PED-t, did statistical analysis, and wrote the manuscript. SBS, JHR and GP participated in planning the trial and in writing the manuscript. OF participated in planning the trial, were responsible for statistical models, and wrote the manuscript. KV participated in planning the trial, ran the CBT and wrote the manuscript. JSB was project leader, planned the project and wrote the manuscript. All authors read and approved the final manuscript.

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FIGURE LEGENDS AND TABLES

Figure 1: Flow chart of recruitment, screening, randomization and attendance at pre-treatment test (T1), post-treatment test (T2) and the two follow up tests (T3 and T4). EDE-q, Eating disorder examination questionnaire; PED-t, Physical exercise and dietary therapy; CBT, cognitive behavior therapy; BN, bulimia nervosa; BED, binge-eating disorder; CET, compulsive exercise test; PA, physical activity; LFU, lost to follow up.

Table 2: Compulsive Exercise Test Scores at Baseline (T1), Post-Treatment (T2), 6 Months (T3) and 12 Months (T4) Follow-up.

	T1 CI .99	T2 CI .99	T3 CI .99	T4 CI .99	*Within effects, p-value, Effect size (g)*			*Between effects, p-value, Effect size (g)*		
					T2	T3	T4	T2	T3	T4
CET total										
PED-t	14.43	13.14	12.81	12.59	**< .001**	**<.001**	**<.001**			
	13.61–15.26	12.27–14.02	11.92–13.69	11.70–13.47	*g = 0.49*	*g = 0.63*	*g = 0.63*			
CBT	14.21	13.12	13.27	12.87	**<.001**	**.007**	**<.001**			
	13.37–15.04	12.19–14.05	12.28–14.26	11.86-13.87	*g = 0.41*	*g = 0.44*	*g = 0.61*	*n.s.*	*n.s.*	*n.s.*
CONTROL	15.18	14.63	-	-	*n.s.*			*n.s.*		
	13.66–16.68	13.02–16.24								
CET avoidance										
PED-t	2.34	1.84	1.73	1.62	**<.001**	**<.001**	**<.001**			
	1.99–2.69	1.47–2.21	1.36–2.11	1.25–1.99						

	T1 CI .99	T2 CI .99	T3 CI .99	T4 CI .99	*Within effects, p-value, Effect size (g)*			*Between effects, p-value, Effect size (g)*		
					T2	T3	T4	T2	T3	T4
					g = 0.28	*g = 0.33*	*g = 0.39*			
CBT	2.72 1.92–2.63	1.89 1.50–2.69	1.88 1.47–2.30	1.75 1.33–2.17	**.003** *g = 0.24*	**.005** *g = 0.25*	**<.001** *g = 0.41*	*n.s.*	*n.s.*	*n.s.*
CONTROL	2.72 2.23–3.20	2.56 1.88–3.24	-	-	*n.s.*			*n.s.*		
CET weight control										
PED-t	3.32 3.04-3.61	2.57 2.26-.2.87	2.71 2.40-3.02	2.64 2.33-2.95	**<.001** *g = 0.57*	**<.001** *g = 0.41*	**<.001** *g = 0.49*			
CBT	3.34 3.05-3.63	2.96 2.63-3.29	3.09 2.73-3.44	2.80 2.44-3.15	**.002** *g = 0.33*	*n.s.*	**<.001** *g = 0.49*	*n.s.*	*n.s.*	*n.s.*
CONTROL	3.66 3.26-4.05	3.31 2.75-3.87	-	-	*n.s.*			*n.s.*		
CET mood										
PED-t	4.22 3.97-4.47	4.23 3.96-4.50	4.09 3.82-4.35	3.96 3.69-4.22	*n.s.*	*n.s.*	**0.008** *g = 0.30*			
CBT	4.11 3.86-4.36	4.08 3.79-4.36	4.01 3.70-4.32	4.07 3.75-4.38	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*
CONTROL	4.23 3.77-4.68	4.27 3.78-4.76	-	-	*n.s.*			*n.s.*		

	T1 $_{CI .99}$	T2 $_{CI .99}$	T3 $_{CI .99}$	T4 $_{CI .99}$	*Within effects, p-value, Effect size (g)*			*Between effects, p-value, Effect size (g)*		
					T2	T3	T4	T2	T3	T4
CET lack of enjoy.										
PED-t	1.57 $_{1.24-1.90}$	1.34 $_{0.99-1.69}$	1.43 $_{1.08-1.79}$	1.51 $_{1.16-1.86}$	*n.s.*	*n.s.*	*n.s.*			
CBT	1.64 $_{1.30-1.98}$	1.46 $_{1.09-1.83}$	1.69 $_{1.30-2.08}$	1.56 $_{1.17-1.96}$	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*
CONTROL	1.34 $_{0.73-1.95}$	1.41 $_{0.77-2.06}$	-	-	*n.s.*			*n.s.*		
CET rigidity										
PED-t	2.91 $_{2.59-3.24}$	3.17 $_{2.82-3.52}$	2.86 $_{2.51-3.21}$	2.86 $_{2.50-3.21}$	*n.s.*	*n.s.*	*n.s.*			
CBT	2.85 $_{2.52-3.19}$	2.74 $_{2.36-3.11}$	2.60 $_{2.20-3.00}$	2.70 $_{2.29-3.11}$	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*
CONTROL	3.23 $_{2.63-3.82}$	3.10 $_{2.45-3.74}$	-	-	*n.s.*			*n.s.*		

NOTES: PED-t, Physical exercise and Dietary therapy; CBT, Cognitive Behavior Therapy; CI $_{.99}$ = 99% confidence interval. Within = Change from baseline to any of the three posttests (T2, T3 and T4); Between = Difference between groups (adjusted for baseline) at any of the three posttests (T2, T3 and T4); *g*, effect size of Hedges 'g; *n.s.*, non-significant.

Figure 2: Estimated proportion (SE) of subjects scoring above the cut-off score defining compulsory exercise, across time and the treatment arms. ** Significant different from baseline, P < 0.002.*

Figure 3: Estimated mean (SE) physical activity level (*left)* and time spent in MVPA (*right)*, from baseline (T1) to 12 month posttreatment (T4). PED-t, Physical Exercise and Dietary therapy; CBT, Cognitive Behavior Therapy; MVPA, Moderate to Vigorous Physical Activity.

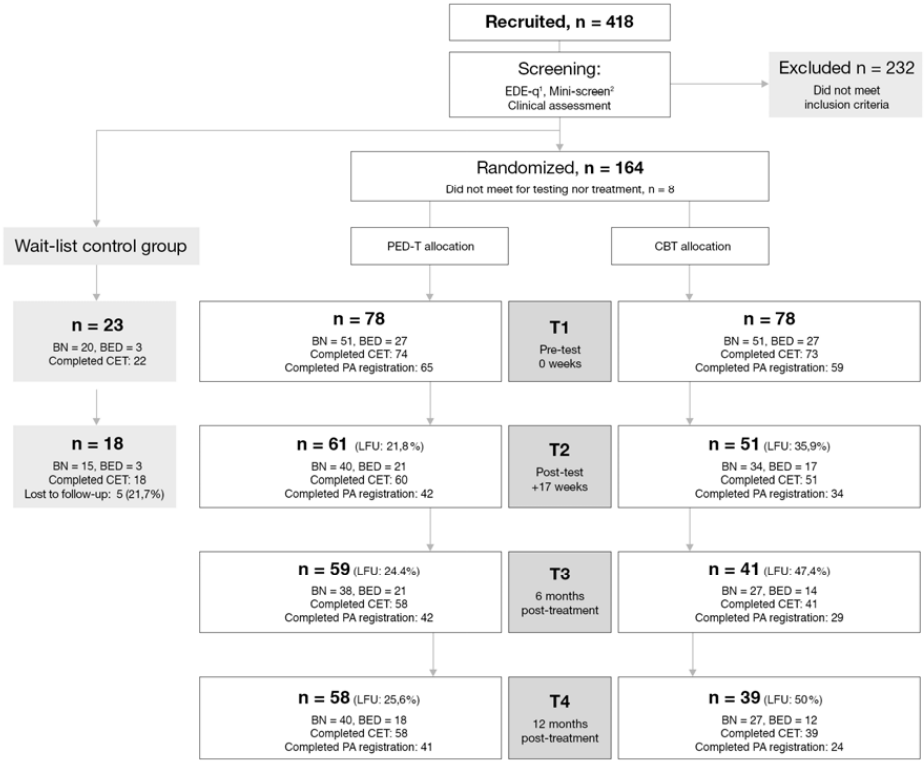
Recruited, n = 418
Screening:
EDE-q[1], Mini-screen[2]
Clinical assessment
Excluded n = 232
Did not meet inclusion criteria
Randomized, n = 164
Did not meet for testing nor treatment, n = 8
Wait-list control group
PED-T allocation
CBT allocation
n = 23
BN = 20, BED = 3
Completed CET: 22
n = 78
BN = 51, BED = 27
Completed CET: 74
Completed PA registration: 65
T1
Pre-test
0 weeks
n = 78
BN = 51, BED = 27
Completed CET: 73
Completed PA registration: 59
n = 18
BN = 15, BED = 3
Completed CET: 18
Lost to follow-up: 5 (21,7%)
n = 61 (LFU: 21,8 %)
BN = 40, BED = 21
Completed CET: 60
Completed PA registration: 42
T2
Post-test
+17 weeks
n = 51 (LFU: 35,9%)
BN = 34, BED = 17
Completed CET: 51
Completed PA registration: 34
n = 59 (LFU: 24.4%)
BN = 38, BED = 21
Completed CET: 58
Completed PA registration: 42
T3
6 months
post-treatment
n = 41 (LFU: 47,4%)
BN = 27, BED = 14
Completed CET: 41
Completed PA registration: 29
n = 58 (LFU: 25,6%)
BN = 40, BED = 18
Completed CET: 58
Completed PA registration: 41
T4
12 months
post-treatment
n = 39 (LFU: 50 %)
BN = 27, BED = 12
Completed CET: 39
Completed PA registration: 24

Figure 1.

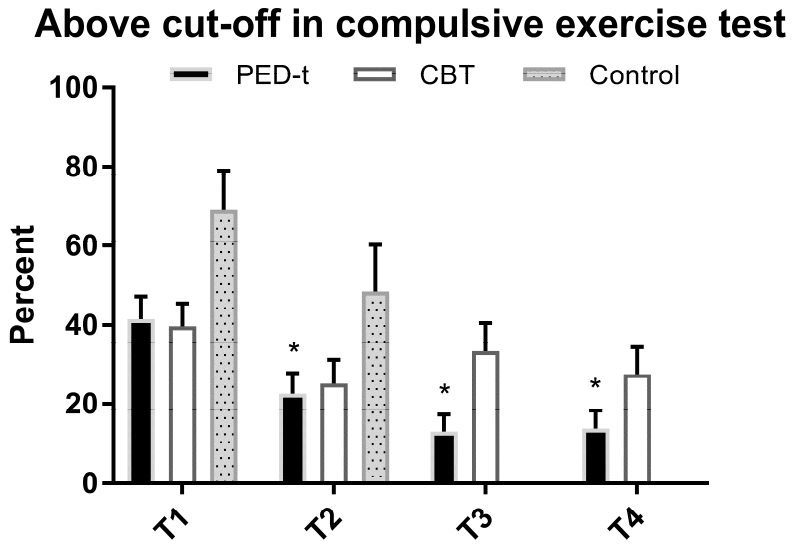
Above cut-off in compulsive exercise test
PED-t
CBT
Control
Percent
100
80
60
40
20
0
*
*
*
T1
T2
T3
T4

Figure 2.

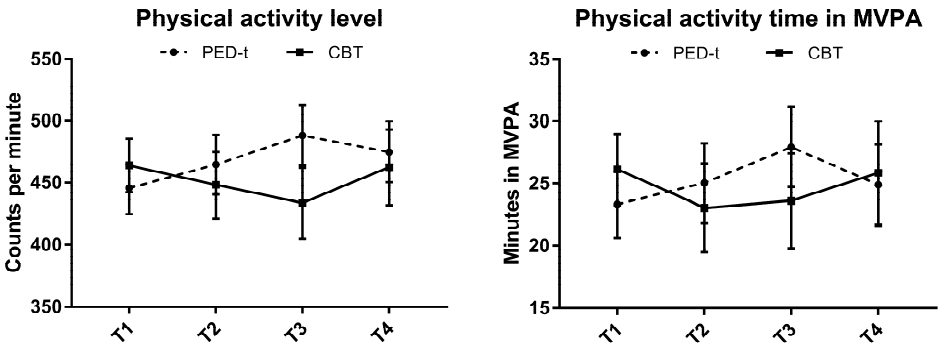
Physical activity level
PED-t
CBT
Counts per minute
550
500
450
400
350
T1
T2
T3
T4
Physical activity time in MVPA
PED-t
CBT
Minutes in MVPA
35
30
25
20
15
T1
T2
T3
T4

Figure 3.

Paper IV

Eating disorders can be treated with physical exercise and dietary therapy. A randomized controlled trial with 12 months follow-up.

Running head: Physical exercise and dietary therapy

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Norway; Jorunn Sundgot-Borgen, Department of Sports Medicine, Norwegian School of Sport Sciences.

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Abstract

Objective: Because few persons with bulimia nervosa (BN) and binge-eating disorder (BED) receive treatment, and <60% respond to evidence based therapies, we need to explore new treatment options. Since physical activity is a favorable element to treat many mental disorders, we hypothesized that guided physical exercise and dietary therapy (PED-t), could be an alternative pathway to recovery from BN and BED. **Methods**: We recruited 187 women with BN or BED, aged 18-40 and with BMI 17.5-35, randomized to PED-t or CBT, and placed late responders to recruitment in a waitlist control group. Measures were EDE-q, remission from diagnosis, quality of life and mood rating, measured at baseline, after treatment, and at follow up 6- and 12 months. **Results:** The PED-t group improved more than the CBT group (-0.66, [CI_{99} -1.23, -0.1], g=0.52, p <0.003) and the control group (-1.15, [CI_{99} -1.97, -0.34], g=1.00, p<0.001) in EDE-q global score after treatment, whereas CBT did not differ from the controls (-0.49 [CI_{99}-1.32, 0.34], g=0.48, p=0.12). Numbers in full- and partial remission were higher in PED-t (29.0% and 19.7%) and CBT (12.4% and 16.7%) compared to control (0.1% and 5.6%), p<0.004. The PED-t advantages disappeared at follow-up (p>0.05). Both therapies resulted in significant improvement in life quality, but mood rating only improved in PED-t with short-lived effect. **Discussion** PED-t is an effective treatment for BN and BED. A high availability of professionals within exercise medicine and nutrition may attract new segments of ED patients and circumvent the poor access to mental health services.

Keywords

Bulimia nervosa, binge-eating disorder, physical activity, cognitive behavior therapy, clinical impairment, depression, treatment

Trial registration

Prospectively registered in REC the 16th of December 2013 with the identifier number 2013/1871, and in Clinical Trials the 17th of February 2014 with the identifier number NCT02079935.

Introduction

Cognitive behavior therapy (CBT) is recognized as the preferred evidence based treatment option for BN and BED in terms of remission and symptom relief by focusing on behavioral and cognitive maintaining factors (Hay, 2013). Nevertheless, like many other psychological treatments, the effectiveness of CBT is challenged by high rates of premature termination from treatment (Linardon, Hindle, & Brennan, 2018), and relapses (Södersten, Bergh, Leon, Brodin & Sandin, 2017). In addition, more than 60% do not fully abstain from symptoms (Linardon & Wade, 2018). A moderate success in attempts to optimize CBT to fit individual differences prompts the exploring of other treatment options (Keski-Rahkonen & Mustelin, 2016).

Regular physical exercise has several benefits relevant to combat the morbidity of BN and BED and thereby improve quality of life. First, exercise may regulate negative mood, bodily tensions, and increase tolerance to everyday stress (Fox, 1999), which all have been identified as triggers for bingeing and purging (Alpers & Tuschen-Caffier, 2001). Secondly, improved physical fitness may raise self-esteem, self-perception and self-efficacy (Fox, 1999; Vancampfort, Probst, Adriaens, Pieters, De Hert, et al., 2014). Third, regular physical exercise may prevent and alleviate comorbid depression and anxiety (Fox, 1999), as well as lowering the risk of non-communicable diseases (Reiner, Niermann, Jekauc & Woll, 2013) that may occur in BN or BED (Keski-Rahkonen & Mustelin, 2016; Mathisen, Rosenvinge, Friborg, Pettersen, Stensrud, et al., 2018). Physical exercise is however, rarely incorporated in treatments of EDs out of fear of exacerbating the compulsive and excessive nature of exercise in patients for compensatory or affect regulation purposes (Quesnel, Libben, Oelke, Clark, Willis-Stewart, et al., 2017). Such purposes are observed in about 20-40% of those with BN (Dalle Grave, Calugi, & Marchesini, 2008), and is associated with poor treatment response or relapse (Dalle Grave et al., 2008). In a recent study (*in review*) we have however,

demonstrated that physical exercise in treatment of BN and BED may reduce compulsiveness without provoking excessive physical activity.

In a previous randomized controlled study by our research group, we found that *therapist guided* physical exercise was equal to CBT in treating females with BN at the end of treatment, and even superior to CBT at 18 months follow up (Sundgot-Borgen, Rosenvinge, Bahr, & Schneider, 2002). Moreover, uncontrolled studies indicate that exercise to treat BED reduces binge eating and body weight (Vancampfort, Vanderlinden, De Hert, Adamkova, Skjaerven, et al., 2013), and increases self-efficacy (Vancampfort et al., 2014), and hence, a favorable treatment outcome (Vancampfort et al., 2013). Previous studies offer mixed evidence for dietary counselling as a single treatment option for BN (Sundgot-Borgen et al., 2002; Laessle, Beumont, Butow, Lennerts, O'connor, et al., 1991) and BED (Hay, 2013). However, the effects of other treatments may be amplified by dietary counselling (Hsu, Rand, Sullivan, Liu, Mulliken, et al, 2001), and we argue that to combine it with guided physical exercise (Physical exercise and dietary therapy, PED-t) may represent an effective, alternative treatment option for BN and BED. This combination has to our knowledge, never been tested in studies using a high-quality design. We have developed and tested a new treatment, where we combine regular physical exercise and dietary therapy. It rests on the knowledge that eating and physical activity are unbalanced or dysfunctional affect regulation strategies that occupy these persons' minds and everyday life. We hypothesize that 1) PED-t and CBT outperform a waiting list control condition, and 2) that PED-t is comparable or better than CBT in alleviating scores on symptoms and impairments of BN and BED, as well as depressive symptoms and increase subjective wellbeing and psychosocial impairment secondary to ED.

Methods

Study design

This randomized controlled trial requited female participants with BN or BED for outpatient treatment arranged at the Norwegian School of Sport Sciences, in Oslo (Norway). A detailed account of the participants, the design, recruitment and test procedures have been described previously (Mathisen, Rosenvinge, Pettersen, Friborg, Vrabel, et al., 2017).

Study sample

We recruited participants through general practitioners (GP's), magazines, newspapers, national TV, social media, posters, handouts, and through webpages of the ED organizations. We interviewed participants by phone 2-6 weeks prior to the baseline measures and randomization (Figure 1).

Eligible to the study were female 18-40 years of age with BN or BED according to the DSM-5 diagnostic criteria and a BMI between 17.5 and 35 kg/(m)^2. Participants were excluded if currently being pregnant, being a competitive athlete, having a concurrent severe mental disorder in need of other treatment options, or having received CBT for an ED during the past two years prior to the present study.

All participants and their general practitioners were required to sign informed consents before participation.

Insert figure 1 about here

Randomization and masking

A colleague involved in administrative work at the department produced the randomization list (by www.randomizer.org) with block size of eight, and concealed allocation to one of two treatments arranged as group therapy: cognitive behavior therapy

(CBT) or physical exercise- and dietary therapy (PED-t). A second colleague performed allocation by listing the randomization results by id-number. The project leader conveyed the allocation to each participant by email when they had completed the baseline measures. Participants waiting for treatment were put on a waitlist for 16 weeks, and served as a control comparison condition for T1 and T2 measures, respectively.

All outcomes, anonymously coded by ID-number, were transferred to SPSS files by blinded statistical staff before the final statistical analyses.

Procedure

The 16-week treatment consisted of 20 group sessions, each of 90 min duration with 5-8 participants in each group. Between-session homework was included. A detailed account of the treatments are described elsewhere (Mathisen et al., 2017).

The manual-based CBT rests on a transdiagnostic model positing generic core ED-characteristics across ED-diagnoses (Fairburn, Cooper, Zafra, Doll, O'Connor, et al., 2009). The CBT-treatment consists of 1-2 weekly therapy sessions. The manual outlined four stages; 1) engagement and behavioral change, 2) monitoring and evaluating progress, 3) addressing the core ED- pathology and 4) relapse prevention. Psychologists certified in CBT were conducting this therapy.

The PED-t consists of the combination of dietary therapy, and progressive resistance training and high intensity interval running to increase physical fitness (Mathisen et al., 2017). The dietary manual focuses on discussions and practical skills in overcoming challenges in establishing regular daily eating patterns, and consists of the three modules; 1) meal frequency, portion sizes and the eating context, 2) detailed knowledge about energy and nutrient needs, and exercise physiology, and 3) presentation of a personal plan for the future. Specialists in physical exercise and dietetics were responsible for this therapy.

All outcomes were measured by self-reports at baseline (T1), after treatment of 16 weeks (T2), and at 6- (T3) and 12 months (T4) post-treatment. Remission from diagnosis was additionally assured by clinical assessment.

Outcomes

Eating Disorder Examination Questionnaire (EDE-q)

The EDE-q 6.0 (Cronbach's $\alpha = 0.87$, T1 current study) validly assesses the frequency and severity of ED features to produce ED diagnoses according to the DSM-5 (Fairburn & Beglin, 2008). Apart from a global score four subscales measure eating restraint (ER), eating concern (EC), shape concern (SC) and weight concern (WC). Mean (SD) global score for a Norwegian cohort of healthy female controls is 1.25 (1.10), while corresponding national clinical cut-off for probable BN and BED are 2.62, and 2.63, respectively (Rø, Reas, & Stedal, 2015). Reported binge eating episodes (BE) are based on scores from EDE-q item 14 (*reported BE with loss of control*).

Remission

Calculation of numbers in full remission, is based on the EDE-q global score of the national cohort sample's normative value +1 SD (i.e. ≤2.35) (Rø et al, 2015), with concurrently abstinence from BE- and purging episodes (i.e. 0 episodes last 28 days, as reported in EDE-q). Calculation of numbers in partial remission is based on the EDE-q global score below the diagnostic specific cutoff (i.e. 2.62 in BN and 2.63 in BED) (Rø et al, 2015), with concurrently less BE-and purging episodes defined as diagnostic criteria (i.e. < 4 times last 28 days, as reported in EDE-q). Additionally, an experienced therapist conducted clinical interviews according to the DSM-5 diagnostic criteria for quality assurance of the self-reported questionnaire.

Clinical Impairment Assessment (CIA 3.0)

The CIA 3.0 (Cronbach's α = 0.90, T1 current study) measures ED-elicited personal, social, and cognitive impairment (22). The CIA consists of 16 items scored on a 4-point Likert scale ranging from 0 (not at all) to 3 (a lot) during the past 28 days, with total scores ranging 0-48 (Bohn, Doll, Cooper, O'Connor, Palmer, et al., 2008), and a normative mean (SD) value from gender-matched, healthy Norwegian sample of 6.4 (7.5) (Reas, Rø, Kapstad, & Rø, 2010). The numbers with healthy CIA scoring are calculated as proportion within +1SD from mean normative score from national cohort sample (i.e. ≤ 13.9) (Reas et al 2010).

Beck Depression Inventory (BDI-Ia)

The BDI-Ia (Cronbach's α = 0.86, based on T1) measures current (past two weeks) self-reported symptoms of depression. It consists of 21 items scored with a 4-point Likert scale ranging from 0 (not at all) to 3 (extreme). Total score range is 0-62, and a cut-off score of ≥21 is commonly used to detect a clinically significant episode of major depression (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961).

Satisfaction with Life Scale (SWLS)

The SWLS (Cronbach's α = 0.89, based on T1) is a short 5-item scale measuring overall contentment with life compared to personal standards and expectations (Diener, 1994). It uses a 5-point Likert scale ranging from 1 (never true) to 7 (always true). An age-matched mean normative value from a Norwegian cross sectional health investigation is 26.3 (Clench-Aas, Nes, Dalgard, & Aarø, 2011).

Working Alliance Inventory (WAI)

The 12-item WAI-short form (Cronbach's α = 0.90, week 1 in treatment in current study) is scored with a 7-point Likert scale, and measures clients perception of alliance with therapist (Hatcher & Gillapsy, 2006).

Dropout

We defined dropouts as those who did not complete the treatment, and consequently, not providing post-treatment data. Lost to follow up are those not attending follow up testing (T3 and T4), typically for reasons like work/studies, moving too far away, injuries or illness, pregnancy, not willing to attend physically to the testing facilities, or not responding to email, mail or electronic questionnaires.

Statistical analysis

Power calculations for this trial is provided elsewhere (Mathisen et al 2017).

All analyses were conducted in SPSS version 24. Linear mixed regression models were built to estimate the between-group differences (PED-t vs. CBT) and the within-group changes (baseline vs. any of the three posttest measures). This analysis yields relatively unbiased estimates despite drop out given that data are missing completely at random or missing at random. Moreover, it can be safely used without conducting beforehand multiple imputations (Twisc, de Boer, de Vente, & Heymans, 2013). Standard errors were estimated with the restricted maximum likelihood function, and type III *F*-tests were preferred. Dependency in the repeated outcome measures was accounted for by including a random intercept factor. The fixed factors were: *Group* (0-PED-t, 1-CBT) representing the overall treatment difference, *Time* (repeated measures) representing change across measurements, and the *Group*×*Time* interaction in order to detect treatment differences at certain time points only. The between-group analyses used the baseline values as a covariate to increase the statistical power (Egbewale, Lewis & Sim, 2014). Differences between the treatment arms were examined with planned comparisons at each time point (least square difference tests). The within-group analyses included all four measurements in the *Time* factor. Due to the number of tests, differences with p-values < 0.01 were considered as significant. A

comparable statistical approach was used for the dichotomous outcome variables, replacing the analysis with a generalized linear model using a binominal distribution and logit link function (reference coded 0). Degrees of freedom were computed using Satterthwaite approximation. The outcome data are presented as estimated means including 99% confidence intervals.

Standardized Hedge's *g* effect-sizes for continuous data were calculated as a ratio of the estimated means (extracted from the mixed model) to the observed pooled standard deviations (SD). Values around 0.2, 0.5 and 0.8 were interpreted as weak, medium and strong, respectively (Hedges & Olkin, 1985). The moderating effect of treatment alliance (WAI) was studied by including WAI as main effect, and WAI×group and WAI×group×time as interaction effects.

Attrition rates were analyzed separately for each time (T2-T4) with independent t-test or chi-square analyses as appropriate, using a significance level of $p<0.05$.

Results

Between March 2014 and August 2016, 418 females responded to recruitment, of which 232 were excluded according to exclusion criteria. In total 14 did not respond to further communication during screening-period, 23 were temporarily placed on a waitlist serving as controls, and finally 164 were randomized to the two treatment groups. In total 76 of the allocated participants in PED-t and 73 in CBT initiated treatment, and 61 and 51, respectively, completed treatment. In control group; 18 of the originally 23 participants completed control group period. The attendance rate to therapy in PED-t was 81% and 75% in CBT. In PED-t the adherence rate to exercise sessions (supervised + unsupervised) was 69.8% for resistance exercise, and 56.7% for interval training. No between-group differences ($p>0.03$) were found at T1 for demographic and clinical features between treatment groups and control (Table 1).

The difference in number of dropout from treatment was not significantly different across groups or ED diagnoses. Amongst those who dropped out at T2 (n = 37) a higher mean (CI_{95}) baseline score for depression was found compared to completers (n=112), (-3.08 $_{-5.95, -0.21}$, g=0.39, p=0.035). Significantly more CBT-participants were lost to follow-up (LFU) both at T3 (PED-t = 19 (24.4%), CBT=37 (47.4%), p =0.005), and T4 (PED-t = 20 (25.6%), CBT= 39 (50.0%), p = 0.006). Overall, there was no difference in LFU across the BN and BED diagnoses (p>0.02), however, more with BN in CBT were LFU at T3 and T4 compared to BN in PED-t (p<0.03) (Figure 1). There were no differences (p>0.06) between attending participants at T3 (n=100, 64.1%) and LFU (n=56, 35.9%) with respect to the scoring at T2, as was the case at T4 with respect to T3 scores (attendees; n=97, 62.2%; LFU; n=59, 37.8%) (p>0.05).

Insert table 1 about here

Effects of the PED-t and CBT on ED symptoms

Within-groups changes in symptoms of ED

Compared to baseline, both treatment groups had lower EDE-q global- and subscales scores at posttest (p<0.001) and at follow-up (T3 p<0.003 and T4 p<0.001), whereas we found no effect in the control group from T1 to T2 (p>0.02) (Figures 2 and 3). The effect sizes in the mean change (SE) of EDE-q global scores ranged between medium to strong in both groups: PED-t ($_{T1\text{-}T2}$=-1.67 (0.14), g=0.98, $_{T1\text{-}T3}$=-1.28 (0.14), g=0.63, and $_{T1\text{-}T4=}$-1.48 (0.17), g=0.85) and CBT ($_{T1\text{-}T2}$=-1.02 (0.15), g=0.70, $_{T1\text{-}T3}$=-0.80 (0.16), g=0.46, and $_{T1\text{-}T4}$=-1.48 (0.17), g=0.88).

Both treatment groups reported a significant alleviation of ED behavioral symptoms, with medium effect sizes, from baseline to T2 and to follow ups respectively (p<0.001, Table 2).

Between-groups differences in symptom changes with baseline scores as covariate

PED-t improved more than the CBT (-0.66 (0.22), g=0.52, p <0.003) and the control group (-1.15 (0.31), g=1.00, p<0.001) in EDE-q global score after treatment (T2), whereas we found no effect from CBT compared to the control group (-0.49 (0.32), g=0.48, p=0.12). The advantage of the PED-t compared to the CBT disappeared at the two follow-up tests (p>0.05) (Figure 2). Adding therapy alliance (WAI) as a treatment moderator did not contribute significantly to the model.

At T2, the PED-t provided better improvement in the EDE-q subscales "eating concern" (g=1.10, p<0.001) and "eating restriction" compared to controls (g=0.82, p<0.001), and more than CBT in subscale "body weight concern" (g=0.54, p=0.002) (Figure 3). A comparable difference between PED-t and CBT was also found for "eating concern" at T3 (g=0.46, p=0.009), while there were no other between-groups differences (p>0.01).

At T2, PED-t participants displayed less binge eating (g=0.60, p=0.008) and driven exercise (g=0.70, p<0.001) compared to controls. No other between-group differences were found (table 2).

Insert figure 2 about here

Insert table 2 about here

Insert figure 3 about here

Effects of the PED-t and CBT on full- and partial remission from diagnosis

Within-groups changes in terms of full remission

In both the PED-t and the CBT group, the number of participants in remission was significantly higher at T2, T3 and T4, respectively, compared to T1 ($p < 0.001$) (Figure 4). From T2 to T4 the number of remitted participants increased significantly ($p < 0.007$) only in the CBT group. There was no change in the control group.

Between-groups differences in terms of full remission

The proportion of PED-t and CBT participants in full remission was not significantly different, but the proportions were higher than among the controls ($p<0.004$) (Figure 4).

Within group changes in partial remission

Less participants in PED-t group qualified for BN or BED diagnosis, still were without full remission, at T2 ($p<0.001$) and T3 ($p=0.005$) compared to T1, while no significant change was found in CBT ($p>0.02$) or control group ($p=0.30$) (Figure 4).

Between-groups differences in partial remission

No differences between groups in partial remission from BN or BED diagnosis were found ($p>0.10$, Figure 4).

Insert figure 4 about here

Effects of the PED-t and CBT on clinical impairment (CIA) from ED

Within-groups change in CIA

Mean CIA score decreased with strong effect size in both treatment groups at T2 -T4 compared to T1 respectively ($p<0.01$) (table 3).

The number of PED-t participants who scored within a normal population range increased significantly ($p < 0.001$) from 3 (4.3%) at T1 to 32 (59.3%) at T2, 24 (47.1%) at T3, and 23 (46.9%) at T4. The same was found for CBT; 6 (8.8%) at T1, 15 (31.9%) at T2, 12 (30.8%) at T3, and 18 (54.5%) at T4) ($p<0.002$). No such change ($p = 0.23$) was found in the control group; 2 (9.5%) and 4 (22.2%) respectively.

Between-groups differences in CIA

Improvement in CIA was significantly better in PED-t at T2 compared to CBT and control, with no further difference between groups at follow-ups, and no effect from CBT compared to control (table 3). Adding therapy alliance (WAI) as a treatment moderator did

not contribute significantly to the model. No differences (p>0.02) were found in numbers of participants scoring within a normal population range.

Effects of the PED-t and CBT on depressive symptoms

Within-groups changes in depressive symptoms (BDI)

Estimated mean BDI scores in all groups, at all times were below suggested threshold for probability of any depression (T1-T4). Only PED-t improved from T1 to T2, and to T3 respectively, in mean BDI scoring with medium to strong effect size (g>0.64, p<0.001, table 2), and no other significant effects were found. There were no effect from time on percentage scoring above BDI clinical cutoff in none of the groups (p >0.01).

Between-groups differences in depressive symptoms (BDI)

The score in behavioral manifestation of depression decreased more from baseline to post-treatment in PED-t compared to CBT (g=0.36, p=0.006), but not compared to control (p>0.17, table 3). No difference was found between CBT and control (p=0.60), neither were there any differences between treatment groups during follow-ups (p>0.09).

There was an effect from therapy alliance (WAI) by group (WAI×grp) on BDI, resulting in differences between treatment groups in favor of PED-t at T2 and T3. By separating the participants according to Z-scores for WAI, subgroup analysis found no significant difference between treatment groups for Z-score -1SD for any time (p>0.15). However there were effects with the average Z-score at T2 (mean difference, CI_{99}: -4.8 $_{-8.9, -0.6}$, p=0.003), and with Z-score +1SD for T2 (mean difference, CI_{99}: -8.6 $_{-13.9, -3.2}$, p<0.001) and T3 (mean difference, CI_{99}: -7.3 $_{-13.1, -1.6}$, p=0.001).

There were no effect from group on percentage scoring above BDI clinical cutoff (p>0.18).

Effects of the PED-t and CBT on subjective well-being

Within-group changes in subjective well-being (SWLS)

There was a significant improvement in rating of subjective well-being in both groups after treatment ($p<0.004$, table 3), with no change in control group.

Between-groups differences in subjective well-being (SWLS)

There were no differences between groups in improvements of rating of subjective well-being after treatment or during follow up (table 3).

Adding WAI as a treatment moderator did not significantly influence the model.

Insert table 3 about here

Discussion

Principal findings

This study has shown that combining physical exercise and dietary therapy may be an alternative pathway to recovery from BN and BED to the highly recommended cognitive behavioral therapy (CBT). The efficacy of such a pathway might be disturbing considering the established notion that psychotherapy to provide cognitive restructuring or insight, is a prerequisite for recovery. However, our results aligns with previous findings that behavioral components of CBT are more powerful change mechanisms than the cognitive restructuring elements (Södersten et al., 2017). It may be the case that the behavioral CBT-elements, targeting and changing discriminative stimuli for bingeing and purging, serve the same regulative purpose as physical exercise. Additionally, both treatments included the (re)introduction of regular meals; behavior that also serves regulatory purposes.

Comparison with other studies

The present result corresponds well with previous findings on treatment outcome from CBT, i.e. ~37% remits from diagnosis (Södersten et al., 2017), with one year follow up remission rate at 27-28% (Keel & Brown, 2010). Early symptom changes promote treatment success and predict a favorable long-term outcome (Graves, Tabri, Thompson-Brenner, Franko, Eddy, et al., 2017). An important asset of CBT compared to psychodynamic treatments of EDs, is that CBT produces such early changes (Hay, 2013; Södersten et al., 2017), thus leading to a shorter time of suffering from EDs. A similar asset may be transferred to the PED-t compared to CBT in terms of less impairment, and a remission from the BN and BED diagnoses. This asset is somewhat tempered by non-significant treatment differences in the more fine-grained measures (i.e. the EDE-q), and by the fact that both treatments performed equally well at the final (T4) follow-up.

Although alleviations of core ED symptoms is necessary for a treatment success, improvements in secondary outcomes is important to consolidate symptom improvement and to strengthen positive circuits by a rapid symptom change. Hence, participants' subjective wellbeing was improved in both treatments, and about 60-70% of all participants rated their wellbeing equal to or above average during follow up, which is close to the 80% in national cohort studies (Diener & Diener, 2009). An additional benefit is that the PED-t may improve a rather poor physical health (Mathisen et al., 2018). Moreover, a strong immediate (T2 and T3) effect from PED-t on scores for depression runs in line with previous findings on improvements from depression with physical activity (Fox, 1999). Excluding comorbid depression may account for low BDI-scores throughout. Thus, a floor-effect may account for no long-term changes.

Strengths and weaknesses of the study

Methodological strengths add credibility to the findings, i.e. the randomized controlled prospective design, the equal length and duration of the treatments, the unlikely diffusion of effects from previous or concurrent treatments, and that therapeutic alliance was not a significant moderator. The latter is in accordance with previous findings that early alliance is weakly related to outcome of treatments with a strong behavioral focus (Graves et al., 2017). A secondary advantageous effect from PED-t, is the potential impact on physical health, as high numbers of females with BN or BED are identified with impaired physical health (Mathisen et al., 2018). Four aspects tempering credibility are the non-randomization of the control group, a failure to control for therapist factors, the 50% of CBT- participants lost to follow-ups, and that data on treatment fidelity are presently unavailable.

Conclusion and implications

Taken together, the PED-t can be regarded as a new treatment for BN and BED. Its focus on physical exercise and nutrition is quite different from the common understanding of "psychotherapy", and may thus be relevant to new segments from the pool of ED patients in the general population, as well as ED patients who do not respond to CBT or other psychological treatments. Such an appeal can be accommodated by the higher availability of more professionals with expertise in exercise medicine and nutrition. Replications of the present study within the realm of effectiveness is a priority for further research.

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Table 1: Demographics of participants. Baseline demographic and clinical information for randomized participants initiating treatment- or control period. Results are mean (SD).

	Bulimia nervosa n=117	**Binge-eating disorder** n=55	**PED-t** n = 76	**CBT** n = 73	**Control** n = 23
Age, years	27.2 (5.6)	29.0 (6.1)	28.2 (6.2)	27.7 (5.3)	26.5 (5.6)
BW, kg	66.0 (12.2)	81.9 (15.1)	71.7 (16.0)	71.4 (14.4)	67.2 (14.1)
BMI, kg/m^2	23.5 (3.8)	28.9 (5.0)	25.3 (5.1)	25.5 (4.7)	24.1 (4.9)
Illness duration, years	12.0 (6.6)	13.0 (8.2)	13.0 (7.5)	12.1 (6.7)	10.6 (7.4)
EDE-q global score	3.79 (0.9)	3.49 (0.9)	3,70 (0.8)	3.67 (1.0)	3.81 (1.0)

NOTE: PED-t, Physical Exercise and Dietary Therapy; CBT, Cognitive behavior therapy; BN, bulimia nervosa; BED, binge eating disorder; BW, body weight; BMI, Body Mass Index; EDE-q global, Eating Disorder Examination Questionnaire.

Table 2: Frequency of binge-eating and purging episodes. Frequency of behavioral symptoms (estimated mean, 99% confidence interval, CI) in treatment groups and control group at baseline (T1) and the subsequent changes (99% CI) after treatment (T2) and during follow ups (T3-T4), and numbers (%) of attending participants above clinical cutoff for behavior frequencies (i.e. ≥4 episodes last month).

							Between effects, p-value, Effect size (g)		
		T1		T1-T2	T1-T3	T1-T4	*T2*	*T3*	*T4*
Binge eating episode	**PED-t**	Me (CI99)	12.4 9.4,15.4	Δ (CI99)	-7.30 -10.5,0-4.10 *p<0.001, g=0.52*	-8.06 -11.31,-4.81 *p<0.001, g=0.63*	-8.02 -11.29,-4.76 *p<0.001, g=0.66*			
		n (%)	*64 (84.2)*		*21 (34.4)*	*24 (40.7)*	*19 (32.8)*			
	CBT	Me (CI99)	11.3 8.3,14.4	Δ (CI99)	-6.29 -9.75,-2.82 *p<0.001, g=0.64*	-5.03 -8.78,-1.29 *p=0.001, g=0.45*	-5.93 -9.75,-2.12 *p<0.001, g=0.60*	*n.s*	*n.s*	*n.s*
		n (%)	*61 (83.6)*		*21 (41.2)*	*18 (43.9)*	*12 (30.8)*			
	Con	Me (CI99)	12.7 7.3,18.2	Δ (CI99)	-1.38 -7.30,4.55 *n.s.*	-	-	-6.25 † -12.29,-0.21 *p=0.008 g=0.54*	-	-
		n (%)	*22 (95.7)*		*14 (77.8)*	-	-			

							Between effects, p-value, Effect size (g)		
		T1		T1-T2	T1-T3	T1-T4	*T2*	*T3*	*T4*
Self-induced vomiting	**PED-t**	Me (CI99)	12.8 6.1,19.5	Δ (CI99)	-7.18 -10.76,-3.59 *p*<0.001, *g=0.51*	-7.94 -11.57-4.31 *p* <0.001, *g=0.50*	-5.78 -9.44,-2.13 *p* <0.001, *g=0.51*			
		n (%)	*33 (43.0)*		*13 (21.3)*	*14 (23.7)*	*13 (22.4)*			
	CBT	Me (CI99)	8.8 2.0,15.7	Δ (CI99)	-4.20 -8.11,-0.29 *p* =0.006, *g=0.43*	-3.77 -8.01,0.47 *n.s*	-3.01 -7.32,1.30 *n.s.*	*n.s.*	*n.s*	*n.s.*
		n (%)	*29 (39.7)*		*10 (19.6)*	*10 (24.4)*	*4 (10.3)*			
	Con	Me (CI99)	5.2 -7.0,17.4	Δ (CI99)	-0.43 -7.10,6.24 *n.s.*	-	-	*n.s.*	-	-
		n (%)	*5 (21.7)*		*5 (27.8)*	-	-			
Driven exercise	**PED-t**	Me (CI99)	10.8 8.0,13.5	Δ (CI99)	-8.53 -11.32,-5.75 *p* <0.001, *g=0.69*	-6.43 -9.25,-3.61 *p* <0.001, *g=0.50*	-5.91 -8.75,-3.09 *p* <0.001, *g=0.45*			
		n (%)	*52 (68.4)*		*6 (9.8)*	*18 (30.5)*	*21 (36.5)*			
	CBT	Me (CI99)	8.3 5.5,11.0	Δ (CI99)	-4.43 -7.43,-1.42 *p* <0.001, *g=0.58*	-3.55 -6.81,-0.30 *p* =0.005, *g=0.46*	-4.65 -7.96,-1.34 *p* <0.001, *g=0.57*	*n.s.*	*n.s*	*n.s.*

							Between effects, p-value, Effect size (g)		
		T1		T1-T2	T1-T3	T1-T4	*T2*	*T3*	*T4*
Con	*n (%)*	*50 (68.5)*		*16 (31.4)*	*16 (39.0)*	*13 (33.3)*			
	Me (CI$_{99}$)	14.6 9.5,19.7	Δ (CI$_{99}$)	-5.05 -10.39,0.29 *n.s.*	-	-	-5.83 † -10.23,-1.42 *p*<0.001 *g=1.27*	-	-
	n (%)	*16 (76.2)*		*11 (61.1)*	-	-			

NOTE: PED-t, physical exercise and dietary therapy; CBT, cognitive behavior therapy; Con, control group; Δ , change; T1, baseline measure; T2, post-treatment; T3, 6 months follow up post treatment; T4, 12 months follow-up post treatment; CI$_{99}$, 99% confidence interval; † between PED-t and control.

Table 3: Satisfaction with Life Scale (SWLS), Beck Depression Inventory (BDI), and Clinical Impairment Assessment (CIA). Estimated mean scores according to group affiliation (PED-t, CBT or Control) and time (T1-T4).

							Between effects, p-value, Effect size (g)		
		T1 $_{CI\ .99}$		T1-T2	T1-T3	T1-T4	*T2*	*T3*	*T4*
SWLS	**PED-t**	16.5 14.38-18.62	Δ (CI_{99})	4.63 2.78,6.49 *p*<0.001 *g=0.67*	2.94 1.03,4.85 *p* <0.001 *g=0.42*	3.82 1.94,5.69 *p* <0.001 *g=0.61*			
	CBT	16.6 14,47-18.79	Δ (CI_{99})	2.26 0.27,4.26 *p* =0.004 *g=0.59*	*n.s.*	2.58 0.37,4.78 *p* =0.003 *g=0.42*	*n.s*	*n.s*	*n.s*
	Control	16.17 12.33-20.02	Δ (CI_{99})	*n.s.*			*n.s*		
BDI	**PED-t**	16.5 13.76-19.21	Δ (CI_{99})	-6.79 -9.79,-3.78 *p* <0.001 *g=0.89*	-5.12 -8.18,-2.06 *p* <0.001 *g= 0.64*	*n.s.*			
	CBT	14.6 11.79-17.35	Δ (CI_{99})	*n.s.*	*n.s.*	*n.s.*	-3.13 -9.08,2.82 *p*=0.006 *g=0.36*	*n.s.*	*n.s*
	Control	18.5 13.59-23.45	Δ (CI_{99})	*n.s.*	-	-	*n.s.*		
CIA	**PED-t**	28.15 24.82-31.47	Δ (CI_{99})	-13.86 -17.63,-10.09	-12.55 -16.38,-8.72	-12.32 -16.22,-8.42			

						Between effects, p-value, Effect size (g)		
	T1 $_{CI .99}$		T1-T2	T1-T3	T1-T4	*T2*	*T3*	*T4*
CBT	26.94 23.58-30.30	Δ (CI_{99})	*p* <0.001 *g=1.13* -7.08 -11.07,-3.09 *p* <0.001 *g=0.76*	*p* <0.001 *g=0.83* -5.93 -10.20,-1.66 *p* <0.001 *g=0.54*	*p* <0.001 *g=0.97* -11.95 -16.48,-7.43 *p* <0.001 *g=1.00*	-6.13 -11.89,-0.37 *p*=0.006 *g=0.49*	*n.s.*	*n.s*
Control	29.99 23.96-36.02	Δ (CI_{99})	*n.s.*	-	-	-9.78 -17.89,-1.66 *p*=0.002[†] *g=0.93*		

NOTE: PED-t, physical exercise and dietary therapy; CBT, cognitive behavior therapy; T1, baseline measure; T2, post-treatment; T3, 6-month follow up post treatment; T4, 12-month follow up post treatment; Δ , change; CI $_{.99}$ = 99% confidence interval; Within = Change from baseline to any of the three posttests (T2, T3 and T4); Between = Difference between groups (adjusted for baseline) at any of the three posttests (T2, T3 and T4); g, effect size of Hedges 'g; n.s., non-significant; [†] significant different to PED-t.

Figure 1: Recruitment, retention and attrition during test periods. Overview of recruitment, screening, randomization and attendance to the baseline (T1), post-treatment (T2) and follow-up measures (T3-T4). NOTE: PED-t, physical exercise and dietary therapy; CBT, cognitive behavior therapy; BN, bulimia nervosa; BED, binge-eating disorder; EDE-q, eating disorder examination questionnaire; LFU, lost to follow up; [1]Fairburn & Beglin, 2008; [2] Sheehan, Lecrubier, Sheehan, et al., 1998

Figure 2: EDE-Q global score. Estimated mean EDE-q (CI 99%) in each group from baseline (T1) to post-treatment (T2) and follow-ups (T3 and T4). NOTE: PED-t, physical exercise and dietary therapy; CBT, cognitive behavior therapy; EDE-q, eating disorder examination questionnaire; T1, baseline measure; T2, post-treatment; T3, 6 months follow up post treatment; T4, 12 months follow up post treatment; †significant change from baseline in each of the treatment groups, $p<0.001$; ‡ significant difference between treatment groups ($p=0.003$); § significant difference between PED-t and control ($p<0.001$).

Figure 3: EDE-q subscales. Estimated (CI 99%) scores according to group affiliation during the reported study period. NOTE: PED-t, physical exercise and dietary therapy; CBT, cognitive behavior therapy; EDE-q, eating disorder examination questionnaire; T1, baseline measure; T2, post-treatment; T3, 6 months follow up post treatment; T4, 12 months follow up post treatment; † significant change from baseline in each of the treatment groups, $p<0.003$; ‡ significant difference between treatment groups $p<0.009$; § significant difference between PED-t and control $p<0.001$

Figure 4: Remission from diagnosis. Estimated mean (SE) percent in each group in full remission (left) and partial remission (right) at post-treatment (T2) and follow-ups (T3, T4). Note: PED-t, physical exercise and dietary therapy; CBT, cognitive behavior therapy; T2, post-treatment; T3, 6-month post-treatment; T4, 12-month post-treatment; † significant change from baseline, $p<0.005$; ‡ significantly different to control group, $p<0.004$; § significant change from T2, $p=0.007$.

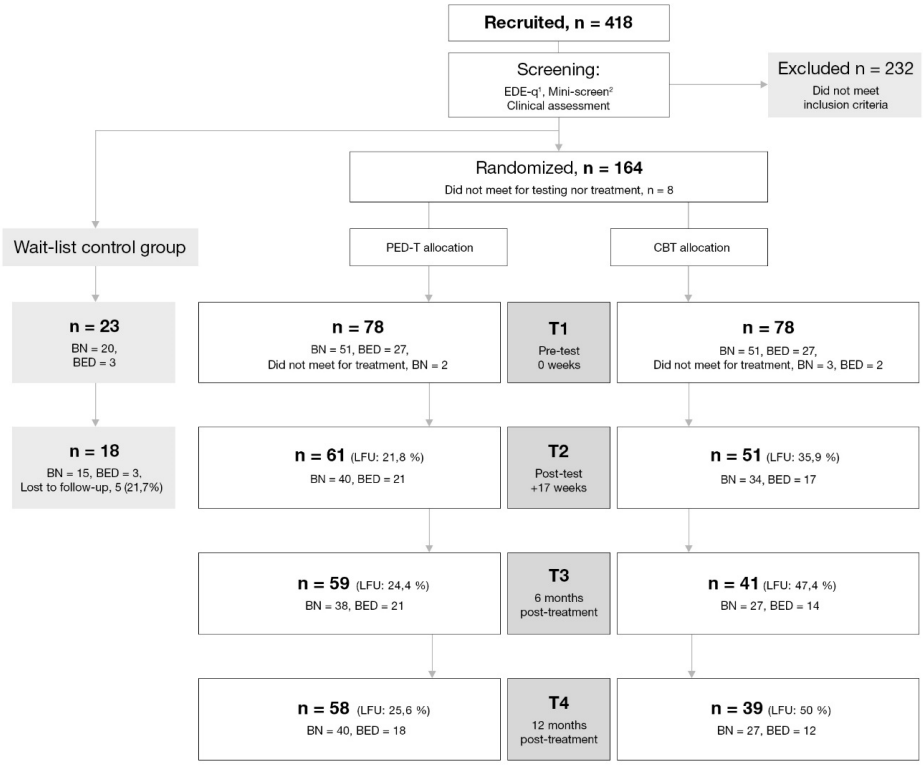
Recruited, n = 418
Screening:
EDE-q[1], Mini-screen[2]
Clinical assessment
Excluded n = 232
Did not meet inclusion criteria
Randomized, n = 164
Did not meet for testing nor treatment, n = 8
Wait-list control group
PED-T allocation
CBT allocation
n = 23
BN = 20, BED = 3
n = 78
BN = 51, BED = 27, Did not meet for treatment, BN = 2
T1
Pre-test
0 weeks
n = 78
BN = 51, BED = 27, Did not meet for treatment, BN = 3, BED = 2
n = 18
BN = 15, BED = 3, Lost to follow-up, 5 (21,7%)
n = 61 (LFU: 21,8 %)
BN = 40, BED = 21
T2
Post-test
+17 weeks
n = 51 (LFU: 35,9 %)
BN = 34, BED = 17
n = 59 (LFU: 24,4 %)
BN = 38, BED = 21
T3
6 months
post-treatment
n = 41 (LFU: 47,4 %)
BN = 27, BED = 14
n = 58 (LFU: 25,6 %)
BN = 40, BED = 18
T4
12 months
post-treatment
n = 39 (LFU: 50 %)
BN = 27, BED = 12

Figure 1

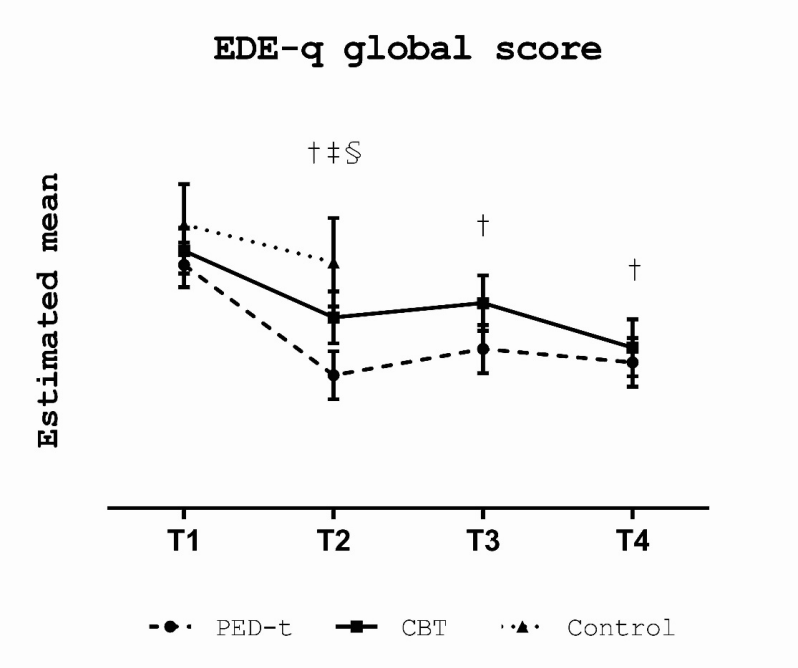
EDE-q global score
Estimated mean
†‡§
†
†
T1
T2
T3
T4
PED-t
CBT
Control

Figure 2

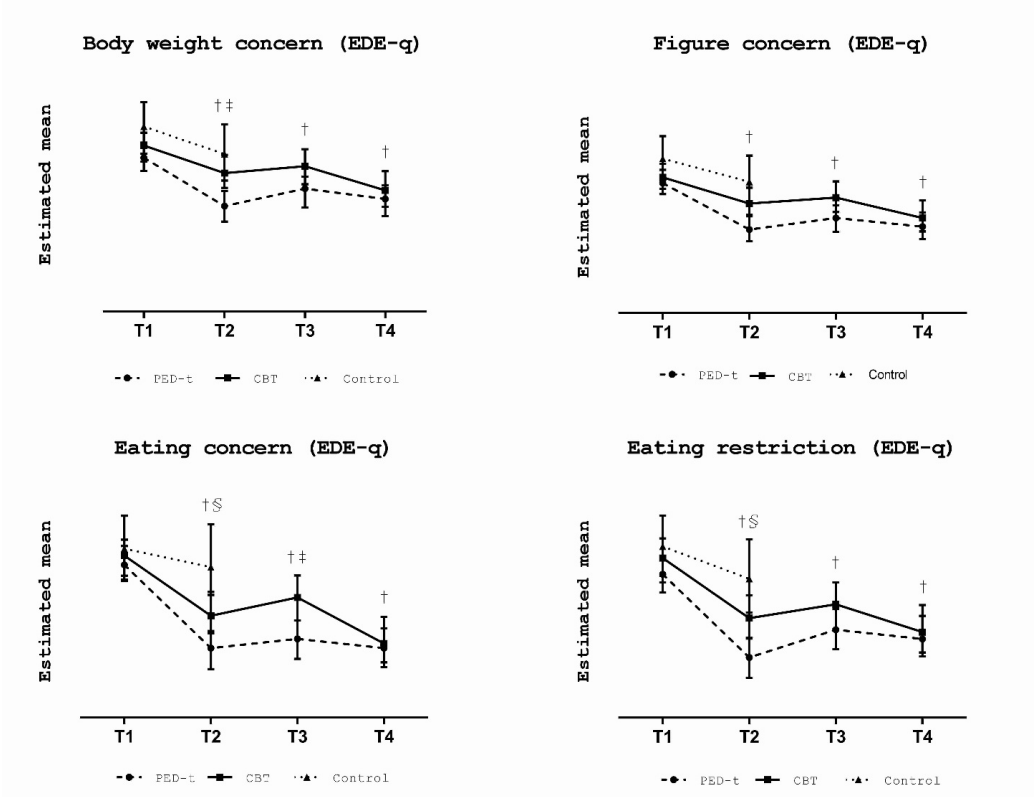
Body weight concern (EDE-q)
Estimated mean
T1
T2
T3
T4
PED-t
CBT
Control
Figure concern (EDE-q)
Estimated mean
T1
T2
T3
T4
PED-t
CBT
Control
Eating concern (EDE-q)
Estimated mean
T1
T2
T3
T4
PED-t
CBT
Control
Eating restriction (EDE-q)
Estimated mean
T1
T2
T3
T4
PED-t
CBT
Control

Figure 3

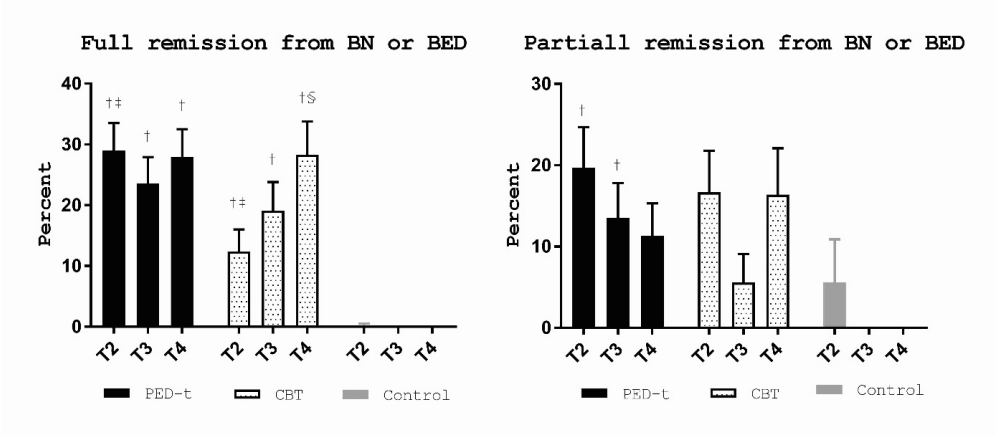
Full remission from BN or BED
Percent
40
30
20
10
0
†‡
†
†
†‡
†
†§
T2 T3 T4 T2 T3 T4 T2 T3 T4
PED-t
CBT
Control
Partiall remission from BN or BED
Percent
30
20
10
0
†
†
T2 T3 T4 T2 T3 T4 T2 T3 T4
PED-t
CBT
Control

Figure 4

Appendix I

Approval letter from the Regional Committees for Medical Research Ethics,
Registration by the international Clinical Trial Registration.

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

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

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 bulimisymptomer like godt som kognitiv terapi, men at også kostrådgivning hadde effekt. Dette kan bety at kostrådsgivning 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 avidentifisert, 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.sjøstedt@nih.no; postmottak@nih.no

ClinicalTrials.gov PRS
Protocol Registration and Results System

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: November 6, 2017

ClinicalTrials.gov ID: NCT02079935

Study Identification

Unique Protocol ID:	2013/344
Brief Title:	Treatment of Eating Disorders by Physical Activity and Nutrition Counseling (FAKT)
Official Title:	Treatment of Eating Disorders - a Randomised, Controlled, Prospective Study
Secondary IDs:	2013/1871 [Grantor or Funder: Regional Committees for Medical and Health Research Ethics]

Study Status

Record Verification:	November 2017
Overall Status:	Active, not recruiting
Study Start:	March 2014 []
Primary Completion:	December 2018 [Anticipated]
Study Completion:	December 2018 [Anticipated]

Sponsor/Collaborators

Sponsor:	Norwegian School of Sport Sciences
Responsible Party:	Principal Investigator Investigator: Professor Jorunn Sundgot-Borgen [jsundgot-borgen] Official Title: Professor Affiliation: Norwegian School of Sport Sciences
Collaborators:	The Norwegian Women´s Public Health Association University of Tromso

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: 2013/1871 Board Name: Regional Committees for Medical and Health Research Ethics Board Affiliation: Regional Committees for Medical and Health Research Ethics Phone: 22845520 Email: post@helseforskning.etikkom.no Address:

Gullhaugveien 1-3, 0484 Oslo, Norway

Data Monitoring: Yes

FDA Regulated Intervention: No

Study Description

Brief Summary: "Eating disorders" includes anorexia nervosa, bulimia nervosa, binge eating and other specified feeding or eating disorder (OSFED). Common to all is the intensively occupation to control food intake, body image and body weight. Most people with this kind of disorder don't reach for professional help, or there may be more than 4 years before they do. Cognitive behavior therapy is the foremost method of treatment of eating disorders, but up to 30-50% of the patients don't respond to this. The investigators find it important to identify science based alternatives of therapy, as this may reduce the health concern, and broaden the choice of therapy methods. A former study by Sundgot-Borgen et al in 2002, found guided physical activity to reduce symptoms of bulimia nervosa just as good as the traditional cognitive therapy.

The primary objective of the project is to see whether the combination of physical exercise and dietary therapy is more effective in treating eating disorders, than cognitive therapy.

Secondly, the investigators want to see whether there are any differences with regard to the individual satisfaction of treatment method, and to associated costs. Interviews with a sufficient number of participants from the PED-t arm to meet data saturation criteria, and all theraphists in the new treatment offer, will give uniqe insight to experiences with the treatment method and the delivery of treatment.

Detailed Description: Subjects are recruited through primary doctors, social media and newspapers, and will be included continuously by screening interviews. There will be a randomization into two treatment groups (cognitive behavior, or physical activity and nutrition education) to be followed for 16 weeks. Each week includes one meeting of group therapy (90 minutes) and homework related to treatment, and for 4 weeks midway there will be two therapy meetings pr week (a total of 20 meetings). Post tests are planned at week 17, and at 6, 12, and 24 months after treatment.

Participants reqruited during ongoing treatment groups are placed on a waitlist, serving as controls to the treatment groups.

Conditions

Conditions: Bulimia Nervosa
Binge Eating Disorder

Keywords: BN
Binge
overconsumption of food
purging
purge

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase:	N/A
Interventional Study Model:	Parallel Assignment Comparing treatment of cognitive behavioural therapy, with treatment of physical exercise and dietary therapy. All participants randomized to either of the two treatment offers. Waitlist serves as control group.
Number of Arms:	2
Masking:	Single (Outcomes Assessor) The one transferring results from lab's and questionaires to SPSS are blinded for group affiliation.
Allocation:	Randomized
Enrollment:	128 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Cognitive Behaviour Therapy Treatment with small groups following a modified protocol first described by Fairburn 2008	Behavioral: Cognitive Behaviour Therapy Following group-modified protocol for cognitive behavioral therapy, CBT, first described by Fairburn 2008, modified by Modum Bad, Norway. Other Names: • CBT-ED • CBT-enhanced • CBT-e
Experimental: Physical activity and dietary therapy Treatment with guided physical activity and dietary therapy in small groups	Behavioral: Physical Activity and Dietary Therapy Guided physical activity and dietary therapy, to (re-)introduce a more healthy lifestyle and help stabilizing a healthy weight. A detailed manual will be published. Other Names: • PADT • FAKT • PED-t

Outcome Measures

Primary Outcome Measure:

1. Effectiveness of treatment, evaluated through the change in symptoms of eating disorder
   Change in ED-symptoms are evaluated through screening and surveys: EDE-questionaire (Episodes of binge eating, episodes of purging, concern for body weight and appearance)(Fairburn, 2008), Clinical Impairment Assessment (CIA) (Fairburn, 2008), Eating Disorder Inventory-3 (EDI) (Garner, 2004), Eating Disturbance Scale (EDS-5) (Rosenvinge et al., 2000), DSM-5 (APA, 2013)

   [Time Frame: Pre-test in week 0, Post-tests (week 17), and at 6, 12, and 24 months after intervention.]

Secondary Outcome Measure:

2. Expectations of treatment method for eating disorders
   Interview on the expectations the patients have to the specified treatment method of eating disorders (arm of intervention) EPDEX (Clinton 2001)

   [Time Frame: Pre-test]
3. Experiences of the treatment method for eating disorders

Interview on the experiences the patients have to the specified treatment method of eating disorders (arm of intervention), EPDEX (Clinton 2001)

[Time Frame: Post-test (week 17)]

4. Associated cost with treatment method
   Calculation of the directly and indirectly cost related to treatment method

   [Time Frame: Pre-test]

5. Associated cost with treatment method
   Calculation of the directly and indirectly cost related to treatment method

   [Time Frame: Post-test (week 17)]

6. Associated cost With treatment method
   Calculation of the directly and indirectly cost related to treatment method

   [Time Frame: Post-test (by 6th month post-treatment)]

7. Associated cost With treatment method
   Calculation of the directly and indirectly cost related to treatment method

   [Time Frame: Post-test (by 12th month post-treatment)]

8. Associated cost with treatment method
   Calculation of the directly and indirectly cost related to treatment method

   [Time Frame: Post-test (by 24th month post-treatment)]

9. Global measurement of general psychopathology
   Beck's Anxiety Inventory (BAI), Beck Depression Inventory (BDI), QoL (Diener), Utrecht Coping List, Resilience Scale for Adults, the outcome rating scale (ORS), the three-factor eating questionnaire (TFEQ), Binge eating Scale (BES), Cantril's Ladder, Exercise dependency test, compulsice exercise test

   [Time Frame: Pre-treatment]

10. Global measurement of general psychopathology
    Beck's Anxiety Inventory (BAI), Beck Depression Inventory (BDI), QoL (Diener), Utrecht Coping List, Resilience Scale for Adults, the outcome rating scale (ORS), the three-factor eating questionnaire (TFEQ), Binge eating Scale (BES), Cantril's Ladder, Exercise dependency test, compulsice exercise test

    [Time Frame: Post-treatment (week 17)]

11. Global measurement of general psychopathology
    Beck's Anxiety Inventory (BAI), Beck Depression Inventory (BDI), QoL (Diener), Utrecht Coping List, Resilience Scale for Adults, the outcome rating scale (ORS), the three-factor eating questionnaire (TFEQ), Binge eating Scale (BES), Cantril's Ladder, Exercise dependency test, compulsice exercise test

    [Time Frame: Post-treatment (by the 6th month post-treatment)]

12. Global measurement of general psychopathology
    Beck's Anxiety Inventory (BAI), Beck Depression Inventory (BDI), QoL (Diener), Utrecht Coping List, Resilience Scale for Adults, the outcome rating scale (ORS), the three-factor eating questionnaire (TFEQ), Binge eating Scale (BES), Cantril's Ladder, Exercise dependency test, compulsice exercise test

    [Time Frame: Post-test (by 12th month post-treatment)]

13. Global measurement of general psychopathology
    Beck's Anxiety Inventory (BAI), Beck Depression Inventory (BDI), QoL (Diener), Utrecht Coping List, Resilience Scale for Adults, the outcome rating scale (ORS), the three-factor eating questionnaire (TFEQ), Binge eating Scale (BES), Cantril's Ladder, Exercise dependency test, compulsice exercise test

    [Time Frame: Post-test (by 24th month post-treatment)]

14. Group climate
    coerciveness scale from Therapeutic Factor Inventory (Lese & MacNair-Semands, 2000).

    [Time Frame: week 1-16]

15. Working Alliance

Working Alliance Inventory (Horwath & Greenberg, 1989)

[Time Frame: week 1-16]

16. Experiences of the treatment method for eating disorders
Interview on the experiences the patients have to the specified treatment method of eating disorders (arm of intervention) (Clinton 2001)

[Time Frame: Post-test (6 months)]

17. Experiences of the treatment method for eating disorders
Interview on the experiences the patients have to the specified treatment method of eating disorders (arm of intervention) (Clinton 2001)

[Time Frame: Post-test (by 12th month post-treatment)]

18. Experiences of the treatment method for eating disorders
Interview on the experiences the patients have to the specified treatment method of eating disorders (arm of intervention) (Clinton 2001)

[Time Frame: Post-test (by 24th month post-treatment)]

19. Change in eating disorder behavior and cognitions related to body figure and bodyweight
Evaluation after each therapy session on progress in reducing eating disordered behaviour (binging and purging) and on changes of cognitions on body figure and -weight

[Time Frame: Week 1-16 during treatment]

Other Pre-specified Outcome Measures:

20. Change in muscular strength
Status of 1 repetition maximum, 1RM, muscular strength in squats, bench press and seated row

[Time Frame: Pretest (week 0), post-test (week 17) and at 6, 12 and 24 months after treatment]

21. Change in cardiovascular endurance
CPET: with the use of modified Balke Treadmill performance evaluation test, The Borg scale (Borg, 1982)

[Time Frame: Pre-test in week 0, Post-tests (week 17), and at 6, 12 and 24 months after intervention.]

22. Change in bone mineral density
DXA (Dual-energy X-ray absorptiometry)

[Time Frame: Pre-test in week 0, Post-test (week 17) and 6, 12, and 24 months post-treatment]

23. Change in body weight and bodycomposition
DXA (dual-energy x-ray absorptiometry) (weekly weight registration will also be kept in each arm of treatment)

[Time Frame: Pre-test and post-test (week 17) and at 6,12,18 and 24 months post-treatment]

24. Change in nutritional status
Blood test to identify nutritional status of iron, folate, cholesterol and triglycerides, ApoA, ApoB and vitamin-D, folic acid

[Time Frame: Pre-test, in week 8 of treatment, post-test (week 17) and at 6,12,18 and 24 months post-treatment]

25. Change in hormonal status
Blood test to evaluate hormonal status of estradiol, progesterone, CTX, P1nP, insulin, leptin, TSH, T3, T4, FSH, LH, cortisol

[Time Frame: Pre-test, week 8 of treatment, post-test (week 17) and at 6,12,18 and 24 months post-treatment]

26. Change in dietary and nutritional intake
24 hour recall interview: interview on the intake of food and beverage during the past 24 hours.

[Time Frame: Pre-test, each 3rd week in treatment (a total of 5 interviews), post-test (week 17), and post-treatment (6,12, and 24 months post-treatment)]

27. Change in physical activity level
Wearing a GT3X-BT actigraph accelerometer for 7 consecutive days and making notes on daily activity in 30 minutes intervals

[Time Frame: Pre-test in week 0, Post-test (week 17) and 6, 12, and 24 months post-treatment]

28. Interview: measure and explore patients experienced treatment satisfaction and outcome/benefits with PED-t. Qualitative approaches, such as in-depth interviews, will give additional insights into ED-patients' perspectives, notably experiences and satisfaction with the treatment. A sufficient number of participants to meet data saturation criteria are qualitatively interviewed.

    Data are analyzed in four steps within the framework of systematic text condensation (Malterud 2012).

    [Time Frame: Post treatment]

29. Interview: What are the theraphists experiences of their contribution to the PED-t program
    Qualitative approaches, such as in-depth interviews, will give additional insights into the therapists' perspectives and experiences on delivering a new treatment offer for eating disorder.

    Data are analyzed in four steps within the framework of systematic text condensation (Malterud 2012).

    [Time Frame: Post treatment]

30. Interview: What are the experiences of the participants who drop out of the PED-t program?
    Data are analyzed in four steps within the framework of systematic text condensation (Malterud 2012).

    [Time Frame: Post treatment]

Eligibility

Minimum Age:	18 Years
Maximum Age:	40 Years
Sex:	Female
Gender Based:	
Accepts Healthy Volunteers:	No
Criteria:	Inclusion Criteria:

- Women,
- BMI 17,5-35,
- Age of 18-40 years,
- DSM-5 criteria of bulimia nervosa,
- DSM-5 criteria of Binge eating disorder
- Living nearby Norwegian School of Sports Sciences, NSSS, in Oslo (Norway)

Exclusion Criteria:

- Age <18 and >40 years
- BMI <17,5 and >35
- Pregnancy
- Competing/experienced athlete
- Anorexia nervosa
- Currently, or during the past 2 years, in active treatment with cognitive therapy
- Other personality disturbances
- Suicidality

Contacts/Locations

Central Contact Person: Therese F Mathisen, PhDcandidate
Telephone: 95752818 Ext. +47
Email: t.f.mathisen@nih.no

Central Contact Backup:	Jorunn Sundgot-Borgen, Professor Telephone: 92241745 Ext. +47 Email: jorunn.sundgot-borgen@nih.no
Study Officials:	Jorunn Sundgot-Borgen, Professor Study Chair Norwegian School of Sports Sciences Therese F Mathisen, PhDcandidate Study Principal Investigator Norwegian School of Sports Sciences Jan Rosenvinge, Professor Study Director University of Tromsø
Locations:	Norway Norwegian School of Sports Sciences Oslo, Norway, 0806 Contact: Jorunn Sundgot-Borgen, Professor 922 41 745 Ext. +47 jorunn.sundgot-borgen@nih.no Principal Investigator: Therese F Mathisen, PhDcandidate

IPDSharing

Plan to Share IPD:	Undecided

References

Citations:	[Study Results] Sundgot-Borgen J, Rosenvinge JH, Bahr R, Schneider LS. The effect of exercise, cognitive therapy, and nutritional counseling in treating bulimia nervosa. Med Sci Sports Exerc. 2002 Feb;34(2):190-5. PubMed 11828224
Links:	URL: http://www.nih.no/en/ Description Norwegian School of Sports Sciences URL: http://www.sanitetskvinnene.no/ Description The Norwegian Women's Public Health Association URL: http://en.uit.no/startsida Description University of Tromsø URL: http://translate.google.com/translate?hl=no&langpair=no%7Cen&u=http://www.modum-bad.no/ Description Modum Bad URL: http://nihfakt.blogspot.no/ Description Recruitment webpage
Available IPD/Information:	

Appendix II

Informed consents

A. Consent on participation (participant)

B. Confidentiality agreement

C. Consent and approval on videotaping from group therapy

D. Consent from General Practitioner

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 Idrettshøyskole, 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 á 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 kjennes 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.mathisen@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 deltagelse ved Norges Idrettshøyskole). Personer som ikke kvalifiserer til deltagelse, 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 overspisingslidelse 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 spiseforstyrrelsene bulimia nervosa eller overspisingslidelse.

- **Undersøkelser, blodprøver og annet den inkluderte må gjennom**
  Det vil tas stilling til om du kvalifiserer til deltagelse i studien gjennom et innledende telefonintervju, spørsmålsskjema og skriftlig erklæring fra egen fastlege. Før studien starter, og etter de 16 behandlingsukene 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 behandlingsukene. Etter behandlingsukene 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 behandlingsopplegg. 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 erfarende 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 tankemønster.

- **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 relater 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 scoreresultater på de ulike psykologiske tester som distribueres og gjennomføres via spørreskjema og intervju.

Norges Idrettshøyskole 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.

Rett 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 korrigert 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 livssynsnøytral 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)

B

TAUSHETSERKLÆRING

F.A.K.T. STUDIEN

Jeg forplikter meg med dette til absolutt taushet med hensyn til hva jeg måtte få se og høre i min selvhjelpsgruppe.
Taushetsplikten gjelder for all den informasjon jeg måtte få om enkeltmennesker, deres familie, bekjente eller andre omtalte personer. Jeg forstår at jeg kan snakke med andre om meg selv og hva jeg opplever, men jeg skal ikke omtale andre ved navn eller på annen måte utgi informasjon som kan bidra til å gjenkjenne enkeltpersonene i gruppene.

Taushetsplikten er **moralsk og etisk.** Brudd på taushetsplikten kan ikke gjøres til gjenstand for strafferettslig forfølging.

Dato:_____

Navn med blokkbokstaver:_____

Signatur:_____

Bekreftelse

Jeg bekrefter herved at det er i orden at sesjonene filmes og at det brukes som grunnlag for vurderingen av behandlingen som jeg deltar i

Dato:.....

Signatur.....

D

INFORMASJON OM BEHANDLINGSSTUDIE FOR SPISEFORSTYRRELSER

Ved Norges Idrettshøyskole settes det i februar i gang en behandlingsstudie for kvinner med spiseforstyrrelser. Studiens størrelse, varighet og tverrfaglighet vekker stor interesse både i nasjonale og internasjonale fagmiljø. Prosjektleder er professor Jorunn Sundgot-Borgen, som sammen med professor Jan Rosenvinge fra Universitetet i Tromsø, vil veilede doktorgradsstipendiat Therese Fostervold Mathisen i dette arbeidet. Med i prosjektgruppen er Universitetet i Tromsø, Modum Bad og Oslo Universitetssykehus. Studien finansieres av **Norske Kvinners Sanitetsforening**, samt ved bidrag fra Universitetet i Tromsø og Universitetssykehuset i Nord-Norge

BAKGRUNN FOR PROSJEKTET

Spiseforstyrrelser omfatter anorexia nervosa, bulimia nervosa, overspisingslidelse eller uspesifikke varianter. Felles for lidelsene er overbevisningen om betydningen av å kontrollere mat, kropp og vekt. Flertallet av mennesker med bulimi og overspisingslidelse 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 for bulimi 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.

BEHANDLINGSSTUDIET

Vi ønsker å undersøke effekten av et nytt, designet behandlingstilbud bestående av veiledet fysisk aktivitet og kostholdsopplæring for **kvinner med spiseforstyrrelsene bulimia nervosa eller overspisingslidelse**.

Deltagere ønskes rekruttert via fastleger, sosiale medier og medieomtaler, og vil inkluderes fortløpende etter screeningintervju. Deltagere fordeles til 2 ulike behandlingsgrupper (kognitiv terapi, eller fysisk aktivitet og kostholdsveiledning), og deltar på et 16 ukers gruppeterapi program basert på professor Fairburn's tidligere beskrevne kognitive behandlingsmetode for spiseforstyrrelser (2008). Etter de 16 behandlingsukene gjøres det oppfølginger ved 6, 12, og 24 mnd.

Det **primære forskningsspørsmålet** er hvorvidt kombinasjonen fysisk aktivitet og kostholdsrådgivning har større effekt enn kognitiv terapi alene. Primære utfallsmål er symptommål på spiseforstyrrelser. Det **sekundære forskningsspørsmålet** er om det er gruppeforskjeller med hensyn til brukertilfredshet og direkte/indirekte kostnader. Det vil også gjøres undersøkelser av fysisk- og helserelatert karakter (styrke, kondisjon, kroppssammensetning, benmineraltetthet og ernæringsstatus).

KORT OM MÅLGRUPPEN

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 deltagelse ved Norges Idrettshøyskole). Personer som ikke kvalifiserer til deltagelse, er aktive/konkurrerende idrettsutøvere, personer som allerede er under aktiv behandling eller har vært så de siste 2 årene, alvorlige tilleggsdiagnoser (slik som alvorlig depresjon, personlighetsforstyrrelse eller andre psykiske lidelser, suicidalproblematikk, post traumatisk stresslidelse, ruslidelser, tvangslidelse, generalisert angst, panikklidelse eller fobisk angstlidelse), og gravide. Ytterligere og mer detaljert informasjon kan gis på forespørsel!

KONTAKT

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Dr.grads stipendiat Therese Fostervold Mathisen; t.f.mathisen@nih.no, tlf 95 75 28 18

BEKREFTELSE FRA DELTAKERS FASTLEGE/LEGE

Jeg bekrefter å ha mottatt informasjon om behandlingsstudien for spiseforstyrrelser ved NIH, og bekrefter at min pasient kan delta.

Dato:.....Sted:..... Lege:.....

Appendix III

Exercise programs from PED-t

- High intensity exercise program
- Resistance exercise program, 5 modules

Pyramid interval with treadmill (week 1-10)

<u>Incline position 1%</u> - Warm up for 10 minutes. The interval exercise starts with 1 minute of high intensity running, followed by 30 seconds of pause. Continue with 2 min high intensity running, followed by 1 min low intensity walking (LIW). Further: 3 minutes of high intensity running, followed by 1,5 min LIW. Repeat the last interval of 3 min high intensity running, and then slowdown 1,5 min LIW. The two last interval periods are of 2 minutes high intensity running and 1 min LIW, and 1 min high intensity running followed by 30 sec pause. Calm down with 5 minutes low intensity jogging.

10 min warm up (treadmill)

1 min – km/t ____, _____, _____, ____, ____, ____,_____,_____,_____,____
Week 1 wk 2 wk 3 wk 4 wk 5 wk 6 wk 7 wk 8 wk 9 wk 10

30 sec pause

2 min – km/t____, _____, _____, ____, ____, ____,_____,_____,_____,____
Week 1 wk 2 wk 3 wk 4 wk 5 wk 6 wk 7 wk 8 wk 9 wk 10

1 min pause

3 min –km/t ____,____,____,____,____,____,____,____,_____,____
Week 1 wk 2 wk 3 wk 4 wk 5 wk 6 wk 7 wk 8 wk 9 wk 10

1,5 min pause

3 min – km/t____,____,____,____,____,____,____,____,_____,_____
Week 1 wk 2 wk 3 wk 4 wk 5 wk 6 wk 7 wk 8 wk 9 wk 10

1,5 min pause

2 min – km/t____, _____, _____, ____, ____, ____,_____,_____,_____,____
Week 1 wk 2 wk 3 wk 4 wk 5 wk 6 wk 7 wk 8 wk 9 wk 10

1 min pause

1 min – km/t____, _____, _____, ____, ____, ____,_____,_____,_____,____
Week 1 wk 2 wk 3 wk 4 wk 5 wk 6 wk 7 wk 8 wk 9 wk 10

5 min cool down (treadmill)

Wk 1 Wk 2 Wk 3 Wk 4 Wk 5 Wk 6 Wk 7 Wk 8 Wk 9 Wk 10

Pyramid interval with treadmill (Week 11-16)

<u>Incline position 1%</u> - Warm up for 10 minutes. The interval exercise starts with 1 minute of high intensity running, followed by 30 seconds of pause. Continue with 2 min high intensity running, followed by 1 min LIW. Further: 3 minutes of high intensity running, followed by 1,5 min LIW. Now, do high intensity running for 4 minutes, before slowing down for 2 minutes LIW. Reduce the next interval of 3 min of high intensity running, and then slowdown 1,5 min LIW. The two last interval periods are of 2 minutes high intensity running and 1 min LIW, and 1 min high intensity running followed by 30 sec pause. Calm down with 5 minutes low intensity jogging.

10 min warm up (treadmill)

1 min – km/t ____, _____, _____, ____, ____, ____
Wk 11 wk 12 wk 13 wk14 wk 15 wk 16

30 sec pause

1 - 10 Borg Rating of Perceived Exertion Scale	
0	Rest
1	Really Easy
2	Easy
3	Moderate
4	Sort of Hard
5	Hard
6	
7	Really Hard
8	
9	Really, Really, Hard
10	Maximal: Just like my hardest race

2 min – km/t____, _____, _____, ____, ____, ____,
Wk 11 wk 12 wk 13 wk14 wk 15 wk 16

1 min pause

3 min –km/t _____,_____,_____,____,____,____,
Wk 11 wk 12 wk 13 wk14 wk 15 wk 16

1,5 min pause

4 min –km/t ____,____,____,____,_____,____,
Wk 11 wk 12 wk 13 wk14 wk 15 wk 16

2 min pause

3 min – km/t____,_____,____,____,_____,____,
Wk 11 wk 12 wk 13 wk14 wk 15 wk 16

1,5 min pause

2 min – km/t____,____,____, ____, ____, ____,
Wk 11 wk 12 wk 13 wk14 wk 15 wk 16

1 min pause

1 min – km/t____, _____,_____, ____,____,____,
Wk 11 wk 12 wk 13 wk14 wk 15 wk 16

5 min cool down (treadmill)

Wk 11 Wk 12 Wk 13 Wk 14 Wk 15 Wk 16

PED-t trial 2013-2016, HIIT Program by Tone Skomakerstuen, Norwegian School of Sport Sciences

PED-t trial Week:…… Id-nr:……

Period 1 (*week 1-3*)

TRAINING DAY 1: Strength exercise

10 min warm up, moderate intensity

	Adjustments	Repetitions	Kg, set 1	Kg, set 2	Kg, set 3	Kg, set 4
Squats, machine		10+10+3*10				
Shoulderpress, manuals	Bench 90*C	3*10				
Walking lunges		(3*10)*2				
Seated row		3*10				
Benchpress		10+10+3*10				
Lat pulldown, front		3*10				

Comments:

TRAINING DAY 2: Intervall run

- 10 min warm up
- 15-20 min intervals (see details in other program)
- 5-10 min cool down

TRAINING DAY 3: Strength exercise

10 min warm up, moderate intensity

	Adjustments	Repetitions	Kg, set 1	Kg, set 2	Kg, set 3	Kg, set 4
Squats, machine		10+ 3*10				
Shoulderpress, manuals	Bench 90*C	3*10				
Walking lunges		(3*10)*2				
Seated row		3*10				
Benchpress		10+3*10				
Lat pulldown, front		3*10				

Comments:

by Therese F Mathisen, Norwegian School of Sports Sciences 2013

PERIOD 2 (week *4-7*)

TRAINING DAY 1: Strength exercise

10 min warm up, moderate intensity

	Adjustments	Repetitions	Kg, set 1	Kg, set 2	Kg, set 3	Kg, set 4
Squats, machine		10+10+3*8				
Shoulderpress, manuals	Bench 90*C	10+8+8				
Walking lunges		(3*8)*2				
Seated row		10+8+8				
Benchpress		10+10+3*8				
Lat pulldown, front		10+8+8				

Comments:

TRAINING DAY 2: Intervall run

- 10 min warm up
- 15-20 min intervals (see details in other program)
- 5-10 min cool down

TRAINING DAY 3: Strength exercise

10 min warm up, moderate intensity

	Adjustments	Repetitions	Kg, set 1	Kg, set 2	Kg, set 3	Kg, set 4
Squats, machine		10+ 3*10				
Shoulderpress, manuals	Bench 90*C	3*10				
Walking lunges		(3*10)*2				
Seated row		3*10				
Benchpress		10+3*10				
Lat pulldown, front		3*10				

Comments:

by Therese F Mathisen, Norwegian School of Sport Sciences 2013-2016

PERIOD 3 (week *8-11*)

TRAINING DAY 1: Strength exercise

10 min warm up, moderate intensity

	Adjustments	Repetitions	Kg, set 1	Kg, set 2	Kg, set 3	Kg, set 4
Squats, machine		10+8+2*6				
Shoulderpress, manuals	Bench 90*C	10+8+6				
Walking lunges		(3*8)*2				
Seated row		10+8+6				
Benchpress		10+8+2*6				
Lat pulldown, front		10+8+6				

Comments:

TRAINING DAY 2: Intervall run

- 10 min warm up
- 15-20 min intervals (see details in other program)
- 5-10 min cool down

TRAINING DAY 3: Strength exercise

10 min warm up, moderate intensity

	Adjustments	Repetitions	Kg, set 1	Kg, set 2	Kg, set 3	Kg, set 4
Squats, machine		10+ 3*10				
Shoulderpress, manuals	Bench 90*C	3*10				
Walking lunges		(3*10)*2				
Seated row		3*10				
Benchpress		10+3*10				
Lat pulldown, front		3*10				

Comments:

by Therese F Mathisen, Norwegian School of Sport Sciences 2013-2016

PERIOD 4 (week *12-14*)

TRAINING DAY 1: Strength exercise

10 min warm up, moderate intensity

	Adjustments	Repetitions	Kg, set 1	Kg, set 2	Kg, set 3	Kg, set 4
Squats, machine		10+8+6+2*4				
Shoulderpress, manuals	Bench 90*C	10+8+5				
Walking lunges		(3*8)*2				
Seated row		10+8+4				
Benchpress		10+8+6+2*4				
Lat pulldown, front		10+8+6				

Comments:

TRAINING DAY 2: Intervall run

- 10 min warm up
- 15-20 min intervals (see details in other program)
- 5-10 min cool down

TRAINING DAY 3: Strength exercise

10 min warm up, moderate intensity

	Adjustments	Repetitions	Kg, set 1	Kg, set 2	Kg, set 3	Kg, set 4
Squats, machine		10+ 3*10				
Shoulderpress, manuals	Bench 90*C	3*10				
Walking lunges		(3*10)*2				
Seated row		3*10				
Benchpress		10+3*10				
Lat pulldown, front		3*10				

Comments:

by Therese F Mathisen, Norwegian School of Sport Sciences 2013-2016

PERIOD 5 (week *15-16*)

TRAINING DAY 1: Resistance exercise

10 min warm up, moderate intensity

	Adjustments	Repetitions	Kg, set 1	Kg, set 2	Kg, set 3	Kg, set 4
Squats, machine		10+8+6+4+2				
Shoulderpress, manuals	Bench 90*C	10+8+4				
Walking lunges		(3*6)*2				
Seated row		10+8+4				
Benchpress		10+8+6+4+2				
Lat pulldown, front		10+8+6				

Comments:

TRAINING DAY 2: Interval run

- 10 min warm up
- 15-20 min intervals (see details in other program)
- 5-10 min cool down

TRAINING DAY 3: Resistance exercise

10 min warm up, moderate intensity

	Adjustments	Repetitions	Kg, set 1	Kg, set 2	Kg, set 3	Kg, set 4
Squats, machine		10+ 3*10				
Shoulderpress, manuals	Bench 90*C	3*10				
Walking lunges		(3*10)*2				
Seated row		3*10				
Benchpress		10+3*10				
Lat pulldown, front		3*10				

Comments:

by Therese F Mathisen, Norwegian School of Sport Sciences 2013-2016