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Patients' and therapists' experiences with a new treatment for eating disorders, combining physical exercise and dietary therapy.

An interview study

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List of papers

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Abstract

Background: Eating disorders (EDs) are mental disorders where effective treatment may be essential for a good outcome. A new group-based treatment, combining physical exercise and dietary therapy (PED-t) for bulimia nervosa (BN) and binge eating disorder (BED) has been tested within a randomized controlled trial, and proved effective in terms of reducing ED symptoms. In the process of evaluating new treatments, therapists and patients' treatment experiences are increasingly being valued and recognized as part of clinical evidence.

Aim: The aim of this study was to explore treatment experiences from therapists and patients who participated in the PED-t.

Methods: Ten therapists running the PED-t and 20 women with BN and BED were semi-structurally interviewed. The transcribed interviews were analysed using thematic analysis. A user advisory group was included in all parts of the research process.

Results: The PED-t therapists found their knowledge about physical exercise and nutrition beneficial for the patients' post treatment recovery. Overall, patients found the treatment beneficial, but for patients who dropped out of the PED-t, various reasons resulted in an experience of standing on the outside.

Discussion and concluding remarks: The development and application of tools to manage ED symptoms was an important perceived impact from participating in the PED-t. The therapists' competence and support, as well as motivating and supporting aspects from the group setting, were elements perceived to help implementing acquired knowledge from the treatment into the patients' daily lives. The elements yielding opportunities for most patients also posed challenges for others. The therapist support was not sufficient for all patients to overcome challenges during therapy, and some patients found themselves standing on the outside of the group-based encounters. The knowledge from this thesis may among other things contribute in improving the treatment for future use, and the PED-t may focus more on pre-treatment expectations and group dynamics. The PED-t may stand out as a promising new treatment for patients with BN or BED, with a new group of professionals who feel confident as therapists. Overall, the PED-t requires replication with other patients and in other settings to further strengthen the chain of clinical evidence.

1 Introduction

Eating disorders (EDs) are mental disorders where negative beliefs about one self, one's eating, body, shape and weight are central (American Psychiatric Association, 2013). Anorexia nervosa (AN), bulimia nervosa (BN) and binge eating disorder (BED) are subgroups within EDs. Briefly described, AN is characterized by extreme weight loss due to restriction of energy intake. BN and BED both involve recurrent episodes of binge eating, and for individuals with a BN diagnosis, the binge-eating episode is followed by compensatory behaviours. Having an ED may have serious consequences such as impaired quality of life (Agh et al., 2015; Agh et al., 2016), long-term physical morbidity and psychosocial challenges (Kaplan & Noble, 2018; Treasure, Claudino, & Zucker, 2010), psychiatric comorbidity (Keski-Rahkonen & Mustelin, 2016; Martinussen et al., 2017) and elevated risk of mortality (Arcelus, Mitchell, Wales, & Nielsen, 2011; Fichter & Quadflieg, 2016; Smink, van Hoeken, & Hoek, 2012; Westmoreland, Krantz, & Mehler, 2016). Receiving effective treatment is essential for a good outcome and for preventing a protracted course (Amianto, Ottone, Daga, & Fassino, 2015; Brownley et al., 2016; Linardon & Wade, 2018; Rosenvinge & Pettersen, 2015; Schaumberg et al., 2019), and studies show that 46-88% of those who receive treatment for their ED have a good outcome (Keski-Rahkonen & Mustelin, 2016; Rosenvinge & Pettersen, 2015; Smink, van Hoeken, & Hoek, 2013). Less is however known about how patients experience treatments they receive.

Although the majority of those who receive treatment have a good outcome, only about one third of individuals having EDs are detected by healthcare (Agh et al., 2015; Keski-Rahkonen & Mustelin, 2016; Reas & Rø, 2018). There may be many reasons for this "treatment gap" (Kazdin, Fitzsimmons, & Wilfley, 2017), and challenges related to competence on EDs and detection among the primary health service (Escobar-Koch et al., 2010; Kaplan & Noble, 2018; Rosenvinge & Götestam, 2002) may explain some of them. Moreover, patients' barriers to seek treatment include fear of losing control, denial or failure to perceive the severity of the illness, as well as low motivation to seek change (Ali et al., 2017; Griffiths, Rossell, Mitchison, Murray, & Mond, 2018; Hart, Granillo, Jorm, & Paxton, 2011). Researchers have suggested that new treatment approaches may reduce the treatment gap (Kazdin et al., 2017), and in the process of evaluating new treatments, patients' and therapists' treatment experiences are increasingly being valued and recognised as part of clinical evidence (Richards & Hallberg, 2015).

Bulimia nervosa and binge eating disorders

The most prevalent ED subtypes are BN and BED (Erskine & Whiteford, 2018; Rosenvinge & Pettersen, 2015), with a lifetime prevalence of approximately 1-2% for BN and 1-4% for BED (Agh et al., 2015; Keski-Rahkonen & Mustelin, 2016; Rosenvinge & Pettersen, 2015). BED was not recognized as a distinct ED until the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) (2013), and was previously introduced as a sub-category of EDs not otherwise specified. The current DSM-5 criteria are provided in Table 1. Research has shown that BN and BED typically occur during adolescence and most often in females (Amianto et al., 2015; Brownley et al., 2016; Keski-Rahkonen & Mustelin, 2016; Reas & Rø, 2018), although the gender differences seems to be smaller in BED than in BN (Erskine & Whiteford, 2018). According to a recent meta-analysis, 35.4% of patients who receive treatment for their BN achieve symptom abstinence (Linardon & Wade, 2018). Treatment for BED show more varying levels of certainty (Brownley et al., 2016), yet a recent meta-analysis for *binge-eating-type disorders* found an abstinence rate of 42.1% (Linardon, Messer, & Fuller-Tyszkiewicz, 2018).

Table 1 DSM-5 diagnostic criteria for bulimia nervosa and binge eating disorder (American Psychiatric Association, 2013).

Bulimia nervosa (BN)	Binge eating disorder (BED)
<p>I. Recurrent episodes of binge eating* with a feeling of lack of control during the episode</p> <p>II. Recurrent inappropriate compensatory behaviors** to prevent weight gain</p> <p>III. The binge eating and the compensatory behaviors both occur, on average, at least once per week for 3 months</p> <p>IV. Self-evaluation is unduly influenced by body shape and weight</p> <p>V. The disturbance does not occur exclusively during episodes of anorexia nervosa</p> <p><i>*eating in a discrete period (usually within two hours), an amount of food that is definitely larger than most other individuals would eat under similar circumstances</i></p> <p><i>** self-induced vomiting; misuse of laxatives, diuretics, or other medications; fasting or excessive exercise</i></p>	<p>I. Recurrent episodes of binge eating* with a feeling of lack of control during the episode</p> <p>II. At least three of the following features follows the episode; eating much more rapidly than normal; eating until feeling uncomfortably full; eating large amounts of food when not feeling physically hungry; eating alone because feeling embarrassed; and feeling disgusted with oneself, depressed or very guilty afterwards</p> <p>III. There is marked distress regarding the binge eating</p> <p>IV. The binge eating occurs, on average, at least once per week for three months</p> <p>V. Absence of inappropriate compensatory behaviors**</p> <p><i>*See parallel textbox** See parallel textbox</i></p>

Individuals with a BN and BED diagnosis both experience recurrent episodes of binge eating, which is eating a large amount of food in a discrete period, accompanied by a sense of lack of control (American Psychiatric Association, 2013). The amount of food is larger than most other people would eat under similar circumstances. In BN, the binge-eating episode is followed by compensatory behaviours like vomiting, misuse of laxatives and diuretics, fasting or excessive exercise. Moreover, self-evaluation is usually low, elicited and reinforced by a focus on, and dissatisfaction with body shape or weight. Transition across ED diagnoses is common, and research suggests that one third of those with BN have a history with AN (Eddy et al., 2007; Schaumberg et al., 2019; Strumila et al., 2020). Recent research however, shows that diagnostic stability may be more common than previously assumed (Schaumberg et al.,

2019). In part this may be explained by the more lenient diagnostic criteria introduced with the DSM-5.

Overvaluation of weight and shape is also common in BED (Amianto et al., 2015; Duarte, Ferreira, & Pinto-Gouveia, 2016), although it is not a diagnostic criterion, like in BN (American Psychiatric Association, 2013). Adults with a BN diagnosis are typically within the normal weight range or overweight range, whereas among those with a BED diagnosis weight may range from normal to obese (American Psychiatric Association, 2013). BED is however, distinct from obesity because most individuals with obesity do not engage in recurrent distinct binge eating episodes. Some studies have shown that having BED is associated with more functional impairment, lower quality of life, more subjective distress and more psychiatric comorbidity compared to non-BED obese (Agh et al., 2015; Amianto et al., 2015).

The symptoms and clinical features of BN or BED may be understood as a way of coping with stress and uncomfortable thoughts and feelings (Amianto et al., 2015; Schulte, Grilo, & Gearhardt, 2016). Moreover, shame is a common negative emotion among individuals having BN and BED (Craven & Fekete, 2019; Duarte et al., 2016; Levinson, Byrne, & Rodebaugh, 2016). A recent review (Blythin et al., 2020) found that shame was substantially more prominent in individuals with BN compared with non-clinical controls, and that shame may increase as a function of clinical severity. Nevertheless, the causal relation between BN and shame is poorly understood. From an experiential point of view patients with BN have expressed the cost of living what they call a “double life” (Pettersen, Rosenvinge, & Ytterhus, 2008). This life was described as being time consuming, energy demanding and associated with guilt, shame and the self-experience of being a failure. In addition, patients feared that revealing the BN symptoms for others would elicit negative sanctions and stigmatization, and then lead to more shame, guilt feelings and lower self-esteem. These aspects, and especially stigma and shame (Ali et al., 2017) are barriers towards help seeking and may in part explain why many people with EDs have had their symptoms for many years before they seek treatment (Hart et al., 2011; Rosenvinge & Klusmeier, 2000).

In addition to the occurrence of diagnostic crossover (Schaumberg et al., 2019; Strumila et al., 2020), different individuals with the same diagnosis vary in disease aetiology, personality, course and outcome (Beltz, Moser, Zhu, Burt, & Klump, 2018; Dakanalis, Gaudio, Riva, & Clerici, 2017; Fairburn & Harrison, 2003; Hopwood, Ansell, Fehon, & Grilo, 2010; Pisetsky,

Crow, & Peterson, 2017; Sysko, Hildebrandt, Wilson, Wilfley, & Agras, 2010). Moreover, individuals have different family situations and resources available. The heterogeneity among patients with BN and BED may be important to consider when planning treatment and no single treatment is suitable for all patients. Exploring treatment experiences from patient and therapists may uncover important knowledge about how the treatment is experienced in relation to the heterogeneity among patients.

1.1 Eating disorder treatment

The Norwegian guidelines for EDs recommends that treatment should focus on symptom reduction (The Norwegian directorate of health, 2017). For BN and BED, treatment should thus focus on normalizing eating patterns and eliminating binge eating and compensatory behaviours. In the literature as well as in clinical guidelines, several treatment options are suggested, among them cognitive behavioural therapy (CBT) for BN, and to some extent also for BED (de Jong, Schoorl, & Hoek, 2018; Hilbert, Hoek, & Schmidt, 2017; Linardon & Wade, 2018; The Norwegian directorate of health, 2017; Treasure et al., 2010; Vocks et al., 2010; Wilson, Grilo, & Vitousek, 2007; Amianto et al., 2015; Brownley et al., 2016; Peat et al., 2017; Hay, 2013).

Earlier CBT for BN focused on the theory for maintenance of BN that is over evaluation of eating, shape and weight and their control (Fairburn, Cooper, & Shafran, 2003). Extending the previous theory, CBT-E (enhanced) has been developed specifically for the full range of EDs. CBT-E is based on the theory that in certain patients, one or more of four additional maintaining processes occur; clinical perfectionism, low self-esteem, mood intolerance and interpersonal difficulties (Fairburn et al., 2003). As such, CBT for EDs targets these trans-diagnostic maintaining processes. CBT is usually provided individually over 20 sessions, and compared to other treatment options for EDs, one prominent feature of CBT is its rapid and enduring effect in remission (Poulsen et al., 2014) which occurs in roughly 30% to 50% of all cases (Linardon & Wade, 2018; Treasure et al., 2010; Wilson et al., 2007). According to a recent meta-analysis (Haderlein, 2019), CBT is an effective strategy for the treatment of certain ED symptoms also when delivered with the use of technology.

Although evidence –based therapy options are suggested in clinical guidelines, they are not as widely used as one would expect (Mulken, de Vos, de Graaff, & Waller, 2018), and research shows that the number of ED-specialised clinicians who report to adhere to an evidence-based protocol or manual is only between 6 and 35% (Waller, 2016). This lack of usage calls for the

inclusion of therapists' perspectives when new treatments are developed, and exploring how they experience to contribute within a given treatment approach. Moreover, the fact 41-65% of patients with BN and BED do not respond to treatment (Brownley et al., 2016; Linardon, Messer, et al., 2018; Linardon & Wade, 2018), calls for the inclusion of patients' perspectives when evaluating newly developed treatments. A patient's perspective may provide knowledge into the challenging and favourable aspects of the treatment, as well as how to improve or adjust the treatment to facilitate better outcomes in the future.

1.2 A new treatment combining physical exercise and dietary therapy (PED-t)

Physical activity interventions have shown to improve both mental and physical health outcomes (Rosenbaum, Tiedemann, Sherrington, Curtis, & Ward, 2014) and have a positive, long term influence on non-communicable diseases, like coronary heart disease, obesity, and diabetes mellitus type 2 (Reiner, Niermann, Jekauc, & Woll, 2013). Within mental health, the association with, and positive effects from physical activity have been demonstrated in numerous studies and meta-analysis (Ashdown-Franks et al., 2019; Biddle & Asare, 2011; Chekroud et al., 2018; Harvey et al., 2018; Rosenbaum et al., 2014). In addition, physical activity is proven beneficial when treating specific mental disorders such as depression (Josefsson, Lindwall, & Archer, 2014; Rosenbaum et al., 2014), anxiety (Jayakody, Gunadasa, & Hosker, 2013) and post-traumatic stress disorder (Rosenbaum et al., 2015). A conceptual model have been proposed to explain the effects from physical activity on mental health (Lubans et al., 2016), and which relies on three intertwined mechanisms. First, a neurobiological mechanism may enhance cognition and mood by structural and functional changes in the central nervous system. Secondly, through a psychosocial mechanism physical activity may improve social connectedness, autonomy, self-acceptance, environmental mastery and purpose in life. Finally, through a behavioural mechanism, changes in mental health outcomes from physical activity may be mediated by changes in relevant and associated behaviours. As an example, participation in physical activity may improve sleep, which may in turn improve mental health outcomes.

Studies also suggest that physical activity can be beneficial during treatment for EDs in terms of psychological- and social wellbeing, improvements in general ED- psychopathology and quality of life (Blanchet et al., 2018; Hausenblas, Cook, & Chittester, 2008; Kerrigan,

Lydecker, & Grilo, 2019; Ng, Ng, & Wong, 2013; Sundgot-Borgen, Rosenvinge, Bahr, & Schneider, 2002; Vancampfort et al., 2013; Vancampfort et al., 2014). .

Dietetic practice in the treatment of patients with EDs is not well defined. Some studies have examined the effectiveness of dietary interventions for EDs, with results mainly showing that dietary consultations alone are not adequate, nevertheless, they may amplify other treatment approaches (Hart, Russell, & Abraham, 2011; Hsu et al., 2001; Painot, Jotterand, Kammer, Fossati, & Golay, 2001). In addition, dietary consultants are highly respected professionals in treatment teams and clinics for ED treatment, and there are many similarities between their ordinary practise and successful elements of for instance CBT (Mathisen, 2018).

Guided physical exercise and dietary therapy have been evaluated as treatments for BN in a previous randomized controlled trial (RCT) by Sundgot-Borgen and colleagues (2002), but as separate treatment components. The guided physical exercise proved to be as effective as CBT, and even better than CBT at follow-up. Moreover, dietary therapy also proved effective alone, yet to a lesser extent. Methodological limitations like a small sample size and restricted to BN only, an uneven total number of sessions and a failure to collect patient experiences have been overcome in a new study (Mathisen, 2018), which aimed to replicate and expand on the previous findings, i.e. the psychical exercise and dietary therapy (PED-t) trial. The PED-t is the first one to examine the combined effects of guided physical exercise and dietary therapy for BN and BED. The main hypothesis was that the PED-t would be on par with CBT in (re)establishing healthy eating and exercise routines (Mathisen, 2018).

In the PED-t trial, 164 women were randomized to receive either PED-t or CBT (Mathisen, 2018). In both treatment conditions, subjective well-being was improved, and symptoms of BN and BED as well as depression were alleviated through measure points from post-treatment to 24 months thereafter (Mathisen et al., 2020). Although the PED-t was effective as a treatment option for BN and BED, there may be a disparity between these effects, and how the patients and therapists experienced to participate in the treatment. Exploring treatment experiences may provide knowledge about the effects of a given treatment as well, but perhaps in a different way, in terms of how the patients themselves experienced that the treatment had an impact in their recovery process. Also relevant concerning the PED-t, is that a new group of professionals are involved as therapists in the treatment of patients with BN and BED. It is thus important to explore how they experienced to contribute as therapists to

these patients, and how the patients themselves experienced to integrate knowledge provided by these professionals.

1.3 Exploring the user perspective in treatment research

Allowing patients and therapists to speak freely of their experiences with treatment may provide access to information previously unknown to or not foreseen by researchers and clinicians. How do patients experience the impact or usefulness of participating in a treatment? Some changes that patients experience may not be detected if the changes are not predefined by the measures used in a trial (Klein, Drummond, Mhizha-Murira, Mansford, & dasNair, 2019). Also interesting is how therapists experience that they can contribute. These issues are important as it would be highly unfortunate to implement an intervention proven effective, in which the patients and therapists find inexpedient in “the real life”. The user perspective may thus contribute in a determination of whether the outcome is justified by the time and resources spent on the intervention. Experiences from patients and therapists who participate in treatment may also provide knowledge about how to adjust and improve the intervention, knowledge that may be valuable when planning future use of the treatment. Finally, exploring treatment experiences may also uncover what elements that promotes the interaction of alliance and symptom change that may facilitate a good treatment outcome.

The therapist perspective

During the previous years, several studies have examined the challenges of being a therapist, like for instance with regards to burnout. A systematic review found that mental health professionals had high levels of emotional exhaustion but still retains a “high” level of personal accomplishment (O’Connor, Neff, & Pitman, 2018). In particular, therapists’ negative reactions to patients with EDs has been investigated, and a review showed that therapists’ negative reactions included feeling frustrated, helpless, incompetent and worried (Thompson-Brenner, Satir, Franko, & Herzog, 2012). In addition, there were potential barriers in training professionals to work with patients with EDs, and those who lacked competence expressed low interest in receiving further training. However, researchers conducted these studies decades ago, and with more competence and more effective treatment options today, the situation may have changed. Today, there are an increasing number of educational programs to improve clinical competence on mental disorders. As an example, clinical confidence and engagement were outputs from professionals, after they had

participated in an interprofessional educational program for EDs (Pettersen, Rosenvinge, Thune-Larsen, & Wynn, 2012).

Some researchers have compared patients' and therapists' perspectives on the significance of different elements of ED treatment. Overall, patients and therapists seem to share the same views on what is needed in therapy, however, therapists value the focus on ED symptoms and behavioural change more highly, whereas patients value the importance of the relationship with the therapist higher (de la Rie, Noordenbos, Donker, & van Furth, 2008; Vanderlinden, Buis, Pieters, & Probst, 2007). Other researchers have addressed therapists' satisfaction with manuals for a wide range of mental disorders, mainly finding positive views, however with some concerns, like the manuals having a dehumanizing effect on the therapeutic process (Addis & Krasnow, 2000; Godley, White, Diamond, Passetti, & Titus, 2001; Najavits et al., 2004; Najavits, Weiss, Shaw, & Dierberger, 2000). In a recent study, therapists were surveyed about their use of CBT techniques for EDs (Mulken et al., 2018). A "non-use" of CBT techniques seemed to be related to therapists' anxiety and beliefs about the power of the therapeutic alliance in driving therapy outcomes.

Within the ED field, only a few studies have been located, exploring therapists' experiences with providing a specific treatment. The therapists mainly had positive experiences and the findings provided ideas for treatment improvements, like for instance therapist training (Dimitropoulos, Freeman, Lock, & Le Grange, 2017; Waterman-Collins et al., 2014; Watt & Dickens, 2018). With the exception of one study (Waterman-Collins et al., 2014), the above studies did not include the corresponding patient perspectives, which may have contributed with more variety in perspectives and a more in-depth understanding. Moreover, the above studies only examined experiences related to treatment for AN patients, further highlighting the need to explore patients' and therapists' experiences with regards to a specific treatment for BN and BED.

The patient perspective

Studies with a patient perspective within the ED field have mainly focused on overall modes of treatment and not so much on specific treatment approaches. This has also been the case within the mental health field in general, and patients' satisfaction has been a widely assessed construct (Miglietta, Belessiotis-Richards, Ruggeri, & Priebe, 2018). Patient satisfaction is seen as an important indicator of quality and outcome as satisfied patients are more likely to engage with services and adhere to therapy (Miglietta et al., 2018; Woodward, Berry, &

Bucci, 2017). A review (Woodward et al., 2017) has also shown an overall good general satisfaction with inpatient psychiatric services. Other studies however have demonstrated more dissatisfaction among hospitalized patients and that patients were more satisfied when they had a case manager and received good continuity of care among a variety of services (Fortin, Bamvita, & Fleury, 2018). In a consumer satisfaction study in Norway, most adolescents and their parents reported high satisfaction with the outpatient mental health services they received (Solberg, Larsson, & Jozefiak, 2015). Some studies within the mental health field have also examined patients' satisfaction with specific forms of therapy. Viefhaus and colleagues (2019) examined satisfaction with routine outpatient CBT among adolescents with mental disorders. A strength to the study is a triple perspective of both patients, parents and therapists, and the overall treatment satisfaction was high among all of them.

A problem with satisfaction studies in general may be a positive response bias due in part to the use of rating scales as a measuring instrument. Open-ended questions would remedy this issue, and furthermore, qualitative interviews with participants could also have revealed what *specific elements* of the treatment that were found satisfactory and not. Finning and colleagues (2017) interviewed patients about their experiences of both behavioural activation and CBT for depression, and both treatments were considered to have a positive impact on symptoms of depression as well as on other areas of life. This study was conducted as a qualitative process evaluation in relation to an RCT. Conducting research in this way may provide further knowledge into *why* the intervention works, and also how it can be optimized, in this case with a patient perspective (Moore et al., 2015). For instance, some participants reported that the most important element of therapy was having someone to talk to, but for others the specific factors associated with the two therapies were most important. To optimize the behavioural activation treatment, findings suggested that inexperienced junior mental health workers should be supported through good quality training and ongoing supervision (Finning et al., 2017).

Also within the ED field, several researchers have explored patients' treatment evaluation and satisfaction. As a contrast to studies showing low therapist adherence to evidence-based protocols and manuals (Waller, 2016) as well as therapists' negative reactions to patients with EDs (Thompson-Brenner et al., 2012), they have mainly found that patients are satisfied with treatment and value the patient-therapist relationship and the therapists' competence (Bell, 2003; Clinton, 2001; Clinton, Björck, Sohlberg, & Norring, 2004; de la Rie, Noordenbos, Donker, & van Furth, 2006; Escobar-Koch et al., 2010; Nishizono Maher et al., 2011;

Rosenvinge & Klusmeier, 2000; Swain-Campbell, Surgenor, & Snell, 2001). As mentioned, the patients have used a range of services in these studies, and they only show more overall satisfaction with *modes of treatment* and not experiences concerning specific treatment approaches.

In the later years, researchers within the ED field have also explored patients' experiences with particular kinds of treatment. In three studies, BN patients' experiences with computerised treatment was explored (McClay, Waters, McHale, Schmidt, & Williams, 2013; Pretorius, Rowlands, Ringwood, & Schmidt, 2010; Sánchez-Ortiz et al., 2011). The online CBT-based self-help packages mainly contained eight interactive sessions aiming at changing users' thoughts, feelings, and behaviours (McClay et al., 2013; Pretorius et al., 2010). The patients received electronic message boards (Pretorius et al., 2010), as well as e-mail support by experienced clinicians (Pretorius et al., 2010; Sánchez-Ortiz et al., 2011). Overall, the patients experienced these treatments in a positive manner. Moreover, these studies informed about treatment elements that could be improved, like for instance making programs more personalized, (Pretorius et al., 2010), and offering more follow-up sessions (McClay et al., 2013). Poulsen and colleagues (2010) explored BN patients' experiences with psychodynamic psychotherapy and found that the treatment was a challenge to most of the patients, and that the therapists' level of training may have contributed to the patients' experiences of difficulties. However, most patients did profit from therapy both symptomatically and with regard to interpersonal relations and affect regulation. In a study by Laberg and colleagues (2001), patients with BN were interviewed about their experience of having participated in group CBT. The findings highlighted treatment elements considered important for patients, who found the treatment to strengthen their confidence in their ability to cope, and showed them how to deal with remaining problems. Finally, Pettersen and colleagues (2017) have explored treatment experiences among patients who completed the physical exercise and dietary therapy within the PED-t trial. They found that patients had a renewed and more positive attitude towards physical activity, as well as a positive shift towards food as a source of health and wellbeing. Although the above studies provided knowledge on patients' experiences with particular treatment approaches, including ways to optimize them, the majority of the studies only included the perspectives of the patients who completed treatment. Perspectives from therapists who provided the treatments as well as perspectives from patients who dropped out could also have been explored.

The perspectives of patients who drop out of treatment

In RCTs, important sources of knowledge regarding treatment efficacy is intention to treat analysis as well as drop out analysis (Gupta, 2011). Qualitative studies may follow the same kind of logic and explore experiences from patients who do not complete treatment (Pettersen et al., 2018). Such a perspective might capture more of the variety of experiences, as well as experiences that may be underreported in treatment satisfaction studies that only include patients who complete treatment.

Searching the literature within the mental health field in general, some studies have explored experiences among patients who have dropped out of treatment. Hummelen and colleagues (2007) interviewed patients with borderline personality disorder who dropped out of group psychotherapy, which was a continuation therapy following intensive day treatment. They found that patients experienced separation and loss from the treatment at the day hospital, and that they needed more time than what the group psychotherapy offered. A strength to this study was that they also interviewed the therapists who provided the treatment, and the therapists put much emphasis on a lack of group cohesion. In a study by Nordheim and colleagues (2018), participants described their reasons for dropping out of treatment for residential substance use disorder. Overall, drop out had one of three following meanings; a break from treatment, an end of treatment, and a means of reduced treatment intensity.

Drop out is common within ED treatment, with estimates ranging from 24% (Linardon, Hindle, & Brennan, 2018) to 51% (Fassino, Pierò, Tomba, & Abbate-Daga, 2009), but still few studies have explored the perspectives of patients who have dropped out. Leavey and colleagues (2011) interviewed patients who failed to attend to an ED service after referral from general practise. The findings showed that patients often reported practical or service related issues as their main reasons for non-attendance, however, complexity and severity of their psychological difficulties seemed to be more relevant in their decision not to attend. Eivors and colleagues (2003) interviewed seven women who had dropped out from treatment services for their AN, and loss of control was a central theme. The women were confused by the focus on the symptoms of weight loss and would have wished for more insight and understanding. Finally, Seidinger-Leibovits and colleagues (2015) interviewed patients who had dropped out of treatment from a specialized outpatient unit for EDs. Their findings were discussed under a theoretical framework that focused on ED's as addictions, and they found elements that indicated such a relevance. No studies have been located who have studied experiences from patients with BN or BED who have dropped out of a specific treatment.

1.4 Aim and research questions

The review of the literature in section 1 has revealed a need for more experiential-based knowledge about specific treatments for BN and BED. Moreover, there is a need for different perspectives, which includes the perspectives of participating patients, the therapists who provided the treatment as well as the perspectives of patients who dropped out of the treatment. A combination of all of these perspectives may capture more of a variance in experiences and provide a more in-depth understanding. Such a combination of perspective has been possible in the PED-t (Mathisen, 2018) through the following research questions:

What are the therapists' experiences of contributing in a new treatment for patients with BN or BED, that is, the PED-t? (Paper I)

What are important aspects of the patients' own perceived benefits (or lack of perceived benefits) of the PED-t, as well as their experiences related to the various treatment components? (Paper II)

What are the treatment experiences of the patients who dropped out of the PED-t? (Paper III)

2 Methods

2.1 Study design

This study was conducted through a qualitative approach, to explore experiences with having participated in a new treatment for BN and BED, the PED-t. Individual face-to face interviews were used to collect data, as interviews provide access to a person's experiences of events (Brinkmann & Kvale, 2015; Malterud, 2001).

There are several research traditions with different theoretical frameworks that may inform qualitative inquiry (Creswell, 2007; McLeod, 2013), and amongst them are phenomenology and hermeneutics. Phenomenology aims at attaining knowledge concerning the meaning of an experience (Brinkmann & Kvale, 2015; Malterud, 2016), and is useful in qualitative research to achieve a more comprehensive appreciation of the possible layers of meaning (McLeod, 2013). Hermeneutics refers to the principles that guide the interpretation of the meaning of a text (Brinkmann & Kvale, 2015; Malterud, 2016), which has also been transferred to research applications such as interpreting the meaning of a research interview (McLeod, 2013).

Therefore, in accordance with the research question, *exploring experiences* with participation in the PED-t treatment, this study relies on the research traditions phenomenology and hermeneutics.

2.2 Study context

The data in this thesis was collected from the PED-t trial, conducted between 2014 and 2017, at the Norwegian School of Sports Science in Oslo, Norway (Mathisen, 2018). The PED-t trial was designed to evaluate the effect of a new treatment for BN and BED, the PED-t.

Participants for the PED-t were recruited through general practitioners, patient organisations, advertisement in newspapers and magazines, national TV, social media and posters at different locations. Included were women aged 18-40 years with a DSM-5 diagnosis of BN or BED with duration of at least three months, a body mass index in the range of 17.5-35 and with mild to severe symptoms. Women not eligible were those who were competitive athletes and those who were, or planned to become pregnant during the study period. Also excluded were women with concurrent severe symptoms or personality disorders obviously in need of other treatments options. Finally, to prevent effect diffusions, individuals who had received CBT for EDs during the last two years before the trial were excluded. Diagnoses were made by using questionnaires and clinical assessments

In the PED-t, 20 therapy sessions were given over a period of 16 weeks, in which the participating women were randomized to receive either CBT or the PED-t treatment in groups of 5-8 participants. Participants that were waiting to be randomized represented a control group. The CBT was conducted by psychologists certified in CBT, with at least 10 years of experience and being supervised by a senior therapist with more than 20 years of experience (Mathisen, 2018). Dieticians and physical trainers conducted the PED-t (Mathisen, 2018). The therapists' formal education was a master or a bachelor degree in sport sciences, physical exercise or exercise medicine. In addition, they had at least three years of practice with supervised exercise.

The exercise program in the PED-t consisted of three weekly exercise sessions, each lasting 40–60 min. Two sessions were resistance exercises, of which one was supervised at the treatment site. The third session consisted of unsupervised pyramid interval running. In the resistance exercise program, the exercises were squats in smith machine, lunges with dumbbells, seated dumbbell shoulder press, bench press, latissimus pulldown and seated row in cable machine. The dietary therapy in the PED-t focused on education on nutrition, group discussions, and practical skills in overcoming challenges in establishing regular daily eating patterns. Between each dietary therapy session, the participants registered their meals and worked on individual tasks related to dietary routines. More details on the nature and rationale of the treatment have been published elsewhere (Mathisen, 2018; Mathisen et al., 2017).

2.3 Participants and recruitment

The participants to the present qualitative investigation were recruited amongst the therapists and patients who participated in the PED-t treatment (Mathisen, 2018; Mathisen et al., 2017), having first-hand experience regarding the research question and central phenomenon of the study (Creswell, 2007; Malterud, 2011).

The project leader of the RCT contacted all participants by email, providing an information sheet with a request to participate. Informed consent from those who responded positively to participate in the individual interviews was returned to the author of this thesis. All ten therapists who provided the PED-t responded positively (Paper I). From the group of 61 women who had completed at least 80% the PED-t treatment, 32 women were contacted consecutively with a request to participate (Paper II). Seventeen did not respond for unknown reasons. All the 15 women who had terminated the PED-t before completing at least 80 % were contacted with a request to participate (Paper III), and ten did not respond for unknown

reasons. In total, 10 therapists who provided the PED-t, 15 participants who had completed the PED-t and five participants who had dropped out from the PED-t responded positively and were included. The individual papers within this thesis provide more information about the participants (Bakland et al., 2019; Bakland et al., 2020; Bakland et al., 2018).

2.4 Data collection

Before the interviews started, the participants were given oral information repeating the aim of the study, the interview-procedure, how the data would be handled and their confidentiality ensured, as well as the right to ask questions or stop the interview at any time.

For the interviews with participants in paper I and II, we drafted semi-structured interview guides in cooperation with a user advisory group, based on relevant ED literature and the authors' ED expertise. The interview guides had open-ended questions which leave the participants with the possibility to speak and describe their experiences freely, whereas the interviewer still has the possibility to guide the conversation in the direction of the research questions (Brinkmann & Kvale, 2015).

The data was collected in three time periods between September 2016 and July 2018 and took place at locations of the participants' own choice, mostly at the Norwegian School of Sports Science where the RCT was conducted. All the interviews lasted between 60–90 minutes.

Contrary to the first two papers, the participants in paper III were encouraged to talk freely in responding to only one open-ended question; can you (as one of those who withdrew from the PED-t) please tell me about your experiences with participating in the treatment? Follow-up questions were then used to gain a deeper understanding in areas that seemed essential for each of the participants.

All participants received a gift card with the value of NOK 250 (approximately USD 32) to cover their travel expenses.

2.5 Data analysis

The software program NVivo 10 (QSR International, 2017) was used to transcribe the audio-recorded interviews into text material and to sort and code the data. The transcriptions were performed in the author's language, rather immediately after the interviews were conducted.

In addition to the spoken words, pauses, laughter and tears were noted, and words that were stressed in the interviews were highlighted as bold font in the transcripts.

The analysing of data in this thesis was done using qualitative methods, in which central steps were reducing the data into themes in a process of coding (Creswell, 2007). In paper I and II, the analysis was inspired by systematic text condensation as described by Malterud (2012). The method is a systematic thematic cross case analysis that in accordance with the research questions of this study, presents the experiences of the participants as expressed by themselves. There are four steps within this procedure, which are described in detail in paper I (Bakland et al., 2018) and II (Bakland et al., 2019). Although systematic text condensation is described to present experiences in a descriptive matter, interpretation is imbedded in all parts of the research process (Brinkmann & Kvale, 2015). Consequently, in addition to the steps of systematic text condensation guiding the analysis, authors from the research team, a user advisory group, and the author of this thesis met regularly to discuss the analyses. The final categories were thus a result of a hermeneutical process with continuous shifts between assessing the transcripts and categories, *the parts*, and the existent literature and relevant theory, *the whole*, to ensure that the findings were grounded in the empirical data (Malterud, 2012).

The analytical process was similar in all three papers. However, according to Malterud (2012), systematic text condensation is descriptive and suitable to present experiences rather than exploring underlying meanings of what is said. To accommodate for the search for underlying meanings, the analysis in paper III was inspired by a phenomenological hermeneutical method (Lindseth & Norberg, 2004), further inspired by Ricoeur's theory of interpretation (1976). According to Ricoeur, what is experienced by one person is private, and cannot be transferred directly to someone else and become their experience. However, *meaning* is passed on and becomes available to others through interpretation. After the author's intention with the text and the meaning of the text no longer co-exist, the meaning of the text is open to an indefinite number of readers and interpretations. Interpretation is a move from understanding to explanation, but at the same time, a move from explanation to comprehension (Ricoeur, 1976). The analysis in paper III was performed following this move from understanding to comprehension. Further descriptions on the different steps in this method for analysis is provided in the corresponding paper (Bakland et al., 2020).

2.6 User involvement in research

In this thesis, the terms “user involvement” and “user advisory group” is used when referring to the participation of members from a patient organisation on EDs into shared research tasks (Oliver et al., 2015).

User involvement may be beneficial at all stages of the research process (Richards & Hallberg, 2015; Sacristán et al., 2016), and we were able to establish a user advisory group in the beginning of the project, in August 2016. We recruited the user advisory group through a patient organisation (“Spisfo”), and the management in the national organisation approved the cooperation before we recruited members from a local organisation. Four women volunteered for the cooperation and they have been involved in different part of the project since.

The first meeting in the cooperation with the user advisory group included getting to know each other and the context of this study, the PED-t treatment. The design and aims of the current study had been pilot drafted beforehand and were presented to the user advisory group. No major adjustments of the design and research questions were made after this first meeting, however, the discussions with the user advisory group provided validation into the clinical relevance of the study (Oliver et al., 2015; Sacristán et al., 2016).

The cooperation with the user advisory group also included drafting the information sheets and interview guides together. The first interview guide was piloted beforehand and presented at the first meeting. Only minor adjustments were made after the user advisory group had been given some time to reflect after the first meeting, and correspondence were made over e-mail. The first author drafted the second interview guide based on mail correspondence with the user advisory group and additional members of the research group, in which all contributed with suggestions for questions. Later, the draft was reviewed and discussed in a two hour long meeting with the user advisory group. The cooperation around the interview guides provided confidence in the relevance and quality of the questions that were asked during the data collection (Oliver et al., 2015; Sacristán et al., 2016).

The process of analysis in paper I and II included discussions with the user advisory group around the interviews and themes that arose both early and later in the process of analysis. In paper III, a step in the analysis was performed together and the members from the user advisory group contributed as co-authors of the paper. In meetings throughout the work with the analysis in paper III, members from the user advisory group provided interpretations of

the data which resulted in specific themes being removed, as well as other themes being included or renamed. As an example, a theme named “Treatment unrelated circumstances” was removed, after a member from the user advisory group argued that challenges outside the treatment setting are evident for all patients with EDs, regardless what specific treatment they participate in.

Reported challenges when involving patients and the public in research include lack of engagement and involvement from researchers, difficulties with reaching participants, and practical issues like the process being timely and costly (Brett et al., 2014). In addition to e-mail correspondence, ten meetings with the user advisory group were held throughout this study. All meetings were coordinated at a time and place of convenience to the members of the user advisory group. A contract was developed and signed together during the process, to clarify roles and refine levels of participation, as well as making explicit the possibility to withdraw at any given time. To record the impact of the involvement, notes were taken during meetings, as well as during other stages of the research process, which were fed back to the user advisory group by e-mail. With the exception of some minor delays when waiting for responses, and two members gradually withdrawing, there were no major challenges during the collaborative process. Notably, the cooperation in this study was mutually rewarding and fulfilling for researchers as well as the members from the user advisory group. The members of the user advisory group expressed that they valued being able to contribute so that other individuals with EDs may profit from receiving good treatment. The members of the user advisory group have received gift cards for compensation of time spent after each meeting.

2.7 Ethics

The Regional Committee for Medical and Health Research Ethics (identifier 2013/1871) has approved the study. Conforming to the Helsinki Declaration (World Medical Association, 2013), we ensured that the informed consent to participate included an option of unconditional withdrawal and the confidential presentation of data to secure anonymity. All participants were anonymized, given pseudonyms linked to their names by a code, and the consent-sheets with their names and the code were stored separately in locked cabinets. Audio and written material have been stored electronically on a secure, password-protected server, to which only the author of this thesis had access.

The latest update to the Declaration of Helsinki states that patients should have the option to receive information about the overall results of the study they have participate in (World

Medical Association, 2013). All the participants were contacted and provided information about the published papers and about the possibility to ask any questions they might have. Moreover, disseminating research results beyond traditional international journals so that they can reach patients, clinicians and policy makers is important (Richards & Hallberg, 2015), and also a part of a researchers' ethical responsibility. After each published paper, Norwegian magazine articles have been drafted based on the results and published in different relevant Norwegian channels, including a magazine published by the patient organisation "Spisfo", from which the user advisory group was recruited.

Although the relationship between a researcher and participant inherently involves power differentials (Brickmann & Kvale, 2014), the author aimed at "equality" and establishing an ethically good meeting. The interview-encounters have been constructed as a dialogue where the intention has been to listen to the participants' stories.

3 Results

Paper I: Therapists' experiences with a new treatment combining physical exercise and dietary therapy (the PED-t) for eating disorders: an interview study in a randomised controlled trial at the Norwegian School of Sport Sciences

The PED-t therapist were able to share their knowledge about physical exercise and nutrition in various ways and with confidence in their own role. They experienced their contribution of knowledge as important for the patients' post treatment recovery, as they provided tools that the patients could use in their daily life after treatment. According to the therapists, it was important that the patients experienced the impact of using these tools, for being able to learn about their beneficence. The therapists were aware of individual differences among the women and they underlined the importance of adjusting the knowledge level and exercises in their teaching to fit each individual. Finally, they reported a difficult balance between when "to push" and "to hold back" the participating women, in relation to their motivation to participate, both in conversations in the dietary therapy and in the physical exercise sessions.

According to the therapists, the participating women had many questions that needed answers. In addition, the therapists were aware of the possibility that the women were having difficult times both during treatment and outside the treatment context. For their strive to always meet the patients' needs, and for their own competence and confidence, the therapists sought supervision and met on a regular basis to discuss challenges.

To accommodate patients' challenges during treatment, and to establish a mutual trust in general, the therapists contributed with personal qualities like being compassionate and understanding. During resistance exercises, the patients had to trust the therapists with choosing the right amount of weights. Moreover, trust involved the therapists putting demands on the patients in expecting them to show up and follow the therapists' recommendations. The groups of patients were very different from each other in their way of functioning and the therapists had to work on creating a good group dynamic.

Paper II: Patients' views on a new treatment for bulimia nervosa and binge eating disorder combining physical exercise and dietary therapy (the PED-t). A qualitative study

The PED-t treatment was overall acceptable to patients who completed the treatment for several reasons. Most importantly, they gained knowledge which served as tools to manage ED symptoms in their everyday life after treatment. The treatments physical exercise-

intervention was such a tool, and the patients found that the exercise was motivating and had positive, direct effects on their mental state. Eating four regular meals was another tool, which formed a solid base that furthermore led to fewer episodes of losing control when eating. Logging the exercise and meals was motivating and useful, and some patients discovered additional benefits of logging their menstrual cycles as well. The regularity in meals and exercise created a routine that eventually resulted in winning back feelings of hunger and satiety.

The participating women found the PED-t therapists to be competent and confident in their own role. Their educational background made them able to answer any questions the women had and to adjust exercises for them if needed. They also found the therapists friendly and caring and attributed their own feelings of safety to their conduct.

Most of the patients had interactions with other group members that were helpful and motivating, like being able to recognise oneself in the story of another and feeling obligations to each other. Some patients, however, felt alienated from the group with respect to age, the nature of their ED or their personal situation. In addition, some patients consumed more time and space than others which caused frustrations.

Paper III: A new treatment for eating disorders combining physical exercise and dietary therapy (the PED-t): experiences from patients who dropped out

Overall, the patients who dropped out of the PED-t felt alienated from their fellow group members in terms of age, interests or being at different phases in terms of illness severity and recovery. The differences further lead to challenges in sharing thoughts and interacting with the rest of the group. For the individual patient, the differences could also result in an overarching experience of standing on the outside.

The patients who dropped out of the PED-t had expected more support, both in utilizing acquired knowledge during the treatment, but also more time to talk to the therapists. Some women were unfamiliar with exercise and they were unable to comply with the exercise program alone between each supervised exercise session. Other women who needed to increase their total amount of food reported that succeeding would require higher treatment intensity.

The impact on the women's recovery process was mixed. For some of the women who dropped out of the treatment, the PED-t resulted in an exacerbation of ED symptoms. The focus on nutrients was stressful, and also having to be weighed at each treatment session. Other women

added the treatments' exercise program on top of their daily exercise routines, which resulted in exercising too much. However, the patients also voiced some positive impacts from participating in the PED-t, like having utilized the potentials of the treatment and having gained some knowledge and tools.

Synthesis of the papers' findings

The key findings from the papers share common elements (Table 2), and the congruencies between the nine key findings may be grouped in to three synthesized themes; *perceptions of impact*, *perceptions of therapist competence and support* and *perceptions of participating in a group based treatment*. A short summary may provide transparency to how the three synthesized themes emerged and how the overall findings are evident within each of them:

The most evident ***Perceptions of impact*** from participating in the PED-t was the development and application of tools to manage ED symptoms. Both therapists and patients found the development of such tools to be an important impact. The therapists focused on how the knowledge they provided could serve as tools in the patient's future recovery processes by having the patients experience themselves the impact of physical exercise and nutrition throughout the treatment. The patients found the physical exercise, regular meals and logging useful and motivating, and serving as tools in their every-day life after treatment. For some patients who dropped out of the treatment, the focus on nutrients and exercise caused stress and their ED symptoms exacerbated.

Perceptions of therapist competence and support was also an emphasized theme. Both patients and therapists recognized the necessity of support for accommodating patients' challenges throughout the treatment; however, some patients had unfulfilled needs in relation to treatment intensity and therapist support, and had more difficulties than others in complying with the treatment exercise program and nutritional advice.

Patients and therapists had both positive and less positive *perceptions of participating in a group-based treatment*. In groups that worked well, the patients motivated and supported each other, however, some patients felt alienated from the rest of their group, which facilitated an experience of standing on the outside. The therapists also found some groups to have a poor start that resulted in absence, and had to work on creating a good environment within these groups. The synthesis may be illustrated in the following table (Table 2).

Table 2. Synthesis of the papers' findings

	Key finding from the papers	Synthesis of the key findings
Paper I	The therapists' knowledge could serve as tools in the future recovery process for the patients	Perceptions of impact
	Supervision and discussions around own contribution was important for the therapists' competence and confidence	Perceptions of therapist competence and support
	To contribute with personal qualities was important for the trust-building with the patients and for creating a good group dynamic	Perceptions of therapist competence and support Perceptions of participating in a group based treatment
Paper II	The patients obtained tools to manage eating disorder symptoms.	Perceptions of impact
	The therapists' competence added credibility to the PED-t rationale and facilitated a feeling of safety.	Perceptions of therapist competence and support
	Participating in a group based treatment was both beneficial and challenging	Perceptions of participating in a group based treatment
Paper III	The patients felt different in terms of symptom load and need for treatment	Perceptions of participating in a group based treatment
	The patients had unmet expectations in relation to treatment intensity and therapist support	Perceptions of therapist competence and support
	Tools to manage symptoms were both beneficial and challenging	Perceptions of impact

4 Discussion

4.1 Perceptions of impact

Obtaining tools

The reported tools of physical exercise, regular meals and logging gained from participating in the PED-t resulted in meaningful and desirable changes for most of the patients. It was evident that the patients had developed tools and new perspectives on how to manage everyday life after treatment (paper II), and accordingly, the therapists found their contribution of knowledge serving as beneficial tools in the patients' future recovery process (paper I).

When faced with negative affect, stress or anxiety after a period of dietary restriction, binge eating is often used as a coping mechanism, as it may distract uncomfortable thoughts and feelings and bring about relief (Amianto et al., 2015; Leavey et al., 2011; Schulte et al., 2016). Having tools like exercise, four regular meals and logging seemed to have strengthened the patients' belief in their own capability to manage their problems, as they were able to make better choices for themselves concerning diet and exercise, but also concerning other aspects of life (paper II). Furthermore, the logging may have been useful to gain awareness on the degree of impact from different stressors in life. As an example, one woman had realised from her logging, the conjunction between having a difficult day and how she had eaten and exercised the previous days (paper II). A difficult day could be explained by a low energy availability due to too much exercise and insufficient energy intake for a day or two prior. Tools to manage EDs, as well as an increased awareness and belief in one's own capabilities, may thus be alternative coping mechanisms for patients with BN and BED after having participated in the PED-t.

Some women had discovered add-on benefits from logging their menstrual cycle as well, as they found that the fluctuations throughout menstrual cycle affected their ED symptoms (paper II). This is in accordance with research showing associations between levels of ovarian hormones and eating behaviour (Baker et al., 2019; Culbert, Racine, & Klump, 2016; Fowler, Vo, Sisk, & Klump, 2019). In view of these associations, it is possible that logging the menstrual cycle can create an awareness, which again may facilitate coping on days that, according to the logging, are more challenging than other days. The coping may include being kind to one self, lowering one's own expectations and accepting that it is more challenging to comply with a meal and exercise plan on certain days during the menstrual cycle.

The regularity in meals and exercise, as well as the awareness created from the logging, seemed to have resulted in a routine for some women (paper II). This routine may be regarded as a first step towards an experience of being able to eat naturally in response to bodily and psychological cues of hunger, an experience that the women claimed to have lost before they participated in the treatment (paper II). This is supported by studies suggesting that patients with EDs, particularly patients with BN, can develop the skills of intuitive eating, and that the ability to eat intuitively is associated with positive treatment outcomes (Richards, Crowton, Berrett, Smith, & Passmore, 2017). Altogether, the findings regarding treatment impacts (paper I, II and III) also echo previous treatment experiences with the PED-t (Pettersen et al., 2017), where patients reported having gained increased ability to identify and neutralise every-day trigger situations, as well as having a renewed attitude towards physical activity and nutrition.

Fortunately, patients who dropped out from the treatment also gained some knowledge and tools (paper III). Previous studies have shown that patients who drop out fare less well (DeJong, Broadbent, & Schmidt, 2012; Fassino et al., 2009; Ogrodniczuk, Joyce, & Piper, 2005). The findings from the current study provide a useful and extended picture, a more positive and more encouraging view, as the patients had gained awareness and ways to regulate and normalize physical exercise and meals (paper III). It is, however worth considering that the findings are reasonable in view of the length of participation. In fact, the patients who withdrew from the PED-t had completed up to ten treatment sessions, and to compare, research has shown that a sizable portion of psychotherapy patients reliably improve after seven sessions of therapy (Lambert, 2013). Interestingly, some previous research has shown that drop out patients are more improved at follow-ups than completers (Fassino et al., 2009), and it is important to keep in mind that drop out may not entirely be a negative decision in a patient's life. Treatment unrelated circumstances may also have an influence on the decision to leave treatment, or patients may have experienced that they had gained what they needed from treatment, and hence, seeing no reason to continue.

Experiencing exacerbation of ED symptoms

Patients who dropped out of the PED-t also provided knowledge on negative treatment experiences (paper III). For some of the patients who did not complete the treatment, a preoccupation with nutrients, meals, physical exercise and weight resulted in an exacerbation of ED symptoms. This may in part be explained by the fact that an important reason why

patients drop out of treatment is to reduce the intensity of the treatment (Nordheim et al., 2018). Moreover, findings suggest that having a history of AN may have caused extra challenges with regards to nutrients and being weighted (paper III), which is in accordance with research showing that BN patients with a history of AN have worse decision-making abilities, worse general and specific functioning and more dietary restraint (Strumila et al., 2020). The therapists seemed to be aware of fluctuations between good days and more challenging days for the patients, as well as how some women needed to be pushed more than others (paper I). This suggests that they were also aware that some patients needed more support than others did. Regardless, future use of the PED-t may take into consideration that patients with a previous AN might experience the PED-t as extra challenging.

Future use of the PED-t may benefit from finding a way to locate patients that might fare less well, to be able to provide additional support to these patients. Notably, patients also requested more of such support (Paper III). The PED-t therapists had conversations with the patients during the patients' warm-up at the treadmill (paper I), in which the patients themselves seemed to value (paper II). As an example, the therapists could use this time more specifically to try to detect patients who experience extra challenges. Another solution may be that patients write diaries as part of homework and give the therapists feedback regarding these matters.

4.2 Perceptions of therapist competence and support

A new group of professionals in treatment of EDs

The PED-t therapists, being physical trainers and dieticians, are groups of professionals that traditionally have not been used *as therapists* for patients with BN and BED. The patients valued the PED-t therapists' level of knowledge, support and personal confidence, and these aspects were important for the patients' trust and confidence of the PED-t itself (paper II). Accordingly, the PED-t therapists had confidence in their own competence and in their ability to serve as therapists for patients with BN and BED (paper I).

Previous studies have shown that few therapists within the ED field actually use evidence-based protocols or manuals (Waller, 2016) and that a non-use of, for instance CBT techniques, is related to therapists' anxiety (Mulken et al., 2018). It is thus promising that the PED-t therapists had confidence in their own competence, and more importantly, they were aware of their own limitations and sought supervision when they needed (paper I).

Supervision and training is essential when treating patients with EDs (Escobar-Koch et al.,

2010; NICE, 2017; Thompson-Brenner et al., 2012), and both patients, carers and health professionals find the most important key indicators of high quality ED service to be the professional qualities of staff (Maher et al., 2011). Studies that have explored treatment experiences, both among ED patients, mental health patients in general, and therapists in the ED field, have suggested more therapists training and supervision as a way of optimizing treatment (Dimitropoulos et al., 2017; Finning et al., 2017; Poulsen et al., 2010; Waterman-Collins et al., 2014; Watt & Dickens, 2018). Notably, supervision is also a protective element against burnout for mental health professionals in general (O'Connor et al., 2018).

Some psychological treatments may be difficult to implement well because they rely on highly trained specialists (Fairburn & Wilson, 2013; Kazdin et al., 2017). Expanding the portfolio of professionals to deliver treatment may be beneficial in a search for effective treatments, and treatments that can be delivered by other health care professionals with lesser training are more scalable and potentially equally effective (Fairburn & Wilson, 2013). Within the field of EDs, findings strongly suggest that such re-distribution of tasks can be done successfully without compromising clinical outcomes (Kazdin et al., 2017). In relation to the PED-t, what seems more important than what professional background the therapists have, is that they have specific knowledge and understanding of therapeutic procedures, as well as the confidence to implement this knowledge in clinical settings. The PED-t therapists were specific about how their main responsibility in the project was teaching the patients how to exercise and eat in a normal and healthy way (paper I). Moreover, they had confidence in their knowledge and competence on nutrition and exercise, and found it to be a result of their education from the Norwegian School of Sports Science, as well as their work experience and daily life. Within the field of EDs, such clinical confidence has been found important for patients' positive experience of treatment success (Pettersen et al., 2012). The coinciding positive experiences regarding the PED-t therapists' contribution (paper I and II), align with those from a previous study on patients' experiences with the PED-t (Pettersen et al., 2017) where patients valued the factual information they received and viewed the expertise knowledge as more trustful than information conveyed through newspapers and social media. Together these findings are promising and a new group of professionals may contribute as therapists in treatment of BN and BED.

The importance of therapist support for overcoming challenges in therapy

Our study showed that the PED-t therapists also contributed with personal qualities (paper I and II). The therapists perceived their responsibility of teaching not only as a transference of knowledge, but something that needed to be done with respect, empathy, interest and joy (paper I). Being compassionate, understanding and having a desire to help were qualities that the therapists reported having acquired through practical professional experience, and they found these qualities essential because the PED-t treatment required a mutual trust building. Also from the patients' perspectives, what seemed most important was the therapists' support in overcoming challenges during therapy (paper II). Patients found that they were able to talk to the therapists about individual challenges in a non- intrusive way, and that the therapists' personal qualities motivated them to show up to the treatment sessions even when they had a bad day. As such, both patients and therapists regarded the therapist-patient relationship as important for the patients' acceptability of the PED-t. This supports previous findings regarding the importance of the therapeutic relationship, both among patients with EDs (Bell, 2003; Clinton, 2001; Escobar-Koch et al., 2010; Pettersen & Rosenvinge, 2002; Rosenvinge & Klusmeier, 2000), and other groups of patients with mental health problems (Finning et al., 2017; Kingstone et al., 2019). Empathy and understanding are treatment –related experiences found most helpful in general (Bell, 2003; Escobar-Koch et al., 2010; Nishizono Maher et al., 2011; Pettersen & Rosenvinge, 2002), suggesting that the way in which care is delivered may play as important a role as the therapeutic intervention itself (Escobar-Koch et al., 2010).

Different therapies can embody common factors that are curative, but not explained by the theory of change central to a particular treatment (Lambert, 2013). They all facilitate that patients experience increased sense of trust, security and safety, and at the same time, decreased sense of tension, threat and anxiety. The patient-therapist relationship is a common factor that makes substantial and consistent contribution to psychotherapy outcome, independent of the specific type of treatment, and has clear implications for practise (Finning et al., 2017; Lambert, 2013). Being a measurement of how well the therapist and patient work together, the therapeutic alliance is a well-researched aspect of the patient-therapist relationship and there is a moderate, but highly reliable relation between alliance and psychotherapy outcome across a variety of treatments and patient populations (Horvath & Luborsky, 1993; Horvath, Re, Fluckiger, & Symonds, 2011; Lambert, 2013). This relation is sometimes mistakenly assumed to only portray how a good alliance leads to better outcome for patients, however, within ED treatment, early symptom reduction seems to enhance the

therapeutic alliance, which again facilitates a better treatment outcome (Graves et al., 2017). Considering the importance of early symptom reduction together with findings showing that the patients found the exercise to have rather direct positive effects on their mental state (paper II), the PED-t may be a good arena for building alliance. Notably, the PED-t in fact provided patients with tools to manage ED symptoms (paper I and II).

Unfortunately, some patients found the level of therapists support insufficient. Findings showed (paper II and III) that both patients who completed the treatment and those who did not, needed more time to talk to the therapists about challenges during therapy. In addition, although informed about the total number of sessions, patients suggested that there could be follow-up sessions to prevent a sudden end of treatment (paper II). Inevitably, group therapy may go at the expense of each patient's amount of individual time with the therapist, and within other groups of patients such a general plea for more treatment sessions and follow-up is also evident (Hummelen et al., 2007; Kerkelä, Jonsson, Lindwall, & Strand, 2015). Findings from the current study are more specific and suggests that the patients needed more support in implementing physical exercise and new dietary routines, as well as more support in their daily lives (paper III). On the other hand, the focus on nutrients and meals in the dietary therapy was experienced as stressful for a minority of the patients (paper III), and there may be a fine line between sufficient and insufficient level of support for some patients. Importantly, future use of the PED-t may profit from exploring and clarifying patients' pre-treatment expectations, in order to adjust the patients expectations to the treatment offered.

4.3 Perceptions of participating in a group-based treatment

Motivating and supporting each other

The group format of the PED-t was an evident theme in the findings (paper I, II, and III). Both patients and therapists found most groups within the PED-t to be well established, with a good and mutually rewarding and fulfilling environment (paper I and II). The user perspective may furthermore provide knowledge into *what specific elements* within the group composition that facilitated a good group environment, which may be useful information in planning of future treatment delivery. Beneficial aspects within the groups were being able to recognise oneself in the stories of other group members, and a relief in knowing that someone else shared the same thoughts (paper II). These findings echo previous findings within ED treatment (Laberg et al., 2001; Pettersen et al., 2017). Moreover, patients who have recovered

from their EDs also valued meeting other people with EDs for these same matters (Pettersen & Rosenvinge, 2002).

The findings of positive perceptions to a good group environment (paper I and II) may be viewed in light of the well-researched group construct *cohesion*. Cohesion is the most favoured of the relationship constructs in the group therapy literature, and it is reliably associated with, and predictive of group outcome (Burlingame, McClendon, & Yang, 2018). Furthermore, it seems that groups of five to nine members have a stronger relationship between cohesion and outcome than smaller or larger groups. In addition, groups of more than 12 sessions seem conducive to a stronger relationship than groups of less than twelve sessions (Burlingame, Strauss, & Joyce, 2013), which is in accordance with how the PED-t was organized. Together with findings of efficacy (Mathisen et al., 2020), the positive perceptions regarding the group format of the PED-t are promising, and give support for further evaluation of the PED-t as a treatment option for patients with BN and BED.

Standing on the outside

Although most groups worked well and most patients valued the group format, some patients profited less from this way of organizing treatment. The patients who withdrew from the PED-t found the group setting challenging (paper III), which is not surprising in light of the reliable relation between cohesion and group outcome (Burlingame et al., 2018). However, the synchronicity across all three papers, in relation to the challenges with the group composition is more surprising. The therapists had to work on creating a good group dynamic as some groups worked less well than others did (paper I), and also some of the patients who completed the treatment had challenges with the group setting (paper II).

Importantly, the current study may provide further knowledge into what aspects of the group composition that may have caused challenges, and consequently, how the composition of groups may be adjusted and improved in the future. Patients with BN and BED are not a homogeneous group, and accordingly, the patients who completed the PED-t found themselves alienated to their fellow group members and suggested that future PED-t groups would benefit from being more homogenous (paper II). Alienation between patients within treatment groups is also evident in research on other groups of patients (Hummelen et al., 2007). More interestingly, the patients who dropped out of the PED-t found themselves alienated from the rest of the group, in terms of age, the nature of their ED, or their personal situation and consequently, this further challenged their participation in the treatment (paper

III). Considering this together with findings showing that patients benefitted from being able to recognise themselves in others (paper II), it seems that within the PED-t, groups may profit more from being homogeneous in terms of personal situation and interests, as opposed to solely having a composition based on a BN or BED diagnosis. As an example, those familiar with exercise may profit less from participating in a group were others have no experience with exercise. Moreover, those who have had their ED problem for many years, may profit less from participating in groups were others have not yet shared their problem with anyone. Importantly, a diversity of findings regarding the most favourable composition of groups, suggests that there is no simple rule to follow (Burlingame et al., 2013).

Time sharing between patients within the treatment groups also seemed to be a challenge and some women were found to consume more time and space than others (paper I, II, and III). Notably, previous research has shown that patients with EDs seem to prefer individual psychotherapy and counselling to group therapy (Escobar-Koch et al., 2010; Griffiths et al., 2018). Such preferences may be uncovered when exploring patients' pre-treatment expectations. Moreover, previous studies exploring patients' experiences with group psychotherapy have also found challenges with the sharing of time and attention (Hummelen et al., 2007). Although the therapists seemed to be aware of the problem with timesharing (paper I), the results may highlight a need for therapists to work on dividing time more evenly among patients in future use of the PED-t. Moreover, the therapists may benefit from further training into group dynamics. Leaders of all theoretical orientations have been encouraged to foster cohesion (Burlingame et al., 2018).

4.4 Methodological considerations

Standardized checklists like the consolidated criteria for reporting qualitative research (Tong, Sainsbury, & Craig, 2007) have been used for the submitted papers. Using concepts like “engagement” and “process” (Stige, Malterud, & Midtgarden, 2009) may be fruitful when further evaluating this qualitative inquiry.

As for *engagement*, is well established that a researcher affects the research process and its results (Malterud, 2011; Stige et al., 2009). Hence, any engagement or preconceived interests should be declared and reflected upon. The author of this thesis had scarce experience with EDs and ED treatment and preconceptions have most likely not influenced in any major way. This background may even be considered an advantage in the sense that there were no expectations or interests in favouring the usefulness of the PED-t. In relation to each paper,

the remaining authors within the research group, including supervisors, other co-authors and the user advisory group, have extensive experience in ED treatment and mental health treatment in general. Consensus-based discussions in the research team about how to interpret the data, provided confidence about their relevance for an ED context. Moreover, the result sections and discussions of the papers in this thesis have demonstrated that both positive and negative experiences with the PED-t were considered thoroughly.

Despite the inductive interpretive process, some “theory” may have come into play (Creswell, 2007; Malterud, 2001), i.e. previous research within the ED field, as well as a belief in that an outcome from the research will be new insights of importance to the existing knowledge on effect and effectiveness of ED treatment.

As for *processing*, most stages of the research process have been conducted in a cooperation with the research group and the user advisory group, aiming to increase the quality of the research (Brett et al., 2014; Chalmers et al., 2014; Oliver et al., 2015; Sacristán et al., 2016). This thesis is based on a relatively large amount of data, approximately 30-35 hours of audio-recorded interviews, and having a well-planned and systematic process has been vital to ensure a responsible analysis. At least for paper I and II, the data were collected and analysed prior to completion of the outcome analyses from the corresponding RCT, in order to reduce biased interpretations.

In qualitative studies, sample size is often evaluated by inconsistently applying the concept of “saturation”, which is commonly defined as a state achieved when adding more data does not affect the analysis (Malterud, Siersma, & Guassora, 2015). The concept of “information power” on the other hand, indicates that the more information a sample holds that is relevant for the actual study, the lower amount of participants is needed (Malterud et al., 2015). The latter concept inspired this study, and thus, the sample size was considered in relation to the research question, the specificity of the sample, the quality of the data and the strategy of analysis. We found the samples in each study sufficient to accomplish the studies’ aims.

Qualitative methods do not produce a representative overview of the phenomenon in question, but are generally conducted to explore a specific phenomenon in a specific place and time and with a specific group of people (Leung, 2015). The findings from the current study may however, have value in other settings with other patients, and thorough descriptions of the research setting, the participants, and the analysis have been given to provide transparency to

the research project. Some further considerations should be given regarding the relevance of the findings from this RCT context, in relation to other clinical settings. First, included in the PED-t trial were only females aged 18-40, explained by the low ratio of males-to-females in the occurrence of ED in Norway (Mathisen, 2018). The population of patients in the current study is thus similar in age and gender to the majority of persons diagnosed with BN and BED (American Psychiatric Association, 2013). Second, the PED-t treatment was carried out in an experimental condition with presumably highly motivated participants, which may have affected their reports on experiences. Third, it is possible that some participants who desired CBT and were randomized to the PED-t treatment arm could have been resentful and demoralized, which also might have affected their reports on experiences (Shadish, Cook, & Campbell, 2002). Finally, it is likely that the current study primarily recruited those participants who were satisfied with the PED-t, and that those who did not respond could be less satisfied (Bell, 2003).

There are limitations to the current study that needs to be considered. Interviewing therapists about their own contribution may cause questionings. The RCT context with testing new professionals as therapists for treating BN and BED may also lead to questionings about whether the therapists might have wished to promote their own profession. It seems unlikely however, that this is the case with the PED-t therapists, as they also reported challenges and acknowledged their own limitations (paper I).

The fact that interviews (paper II and III) were conducted some time (16-24 months) after the PED-t was finished may have introduced a selective and biased memory recall. As an example, some patients who dropped out of the PED-t reported that they had problems remembering different elements within the treatment. On the other hand, the participants might also have used the time lag to reflect on their experiences of participating in the treatment, and as an example, participants who dropped out of the PED-t treatment reported that they were able to realise in retrospect how they made use of the knowledge they obtained from participating in the treatment (paper III).

From the RCT (Mathisen, 2018), dropouts of the PED-t were participants with an attendance rate less than 80%. A limitation to the current investigation may thus be that participants who were interviewed in paper III could have completed up to 16 sessions. In a clinical setting, such an attendance may not be regarded as non-completion, and research has shown that a sizable portion of psychotherapy patients reliably improve after seven sessions of therapy

(Lambert, 2013). Regardless, the results should be viewed within their context, which is that the patients in the interviews shared their treatment experiences *in light of having dropped out of the PED-t*. Also in relation to paper III, the fact that only five of the 15 eligible patients were willing to participate may have restricted the variety of experiences.

A strength to this study is a unique combination of perspectives when exploring treatment experiences. This combination of perspectives with regards to a specific treatment for BN and BED have not been addressed within ED treatment literature earlier.

A further strength is the integration of the user perspective into the different parts of the research process. It is increasingly recognized that involvement from patients and the public may improve the relevance and quality of a research project (Brett et al., 2014; Chalmers et al., 2014; Oliver, Liabo, Stewart, & Rees, 2015; Sacristán et al., 2016). Involving users in research may also maximize the chances that knowledge generated will be transferred to the clinical field and benefit its potential users (Chalmers et al., 2014; Oliver et al., 2015; Richards & Hallberg, 2015). In this study, the user perspective had a two-fold agenda. First, for the purpose of exploring the user perspective with regards to a newly developed treatment, we included the patients' and therapists' treatment experiences. Secondly, for the purpose of increasing the quality of the current qualitative investigation, we included perspectives of members from a patient organisation on EDs. In relation to the latter, we found that the cooperation with the user advisory group allowed new perspectives to arise and provided validity to the findings, as well as the presentation of them (Oliver et al., 2015).

5 Concluding remarks and implications

The development and application of tools to manage ED symptoms was an important perceived impact from participating in the treatment. The therapists' competence and support, as well as motivating and supporting aspects from the group setting, were elements perceived to help in implementing acquired knowledge from the treatment into the patients' daily lives. The perceived tools of exercise, regular meal and logging created awareness and may have strengthened patients' belief in their own capabilities. For being able to contribute with confidence and facilitate an arena for alliance and change, the therapists reflected around their competence and sought supervision.

The elements yielding opportunities for most patients also posited challenges for others. The therapist support was not sufficient for all patients to overcome challenges during therapy, and some patients found themselves standing on the outside of the group-based encounters.

Based on the findings in the current study, suggestions for adjusting and improving the PED-t can be offered, and future use of the program may be more beneficial for patients as well as for therapists. Future, clinical use of the PED-t may need to consider treatment suitability and group composition. Pre-treatment expectations may also need further attention in order to adjust the patients expectations to the treatment offered.

In future, clinical use of the PED-t, therapists delivering the treatment may receive further training into group dynamics. A stronger focus on group dynamics may increase group cohesion and facilitate a motivating and supporting environment for the patients.

Future use of the PED-t could also benefit from finding a way to locate patients who may experience challenges during therapy, to be able to provide additional support to these patients. Finally, follow-up sessions may be considered for a less abrupt end of treatment and to prevent relapse (Brauhardt, de Zwaan, & Hilbert, 2014; Escobar-Koch et al., 2010).

For clinicians, as well as other researchers, it may be useful to know how therapists in physical exercise and dieticians experienced their own contribution, as they may be viewed as a rather new group of professionals working as therapists for patients with BN and BED. The findings from this thesis imply that therapists in physical exercise and nutrition may contribute with useful knowledge for patients with BN and BED. This implication may also apply outside the settings of the PED-t.

The findings from the current study contribute in the chain of clinical evidence regarding the PED-t, and overall, the PED-t may stand out as a promising new treatment for patients with BN or BED, with a new group of professionals who feel confident as therapists. In expanding the portfolio of treatments, the focus on physical exercise and nutrition may appeal to many patients with EDs. Nevertheless, the PED-t requires replication with other patients and in other settings to further strengthen the chain of clinical evidence. Such efforts may well be planned within a complex intervention framework (Richards & Hallberg, 2015), in which a qualitative component is incorporated in RCTs to access therapist' and patients' treatment experiences and to address the issue of non-completers.

References

- Addis, M. E., & Krasnow, A. D. (2000). A national survey of practicing psychologists' attitudes toward psychotherapy treatment manuals. *Journal of Consulting and Clinical Psychology, 68*(2), 331.
- Agh, T., Kovács, G., Pawaskar, M., Supina, D., Inotai, A., & Vokó, Z. (2015). Epidemiology, health-related quality of life and economic burden of binge eating disorder: a systematic literature review. *Eating and Weight Disorders, 20*(1), 1-12.
- Agh, T., Kovács, G., Supina, D., Pawaskar, M., Herman, B. K., Vokó, Z., & Sheehan, D. V. (2016). A systematic review of the health-related quality of life and economic burdens of anorexia nervosa, bulimia nervosa, and binge eating disorder. *Eating and Weight Disorders, 21*(3), 353-364.
- Ali, K., Farrer, L., Fassnacht, D. B., Gulliver, A., Bauer, S., & Griffiths, K. M. (2017). Perceived barriers and facilitators towards help-seeking for eating disorders: A systematic review. *International Journal of Eating Disorders, 50*(1), 9-21.
- Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, (2013).
- Amianto, F., Ottone, L., Daga, G. A., & Fassino, S. (2015). Binge-eating disorder diagnosis and treatment: a recap in front of DSM-5. *BMC Psychiatry, 15*(1), 70.
- Arcelus, J., Mitchell, A. J., Wales, J., & Nielsen, S. (2011). Mortality rates in patients with anorexia nervosa and other eating disorders: a meta-analysis of 36 studies. *Archives of General Psychiatry, 68*(7), 724-731.
- Ashdown-Franks, G., Firth, J., Carney, R., Carvalho, A. F., Hallgren, M., Koyanagi, A., . . . Solmi, M. (2019). Exercise as medicine for mental and substance use disorders: A meta-review of the benefits for neuropsychiatric and cognitive outcomes. *Sports Medicine, 1-20*.
- Baker, J. H., Eisenlohr-Moul, T., Wu, Y.-K., Schiller, C. E., Bulik, C. M., & Girdler, S. S. (2019). Ovarian hormones influence eating disorder symptom variability during the menopause transition: A pilot study. *Eating behaviors, 35*, 101337.
- Bakland, M., Rosenvinge, J. H., Wynn, R., Sundgot-Borgen, J., Fostervold Mathisen, T., Liabø, K., . . . Pettersen, G. (2019). Patients' views on a new treatment for Bulimia nervosa and binge eating disorder combining physical exercise and dietary therapy (the PED-t). A qualitative study. *Eating Disorders The Journal of Treatment & Prevention, 1-18*.
- Bakland, M., Rosenvinge, J. H., Wynn, R., Sørli, V., Sundgot-Borgen, J., Fostervold Mathisen, T., . . . Pettersen, G. (2020). A new treatment for eating disorders combining physical exercise and dietary therapy (the PED-t): experiences from patients who dropped out. *International Journal of Qualitative Studies on Health and Well-Being, 15*(1), 1731994.
- Bakland, M., Sundgot-Borgen, J., Wynn, R., Rosenvinge, J. H., Stornæs, A. V., & Pettersen, G. (2018). Therapists' experiences with a new treatment combining physical exercise and dietary therapy (the PED-t) for eating disorders: an interview study in a randomised controlled trial at the Norwegian School of Sport Sciences. *BMJ Open, 8*(1), e019386.
- Bell, L. (2003). What can we learn from consumer studies and qualitative research in the treatment of eating disorders? *Eating and Weight Disorders, 8*(3), 181-187.
- Beltz, A. M., Moser, J. S., Zhu, D. C., Burt, S. A., & Klump, K. L. (2018). Using person-specific neural networks to characterize heterogeneity in eating disorders: Illustrative links between emotional eating and ovarian hormones. *International Journal of Eating Disorders, 51*(7), 730-740.

- Biddle, S. J., & Asare, M. (2011). Physical activity and mental health in children and adolescents: a review of reviews. *British Journal of Sports Medicine*, 45(11), 886-895.
- Blanchet, C., Mathieu, M.-È., St-Laurent, A., Fecteau, S., St-Amour, N., & Drapeau, V. (2018). A systematic review of physical activity interventions in individuals with Binge Eating Disorders. *Current Obesity Reports*, 7(1), 76-88.
- Blythin, S. P., Nicholson, H. L., Macintyre, V. G., Dickson, J. M., Fox, J. R., & Taylor, P. J. (2020). Experiences of shame and guilt in anorexia and bulimia nervosa: A systematic review. *Psychology and Psychotherapy: Theory, Research and Practice*, 93(1), 134-159.
- Brauhardt, A., de Zwaan, M., & Hilbert, A. (2014). The therapeutic process in psychological treatments for eating disorders: A systematic review. *International Journal of Eating Disorders*, 47(6), 565-584.
- Brett, J., Staniszewska, S., Mockford, C., Herron-Marx, S., Hughes, J., Tysall, C., & Suleman, R. (2014). Mapping the impact of patient and public involvement on health and social care research: a systematic review. *Health Expectations*, 17(5), 637-650.
- Brinkmann, S., & Kvale, S. (2015). *Interviews: Learning the craft of qualitative research interviewing* (Vol. 3): Sage Thousand Oaks, CA.
- Brownley, K. A., Berkman, N. D., Peat, C. M., Lohr, K. N., Cullen, K. E., Bann, C. M., & Bulik, C. M. (2016). Binge-eating disorder in adults: a systematic review and meta-analysis. *Annals of Internal Medicine*, 165(6), 409-420.
- Burlingame, G. M., McClendon, D. T., & Yang, C. (2018). Cohesion in group therapy: A meta-analysis. *Psychotherapy*, 55(4), 384-398.
- Burlingame, G. M., Strauss, B., & Joyce, A. S. (2013). Change mechanisms and effectiveness of small group treatments. In M. Lambert (Ed.), *Handbook of psychotherapy and behavior change* New Jersey: John Wiley & Sons, Inc.
- Chalmers, I., Bracken, M. B., Djulbegovic, B., Garattini, S., Grant, J., Gülmezoglu, A. M., . . . Oliver, S. (2014). How to increase value and reduce waste when research priorities are set. *The Lancet*, 383(9912), 156-165.
- Chekroud, S. R., Gueorguieva, R., Zheutlin, A. B., Paulus, M., Krumholz, H. M., Krystal, J. H., & Chekroud, A. M. (2018). Association between physical exercise and mental health in 1·2 million individuals in the USA between 2011 and 2015: a cross-sectional study. *The Lancet Psychiatry*, 5(9), 739-746.
- Clinton, D. (2001). Expectations and experiences of treatment in eating disorders. *Eating Disorders*, 9(4), 361-371.
- Clinton, D., Björck, C., Sohlberg, S., & Norring, C. (2004). Patient satisfaction with treatment in eating disorders: cause for complacency or concern? *European Eating Disorders Review*, 12(4), 240-246.
- Craven, M. P., & Fekete, E. M. (2019). Weight-related shame and guilt, intuitive eating, and binge eating in female college students. *Eating Behaviors*, 33, 44-48.
- Creswell, J. W. (2007). Qualitative enquiry and research design: Choosing among five approaches. In: SAGE Publications Ltd.
- Culbert, K. M., Racine, S. E., & Klump, K. L. (2016). Hormonal factors and disturbances in eating disorders. *Current Psychiatry Reports*, 18(7), 65.
- Dakanalis, A., Gaudio, S., Riva, G., & Clerici, M. (2017). Severity of bulimia nervosa and its impact on treatment outcome. *Eating and Weight Disorders*, 22(4), 727-729.
- de Jong, M., Schoorl, M., & Hoek, H. W. (2018). Enhanced cognitive behavioural therapy for patients with eating disorders: A systematic review. *Current opinion in psychiatry*, 31(6), 436.

- de la Rie, S., Noordenbos, G., Donker, M., & van Furth, E. (2006). Evaluating the treatment of eating disorders from the patient's perspective. *International Journal of Eating Disorders*, 39(8), 667-676.
- de la Rie, S., Noordenbos, G., Donker, M., & van Furth, E. (2008). The quality of treatment of eating disorders: a comparison of the therapists' and the patients' perspective. *International Journal of Eating Disorders*, 41(4), 307-317.
- DeJong, H., Broadbent, H., & Schmidt, U. (2012). A systematic review of dropout from treatment in outpatients with anorexia nervosa. *International Journal of Eating Disorders*, 45(5), 635-647.
- Dimitropoulos, G., Freeman, V. E., Lock, J., & Le Grange, D. (2017). Clinician perspective on parental empowerment in family-based treatment for adolescent anorexia nervosa. *Journal of Family Therapy*, 39(4), 537-562.
- Duarte, C., Ferreira, C., & Pinto-Gouveia, J. (2016). At the core of eating disorders: Overvaluation, social rank, self-criticism and shame in anorexia, bulimia and binge eating disorder. *Comprehensive Psychiatry*, 66, 123-131.
- Eddy, K. T., Dorer, D. J., Franko, D. L., Tahilani, K., Thompson-Brenner, H., & Herzog, D. B. (2007). Should bulimia nervosa be subtyped by history of anorexia nervosa? A longitudinal validation. *International Journal of Eating Disorders*, 40(S3), S67-S71.
- Eivors, A., Button, E., Warner, S., & Turner, K. (2003). Understanding the experience of drop-out from treatment for anorexia nervosa. *European Eating Disorders Review: The Professional Journal of the Eating Disorders Association*, 11(2), 90-107.
- Erskine, H. E., & Whiteford, H. A. (2018). Epidemiology of binge eating disorder. *Current opinion in psychiatry*, 31(6), 462-470.
- Escobar-Koch, T., Banker, J. D., Crow, S., Cullis, J., Ringwood, S., Smith, G., . . . Schmidt, U. (2010). Service users' views of eating disorder services: an international comparison. *International Journal of Eating Disorders*, 43(6), 549-559.
- Fairburn, C. G., Cooper, Z., & Shafran, R. (2003). Cognitive behaviour therapy for eating disorders: A "transdiagnostic" theory and treatment. *Behaviour Research and Therapy*, 41(5), 509-528.
- Fairburn, C. G., & Harrison, P. J. (2003). Eating disorders. *The Lancet*, 361(9355), 407-416.
- Fairburn, C. G., & Wilson, G. T. (2013). The dissemination and implementation of psychological treatments: problems and solutions. *International Journal of Eating Disorders*, 46(5), 516-521.
- Fassino, S., Pierò, A., Tomba, E., & Abbate-Daga, G. (2009). Factors associated with dropout from treatment for eating disorders: a comprehensive literature review. *BMC Psychiatry*, 9(1), 1-9.
- Fichter, M. M., & Quadflieg, N. (2016). Mortality in eating disorders-results of a large prospective clinical longitudinal study. *International Journal of Eating Disorders*, 49(4), 391-401.
- Finning, K., Richards, D. A., Moore, L., Ekers, D., McMillan, D., Farrand, P. A., . . . Fletcher, E. (2017). Cost and outcome of behavioural activation versus cognitive behavioural therapy for depression (COBRA): a qualitative process evaluation. *BMJ open*, 7(4), e014161.
- Fortin, M., Bamvita, J.-M., & Fleury, M.-J. (2018). Patient satisfaction with mental health services based on Andersen's behavioral model. *The Canadian Journal of Psychiatry*, 63(2), 103-114.
- Fowler, N., Vo, P. T., Sisk, C. L., & Klump, K. L. (2019). Stress as a potential moderator of ovarian hormone influences on binge eating in women. *F1000Research*, 8.

- Godley, S. H., White, W. L., Diamond, G., Passeti, L., & Titus, J. C. (2001). Therapist reactions to manual-guided therapies for the treatment of adolescent marijuana users. *Clinical Psychology: Science and Practice*, 8(4), 405-417.
- Graves, T. A., Tabri, N., Thompson-Brenner, H., Franko, D. L., Eddy, K. T., Bourion-Bedes, S., . . . Forsberg, S. (2017). A meta-analysis of the relation between therapeutic alliance and treatment outcome in eating disorders. *International Journal of Eating Disorders*.
- Griffiths, S., Rossell, S. L., Mitchison, D., Murray, S. B., & Mond, J. M. (2018). Pathways into treatment for eating disorders: A quantitative examination of treatment barriers and treatment attitudes. *Eating Disorders*, 26(6), 556-574.
- Gupta, S. K. (2011). Intention-to-treat concept: a review. *Perspectives in Clinical Research*, 2(3), 109.
- Haderlein, T. P. (2019). Efficacy of technology-based eating disorder treatment: A meta-analysis. *Current Psychology*, 1-11.
- Hart, L., Granillo, M. T., Jorm, A. F., & Paxton, S. J. (2011). Unmet need for treatment in the eating disorders: a systematic review of eating disorder specific treatment seeking among community cases. *Clinical Psychology Review*, 31(5), 727-735.
- Hart, S., Russell, J., & Abraham, S. (2011). Nutrition and dietetic practice in eating disorder management. *Journal of Human Nutrition and Dietetics*, 24(2), 144-153.
- Harvey, S. B., Øverland, S., Hatch, S. L., Wessely, S., Mykletun, A., & Hotopf, M. (2018). Exercise and the prevention of depression: results of the HUNT cohort study. *American Journal of Psychiatry*, 175(1), 28-36.
- Hausenblas, H. A., Cook, B. J., & Chittester, N. I. (2008). Can exercise treat eating disorders? *Exercise and Sport Sciences Reviews*, 36(1), 43-47.
- Hay, P. (2013). A systematic review of evidence for psychological treatments in eating disorders: 2005–2012. *International Journal of Eating Disorders*, 46(5), 462-469.
- Hilbert, A., Hoek, H. W., & Schmidt, R. (2017). Evidence-based clinical guidelines for eating disorders: international comparison. *Current Opinion in Psychiatry*, 30(6), 423.
- Hopwood, C. J., Ansell, E. B., Fehon, D. C., & Grilo, C. M. (2010). Personality heterogeneity in female adolescent inpatients with features of eating disorders. *Comprehensive Psychiatry*, 51(6), 585-591.
- Horvath, A. O., & Luborsky, L. (1993). The role of the therapeutic alliance in psychotherapy. *Journal of Consulting and Clinical Psychology*, 61(4), 561.
- Horvath, A. O., Re, A. C. D., Fluckiger, C., & Symonds, D. (2011). Alliance in individual psychotherapy. In *Psychotherapy relationships that work: Evidence-based responsiveness* (2nd ed., pp. 25-69). New York, NY: Oxford University Press; US.
- Hsu, L., Rand, W., Sullivan, S., Liu, D., Mulliken, B., McDonagh, B., & Kaye, W. (2001). Cognitive therapy, nutritional therapy and their combination in the treatment of bulimia nervosa. *Psychological Medicine*, 31(5), 871-879.
- Hummelen, B., Wilberg, T., & Karterud, S. (2007). Interviews of female patients with borderline personality disorder who dropped out of group psychotherapy. *International Journal of Group Psychotherapy*, 57(1), 67-92.
- Jayakody, K., Gunadasa, S., & Hosker, C. (2013). Exercise for anxiety disorders: systematic review. *British Journal of Sports Medicine*, bjsports-2012-091287.
- Josefsson, T., Lindwall, M., & Archer, T. (2014). Physical exercise intervention in depressive disorders: Meta-analysis and systematic review. *Scandinavian Journal of Medicine and Science in Sports*, 24(2), 259-272.
- Kaplan, A. S., & Noble, S. (2018). Medical complications of eating disorders. In *Annual Review of Eating Disorders* (pp. 101-112): CRC Press.

- Kazdin, A. E., Fitzsimmons, E. E., & Wilfley, D. E. (2017). Addressing critical gaps in the treatment of eating disorders. *International Journal of Eating Disorders*, 50(3), 170-189.
- Kerkelä, E. S., Jonsson, L., Lindwall, M., & Strand, J. (2015). Individual experiences following a 6-month exercise intervention: A qualitative study. *International Journal of Qualitative Studies on Health and Well-Being*, 10(1), 26376.
- Kerrigan, S. G., Lydecker, J. A., & Grilo, C. M. (2019). Associations between physical activity and eating-disorder psychopathology among individuals categorised with binge-eating disorder and bulimia nervosa. *International Journal of Clinical Practice*, 73(11), e13401.
- Keski-Rahkonen, A., & Mustelin, L. (2016). Epidemiology of eating disorders in Europe: prevalence, incidence, comorbidity, course, consequences, and risk factors. *Current Opinion in Psychiatry*, 29(6), 340-345.
- Kingstone, T., Bartlam, B., Burroughs, H., Bullock, P., Lovell, K., Ray, M., . . . Nicholls, E. (2019). Can support workers from AgeUK deliver an intervention to support older people with anxiety and depression? A qualitative evaluation. *BMC Family Practice*, 20(1), 16.
- Klein, O. A., Drummond, A., Mhizha-Murira, J. R., Mansford, L., & dasNair, R. (2019). Effectiveness of cognitive rehabilitation for people with multiple sclerosis: a meta-synthesis of patient perspectives. *Neuropsychological Rehabilitation*, 29(4), 491-512.
- Laberg, S., Törnkvist, Å., & Andersson, G. (2001). Experiences of patients in cognitive behavioural group therapy: a qualitative study of eating disorders. *Scandinavian Journal of Behaviour Therapy*, 30(4), 161-178.
- Lambert, M. (2013). The Efficacy and Effectiveness of Psychotherapy. In M. Lambert (Ed.), *Handbook of psychotherapy and behaviour change*. New Jersey: John Wiley & Sons, Inc.
- Leavey, G., Vallianatou, C., Johnson-Sabine, E., Rae, S., & Gunpath, V. (2011). Psychosocial barriers to engagement with an eating disorder service: A qualitative analysis of failure to attend. *Eating Disorders*, 19(5), 425-440.
- Leung, L. (2015). Validity, reliability, and generalizability in qualitative research. *Journal of Family Medicine and Primary Care*, 4(3), 324.
- Levinson, C. A., Byrne, M., & Rodebaugh, T. L. (2016). Shame and guilt as shared vulnerability factors: Shame, but not guilt, prospectively predicts both social anxiety and bulimic symptoms. *Eating Behaviors*, 22, 188-193.
- Linardon, J., Hindle, A., & Brennan, L. (2018). Dropout from cognitive-behavioral therapy for eating disorders: A meta-analysis of randomized, controlled trials. *International Journal of Eating Disorders*, 51(5), 381-391.
- Linardon, J., Messer, M., & Fuller-Tyszkiewicz, M. (2018). Meta-analysis of the effects of cognitive-behavioral therapy for binge-eating-type disorders on abstinence rates in nonrandomized effectiveness studies: Comparable outcomes to randomized, controlled trials? *International Journal of Eating Disorders*, 51(12), 1303-1311.
- Linardon, J., & Wade, T. D. (2018). How many individuals achieve symptom abstinence following psychological treatments for bulimia nervosa? A meta-analytic review. *International Journal of Eating Disorders*, 51(4), 287-294.
- Lindseth, A., & Norberg, A. (2004). A phenomenological hermeneutical method for researching lived experience. *Scandinavian Journal of Caring Sciences*, 18(2), 145-153.
- Lubans, D., Richards, J., Hillman, C., Faulkner, G., Beauchamp, M., Nilsson, M., . . . Biddle, S. (2016). Physical activity for cognitive and mental health in youth: a systematic review of mechanisms. *Pediatrics*, e20161642.

- Malterud, K. (2001). Qualitative research: standards, challenges, and guidelines. *The Lancet*, 358(9280), 483-488.
- Malterud, K. (2011). *Kvalitative metoder i medisinsk forskning*. Oslo: Universitetsforlaget.
- Malterud, K. (2012). Systematic text condensation: A strategy for qualitative analysis. *Scandinavian journal of public health*, 40(8), 795-805.
- Malterud, K. (2016). Theory and interpretation in qualitative studies from general practice: why and how? *Scandinavian Journal of Public Health*, 44(2), 120-129.
- Malterud, K., Siersma, V. D., & Guassora, A. D. (2015). Sample size in qualitative interview studies: guided by information power. *Qualitative Health Research*, 26(13), 1753-1760.
- Martinussen, M., Friberg, O., Schmierer, P., Kaiser, S., Øvergård, K. T., Neunhoeffer, A.-L., . . . Rosenvinge, J. H. (2017). The comorbidity of personality disorders in eating disorders: a meta-analysis. *Eating and Weight Disorders*, 22(2), 201-209.
- Mathisen, T. F. (2018). *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*. Doctoral thesis, Norwegian School of Sports sciences.
- Mathisen, T. F., Rosenvinge, J. H., Friberg, O., Vrabel, K., Bratland-Sanda, S., Pettersen, G., & Sundgot-Borgen, J. (2020). Is physical exercise and dietary therapy a feasible alternative to cognitive behavior therapy in treatment of eating disorders? A randomized controlled trial of two group therapies. *International Journal of Eating Disorders*.
- Mathisen, T. F., Rosenvinge, J. H., Pettersen, G., Friberg, O., Vrabel, K., Bratland-Sanda, S., . . . Wynn, R. (2017). 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. *BMC Psychiatry*, 17(1), 2-11.
- McClay, C.-A., Waters, L., McHale, C., Schmidt, U., & Williams, C. (2013). Online cognitive behavioral therapy for bulimic type disorders, delivered in the community by a nonclinician: qualitative study. *Journal of Medical Internet Research*, 15(3), e46.
- McLeod, J. (2013). Qualitative research methods and contributions. In M. Lambert (Ed.), *Handbook of Psychotherapy and Behavior Change*. New Jersey: John Wiley & Sons.
- Miglietta, E., Belessiotis-Richards, C., Ruggeri, M., & Priebe, S. (2018). Scales for assessing patient satisfaction with mental health care: A systematic review. *Journal of Psychiatric Research*, 100, 33-46.
- Moore, G. F., Audrey, S., Barker, M., Bond, L., Bonell, C., Hardeman, W., . . . Wight, D. (2015). Process evaluation of complex interventions: Medical Research Council guidance. *BMJ*, 350, h1258.
- Mulkens, S., de Vos, C., de Graaff, A., & Waller, G. (2018). To deliver or not to deliver cognitive behavioral therapy for eating disorders: Replication and extension of our understanding of why therapists fail to do what they should do. *Behaviour Research and Therapy*, 106, 57-63.
- Najavits, L. M., Ghinassi, F., Van Horn, A., Weiss, R. D., Siqueland, L., Frank, A., . . . Luborsky, L. (2004). Therapist Satisfaction With Four Manual-Based Treatments on a National Multisite Trial: An Exploratory Study. *Psychotherapy: Theory, Rresearch, Practice, Training*, 41(1), 26.
- Najavits, L. M., Weiss, R. D., Shaw, S. R., & Dierberger, A. E. (2000). Psychotherapists' views of treatment manuals. *Professional Psychology: Research and Practice*, 31(4), 404.
- Ng, L., Ng, D., & Wong, W. (2013). Is supervised exercise training safe in patients with anorexia nervosa? A meta-analysis. *Physiotherapy*, 99(1), 1-11.

- NICE. (2017). *Eating disorders: Recognition and treatment*. UK: National Institute for Health and Care Excellence
- Nishizono Maher, A., Escobar Koch, T., Ringwood, S., Banker, J., van Fürth, E., & Schmidt, U. (2011). What are the top five essential features of a high quality eating disorder service? A comparison of the views of US and UK eating disorder sufferers, carers and health professionals. *European Eating Disorders Review*, 19(5), 411-416.
- Nordheim, K., Walderhaug, E., Alstadius, S., Kern-Godal, A., Arnevik, E., & Duckert, F. (2018). Young adults' reasons for dropout from residential substance use disorder treatment. *Qualitative Social Work*, 17(1), 24-40.
- O'Connor, K., Neff, D. M., & Pitman, S. (2018). Burnout in mental health professionals: A systematic review and meta-analysis of prevalence and determinants. *European Psychiatry*, 53, 74-99.
- Ogrodniczuk, J. S., Joyce, A. S., & Piper, W. E. (2005). Strategies for reducing patient-initiated premature termination of psychotherapy. *Harvard Review of Psychiatry*, 13(2), 57-70.
- Oliver, S., Liabo, K., Stewart, R., & Rees, R. (2015). Public involvement in research: making sense of the diversity. *Journal of Health Services Research and Policy*, 20(1), 45-51.
- Painot, D., Jotterand, S., Kammer, A., Fossati, M., & Golay, A. (2001). Simultaneous nutritional cognitive-behavioural therapy in obese patients. *Patient Education and Counseling*, 42(1), 47-52.
- Peat, C. M., Berkman, N. D., Lohr, K. N., Brownley, K. A., Bann, C. M., Cullen, K., . . . Bulik, C. M. (2017). Comparative effectiveness of treatments for binge-eating disorder: Systematic review and network meta-analysis. *European Eating Disorders Review*, 25(5), 317-328.
- Pettersen, G., & Rosenvinge, J. H. (2002). Improvement and recovery from eating disorders: A patient perspective. *Eating Disorders*, 10(1), 61-71.
- Pettersen, G., Rosenvinge, J. H., Bakland, M., Wynn, R., Mathisen, T. F., & Sundgot-Borgen, J. (2018). Patients' and therapists' experiences with a new treatment programme for eating disorders that combines physical exercise and dietary therapy: the PED-t trial. A qualitative study protocol. *BMJ Open*, 8(1), e018708.
- Pettersen, G., Rosenvinge, J. H., Thune-Larsen, K.-B., & Wynn, R. (2012). Clinical confidence following an interprofessional educational program on eating disorders for health care professionals: A qualitative analysis. *Journal of Multidisciplinary Healthcare*, 5, 201.
- Pettersen, G., Rosenvinge, J. H., & Ytterhus, B. (2008). The "double life" of bulimia: patients' experiences in daily life interactions. *Eating Disorders*, 16(3), 204-211.
- Pettersen, G., SørDAL, S., Rosenvinge, J. H., Skomakerstuen, T., Mathisen, T. F., & Sundgot-Borgen, J. (2017). How do women with eating disorders experience a new treatment combining guided physical exercise and dietary therapy? An interview study of women participating in a randomised controlled trial at the Norwegian School of Sport Sciences. *BMJ Open*, 7(12), e018588.
- Pisetsky, E. M., Crow, S. J., & Peterson, C. B. (2017). An empirical test of the interpersonal theory of suicide in a heterogeneous eating disorder sample. *International Journal of Eating Disorders*, 50(2), 162-165.
- Poulsen, S., Lunn, S., Daniel, S. I., Folke, S., Mathiesen, B. B., Katznelson, H., & Fairburn, C. G. (2014). A randomized controlled trial of psychoanalytic psychotherapy or cognitive-behavioral therapy for bulimia nervosa. *American Journal of Psychiatry*, 171(1), 109-116.

- Poulsen, S., Lunn, S., & Sandros, C. (2010). Client experience of psychodynamic psychotherapy for bulimia nervosa: An interview study. *Psychotherapy: Theory, Research, Practice, Training*, 47(4), 469-483.
- Pretorius, N., Rowlands, L., Ringwood, S., & Schmidt, U. (2010). Young people's perceptions of and reasons for accessing a web - based cognitive behavioural intervention for bulimia nervosa. *European Eating Disorders Review: The Professional Journal of the Eating Disorders Association*, 18(3), 197-206.
- QSR International. (2017). What is NVivi. Retrieved from <http://www.qsrinternational.com>
- Reas, D. L., & Rø, Ø. (2018). Time trends in healthcare-detected incidence of anorexia nervosa and bulimia nervosa in the Norwegian National Patient Register (2010–2016). *International Journal of Eating Disorders*, 51(10), 1144-1152.
- Reiner, M., Niermann, C., Jekauc, D., & Woll, A. (2013). Long-term health benefits of physical activity-a systematic review of longitudinal studies. *BMC Public Health*, 13(1), 813.
- Richards, D. A., & Hallberg, I. R. (2015). *Complex interventions in health: An overview of research methods*. (D. A. Richards & I. R. Hallberg Eds.). New York: Routledge.
- Richards, P. S., Crowton, S., Berrett, M. E., Smith, M. H., & Passmore, K. (2017). Can patients with eating disorders learn to eat intuitively? A 2-year pilot study. *Eating Disorders*, 25(2), 99-113.
- Ricœur, P. (1976). *Interpretation theory : discourse and the surplus of meaning*. Fort Worth, Tex: Texas Christian University Press.
- Rosenbaum, S., Tiedemann, A., Sherrington, C., Curtis, J., & Ward, P. B. (2014). Physical activity interventions for people with mental illness: a systematic review and meta-analysis. *Psychiatry Research*, 230, 137-142.
- Rosenbaum, S., Vancampfort, D., Steel, Z., Newby, J., Ward, P. B., & Stubbs, B. (2015). Physical activity in the treatment of post-traumatic stress disorder: a systematic review and meta-analysis. *Psychiatry Research*, 230(2), 130-136.
- Rosenvinge, J. H., & Gøtestam, K. G. (2002). [Eating disorders--how should treatment be organized?]. *Journal of the Norwegian Medical Association*, 122(3), 285-288.
- Rosenvinge, J. H., & Klusmeier, A. K. (2000). Treatment for eating disorders from a patient satisfaction perspective: a Norwegian replication of a British study. *European Eating Disorders Review*, 8(4), 293-300.
- Rosenvinge, J. H., & Pettersen, G. (2015). Epidemiology of eating disorders part II: an update with a special reference to the DSM-5. *Advances in Eating Disorders*, 3(2), 198-220.
- Sacristán, J. A., Aguarón, A., Avendaño-Solá, C., Garrido, P., Carrión, J., Gutiérrez, A., . . . Flores, A. (2016). Patient involvement in clinical research: why, when, and how. *Patient Preference and Adherence*, 10, 631.
- Sánchez-Ortiz, V., House, J., Munro, C., Treasure, J., Startup, H., Williams, C., & Schmidt, U. (2011). "A computer isn't gonna judge you": A qualitative study of users' views of an internet-based cognitive behavioural guided self-care treatment package for bulimia nervosa and related disorders. *Eating and Weight Disorders*, 16(2), e93-e101.
- Schaumberg, K., Jangmo, A., Thornton, L. M., Birgegård, A., Almqvist, C., Norring, C., . . . Bulik, C. M. (2019). Patterns of diagnostic transition in eating disorders: a longitudinal population study in Sweden. *Psychological Medicine*, 49(5), 819-827.
- Schulte, E. M., Grilo, C. M., & Gearhardt, A. N. (2016). Shared and unique mechanisms underlying binge eating disorder and addictive disorders. *Clinical Psychology Review*, 44, 125-139.
- Seidinger-Leibovitz, F. M., Junior, C. G., Vieira, C. M., Tófoli, L. F., & Turato, E. R. (2015). Slavery to addiction as meaning of dropout in eating disorders: Psychological aspects

- among women that have interrupted treatment at a specialized service in Brazil. *Psychology (Savannah, Ga.)*, 6(06), 788.
- Shadish, W. R., Cook, T. D., & Campbell, D. (2002). *Experimental and quasi-experimental designs for generalized causal inference*. Boston, USA: Houghton Mifflin Company.
- Smink, F. R., van Hoeken, D., & Hoek, H. W. (2012). Epidemiology of eating disorders: incidence, prevalence and mortality rates. *Current Psychiatry Reports*, 14(4), 406-414. doi:10.1007/s11920-012-0282-y
- Smink, F. R., van Hoeken, D., & Hoek, H. W. (2013). Epidemiology, course, and outcome of eating disorders. *Current Opinion in Psychiatry*, 26(6), 543-548.
- Solberg, C., Larsson, B., & Jozefiak, T. (2015). Consumer satisfaction with the child and adolescent mental health service and its association with treatment outcome: A 3–4-year follow-up study. *Nordic Journal of Psychiatry*, 69(3), 224-232.
- Stige, B., Malterud, K., & Midtgarden, T. (2009). Toward an agenda for evaluation of qualitative research. *Qualitative Health Research*, 19(10), 1504-1516.
- Strumila, R., Nobile, B., Maimoun, L., Jaussent, I., Seneque, M., Thiebaut, S., . . . Courtet, P. (2020). The implications of previous history of anorexia nervosa in patients with current bulimia nervosa: Alterations in daily functioning, decision-making, and bone status. *European Eating Disorders Review*, 28(1), 34-45.
- Sundgot-Borgen, J., Rosenvinge, J. H., Bahr, R., & Schneider, L. S. (2002). The effect of exercise, cognitive therapy, and nutritional counseling in treating bulimia nervosa. *Medicine and Science in Sports and Exercise*, 34(2), 190-195.
- Swain-Campbell, N. R., Surgenor, L. J., & Snell, D. L. (2001). An analysis of consumer perspectives following contact with an eating-disorders service. *Australian and New Zealand Journal of Psychiatry*, 35(1), 99-103.
- Sysko, R., Hildebrandt, T., Wilson, G. T., Wilfley, D. E., & Agras, W. S. (2010). Heterogeneity moderates treatment response among patients with binge eating disorder. *Journal of Consulting and Clinical Psychology*, 78(5), 681.
- The Norwegian directorate of health. (2017). [National guideline for early recognition and treatment of eating disorders]. Retrieved from <https://helsedirektoratet.no/retningslinjer/spiseforstyrrelser>
- Thompson-Brenner, H., Satir, D. A., Franko, D. L., & Herzog, D. B. (2012). Clinician reactions to patients with eating disorders: a review of the literature. *Psychiatric Services*, 63(1), 73-78.
- Tjora, A. H. (2006). Writing small discoveries: an exploration of fresh observers' observations. *Qualitative Research*, 6(4), 429-451.
- Tong, A., Sainsbury, P., & Craig, J. (2007). Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*, 19(6), 349-357.
- Treasure, J., Claudino, A. M., & Zucker, N. (2010). Eating disorders. *The Lancet*, 375(9714), 583-593.
- Vancampfort, D., Vanderlinden, J., De Hert, M., Adámkova, M., Skjaerven, L. H., Catalán-Matamoros, D., . . . Probst, M. (2013). A systematic review on physical therapy interventions for patients with binge eating disorder. *Disability and Rehabilitation*, 35(26), 2191-2196.
- Vancampfort, D., Vanderlinden, J., De Hert, M., Soundy, A., Adámkova, M., Skjaerven, L. H., . . . Probst, M. (2014). A systematic review of physical therapy interventions for patients with anorexia and bulimia nervosa. *Disability and Rehabilitation*, 36(8), 628-634.
- Vanderlinden, J., Buis, H., Pieters, G., & Probst, M. (2007). Which elements in the treatment of eating disorders are necessary 'ingredients' in the recovery process?—A

- comparison between the patient's and therapist's view. *European Eating Disorders Review*, 15(5), 357-365.
- Viefhaus, P., Döpfner, M., Dachs, L., Goletz, H., Görtz-Dorten, A., Kinnen, C., . . . Woitecki, K. (2019). Treatment satisfaction following routine outpatient cognitive-behavioral therapy of adolescents with mental disorders: a triple perspective of patients, parents and therapists. *European Child and Adolescent Psychiatry*, 28(4), 543-556.
- Vocks, S., Tuschen-Caffier, B., Pietrowsky, R., Rustenbach, S. J., Kersting, A., & Herpertz, S. (2010). Meta-analysis of the effectiveness of psychological and pharmacological treatments for binge eating disorder. *International Journal of Eating Disorders*, 43(3), 205-217.
- Waller, G. (2016). Treatment protocols for eating disorders: Clinicians' attitudes, concerns, adherence and difficulties delivering evidence-based psychological interventions. *Current psychiatry reports*, 18(4), 36.
- Waterman-Collins, D., Renwick, B., Lose, A., Kenyon, M., Serpell, L., Richards, L. K., . . . Schmidt, U. (2014). Process evaluation of the MOSAIC Trial, Part I: therapist experiences of delivering two psychological therapies for treatment of anorexia nervosa. *European Eating Disorders Review*, 22(2), 122-130.
- Watt, J., & Dickens, G. L. (2018). Community-based mealtime management for adolescents with anorexia nervosa: A qualitative study of clinicians' perspectives and experiences. *Journal of Child and Adolescent Psychiatric Nursing*, 31(1), 30-38.
- Westmoreland, P., Krantz, M. J., & Mehler, P. S. (2016). Medical complications of anorexia nervosa and bulimia. *The American Journal of Medicine*, 129(1), 30-37.
- Wilson, G., Grilo, C. M., & Vitousek, K. M. (2007). Psychological treatment of eating disorders. *American Psychologist*, 62(3), 199-216.
- Woodward, S., Berry, K., & Bucci, S. (2017). A systematic review of factors associated with service user satisfaction with psychiatric inpatient services. *Journal of Psychiatric Research*, 92, 81-93.
- World Medical Association. (2013). *WMA Declaration of Helsinki-Ethical Principles for Medical Research Involving Human Subjects*.

Paper I

BMJ Open Therapists' experiences with a new treatment combining physical exercise and dietary therapy (the PED-t) for eating disorders: an interview study in a randomised controlled trial at the Norwegian School of Sport Sciences

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ABSTRACT

Objectives The aim of the current study is to explore how therapists running a guided physical exercise and dietary therapy programme (PED-t) experience their contribution to the treatment of patients with bulimia nervosa and binge eating disorder.

Methods Ten therapists running the PED-t were semistructurally interviewed and the transcribed interviews were analysed using a systematic text condensation approach.

Setting The study was run within the context of a randomised controlled trial at the Norwegian School of Sport Sciences.

Results The therapists experienced their knowledge about physical exercise and nutrition as important and useful, and that they could share their knowledge with the patients in different ways and with confidence in their own role. They also believed that their knowledge could serve as tools for the patients' post-treatment recovery and management of their daily lives. Moreover, the therapists put much effort in adjusting their teaching to fit each individual participant. Finally, they reported their personal qualities as important to build trust and therapeutic alliance.

Conclusions The terms 'clinical confidence' and 'alliance' may stand out as the overarching 'metacategories' covering the experiences revealed in this study. The clinical implication is that new groups of professionals may have an important role in the treatment of eating disorders.

Trial registration number NCT02079935; Results.

INTRODUCTION

Treatment and recovery from binge eating disorder (BED) and bulimia nervosa (BN) may be challenging for therapists and patients. First, fragile motivation to change and the processual nature of recovery may conflict with the need for a rapid improvement of symptoms to lower the risk of an

Strengths and limitations of this study

- This study is the first reporting therapists' experiences with a specific treatment for eating disorders, and notably with a new group of professionals in the field.
- All therapists in the treatment programme were included in the study and were willing to participate in the study and share their experiences.
- A limitation with the study might be demand characteristic elicited by the recruitment procedure and the study context.

unfavourable longer-term course of illness.^{1–3} A second challenge is to address the heterogeneity of BN and BED in treatments. Apart from core symptoms such as binge eating (BED and BN) and purging behaviours (BN), the heterogeneity relates to additional symptoms and complications of unhealthy nutritional and physical activity status, cognitive and regulatory processes, as well as experiential aspects related to suffering, the response to treatments and to the recovery process. The challenge then is to design effective treatments for BN and BED that address the heterogeneity of the disorders and the sufferers.

At present, however, the portfolio of evidence-based treatments for adults with BED and BN is virtually limited to cognitive-behavioural therapy (CBT).⁴ Responding to the need to extend this portfolio to address the heterogeneity, a previous randomised controlled trial (RCT)⁵ has shown that both nutritional therapy and guided physical exercise (PE) had equally beneficial effects as CBT in reducing bulimic symptoms. As a follow-up,

a new RCT with an improved research design is in progress⁶ where treatment effects of CBT are compared with a combination of physical exercise and dietary therapy (the PED-t programme) for patients with BN and BED.

Much is known from previous experiential research^{7–14} about the level of patient satisfaction with various modes of treatment. However, the body of knowledge is limited about therapists' experiences. A few studies have shown some concordances between patients and therapists with respect to treatment qualities needed to ease recovery.^{15 16} While such kind of studies have their merit in providing overall knowledge about treatments of eating disorders (EDs), there is a gap of knowledge about experiences from a therapist's perspective with a *particular* treatment programme, such as the new PED-t. How patients and their therapists experience different aspects of treatments is important to secure proper documentation of efficacy and effectiveness.

A focus on therapists' experiences with a particular treatment is important for at least three reasons. First, therapists' experiences with a particular treatment may provide a new and yet unexplored gateway to improve or adjust a treatment protocol or manual. Second, the therapists' experiences with a treatment and its procedures may determine the kind of clinical confidence that promotes the interaction of alliance and symptom change that may bring about a good treatment outcome.¹⁷ A third, specific reason is related to the PED-t programme, where representatives from uncommon professions, that is, dietitians and specialists in PE, are the therapists.

The aim of this study is to explore the therapists' experiences of contributing in a new treatment for patients with BN and BED—that is, PED-t.

METHODS

Study context

The current study was conducted within the context of an RCT.⁶ This trial's aim was to test whether the combination of physical activity and dietary therapy was more effective in treating EDs than CBT. Included in this RCT were women aged 18–40 years with a Diagnostic and Statistical Manual of Mental Disorders-5 (DSM-5) BN or BED for at least 3 months prior to the current study, and who had no major comorbid disorders.⁶ Both treatments were run within a group format of 20 sessions over 16 weeks and each group consisted of five to seven participants. Ten therapists were engaged to run the PE and nutritional treatment groups (PED-T programme).

Participants and recruitment

All therapists (n=10) engaged in the RCT, having finished one or more treatment groups, comprised the sample of the present study. They were 25–35 years of age and with a professional background as physical trainers or dietitians, holding a master or a bachelor degree in sport sciences, PE or exercise medicine, and with at least 3 years of practice with supervised exercise.

The principal investigator of the RCT (JS-B) contacted all therapists with a request to participate. As the therapists responded positively to participate in the study, the first author (MB) contacted them and made appointments for the interviews.

Interview procedure

The first author conducted the interviews between September 2016 and January 2017. Six of the interviews took place at the Norwegian School of Sport Sciences where the RCT was running. The remaining four interviews took place at other locations of the informants' own choice. The interviews lasted for about 1 hour. Using a semistructured interview guide, the interviews were conversations about the therapists' experiences of their own contribution in the RCT treatment. All interviews were recorded and transcribed verbatim by the first author. The participants received a gift card with the value of £25 for their participation.

Data analysis

The data were analysed inspired by the principles of systematic text condensation (STC).¹⁸ The STC analysis is organised as a four-step approach. The first step comprised reading the transcribed interviews thoroughly to achieve an overview of the data and to approach first-impression themes. The transcripts were also compared with the audiotaped interviews to check the accuracy of the text. In the second step, the first author identified and coded units of meaning related to the therapists' experiences of their contributions to the trial, and V.10 of the NVivo software was used to document this step. The analysis then continued with the third step where the coded data were condensed and meanings were abstracted within each of the categories and subcategories and quotes were selected to illustrate the meaning of each group. In the final step, the content within each group was synthesised and re-narrated.¹⁸ The first author (MB) who has a background as a mental health nurse with knowledge and experience in the field conducted the analysis, while additional authors validated the process of STC and discussed the interpretations until agreement was reached. The findings were also subsequently discussed in the author group, and the final descriptions were a result of a (hermeneutical) process moving back and forth between the transcripts, the findings, the literature and relevant theory, to secure that the constructed descriptions were grounded in the empirical data.¹⁸ The analysis resulted in two main categories: contributing with knowledge and contributing with personal qualities.

Table 1 gives examples of first-impression themes, meaning units, codes, code groups, condensed units and descriptions.

Ethical considerations and data security

The therapists signed an informed consent form to participate, and they were informed about the possibility that they could withdraw from the study at any time, without

Table 1 Examples of first-impression themes, meaning units, codes, code groups, condensed units and descriptions derived from the data analysis

Step 1: total impression (from chaos to themes)	Step 2 Meaning units	Code	Code group	Step 3: condensed unit	Step 4: description
To know one's own limitations	"I can give advice, as a compassionate fellow human, but I do not have sufficient knowledge to give the conversation a psychologist would give."	To contribute with knowledge	To know one's own limitations	It is sometimes challenging to know what to say	Sometimes feeling a lack of knowledge, wanting to not give misleading information
Trust	"You have to express care as well, for them to trust you. The trust is important."	To contribute with personal qualities	Building trust	The trust is important and not everyone experience it from the beginning	Underlining the importance of mutual trust

giving any reason. Data were treated confidentially and information about the therapists was presented in a way so that they were not identifiable. All transcripts were deidentified and pseudonyms were used.

User involvement in the study

Prior to the data collection, the focus and aim of the study were discussed in cooperation with coresearchers who are members from a local patient organisation on EDs. User involvement is anticipated to lead to more relevant research questions, more accurate data and research findings that are more likely to have influence.¹⁹ The coresearchers have been a part of the project, including the current study, from the beginning and will continue throughout the project and the next two studies. In addition to discussing focus and aim of all three studies, the coresearchers have been part of preparing interview guides and information sheets. In regular meetings throughout the project, they have also been good discussion partners and have shared valuable personal experiences about ED.

RESULTS

To contribute with knowledge

This main category concerns the physical trainers and dietitians' experiences of contributing in the treatment programme with knowledge about PE and nutrition. They described being able to share their knowledge with the women with EDs in different ways and with confidence in their own role. The category is described through three subgroups: 'Giving away tools by teaching', 'A balancing act' and 'To know one's own limitations'.

Giving away tools by teaching

The therapists reported that their main responsibility in the project was to teach women with EDs how to exercise and eat in a normal and healthy way, in order to correct misinterpretations and misunderstandings about physical activity, food and nutrition.

They expressed that their own knowledge and competence in teaching exercise and nutrition was a result of their education as well as their experiences through work

and daily life. Furthermore, they experienced that this knowledge made them able to teach the women why and how to exercise and eat normally.

Meghan, a physical trainer, described how she experienced teaching:

I believe that is what helps them, mainly because they get to know their own body. How the body reacts after receiving the right amount of food after exercise. How the body feels like after 16 weeks of working out. That the body is functioning in a different way than it used to. That they feel like this is the way they want their body to function.

According to the therapists' opinion, the women's own experiences of the impact of adopting healthier lifestyles and physical activity habits were the best way for the women to learn. However, one PE trainer also mentioned that some of the women might not have been ready to implement this knowledge in their daily lives at that point. Nevertheless, teaching was experienced as important by the therapists because the knowledge might function as tools that the women could use to manage their daily life in the future. Ben, who is also a physical trainer, explained how he trusted his own knowledge and how this gave him confidence in his role:

I trust that knowledge, and especially because it comes from The Norwegian School of Sport Science. I often have great confidence in what I know, and that is important, because then you experience confidence in your own role, and I believe they can tell if you have that.

Ben talked about misinterpretations and described the tools they provided to the participants like this:

You learn some tools when you participate in this treatment. Some tools that you can use, and that you have been able to try out and get feedback on. It is about what to eat and how to exercise in a smart way. You have some of your misinterpretations corrected. That is knowledge that you can carry with you for the rest of your life.

The therapists thus experienced sharing knowledge that could help the women with EDs managing their daily lives after treatment as an important contribution.

A balancing act

The therapists reported being aware of individual differences among the participants and that they put much effort in adjusting their teaching to fit each individual woman. Susan, a physical trainer, described the women's vulnerability:

It is so important though, because they are in such a vulnerable situation, that it might become overwhelming if we focus too much on exercise and food. (...) So it is always a balancing act.

Thus, the physical trainers needed to adjust the exercises, but more importantly, all of the therapists reported the need to adjust the knowledge level and focus in their teaching.

To keep the right balance between to 'push' and to 'hold back' was perceived as difficult at times. According to the therapists, some of the women needed to be 'pushed' a little to be able to lift the right amount of weights, or finding their place in the groups. However, the therapists simultaneously described how one or several women could have a bad day or feel unwell, and in these cases, pushing the participants would be wrong. Meghan, a physical trainer, said it in this way:

We need to find the balance, when to push and when to hold back. It is not suitable to push at all times, in a way you need to adjust to what kind of day they are having.

Knowing how much and when to praise the women was also described as important by the therapists. They reported that for some women, it was important to be worthy of praise, but at the same time this could make the next day for them difficult if they did not manage in the same way. Furthermore, the therapists experienced that some of the women might feel worse when somebody else was praised. Starting each group session talking to the women and sensing how they felt made the therapists being able to adjust to each individual's needs. Kirby, who is a dietitian, described the importance of being open and controlling at the same time:

We should be open to meet the participant where they are, but at the same time we have a plan according to protocol, and therefore we have to be somewhat controlling in the conversation.

Altogether, the therapists found it challenging to follow the protocol and simultaneously make individual adjustments. However, they found themselves being able to balance each individual woman's need, and this was perceived as an important contribution.

To know one's own limitations

The therapists described that the participants asked many questions, to secure an optimal outcome and use of time

in the treatment programme. At times, when the therapists reported being unable to answer, they felt a considerable responsibility of not giving misleading information. Thus, they stressed the importance of bringing such unanswered questions forward, by asking their superiors, in order to provide a good answer on the next occasion.

A minority of the therapists reported having experienced a situation where they felt a lack of knowledge in mental health disorders. Susan, a physical trainer, said it like this:

I can give advice, as a compassionate fellow human, but I do not have sufficient knowledge to give the conversation a psychologist would give.

In these cases, they experienced the participants as having a need for attention and to be listened to. The therapists also reported being aware of the potential that the participants were having a difficult time outside the treatment context.

In general, most of the therapists could give an example where they had to acknowledge not having sufficient knowledge. Kirby, a dietitian, reflected about a situation where he felt not able to help:

So I guess I couldn't help her in that situation, but at the same time I tried to tell her that I couldn't help and I tried to show some compassion or understanding. Yes.

Louise, also a physical trainer, expressed the feeling of responsibility:

Perhaps I could have produced a logical answer if it was to a friend of me, but these are women that have a disease and they deserve an answer that is good enough.

Despite not having the sufficient competence in all situations, the therapists described an insight in their own limitations. However, they reported a feeling of substantial contribution in general because of their strive to always meet the participants' requests.

To contribute with personal qualities

The therapists highlighted the importance of having certain personal qualities themselves. Teaching the women with EDs was perceived not only as a transference of knowledge, but needed to be done with respect, empathy, interest and joy. This category constitutes three subgroups: 'Being a fellow human being', 'Building trust' and 'Creating a good group dynamic'.

Being a fellow human being

The therapists reported the importance of having different qualities when working together in a team, which contributed in providing many forms of help and assistance. Kim, a physical trainer, said:

I believe the fact that we instructors are different as persons is a major advantage. When we are working together, it helps having different qualities,

complementing each other. We received positive feedback regarding that.

Being compassionate, understanding and having a desire to help were highly valued qualities that the therapists reported having acquired through practical professional experience, and which had influenced their way of working with the participants.

Most of the therapists provided examples where they had to give the women something more than just the regular follow-up according to the protocol. When one of the women had a difficult time and rushed out of the group session, the therapist had to follow her out in the hallway, be a good discussion partner and try to make her overcome her difficulties. The therapists reported that these conversations in the hallway, being a fellow human being, most often were sufficient to get the women to return to the group sessions. Louise, who is a physical trainer, described how she used herself as a fellow human being. In the situation below, 'she' is a woman with ED:

Sometimes the important thing is that she feels good when she goes home. Just leave the group, take your time and tell the other therapists that you have to talk to her. Make her understand that you too, have difficult times, even though you're not sick or in a bad shape. Finally, she is able to return to the group session, and you can see, it is as if she is glowing in joy! Then you feel good because you made her day and you put out a small fire.

Emmely, a physical trainer, said:

Trying to get to know them, showing them that you care and have an interest in them as persons. That this isn't just research. Being a fellow human, yes.

Being a fellow human being was among other things described to be an important contribution when it came to helping the participants overcoming challenges.

Building trust

The therapists experienced that the treatment required a mutual trust between themselves and the group members. From some of the women, such a trust came rather immediately, while other women needed more time, and the therapists outlined the need to work throughout the process to establish and maintain this trust. Moreover, the therapists described having used several ways of getting acquainted, and building and maintaining trust.

The physical trainers experienced the building of trust as essential in the sense that they reported the women had to rely on them, placing the right amount of kilos on the weights during the strength training. According to the therapists, the weights should not be too heavy for the women to manage, but conversely, not be too easy to promote progression.

Sometimes the therapists experienced being tested whether they were coordinated and whether they knew what they were doing. For example, a therapist could be

asked a question and then another therapist was asked the same question. To avoid splitting, the therapists thus experienced it as helpful to have regular meetings between themselves beyond what was planned in the protocol. In these meetings other challenges and current needs were also discussed.

In the interviews, the therapists also underlined the importance of mutual trust. This involved the therapists showing the women that they had expectations regarding attendance and involvement. By expecting the women to show up, they reported an experience of being helpful to the women to feel committed to something. The therapists reported a feeling that this commitment might be what lead the woman to show up at practice even if they were having a bad day and wanted to stay at home.

Susan, a physical trainer, described building trust like this:

Of Course, we have to be clear and professional. However, that is not enough. You have to express care as well, for them to trust you. The trust is important.

Tabby, also a physical trainer, described the support a woman needed from her like this:

One of the women wanted me to stand beside her screaming, because she knew that she worked better if I pushed her.

Andrea, who is a dietitian, experienced that being open and direct herself helped the women:

In this treatment-program we discuss openly what happens to your body when you vomit or use laxatives or things like that. I feel that this helps the women to be more open in return, telling us about their experiences.

The importance of the mutual trust was described in different ways but represented evenly among all the ten therapists.

Creating a good group dynamic

The therapists described the groups as very different from each other in their way of functioning. Some groups were well established rather immediately, resulting in a good environment where almost every session was perceived as mutually rewarding and fulfilling. Other groups had a poorer start resulting in a lot of absence, maybe even dropouts.

To contribute in making a good group, the therapists reported being aware of the need to facilitate getting to know one another and having fun together. The physical trainers would sometimes get help from a woman coping with an exercise to help another group participant. However, they also reported being aware of the possibility that this would lead someone coping less well to feel even worse. The physical trainers also described working against groupings by varying who exercised together each time. In general, all the therapists reported working in a manner that would leave a space for every woman in

the groups. Working together as a team, the therapists emphasised the importance of giving each other time to follow the women out into the hallway to talk and comfort when they had a tough time.

Andrea, a dietitian, explained how she contributed to making a good group:

We try to give all the participants the space they need to talk, and sometimes we even have to make them.

Tracey, also a dietitian, described it like this:

It is challenging when we are working with groups, and some of them might have stronger personalities than others. Other women might even dislike them. As a therapist, you have to balance this, or make everyone accept that this is how it is.

All together, working towards good group dynamics was experienced as an important contribution.

DISCUSSION

The aim of this study has been to explore therapists' experiences of their contributions in providing a novel combination of PE and dietary therapy (the PED-t programme) for ED. The results showed that the PED-t therapists experienced that their professional knowledge about PE and nutrition was an important source of patients' trust in the PED-t programme.

Two main findings from this study may serve as indices of therapists' trust and confidence in their professional skills. First, the PED-t therapists reflected around the use of the knowledge they held, and focused on how this knowledge might serve as tools in the future recovery process for the patients. Indeed, it takes confidence to try to use own knowledge to provide others with transferrable skills beyond the original local constellation or context and beyond the mere purpose of adhering to a protocol. Moreover, the PED-t therapists regarded themselves as able to evaluate what knowledge was most important at any time. For instance, it was at times perceived as more important to ensure that the participants left a treatment session feeling good about themselves than always following the protocol. From a research point of view, to divert from the protocol is not very recommendable. Obviously, confidence is not a matter of notoriously breaching a protocol, but is rather a matter of profound knowledge and understanding of the general principles of the protocol, practical skills in implementing it, and the freedom to make temporary adjustments to accommodate for the immediate needs of the patient. In the general psychotherapy research, there is mixed evidence for the importance of confidence to treatment outcome.²⁰ However, in the field of ED, confidence has been found to be central to patients' positive experience of treatment success.²¹ Knowledge is a prerequisite for confidence, yet confidence indicates the ability to flexibly use one's knowledge.

Second, and in contrast to previous research,¹⁶ where therapists valued the focus on changing the behavioural symptoms of ED, this study shows that the PED-t therapists understood their personal qualities as fellow human beings as important for the progress of the participants. Personal qualities were manifested as a focus on creating a good group dynamic and a positive atmosphere through directly communicating empathy, interest and care. The mentioned personal qualities are also among the core qualities of alliance and a good relation between patients and therapists. The fact that the therapists in this study reported being empathic, interested and caring, and that they had no previous experience in treating ED patients, stands in contrast to previous findings²² showing that especially less-experienced clinicians tend to show negative reactions towards these kind of patients.

Our findings then align with psychotherapy research,^{20,23} highlighting the importance of a strong alliance for a good treatment outcome. Within the field of EDs, a meta-analysis¹⁷ shows a reciprocal relation between alliance and symptom change. The current study does not report on symptom change. However, one may at least expect that such change have been promoted by the fact that the therapists reported having been focused on providing tools for recovery as well as building trust between themselves and the group members. Thus, our findings indicate that the PED-t may be an excellent arena for building alliance, as the therapists were able to 'small talk' during the PE sessions and still with a mutual focus on the PEs. Awaiting experiential evidence from the participants, a high correspondence between therapists' focus and participants' priorities might be the case in the PED-t program. Forthcoming research including outcome measures of the intervention may elucidate whether such a possible correspondence is impeding or facilitating treatment progress and recovery.

A clinical implication from the therapists' experiences is that dietitians and specialists in PE can contribute in running a treatment programme for patients with ED. This aligns with dissemination trials with CBT.²⁴⁻²⁷ Hence, what is important seems not to have a particular professional background, but to have specific knowledge and understanding of the therapeutic procedures and the confidence to implement them in a clinical setting. Finally, the therapists also provided important experiences and ideas on how to redefine and adjust the PED-t programme. For instance, further to strengthen their confidence to the benefit of the patients, regular supervision and debriefing should be introduced. By own initiative, the PED-t therapists met on a regular basis throughout the treatment programme to reflect around their own contribution and potential challenges. Such meetings should be obligatory in a future implementation of the programme. In addition, the selection procedure might be slightly revised to provide more information about the purpose and procedures of the PED-t. On the other hand, the therapists expressed the importance of continuing including only patients with mild to severe

symptoms and not those with other, concurrent mental disorders who obviously might benefit from treatments not focusing on the ED. An obvious strength of the present study is the originality in reporting therapists' experiences with a specific treatment of ED. In a study under way, we will explore the experiences of the participating patients. Possible demand characteristic elicited by the recruitment procedure and the study context may have inflated the overall positive experiences reported by the therapists. However, such a limitation seems rather unlikely because diverse opinions and experiences were reported. For this reason, the present results may be transferrable to other clinical and non-clinical contexts. Hence, along with ED-relevant outcome measures, the experiential data may contribute to an evidence base for how the PED-t might be disseminated in new contexts, and possibly catching many sufferers who do not appear as patients in the healthcare system.

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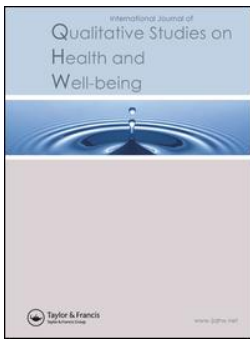
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REFERENCES

- Fichter MM, Quadflieg N, Hedlund S. Long-term course of binge eating disorder and bulimia nervosa: relevance for nosology and diagnostic criteria. *Int J Eat Disord* 2008;41:577–86.
- Keel PK, Brown TA. Update on course and outcome in eating disorders. *Int J Eat Disord* 2010;43:195–204.
- Vall E, Wade TD. Predictors of treatment outcome in individuals with eating disorders: a systematic review and meta-analysis. *Int J Eat Disord* 2015;48:946–71.
- Treasure J, Claudino AM, Zucker N, et al. Eating disorders. *Lancet* 2010;375:583–93.
- Sundgot-Borgen J, Rosenvinge JH, Bahr R, et al. The effect of exercise, cognitive therapy, and nutritional counseling in treating bulimia nervosa. *Med Sci Sports Exerc* 2002;34:190–5.
- Mathisen TF, Rosenvinge JH, Pettersen G, et al. 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. *BMC Psychiatry* 2017;17:180.
- Clinton D, Björck C, Sohlberg S, et al. Patient satisfaction with treatment in eating disorders: cause for complacency or concern? *Eur Eat Disord Rev* 2004;12:240–6.
- Newton T, Hartley P, Sturmey P. Treatment evaluation for eating disorders by clients with eating disorders. *Beh Cogn Psychother* 1993;21:371–4.
- Rosenvinge JH, Klusmeier AK. Treatment for eating disorders from a patient satisfaction perspective: a Norwegian replication of a British study. *Eur Eat Disord Rev* 2000;8:293–300.
- Swain-Campbell NR, Surgenor LJ, Snell DL. An analysis of consumer perspectives following contact with an eating-disorders service. *Aust N Z J Psychiatry* 2001;35:99–103.
- Bell L. What can we learn from consumer studies and qualitative research in the treatment of eating disorders? *Eat Weight Disord* 2003;8:181–7.
- de la Rie S, Noordenbos G, Donker M, et al. Evaluating the treatment of eating disorders from the patient's perspective. *Int J Eat Disord* 2006;39:667–76.
- Pettersen G, Rosenvinge JH, Wynn R. Eating disorders and psychoeducation--patients' experiences of healing processes. *Scand J Caring Sci* 2011;25:12–8.
- Pettersen G, Thune-Larsen KB, Wynn R, et al. Eating disorders: challenges in the later phases of the recovery process: a qualitative study of patients' experiences. *Scand J Caring Sci* 2013;27:92–8.
- Vanderlinden J, Buis H, Pieters G, et al. Which elements in the treatment of eating disorders are necessary "ingredients" in the recovery process? A comparison between the patient's and therapist's view. *Eur Eat Disord Rev* 2007;15:357–65.
- de la Rie S, Noordenbos G, Donker M, et al. The quality of treatment of eating disorders: a comparison of the therapists' and the patients' perspective. *Int J Eat Disord* 2008;41:307–17.
- Graves TA, Tabri N, Thompson-Brenner H, et al. A meta-analysis of the relation between therapeutic alliance and treatment outcome in eating disorders. *Int J Eat Disord* 2017;50:323–40.
- Malterud K. Systematic text condensation: a strategy for qualitative analysis. *Scand J Public Health* 2012;40:795–805.
- Oliver S, Liabo K, Stewart R, et al. Public involvement in research: making sense of the diversity. *J Health Serv Res Policy* 2015;20:1–7.
- Webb CA, Derubeis RJ, Barber JP. Therapist adherence/competence and treatment outcome: A meta-analytic review. *J Consult Clin Psychol* 2010;78:200–11.
- Pettersen G, Rosenvinge JH, Thune-Larsen KB, et al. Clinical confidence following an interprofessional educational program on eating disorders for health care professionals: a qualitative analysis. *J Multidiscip Healthc* 2012;5:201.
- Thompson-Brenner H, Satir DA, Franko DL, et al. Clinician reactions to patients with eating disorders: a review of the literature. *Psychiatr Serv* 2012;63:73–8.
- Horvath AO, Del Re AC, Flückiger C, et al. Alliance in individual psychotherapy. *Psychotherapy* 2011;48:9–16.
- Fairburn CG, Patel V. The global dissemination of psychological treatments: a road map for research and practice. *Am J Psychiatry* 2014;171:495–8.
- Fairburn CG, Patel V. The impact of digital technology on psychological treatments and their dissemination. *Behav Res Ther* 2017;88:19–25.
- Fairburn CG, Wilson GT. The dissemination and implementation of psychological treatments: problems and solutions. *Int J Eat Disord* 2013;46:516–21.
- Montgomery EC, Kunik ME, Wilson N, et al. Can paraprofessionals deliver cognitive-behavioral therapy to treat anxiety and depressive symptoms? *Bull Menninger Clin* 2010;74:45–62.

Paper II

Paper III



A new treatment for eating disorders combining physical exercise and dietary therapy (the PED-t): experiences from patients who dropped out

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A new treatment for eating disorders combining physical exercise and dietary therapy (the PED-t): experiences from patients who dropped out

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ABSTRACT

Purpose: Eating disorders (ED) are complex and severe illnesses where evidence-based treatment is needed to recover. However, about half of the patients with ED do not respond to treatments currently available, which call for efforts to expand the portfolio of treatments. The aim of this study was to explore experiences from patients who dropped out of a new treatment for bulimia nervosa and binge ED, combining physical exercise and dietary therapy (PED-t).

Methods: We conducted open-ended face-to-face interviews. The interviews were transcribed verbatim and the data were analysed with a phenomenological hermeneutical approach.

Results: Three themes emerged: "standing on the outside", "unmet expectations" and "participation not a waste of time". Feelings of standing on the outside were elicited by being different from other group members and having challenges with sharing thoughts. Unmet expectations were related to treatment content and intensity, as well as the development of unhealthy thoughts and behaviours. Finally, some positive experiences were voiced.

Conclusion: A need to clarify pre-treatment expectations and refining criteria for treatment suitability is indicated. The findings have contributed to the chain of clinical evidence regarding the PED-t and may lead to treatment modifications improving the treatment and thereby reducing drop out.

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Eating disorders; treatment; qualitative analysis; patient experiences; dropout

Introduction

Family-based therapy and cognitive-behavioural therapy (CBT) are recommended in several treatment guidelines worldwide and appear as generally accepted evidence-based treatments for eating disorders (ED). However, about half of the patients with ED fail to respond to such treatments (Linardon & Wade, 2018; Wilson, Grilo, & Vitousek, 2007).

Considering the severity of ED, these findings call for efforts to include new treatments in the portfolio of evidence-based treatments. A second reason to increase the portfolio of treatments refers to the diversity of factors that maintain ED or that may help in the recovery process. As far as general societal health is concerned, new treatments should address the most prevalent EDs, i.e., bulimia nervosa (BN) and binge eating disorder (BED) (Rosenvinge & Pettersen, 2015).

A new treatment for patients with BN and BED combining physical exercise and dietary therapy (PED-t) has been developed (Mathisen et al., 2017). The PED-t rests on a conceptual model positing the beneficial effects of physical activity for improving mental health (Lubans et al., 2016). Such effects are documented in the treatment of several mental illnesses, notably depression (Josefsson, Lindwall, & Archer, 2014; Rosenbaum, Tiedemann, & Ward, 2014) and anxiety (Jayakody, Gunadasa, & Hosker, 2013). As for EDs, dietary consultations have promoted an early change in eating routines and enhanced outcomes from established treatment modules (Hsu et al., 2001; Painot, Jotterand, Kammer, Fossati, & Golay, 2001), also for BN (Sundgot-Borgen, Rosenvinge, Bahr, & Schneider, 2002). A randomized controlled trial (RCT) conducted in Norway that framed the present study has so far shown that the PED-t performs equally effective as CBT in alleviating BN and BED

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symptoms both immediately and at a one-year follow-up (Mathisen, 2018).

There may be a disparity between a statistically significant effect and the patients' experiences of a given treatment. This is an important reason why exploring patients' treatment experiences is generally recognized as part of clinical evidence (Richards & Hallberg, 2015). Accordingly, previous studies have explored treatment experiences among the patients who completed the PED-t (Bakland et al., 2019; Pettersen et al., 2017) as well as their pre-treatment expectations (Pettersen et al., 2019). No disparity was detected between the statistically significant effects and their general positive experiences. Overall, the PED-t stands out as helpful in promoting recovery from BN and BED. Importantly, patients' experiences echoed the experiences reported by the PED-t therapists (Bakland et al., 2018). However, some patients wished a more flexible time-frame to allow booster sessions, and voiced feelings of being "different" in terms of age, interests or the nature of their ED (Bakland et al., 2019; Pettersen et al., 2017). These findings were congruent with previous studies which explored treatment experiences with several treatment approaches to ED (Krautter & Lock, 2004; Lose et al., 2014; Money, Genders, Treasure, Schmidt, & Tchanturia, 2011; Poulsen, Lunn, & Sandros, 2010; Sánchez-Ortiz et al., 2011) in terms of overall positive experiences, yet with suggestions for improvements.

In RCT studies, intention-to-treat analyses, as well as dropout analyses, are important sources of knowledge about treatment efficacy. Qualitative studies should follow the same kind of logic and explore experiences among patients who drop out of treatment. Such studies are needed to capture more of the variety of experiences, and which may be under-reported in the traditional treatment-satisfaction studies (Pettersen et al., 2018). However, to our knowledge, no previous qualitative studies have specifically addressed ED patients who have dropped out of a treatment with the intention to explore their treatment experiences. To accommodate this need, the aim of the present study was to explore the experiences of patients who dropped out of the PED-t treatment.

Methods

Context and treatment

The study context was an RCT conducted between 2014–2016 that compared the PED-t treatment with CBT (Mathisen et al., 2017). During 4 months, both treatments were run in a 20-session group therapy format with 5–8 participants per group. The training programme in the PED-t treatment consisted of three weekly exercise sessions, each lasting 40–60 min. Two sessions were resistance exercise, of which physical trainers supervised one. The third session consisted of unsupervised interval

running. Following a traditional pyramid structure, the running program comprised progressive interval periods and active rest periods. The dietary therapy was led by a dietician and included three psychoeducative modules "dietary routines and structure" (five sessions), "nutritional knowledge and practical skills" (12 sessions), and "summary and future plans" (three sessions). Further details about the nature and rationale of the treatment are provided elsewhere (Mathisen et al., 2017; Pettersen et al., 2018).

User advisory group

A user advisory group may improve the relevance and quality of research (Oliver, Liabo, Stewart, & Rees, 2015). Accordingly, in the present study, two members from a national ED patient organization were included. In regular meetings with the research group, they shared their personal experiences with ED treatment and contributed to the understanding and analyses of the data as well as in the writing of the present paper.

Participants

The principal investigator (JSB) contacted all 15 women who did not complete at least 80% of the treatment, with information about, and a request to participate in the present study. Informed consent from five participants was returned to the first author (MB). Their age ranged from 21 to 41 years. Three participants had BN, two had BED, and four reported a history of anorexia nervosa. One woman had children and lived with a partner. Three of them were studying at the university and two were employed. The women had completed between 2 and 10 of the 20 treatment sessions in total.

Data collection

Face-to-face interviews were carried out at locations of the participants' choice. The interviewer had a professional background as a nurse in the mental health field and no prior relations to the participants. Striving for openness towards the women's experiences, they were encouraged to talk freely responding to one open-ended question: Can you (as one of those who left the PED-t) please tell me about your experiences with participating in the treatment? Follow-up questions were used to gain a deeper understanding of areas that seemed essential for each woman. The duration of the interviews ranged between 1 and 1.5 h and they were not repeated. To compensate for travel expenses and other costs, all participants received a gift card of NOK 250 (approximately USD 32). The audio-recorded interviews were transcribed verbatim.

Data analysis

The consolidated criteria for reporting qualitative research (COREQ) (Tong, Sainsbury, & Craig, 2007) were used to promote explicit and comprehensive reporting of the research data. We performed an inductive, three-step data analysis inspired by a phenomenological hermeneutical approach and an interpretation theory of discourse (Lindseth & Norberg, 2004; Ricoeur, 1976). This approach is suitable to explore lived experiences and involves a dialectic movement between the parts of the text and the text as a whole (Lindseth & Norberg, 2004). In the first step, a repetitive, *naïve reading of the whole* text was done to grasp an immediate understanding of the content and what it communicated. Next, a *structural analysis* divided the text into meaning units based on sentences or sections reflecting the research question and eventually themes disclosing meaning were formulated. The third step involved a *comprehensive understanding*. Here, the themes were summarized and reflected on in relation to the aim and context of the study, the authors' pre-understandings, the naïve reading of transcripts, the structural analysis, and relevant literature (Lindseth & Norberg, 2004). All authors continuously monitored and discussed the analysis until consensus was reached about how to best interpret the data.

Ethical considerations and data security

The RCT study was registered in the Clinical Trials registry (identifier: NCT02079935). The Norwegian Regional Committee for Medical and Health Research Ethics approved the present study (identifier: 2013/1871) based on the Helsinki declaration of informed consent, data security and the option to withdraw unconditionally upon request.

Results

Three themes emerged from the analysis, reflecting experiences from those who dropped out from the PED-t. The themes were "standing on the outside", "unmet expectations" and "participation not a waste of time". Each theme is presented below along with sub-themes and illustrative quotations from the interviews.

Standing on the outside

Feeling different

A feeling of being different from other group members was evident, and the participants related their feelings of being different to life in general, age, interests, or being in other phases in terms of illness severity and recovery. One woman who had been ill for many years was afraid that the others' inexperience would affect her benefits of participating:

I was the oldest and I have participated in treatment so many times in the past. The other women had never talked to anybody about their problem. I was afraid that I would fall back into the position of being the one who supports all the others (Participant 2).

A feeling of being different also emerged from listening to other participants talk about their overeating. One woman said:

Maybe I was not in the right target group. The amounts of food the other women talked about was unnatural for me. What I believe is overeating, might not be overeating after all (Participant 5).

Feeling different was furthermore related to previous experiences with physical exercise. Some participants were familiar with exercise and exercised daily before starting the treatment, whilst others had never exercised on a regular basis. These differences affected how the women experienced their benefit from participating in the treatment:

I had no problem talking to the other women, but they were just so different from me in terms of eating and exercising. I believe the treatment would have been more beneficial if the women in my group shared my interests, because then we might have talked about something relevant to me (Participant 4).

Having challenges with sharing thoughts

This subtheme was related to a lack of group atmosphere allowing participants to share mutual experiences in one united conversation. Rather, group discussions tended to evolve around one-to-one conversations between a group member and the therapist. In addition, some women occupied more time by talking than the other group members:

Three of the others in my group took a lot of space. Because of that, I often found myself in a listening position. I had a lot to say but I was never able to share my thoughts (Participant 1).

Perceived lack of experiences of exposing sensitive issues to others could worsen the communication with other group members:

When I came here for the first time, we sat down in a circle to talk about ourselves. This was a bit sudden to me, and I struggled and started crying. I dislike speaking to a group like that and I returned home with a headache (Participant 1).

Unmet expectations

Needing more treatment intensity and support

The need for higher intensity and more support was generated from challenges in implementing the acquired knowledge in their daily life. One such challenge was to make good choices about meal compositions:

The dietary therapy was difficult because I had expected it to be more specific. Food has always been an issue for

me and I felt that they did not go deep enough into the details and left me with too many choices. I wished there would have been a fixed plan for me to follow, on what to eat and when (Participant 3).

Other kinds of challenges were to harmonize the amount of foods and the level of physical exercise:

The therapists told me to exercise less and eat more. I wanted to go all in and do this, but I felt I was not receiving the support I needed. For me to be able to do that, I would have needed to talk to the therapists almost every day (Participant 4).

In addition, those who were unfamiliar with doing physical exercise found it challenging to comply with the exercise programme between each supervised treatment session:

There were too many days where I had to do everything by myself. Gradually I realized that I needed a more intensive treatment, like every other day. Then I might have been able to develop some good routines. When they asked me how I had done since we last met, I did not want to answer because I had not done so well (Participant 1).

Finally, unmet expectations were related to vague and imprecise requirements from the therapists:

The therapists' guidance and suggestions were too vague for me. I need someone to be direct and strict, explaining me that I need to do this for myself, and that I need to work harder (Participant 3).

Lacking trust

Trusting the therapists' advice seemed to be difficult for the participants. For instance, the dietary advice was experienced as too focused on rights and wrongs with little room for flexibility. Another challenge was believing in the sufficiency of the treatments exercise programme. A fear of gaining weight challenged the women's ability to let go of their already established routines;

I was extremely preoccupied with losing weight and did not trust the advice they gave me. Of course, I was afraid to gain weight by giving away control. Eating more and exercising less was not an alternative in my mind (Participant 4).

Lack of trust was also related to the programme and its rationale:

This experience has taught me that when you are ill enough to let your eating disorder run your daily life, you need something more than this treatment. Trying to follow advice on an ideal amount of food and exercise is not enough (Participant 5).

Lastly, lacking trust was experienced as the treatment was run outside a health service institution, and by therapists not obliged by a professional secrecy and code of ethics:

I have never told anyone that I have an ED earlier. You never know if they will keep their promise. I remember having a moment when it was my turn to talk and so I did. Afterwards I did not feel good about that. I guess I never felt completely safe in the treatment setting (Participant 5).

Developing unhealthy thoughts and behaviours

Unmet expectations were also generated by feelings that the programme elicited unhealthy thoughts and behaviours. The focus on nutrients and meals in the dietary therapy was experienced as stressful, particularly for those with a history of anorexia nervosa, and who had worked for a long time to eliminate such a focus. Despite the therapists' advice, the preoccupation of calorie counting revived;

I downloaded the calorie-counting app that I had used on my phone earlier. I told myself that the app was not dangerous in itself. That is how the ball started rolling. Luckily, I was able to stop this unhealthy thinking early enough (Participant 1).

Being weighed at each treatment session was also challenging. Participants found themselves focusing on the weight results, which in return, triggered their weight and shape preoccupation;

We had to step on the weight each session, and I questioned this because I had been strongly advised the opposite when I was struggling with my anorexia. I decided it became too much of an unhealthy focus for me (Participant 1).

Finally, adding the treatments' exercise programme on top of one's own daily exercise routine led to a situation where one exercised too much. One woman reflected around her experience in the following way:

For each treatment session, I felt that something was wrong. I did not expect that the treatment would trigger my eating disorder, but I really became worse. I had expected an easier process and developing a healthier view on everything, but I ended up feeling a pressure to perform (Participant 5).

Participation not a waste of time

Despite dropping out of the treatment, participants also voiced positive experiences and feelings of having utilized the potentials of the programme. In particular, some knowledge and tools were acquired. For example, it was beneficial to become more aware of their ED problem. Furthermore, participants experienced that the programme was helpful in regulating and normalizing the amount of physical exercise from being excessive or just to start exercising. Finally, there was a value in learning about the plate model and various nutrients needed in order to stay healthy:

I feel healthier now. I believe what I needed was some time and space after the treatment to let the knowledge mature. I still have days were I snap and eat too much, but now I have learned something about what too much really means (Participant 1).

Discussion

This study reports on views from patients who dropped out from a new treatment for ED. Overall, patients who dropped out from the PED-t treatment experienced that they were different from other group members and felt that they stood outside. Important sources of such feelings were differences in symptom load, age, interests and life in general, as well as challenges with sharing thoughts. In addition, these patients reported some unmet expectations in terms of treatment content and intensity, and some described developing an unhealthy preoccupation with nutrients, physical exercise and weight. Finally, the patients experienced having gained some knowledge and tools and making use of this knowledge subsequently.

Feelings of standing on the outside are consistent with a previous study (Bakland et al., 2018) from our research group, and which explored experiences among the therapists who provided the PED-t. They reported that patients' monopolization of group sessions jeopardized their efforts to create an including group climate. Challenges in establishing a mutual relationship between individuals in a treatment group are, however, generic, and not confined to ED or the PED-t (Hummelen, Wilberg, & Karterud, 2007) or to patients who actually completed the PED-t (Bakland et al., 2019). Such findings align with a recent meta-analysis (Burlingame, McClendon, & Yang, 2018) demonstrating that group cohesion contributes to outcomes across a variety of clinical conditions and therapeutic settings. Group-leaders in all theoretical orientations are therefore encouraged to foster cohesion. A further refinement of the PED-t should consider a stronger focus on selection criteria.

A plea for more treatment sessions and follow-up is a general finding which is also evident among other patient groups (Hummelen et al., 2007; Kerkelä, Jonsson, Lindwall, & Strand, 2015). However, the present results point to more specified issues, like the need for more support in implementing physical exercise and new dietary routines, as well as more support in the patients' daily lives. Such issues align with other findings showing that experienced treatment benefits are linked to therapists' availability and time to listen and understand the person behind the ED (Pettersen & Rosenvinge, 2002). In a further implementation of the PED-t program, a stronger focus on pre-treatment patient expectations may be important to address motivation.

The plea for more treatment sessions and therapist support could easily be complied for in future use of PED-t; however, the present study also revealed that the patients experienced the treatment as time-consuming and that the focus on nutrients and exercise caused stress. This aligns with previous findings suggesting that an important reason why patients drop out of treatment is to reduce the intensity of the treatment (Nordheim et al., 2018). Again, this may point to a need for discussing motivation for change and pre-treatment expectations. Moreover, having a history of anorexia nervosa seemed to have caused extra challenges with regards to nutrients and being weighted. This point reiterates the argument that the future implementation of the PED-t may need a stronger focus on treatment selection criteria. Such a variety of patient experiences represent a challenge when planning for treatments to fit individual needs.

A strength to this study is its originality in terms of exploring treatment-experiences from ED patients who have dropped out from a particular treatment. Adding credibility to the findings is the fact that the interviewer had no prior relation to the participants or in the developing and implementation of the PED-t. In addition, the data analysis and interpretations were conducted with a user involvement approach. A possible limitation was the sample size. The fact that only five of the 15 eligible patients were willing to participate may have restricted the variety of experiences.

Conclusion

Our findings point to general challenges in developing procedures to explore treatment suitability, as well as capturing diversities between pre-treatment expectations and treatment content. Such procedures are relevant to promote general treatment effect factors like treatment alliance and group cohesion. To include experiences from patients who dropped out has added variety to previous studies of patient experiences with the PED-t treatment (Bakland et al., 2019; Pettersen et al., 2017). Moreover, the findings have contributed to the chain of clinical evidence of the PED-t and may lead to important treatment modifications in order to improve the treatment and thereby reduce drop out.

Disclosure statement

No potential conflict of interest was reported by the authors.

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References

Bakland, M., Rosenvinge, J. H., Wynn, R., Sundgot-Borgen, J., Fostervold Mathisen, T., Liabo, K., ... Pettersen, G. (2019). Patients' views on a new treatment for Bulimia nervosa and binge eating disorder combining physical exercise and dietary therapy (the PED-t). A qualitative study. *Eating Disorders*, 27(6), 503–520.

Bakland, M., Sundgot-Borgen, J., Wynn, R., Rosenvinge, J. H., Stornæs, A. V., & Pettersen, G. (2018). Therapists' experiences with a new treatment combining physical exercise and dietary therapy (the PED-t) for eating disorders: An interview study in a randomised controlled trial at the Norwegian School of Sport Sciences. *BMJ Open*, 8(1), e019386.

Burlingame, G. M., McClendon, D. T., & Yang, C. (2018). Cohesion in group therapy: A meta-analysis. *Psychotherapy*, 55(4), 384–398.

Hsu, L., Rand, W., Sullivan, S., Liu, D., Mulliken, B., McDonagh, B., & Kaye, W. (2001). Cognitive therapy, nutritional therapy and their combination in the treatment of bulimia nervosa. *Psychological Medicine*, 31(5), 871–879.

Hummelen, B., Wilberg, T., & Karterud, S. (2007). Interviews of female patients with borderline personality disorder who dropped out of group psychotherapy. *International Journal of Group Psychotherapy*, 57(1), 67–92.

Jayakody, K., Gunadasa, S., & Hosker, C. (2013). Exercise for anxiety disorders: Systematic review. *British Journal of Sports Medicine*, 48, 187–196. [bjsports-2012-091287](https://doi.org/10.1136/bjsports-2012-091287).

Josefsson, T., Lindwall, M., & Archer, T. (2014). Physical exercise intervention in depressive disorders: Meta-analysis and systematic review. *Scandinavian Journal of Medicine and Science in Sports*, 24(2), 259–272.

Kerkelä, E. S., Jonsson, L., Lindwall, M., & Strand, J. (2015). Individual experiences following a 6-month exercise intervention: A qualitative study. *International Journal of Qualitative Studies on Health and Well-being*, 10(1), 26376.

Krautter, T., & Lock, J. (2004). Is manualized family-based treatment for adolescent anorexia nervosa acceptable to patients? Patient satisfaction at the end of treatment. *Journal of Family Therapy*, 26(1), 66–82.

Linardon, J., & Wade, T. D. (2018). How many individuals achieve symptom abstinence following psychological treatments for bulimia nervosa? A meta-analytic review. *International Journal of Eating Disorders*, 51(4), 287–294.

Lindseth, A., & Norberg, A. (2004). A phenomenological hermeneutical method for researching lived experience. *Scandinavian Journal of Caring Sciences*, 18(2), 145–153.

Lose, A., Davies, C., Renwick, B., Kenyon, M., Treasure, J., Schmidt, U., & group, M. T. (2014). Process evaluation of the maudsley model for treatment of adults with anorexia nervosa trial. Part II: Patient experiences of two psychological therapies for treatment of anorexia nervosa. *European Eating Disorders Review*, 22(2), 131–139.

Lubans, D., Richards, J., Hillman, C., Faulkner, G., Beauchamp, M., Nilsson, M., ... Biddle, S. (2016). Physical activity for cognitive and mental health in youth: A systematic review of mechanisms. *Pediatrics*, 138, e20161642.

Mathisen, T. F. (2018). *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* (Doctoral dissertation). Norwegian School of Sports sciences.

Mathisen, T. F., Rosenvinge, J. H., Pettersen, G., Friberg, O., Vrabel, K., Bratland-Sanda, S., ... Wynn, R. (2017). 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. *BMC Psychiatry*, 17(1), 2–11.

Money, C., Genders, R., Treasure, J., Schmidt, U., & Tchanturia, K. (2011). A brief emotion focused intervention for inpatients with anorexia nervosa: A qualitative study. *Journal of Health Psychology*, 16(6), 947–958.

Nordheim, K., Walderhaug, E., Alstadius, S., Kern-Godal, A., Arnevik, E., & Duckert, F. (2018). Young adults' reasons for

- dropout from residential substance use disorder treatment. *Qualitative Social Work*, 17(1), 24–40.
- Oliver, S., Liabo, K., Stewart, R., & Rees, R. (2015). Public involvement in research: Making sense of the diversity. *Journal of Health Services Research and Policy*, 20(1), 45–51.
- Painot, D., Jotterand, S., Kammer, A., Fossati, M., & Golay, A. (2001). Simultaneous nutritional cognitive-behavioural therapy in obese patients. *Patient Education and Counseling*, 42(1), 47–52.
- Pettersen, G., & Rosenvinge, J. H. (2002). Improvement and recovery from eating disorders: A patient perspective. *Eating Disorders*, 10(1), 61–71.
- Pettersen, G., Rosenvinge, J. H., Bakland, M., Wynn, R., Mathisen, T. F., & Sundgot-Borgen, J. (2018). Patients' and therapists' experiences with a new treatment programme for eating disorders that combines physical exercise and dietary therapy: The PED-t trial. A qualitative study protocol. *BMJ Open*, 8(1), e018708.
- Pettersen, G., Rosenvinge, J. H., Skomakerstuen, T., Sordal, S., Mathisen, T. F., & Sundgot-Borgen, J. (2019). Patient expectations of a new treatment for eating disorders combining guided physical exercise and dietary therapy: An interview study of women participating in a randomised controlled trial at the Norwegian School of Sport Sciences. *BMJ Open*, 9(4), e025344.
- Pettersen, G., Sørđal, S., Rosenvinge, J. H., Skomakerstuen, T., Mathisen, T. F., & Sundgot-Borgen, J. (2017). How do women with eating disorders experience a new treatment combining guided physical exercise and dietary therapy? An interview study of women participating in a randomised controlled trial at the Norwegian School of Sport Sciences. *BMJ Open*, 7(12), e018588.
- Poulsen, S., Lunn, S., & Sandros, C. (2010). Client experience of psychodynamic psychotherapy for bulimia nervosa: An interview study. *Psychotherapy: Theory, Research, Practice, Training*, 47(4), 469–483.
- Richards, D. A., & Hallberg, I. R. (2015). *Complex interventions in health: An overview of research methods* (D. A. Richards & I. R. Hallberg Eds.). New York: Routledge.
- Ricœur, P. (1976). *Interpretation theory: Discourse and the surplus of meaning*. Fort Worth, TX: Texas Christian University Press.
- Rosenbaum, S., Tiedemann, A., & Ward, P. B. (2014). Meta-analysis physical activity interventions for people with mental illness: A systematic review and meta-analysis. *Journal of Clinical Psychiatry*, 75, 1–11.
- Rosenvinge, J. H., & Pettersen, G. (2015). Epidemiology of eating disorders part II: An update with a special reference to the DSM-5. *Advances in Eating Disorders*, 3(2), 198–220.
- Sánchez-Ortiz, V., House, J., Munro, C., Treasure, J., Startup, H., Williams, C., & Schmidt, U. (2011). "A computer isn't gonna judge you": A qualitative study of users' views of an internet-based cognitive behavioural guided self-care treatment package for bulimia nervosa and related disorders. *Eating and Weight Disorders-Studies on Anorexia, Bulimia and Obesity*, 16(2), e93–e101.
- Sundgot-Borgen, J., Rosenvinge, J. H., Bahr, R., & Schneider, L. S. (2002). The effect of exercise, cognitive therapy, and nutritional counseling in treating bulimia nervosa. *Medicine and Science in Sports and Exercise*, 34(2), 190–195.
- Tong, A., Sainsbury, P., & Craig, J. (2007). Consolidated criteria for reporting qualitative research (COREQ): A 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*, 19(6), 349–357.
- Wilson, G., Grilo, C. M., & Vitousek, K. M. (2007). Psychological treatment of eating disorders. *American Psychologist*, 62(3), 199–216.

Appendix 1

Informed consent forms for therapists (in Norwegian)

Forespørsel om å delta i studien «Behandling av spiseforstyrrelser gjennom trenings- og kostholdsrådgivning - en kvalitativ studie av instruktørens erfaringer»

Bakgrunn og formål

Dette er et spørsmål til deg om å delta i en forskningsstudie om erfaringer ved å være instruktør ved FAKT-studien. Det er som treningsinstruktør for pasienter med spiseforstyrrelser du nå forespørres om du vil delta i denne «erfaringsstudien».

De subjektive erfaringer og opplevelser ved å være instruktør for denne pasientgruppen vil kunne bidra til å avdekke forhold rundt hvordan utdanningen og således kompetansen til din yrkesgruppe i fremtiden kan bidra ved behandling av spiseforstyrrelser. Erfaringene dine er også nyttige for å få et fullstendig bilde av den samlede nytteverdi av nye behandlingsmetoder ved spiseforstyrrelser.

Hva innebærer undersøkelsen?

For å kunne delta må du samtykke til å møte frem ved Norges Idrettshøgskole, eller annet ønsket møtested, der du vil bli intervjuet av phd-student Maria Bakland. Temaet under intervjuene vil være hvordan du har opplevd å være instruktør i selve behandlingsstudiet, det kan være både gode og mindre gode erfaringer, og de kan være knyttet til selve behandlingsopplegget, din kompetanse, hvordan du opplevde pasientene eller andre ting du ønsker å trekke frem.

Intervjuet varer ca. 60 min, og et samtykke innebærer at vi tar opp samtalen med deg på bånd. Lydopptaket vil senere bli skrevet ut som tekst og systematisert.

Hva skjer med informasjonen om deg?

Det er kun intervjuerne, samt prosjektleder som har tilgang til lydbåndversjonen av intervjuet med deg, og båndene oppbevares i låssikkert skap ved Universitetet i Tromsø. Når tekstversjonen av intervjuet foreligger vil det ikke være personopplysninger som direkte eller indirekte kan føres tilbake til deg som person, men både lydopptak og tekstversjon får et unikt identifikasjonsnummer. For alle deltagere i studien vil det da foreligge en «kodeliste» som kobler lydbånd- og tekstversjon. Kodelisten oppbevares på samme måte og med samme adgangsbegrensninger som selve lydbåndene. Når alle tekstversjonene er systematisert, destrueres kodelisten. Dette vil si at de intervjutekster som skal systematiseres er anonymisert.

Tekstversjonen av alle intervjuer vi gjør i studien vil så ytterligere systematiseres, og utgjør datagrunnlaget til studiet som vil inngå som en del av en doktorgrad. Deretter vil dataene danne grunnlag for artikler i vitenskapelige tidsskrifter som er offentlig tilgjengelige. Det er en mulighet for at du selv kan gjenkjenne sitater fra deg i slike publikasjoner, men slik datahåndteringen er beskrevet ovenfor og ut fra generelle krav til anonymisering i vitenskapelige artikler, vil ikke *andre* kunne vite hva nettopp du har sagt i intervjuet.

Informasjonen du gir under intervjuene skal bare brukes i denne studien, ikke til andre studier med lignende eller andre formål. Det skal heller ikke gjøres koplinger til offentlige registre.

Frivillig deltakelse

Det er frivillig å delta i studien. Det betyr også at du står fritt til å trekke deg når som helst uten at det får konsekvenser. Gjør du det har du rett til å kreve at opplysningene om deg vil bli slettet. Kravet kan imøtekommes dersom det fremmes før listen som kobler lydbåndversjonen og tekstversjonen av ditt intervju blir slettet.

Hvis du samtykker til å delta i studien ber vi deg bekrefte dette ved å undertegne vedlagte samtykkeerklæring. Når vi har mottatt erklæringen ønsker vi å kontakte deg for å avtale intervjutidspunkt og sted.

Har du spørsmål som ikke er omtalt i dette informasjonsskrivet kan du kontakte enten prosjektleder eller en av prosjektmedarbeiderne:

Maria Bakland, Phd-student; maria.bakland@uit.no, 91 69 54 06

Gunn Pettersen, Førsteamanuensis/prosjektmedarbeider; gunn.pettersen@uit.no,
776 66069/ 99271842

Jorunn Sundgot-Borgen, Prosjektleder; jorunn.sundgot-borgen@nih.no, 92241745

Samtykke til deltakelse i forskningsstudien;

Behandling av spiseforstyrrelser gjennom trenings- og kostholdsrådgivning

- en kvalitativ studie av instruktørens erfaringer

Jeg

.....

har lest gjennom informasjonsskrivet og samtykker herved til å delta i prosjektet.

Min deltakelse er frivillig og jeg kan på hvilket som helst tidspunkt trekke meg fra å delta. Jeg mottar ingen lønn eller annen godtgjørelse for min deltakelse.

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Sted

Dato

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Signatur

Appendix 2

Informed consent forms for patients (in Norwegian)

Forespørsel om å delta i et intervju som inngår som en del-studie av den FAKT-studien som du er en del av.

Bakgrunn og formål

Det er svært ønskelig å få vite mer om hvordan dere som har deltatt i behandlingsstudien har opplevd det å delta. Vi har trukket tilfeldig fra gruppen som har deltatt og du er en av de som vi har trukket ut. Dette er altså et spørsmål til deg om å delta i et intervju angående dine erfaringer ved å være med i behandlingsstudien. Studien inngår i den undersøkelsen du deltar/har deltatt i og som ser på effekt av ulike behandlingsmåter ved spiseforstyrrelser (FAKT). I hovedstudien ser vi på effekt ut fra fysiske prøver og hvordan du svarer på ulike spørreskjemaer, mens vi i dette intervjuet ønsker å høre om dine erfaringer.

De subjektive erfaringer og opplevelser ved å være med i en slik behandlingsstudie er et viktig supplement til spørreskjemaer og fysiske prøver for å få et så fullstendig bilde av den samlede nytteverdi av nye behandlingsmetoder ved spiseforstyrrelser.

Hva innebærer undersøkelsen?

For å kunne delta må du samtykke til å bli intervjuet av PH.D-student Maria Bakland som også er en del av forskningsgruppa vår, men som dere ikke tidligere har møtt. Maria kan møte deg ved NIH, hjemme hos deg hvis ønskelig, eller annet egnet møterom, for eksempel på et hotell. Det er også mulig å velge når på dagen/kvelden det passer deg best. Temaet under intervjuene er hvordan du har opplevd å delta i selve behandlingsstudien, det kan være både gode og mindre gode erfaringer, og de kan være knyttet til selve behandlingsopplegget, hvordan du opplevde terapeuter eller med-deltagere eller til andre ting du ønsker å trekke frem.

Intervjuet varer ca. 60-90 min, og et samtykke innebærer at vi tar opp samtalen med deg på bånd. Lydopptaket vil senere bli skrevet ut som tekst og systematisert.

Hva skjer med informasjonen om deg?

Det er kun Maria som vil ha tilgang til lydbåndversjonen av intervjuet med deg, og båndene oppbevares i låssikkert skap på hennes kontor ved Universitetet i Tromsø. Når tekstversjonen av intervjuet foreligger vil det ikke foreligge personopplysninger som direkte eller indirekte kan føres tilbake til deg som person, men både lydopptak og tekstversjon får et unikt

identifikasjonsnummer. For alle deltagere i studien vil det da foreligge en «kodeliste» som kobler lydbånd- og tekstversjon. Kodelisten oppbevares på samme måte og med samme adgangsbegrensninger som selve lydbåndene. Når alle tekstversjonene er systematisert, destrueres kodelisten. Dette vil si at de intervjuetekster som skal systematiseres er anonymisert.

Tekstversjonen av alle intervjuer som gjøres i studien vil så ytterligere systematiseres, og utgjør datagrunnlaget for studiene som blir en del av Marias doktorgrad. Deretter vil dataene danne grunnlag for artikler i vitenskapelige tidsskrifter som er offentlig tilgjengelige. Det er en mulighet for at du selv kan gjenkjenne sitater fra deg i slike publikasjoner, men slik datahåndteringen er beskrevet ovenfor og ut fra generelle krav til anonymisering i vitenskapelige artikler, vil ikke *andre* kunne vite hva nettopp du har sagt i intervjuet.

Informasjonen du gir under intervjuene skal bare brukes i denne studien, ikke til andre studier med lignende eller andre formål. Det skal heller ikke gjøres koplinger til offentlige registre.

Frivillig deltakelse

Det er frivillig å delta i studien. Det betyr også at du står fritt til å trekke deg når som helst uten at det får konsekvenser. Gjør du det har du rett til å kreve at opplysningene om deg vil bli slettet.

Hvis du samtykker til å delta i studien ber vi deg bekrefte dette ved å sende en mail til Maria innen 1 Mai 2017. Når hun har mottatt mail avtaler dere tid og sted for intervju. De som deltar vil få et gavekort på 250 kroner. Har du spørsmål som ikke er omtalt i dette informasjonsskrivet kan du kontakte meg eller en av prosjektmedarbeiderne:

Jorunn Sundgot-Borgen Prosjektleder, Norges Idrettshøgskole, E-mail: Jorunn.sundgot-Borgen@nih.no

Maria Bakland, PH. D-student, Universitetet i Tromsø E-mail: maria.bakland@uit.no

Tlf: 91 69 54 06

Gunn Pettersen, veileder, Universitetet i Tromsø E-mail: gunn.pettersen@uit.no

Tlf: 99271842

Samtykke til deltakelse i forskningsstudien;

Behandling av spiseforstyrrelser gjennom trenings- og kostholdsrådgivning

- en kvalitativ studie av deltakernes erfaringer

Jeg

har lest gjennom informasjonsskrivet og samtykker herved til å delta i prosjektet.

Min deltakelse er frivillig og jeg kan på hvilket som helst tidspunkt trekke meg fra å delta.

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Sted

Dato

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Signatur

Appendix 3

Informed consent forms for patients who dropped of the PED-t (in Norwegian)

Forespørsel om å delta i et intervju som inngår som en del-studie av behandlingsstudien om spiseforstyrrelser- FAKT, som du var en del av.

Bakgrunn og formål

Mange som starter i behandling for sin spiseforstyrrelse avslutter av ulike grunner behandlingen tidligere enn planlagt. Det å spørre om erfaringer som kan ligge til grunn for en slik avgjørelse kan gi viktig kunnskap som kan bidra til å forbedre behandling til de med spiseforstyrrelser. Det er derfor vi henvender oss til de som fikk tilbud om å være med i FAKT-studien men som valgte å ikke fullføre behandlingen.

Vi forespør deg med dette om du kunne deltatt i et intervju hvor vi snakker om dine erfaringer som deltager i FAKT-studien. Vi understreker at dette IKKE er et forsøk på å få deg til å starte behandlingen igjen, eller å stille kritiske spørsmål til den retten du benyttet deg av for å trekke deg fra studien uten å måtte oppgi noen grunn. Formålet er kun at forskergruppen skal samle, og å trekke lærdom av erfaringer fra de som ikke møtte opp eller som ikke fullførte.

Hva innebærer undersøkelsen?

For å kunne delta må du samtykke til å bli intervjuet av Ph.d-student Maria Bakland som er en del av forskningsgruppen i FAKT-studien, men som dere ikke tidligere har møtt. Hun kan møte deg for intervju ved NIH, hjemme hos deg eller et annet sted som passer deg best. Det er også mulig å velge når på dagen/kvelden det passer deg best. Temaet under intervjuene er dine erfaringer rundt hvorfor du valgte å ikke møte opp til behandlingen eller erfaringer rundt hvorfor du valgte å avslutte før tiden. For de som deltok en stund vil tema være hvordan du har opplevd å delta i selve behandlingsstudien, det kan være både gode og mindre gode erfaringer, og de kan være knyttet til selve behandlingsopplegget, hvordan du opplevde terapeuter eller med-deltagere eller til andre ting du ønsker å trekke frem.

Intervjuet varer ca. 1 time, og det er ønskelig at intervjuet kan tas opp på bånd.

Hva skjer med informasjonen om deg?

Det er kun Maria Bakland som vil ha tilgang til lydbåndversjonen av intervjuet med deg, og båndene oppbevares i låssikkert skap på hennes kontor ved UiT – Norges arktiske universitet, Tromsø. Lydopptaket vil senere bli skrevet ut som tekst og systematisert. Når den skrevne teksten foreligger vil lydopptaket slettes.

I tekstversjonene av alle intervjuene i doktorgrader og vitenskapelige artikler finnes ingen personopplysninger som direkte eller indirekte kan føres tilbake til deg som person. Hvis du leser noe av dette kan det tenkes at du vil kunne gjenkjenne noen sitater fra deg, men poenget er at det er ingen *andre* som kan vite at det stammet nettopp fra deg. Informasjonen du gir under intervjuene skal bare brukes i denne studien, ikke til andre studier med lignende eller andre formål. Det skal heller ikke gjøres koplinger til offentlige registre.

Frivillig deltakelse

Det er frivillig å delta i studien. Det betyr også at du står fritt til å trekke deg når som helst uten at det får konsekvenser. Gjør du det, har du rett til å kreve at opplysningene om deg vil bli slettet.

Hvis du samtykker til å delta i studien ber vi deg bekrefte dette ved å sende en mail til Maria Bakland innen 1 Mai 2018. Når hun har mottatt mail avtaler dere tid og sted for intervju. De som deltar vil få et gavekort på 250 kroner. Har du spørsmål som ikke er omtalt i dette informasjonsskrivet kan du kontakte meg

Jorunn Sundgot-Borgen, prosjektleder, professor, Norges Idrettshøgskole, E-mail:
Jorunn.sundgot-Borgen@nih.no

eller en av prosjektmedarbeiderne:

Maria Bakland, PH. d-student, UiT – Norges arktiske universitet, e-post: maria.bakland@uit.no

Tlf: 91 69 54 06

Gunn Pettersen, professor, veileder, Uit – Norges arktiske universitet, e-post:
gunn.pettersen@uit.no

Tlf: 99271842

Samtykke til deltakelse i forskningsstudien;

Behandling av spiseforstyrrelser gjennom trenings- og kostholdsrådgivning

- en kvalitativ studie av deltakernes erfaringer

Jeg

har lest gjennom informasjonsskrivet og samtykker herved til å delta i prosjektet.

Min deltakelse er frivillig og jeg kan på hvilket som helst tidspunkt trekke meg fra å delta.

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Sted

Dato

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Signatur

Appendix 4

Interview guide for therapists

Interview guide therapists

Briefing:

- Purpose
- Confidentiality and securing anonymity
- Questions?
(Informing about the possibility to ask questions during the interview as well)
- Form and length of the interview
- Tape recorder
- Briefly discussing educational background

<p>Experiences with contributing in the treatment</p>	<p>-Can you tell me about your experiences with being a therapist in the PED-t for patients with eating disorders?</p> <p>-What was your contribution/ what were your tasks</p> <p>-Can you describe a typical session with the group?</p>
<p>Experiences with contributing in light of own education/competence</p> <p>Possible follow up questions;</p> <ul style="list-style-type: none"> -What are your thoughts on that? -Can you elaborate on that? -Can you describe this for me? -Can you describe what happened for me? -Can you give me some additional examples? -Can you give me a more detailed description? <p>Possible additional questions;</p> <ul style="list-style-type: none"> -Do you have some previous experience with patients with eating disorders? -Can you tell me about your expectations to being a therapist for patients with eating disorders? -What may be improved? 	<p>-Can you tell me about a good meeting/session, were you experienced contributing in a good matter?</p> <p>-What specific knowledge from your education did you experience as important when contributing in the PED-t?</p> <p>- Can you tell me about a meeting/session that did not play out as well as you would have hoped for, or were you experienced that your competence was insufficient?</p> <p>-What could have contributed so that this meeting/session went better?</p> <p>Do you experience that this treatment is beneficial for the patients and why/why not? Moreover, how beneficial do you experience that the PED-t is compared to other treatment approaches for these patients?</p> <p>-Is there something else you would like to share, something you find important?</p>

Date of the interview	Sex
Age	Education

Appendix 5

Interview guide for patients who completed the PED-t

Interview guide patients

Briefing:

- Purpose
- Confidentiality and securing anonymity
- Questions?
- (Informing about the possibility to ask questions during the interview as well)
- Briefly about history of illness?
- Form and length of the interview
- Tape recorder

<p>How do women with bulimia nervosa and binge eating disorders experience to participate in a new treatment combining physical exercise and dietary therapy?</p> <p>Possible follow up questions;</p> <ul style="list-style-type: none"> -What are your thoughts on that? -Can you elaborate on that? -Can you describe this for me? -Can you describe what happened for me? -Can you give me some additional examples? -Can you give me a more detailed description? 	<ul style="list-style-type: none"> -How did you become familiar with the PED-t treatment? -Can you tell me about some thoughts and expectations that you had before your participation in the PED-t? What were your goals? -Can you tell me whether these expectations were fulfilled? What are your thoughts on this now? -Can you tell me about your experiences with participating in the PED-t treatment, delivered by therapists in physical exercise and nutrition? -Can you tell me about a meeting or an experience that you had with a therapist? What did the therapist contribute with? -Can you tell me whether and how the treatment has influenced your attitude and opinion about doing physical activity? -Can you tell me whether and how the treatment has influenced your attitude and opinion about nutrition and addressing nutritional needs? -How did you experience to participate in the physical exercise sessions? <ul style="list-style-type: none"> -positive experiences/negative experiences? What could have been better? - How did you experience to participate in the nutritional therapy? <ul style="list-style-type: none"> -positive experiences/negative experiences? What could have been better? -How did you experience to participate in the treatment sessions <i>together with the other women</i>? -What suggestions for improving the treatment do you have? -Is there something else you would like to share, something you find important?
Date of interview	
Age	History of illness?

Appendix 6

Approval from the Regional committee for Medical and Health Research Ethics in Norway
(in Norwegian).

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 bulimisyntomer like godt som kognitiv terapi, men at også kostrådgivning hadde effekt. Dette kan bety at kostrådgivning pluss fysisk aktivitet kan ha en additiv effekt som kan være like god eller bedre enn den man ser ved kognitiv terapi. Formålet med den omsøkte studien er å teste ut effekten av tre ulike behandlingsformer: 1) kognitiv terapi, 2) fysisk aktivitet og kostveiledning og 3) kontrollgruppe med behandling som vanlig hos fastlege. Det skal inkluderes 105 kvinner i alderen 18-35 år, og det skal gjøres en rekke tester som måler fysisk aktivitet, samt DXA-målinger av beinmineralitet, 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.sjostedt@nih.no; postmottak@nih.no

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Ingrid Donåsen	22845523	01.12.2016	2013/1871 REK sør-øst D
			Deres dato:	Deres referanse:
			18.11.2016	

Vår referanse må oppgis ved alle henvendelser

Jorunn Sundgot-Borgen
Norges Idrettshøgskole

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

Forskningsansvarlig: Norges Idrettshøgskole

Prosjektleder: Jorunn Sundgot-Borgen

Vi viser til søknad om prosjektendring datert 18.11.2016 for ovennevnte forskningsprosjekt. Søknaden er behandlet av leder for REK sør-øst D på fullmakt, med hjemmel i helseforskningsloven § 11.

Endringene innebærer:

- Utsettelse av prosjektslutt til 20.12.2018
- Endring i inklusjons- og eksklusjonskriterier. Prosjektleder beskriver endringene slik:

"Inklusjonskriterier var tidligere 18-35 år og er nå hevet til opp til 40 år.

Bmi var angitt mellom 17,5-30 og er nå endret til selvrapportert BMI 17,5-35

Detaljer om alvorlighetsgrad ved bulimi og overspisingslidelse er fjernet, og diagnosen anoreksi er helt fjernet fra inklusjonskriterier da den bare har kommet med i protokoll selv om personer med AN diagnose aldri var tenkt inn i prosjektet.

I eksklusjonskriterier tillot vi opprinnelig ingen form for aktiv behandling mot spiseforstyrrelser de siste 2 år før inkludering, men dette er nå endret til å gjelde kun kognitiv atferdsterapi mot spiseforstyrrelser".

Vurdering

REK har vurdert de omsøkte endringene, og har ingen forskningsetiske innvendinger til endringene slik de er beskrevet i skjema for prosjektendring.

Vedtak

REK godkjenner prosjektet slik det nå foreligger, jfr. helseforskningsloven § 11, annet ledd.

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

Klageadgang

REKs vedtak kan påklages, jf. forvaltningslovens § 28 flg. Eventuell klage 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 referansennummer i korrespondansen.

Med vennlig hilsen

Finn Wisløff
Professor em. dr. med.
Leder

Ingrid Dønåsen
førstekonsulent

Kopi til: turid.sjostedt@nih.no

Norges idrettshøgskole ved øverste administrative ledelse: postmottak@nih.no