

Metacognitive interpersonal therapy-eating disorders *versus* cognitive behavioral therapy for eating disorders for non-underweight adults with eating disorders: study protocol for a pilot pre-registered randomized controlled trial

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ABSTRACT

Eating disorders (ED) are serious disorders characterized by an alteration of eating habits and excessive concern about weight and body shapes (Fairburn, 2002), accompanied by significant impairment inequality of life, high mortality rates and serious organic consequences (Jenkins *et al.*, 2011; Treasure *et al.*, 2015; 2020). Although evidence-based psychological therapies for non-underweight ED presentations such as cognitive behavioral therapy for eating disorders (CBT-ED) are widely available, there is substantial scope for improvements, particularly in terms of efficacy and adherence. One option is to develop interventions to address elements of pathology not fully addressed by existing empirical supported treatments, such as incorporating techniques aimed at addressing interpersonal problems and personality disorder features into existing treatment delivery. We adapted Metacognitive Interpersonal Therapy, a psychological intervention supported by evidence for treating personality disorders and integrated it with existing CBT techniques for eating disorders (MIT-ED). MIT-ED targets aspects of ED that are not included in the transdiagnostic CBT-E model such as poor metacognition, or maladaptive interpersonal schemas. This is a pre-registered (Protocol number: 0000781) pilot randomized clinical trial aimed at assessing acceptability and feasibility of MIT-ED and establishing preliminary evidence of effectiveness for future larger studies. Twenty patients (10 in each arm) will be randomized to 20 sessions of individual psychotherapy, either MIT-ED or CBT-E. Repeated follow-ups will be collected up to 24 months. Participants are recruited at a private outpatient clinic for ED treatment. Acceptability will be assessed via session attendance, completion rates and preliminary outcomes. The primary outcome is ED pathology assessed with the Eating Disorder Examination Questionnaire-6. Other ED outcomes assessed will be eating disorder attitudes, clinical impairment and binge eating pathology. Secondary treatment outcomes are anxiety, depression, and global symptomatology. We will also assess emotional awareness, emotion regulation and therapeutic alliance. Based on previous studies of MIT for personality disorders we hypothesize that MIT-ED will be acceptable to patients, evidenced by high treatment adherence and retention. We hypothesize that MIT-ED will be associated with reductions in eating disorder pathology, at least equivalent to CBT-E. Results will be used to inform the study design, sampling, likely effect sizes and choice of outcome measures for future larger trials of MIT-ED in ED samples.

Key words: eating disorders; cognitive-behaviour therapy; metacognitive interpersonal therapy; personality disorders.

Introduction

Eating disorders (ED) are serious disorders characterized by an alteration of eating habits and excessive concern about weight and body shapes (Fairburn, 2002). ED are accompanied by a significant impairment of quality of life, high mortality rates and serious organic consequences (Jenkins *et al.*, 2011; Treasure *et al.*, 2015; 2020). Eating disorders mainly affect females, ratio 9:1, (Hoek *et al.*, 2003), but in adolescence the ratio is around 3:1 (Kjlesas *et al.*, 2004). Across the lifespan adolescents are at the highest risk of developing an ED (Herpetz-Dahlmann *et al.*, 2011). Eating disorder behaviours in adolescence are a risk factor for their continuation during the next 10 years (Neumark-Sztainer, 2011). Given the prevalence and consequences of ED there is a pressing need for effective psychological interventions. There are currently multiple evidence-based psychological interventions for patients with non-underweight ED.

The most frequently used psychological intervention is Cognitive Behavioral Therapy-Enhanced (CBT-E; Fairburn *et al.*, 2003; 2008) which has evidence of effectiveness across the broad spectrum of ED diagnoses (Atwood & Friedman, 2020; Cooper & Fairburn, 2011; Fairburn *et al.*, 2003; Södersten *et al.*, 2017; Monteleone *et al.*, 2022), including anorexia nervosa (Dalle Grave *et al.*, 2013a,b; Dalle Grave *et al.*, 2014; Fairburn *et al.*, 2013; Zipfel *et al.* 2014; Monteleone, 2022), bulimia nervosa (Poulsen *et al.*, 2014; Wonderlich *et al.*, 2014), and transdiagnostic samples (Fairburn *et al.* 2009; Monteleone *et al.*,) Evidence was found both for adult (Fairburn *et al.*, 2009; Fairburn *et al.*, 2013) and young person samples (Dalle Grave *et al.*, 2013; Monteleone *et al.*, 2022). In a mixed ED sample, CBT-E was found to be more effective than interpersonal psychotherapy (Fairum *et al.*, 2015).

However, CBT-E results are still less than optimal (Byrne *et al.*, 2017; Fairburn *et al.* 2014; Le Grange *et al.*, 2020; Frostad *et al.*, 2018, 2021; Byrne *et al.*, 2017; Linardon, *et al.*, 2018) and remission rates remain a cause for concern. For instance, in a sample of patients with BN, after 5 months, 36% of CBT-E patients were remitted, although this higher than those who received psychoanalytic psychotherapy (23.5% remitted; Poulsen *et al.*, 2014). Other studies report post-treatment remission rates from 37% to 55% for patients who received CBT-E (Byrne *et al.*, 2017; Wonderlich *et al.*, 2014; Allen *et al.*, 2012), with remission rates at 4-months reported to be 40% (Wonderlich *et al.*, 2014).

Further, CBT-E in samples with any ED, (ergo transdiagnostic EDs), appear to result in moderate to large decreases in binge eating behavior but in small to moderate decreases in purging behaviors. For instance, for patients with BN, CBT-E resulted in cessation of bingeing and purging for 22.5% (Wonderlich *et al.*, 2014), 42% (Poulsen *et al.*, 2014), and around 40% (Thompson-Brenner *et al.*, 2016) of patients at post treatment. Finally, most studies have focused on eating behavior as the main outcome, while secondary outcomes such as social and interpersonal functioning, and other comorbid symptom disorders have been less frequently investigated. Those outcomes may have important implications for both relapse prevention and functional recovery. For instance, many patients with improved eating-related outcomes may still experience difficulties in quality of life and their interpersonal relationships (Brugnera *et al.*, 2019; Harris *et al.*, 2022; Eilsen *et al.*, 2022). This is unsurprising given the high prevalence of personality disorder ED populations (Eielsen *et al.*, 2022; Martinussen *et al.*, 2021) and the associated negative impact of personality disorder on treatment outcome (Simpson *et al.*, 2021). CBT for Bulimia Nervosa (CBT-BN) has a completion rate of 80

to 85% and documented effectiveness in reducing core features of BN and improving comorbid psychological problems (Fairburn *et al.*, 1993; Anderson & Maloney, 2001; Murphy *et al.*, 2010; Södersten *et al.*, 2017). Gains on primary outcomes are also mostly maintained at long term follow-up (Fairburn *et al.*, 2009; Wilson *et al.*, 2002; McIntosh *et al.*, 2010; Hay, 2019).

More recently, attention has been paid to transdiagnostic aspects of psychopathology, present across all ED diagnoses (Hay, 2019; Simpson *et al.*, 2022). Transdiagnostic aspects such as clinical perfectionism, low self-esteem, emotion dysregulation and interpersonal difficulties have been identified by CBT-E as important secondary factors for the maintenance of gains in treatment, and if unaddressed also constitute risk factors for relapse (Hay, 2019). In both CBT-E and in general, maladaptive perfectionism has consistently emerged as a transdiagnostic feature of ED (Casper, 1983; Dahlenburg *et al.*, 2019; Costa 2016; Sassaroli *et al.*, 2008) and a precipitant risk factor in development and maintenance of ED (Ruggiero *et al.*, 2003; Vitousek & Hollon, 1990; Colsta *et al.*, 2016; Johnston *et al.*, 2018). In addition, numerous studies have identified low self-esteem as a risk factor for development and maintenance of EDs (Button *et al.*, 1996; Cruz-Sáez *et al.*, 2020; Lilienfeld *et al.*, 1998; Neumark-Sztainer & Hannan, 2000; Fairburn *et al.*, 1997, 1998, 1999; Sassaroli *et al.*, 2005). Patients with low self-esteem endorse a generalized negative self-concept, above and beyond their inability to control their eating patterns, body image and weight. For example, as a function of low self-esteem, patients may have low confidence in their ability to effectively maintain changes in their eating habits (Fairburn *et al.*, 2002). Emotion dysregulation has also been identified as a transdiagnostic factor in ED (Anderson *et al.*, 2018; Steinberg *et al.*, 1990; Trompeter *et al.*, 2021), associated with significant problems of ED such as self-harm (Carlson *et al.*, 2018) and suicidality (Rania, *et al.*, 2021).

Additionally, interpersonal difficulties are also highly prevalent across EDs (Arcelus *et al.*, 2013). Studies report that a dysfunctional family environment is associated with a higher risk of restrictive eating behaviors, particularly in younger patients, such as such as controlling food intake and calories, as a response to a perceived hostile interpersonal environment (Fairburn *et al.*, 1999; Treasure *et al.*, 2008). Bulimia nervosa has also been associated with interpersonal sensitivity in social interactions, further associated with self-criticism and lowered mood (Steiger *et al.*, 1999; Hamann 2009; Maher *et al.*, 2022). In general, poor interpersonal functioning has also been identified as a predictor of poorer treatment response (Agras *et al.*, 2000a; Steiger *et al.*, 1993; Hamann *et al.*, 2009).

Following from this, the transdiagnostic elements that contribute to ED psychopathology.

remain underspecified in CBT-E. One such factor is poor metacognition (Semerari *et al.*, 2003), denoting the capacity to make sense of mental states and use mentalistic knowledge to deal with suffering and interpersonal problems.

Recent evidence suggests that metacognitive difficulties are present in ED. For instance, Aloï and colleagues (2020; 2021) reported poor awareness of emotions and poor emotion regulation in patients with binge eating disorder. Monteleone *et al.* (2020) reported difficulties in overall mentalizing capacities as well as impaired empathy in ED diagnosed patients, and that these were also correlated with ED symptoms. A further element of metacognition, reduced awareness of one's own affects (commonly known as alexithymia), with meta-analytic evidence (Westwood *et al.*, 2017) suggesting that reduced capacity to identify own emotions and communicate them to others is present in all ED types. Over-

all, evidence supports the proposition that poor capacity to recognize and reflect upon the mental states of the self and of the others is impaired across ED populations and that this in turn connected with poor emotion regulation and eating disorder symptoms. Recently, Lysaker *et al.*, (2023) reported that metacognition is severely impaired in women with both anorexia nervosa and bulimia nervosa. Consequently, interventions that increase metacognitive capacity may correspondingly also lead to reductions in ED symptoms. Metacognition, denoting cognitions about cognitions (Wells, 2008) has also been found consistently altered in ED. These individuals tend to adopt thinking attitudes that lead to repetitive thinking that increases the odds of adopting problematic eating behaviors (Palmieri *et al.*, 2021).

CBT-E includes interpersonal difficulties as part of the secondary maintenance mechanisms of ED, but formulation-driven interventions also need to consider how these difficulties are generated and sustained by maladaptive interpersonal patterns of schemas. Interpersonal problems differ based on different definitions and therapeutic schools; however, all refer to problematic internalized ideas about self and other. Problematic interpersonal patterns are consistently present in EDs, particularly relating to low-dominance and lack of assertiveness (Arcelus *et al.*, 2013). Similar findings have also been reported in Binge Eating Disorder (Brugnera *et al.*, 2018), with patterns of non-assertiveness and exploitability remaining elevated after treatment termination (Brugnera *et al.*, 2019). Patients with EDs also present with negative patterns relating to the self, the world and others, alongside autobiographical memories characterized by paternal emotional inhibition and social isolation (Basile *et al.*, 2020).

From a therapeutic perspective, restructuring these interpersonal schemas can reduce ED severity and improve therapeutic alliance (Gilbert & Leahy, 2009). A review of 29 studies suggests that individuals with an ED diagnosis or high level of ED symptomatology reported higher scores across all early maladaptive schemas (EMS) subscales (Maher *et al.*, 2022). In particular, Unrelenting Standards were reported to be pervasive across all ED diagnoses. Insufficient Self-control was associated with binge eating and purging behaviors. Social Isolation, Social Undesirability and Emotional Inhibition were also common across ED diagnoses (Maher *et al.*, 2022). It has also been suggested that there is a mediating relationship between EMS, and multidimensional perfectionism, specifically in relation to body image concern in Eds (Boone *et al.*, 2012), leading to differential patterns in treatment. Jones and colleagues (2015) reported that patients with binge purging behaviors were more likely to distrust others, while patients with restricting anorexia were more focused on being perceived negatively by others; with these diagnosis specific patterns differentially affecting treatment outcome.

Finally, experiences of childhood trauma have also been associated with more severe ED symptoms, further linked to “disconnection and rejection” (Meneguzzo *et al.*, 2021). Harris *et al.* (2022) reported increased levels of both cold and domineering interpersonal styles. Both patterns were malleable, but the domineering style predicted slower treatment response. Even if the non-assertive, inhibited style appear to be most frequent across ED, it is possible that those with a domineering style are harder to treat and require treatment to be adjusted to meet this complexity. CBT-E considers interpersonal difficulties as part of the secondary mechanisms of ED maintenance. Accordingly, we reasoned that their role may be more central that CBT-E assumes so their presence in psychotherapy may be a more prominent treatment target, in particular in those with PD comorbidity.

Given the potential for targeting transdiagnostic factors such

as metacognition and give maladaptive interpersonal schemas a more central treatment role, we hypothesized that Metacognitive Interpersonal Therapy (MIT; Dimaggio *et al.*, 2007; 2015; 2020) could be a candidate integrative psychological intervention to enhance treatment adherence and improve outcomes. This is particularly pertinent in the case of those who have either struggled to engage with or not responded to CBT-E or other interventions.

In the formulation adopted here, MIT (Dimaggio *et al.*, 2015; 2020) is focused on achieving a fine-grained understanding of personality pathology, incorporating consideration of metacognitive difficulties and maladaptive interpersonal schemas. MIT is an empirically supported intervention, with evidence for its effectiveness for PD and other complex mental health conditions, across multiple settings and geographies, both alone (Dimaggio *et al.*, 2017; Cheli *et al.*, 2019; Gordon-King *et al.*, 2018; Inchausti *et al.*, 2018; 2020; Popolo *et al.*, 2018; 2019; 2021; Pasetto *et al.*, 2021) or combined with other treatments such as Mentalization Based Treatments (Simonsen *et al.*, 2022; Wilberg *et al.*, 2023) or combined with elements of compassion focused therapy (Cheli *et al.*, 2023). Overall, MIT and combined treatment including MIT or its components, has mostly been investigated in the full spectrum of non-borderline PD, with some studies focusing on specific disorders such as avoidant PD (Simonsen *et al.*, 2022; Wilberg *et al.*, 2023) or schizotypal PD (Cheli *et al.*, 2023). Treatment retention is high, with overall drop-out rates of <10%, and positive outcomes for improvements in both symptoms and interpersonal problems.

Integrating MIT with specific aspects coming from CBT-ED focused on ED symptoms could therefore offer an approach to targeting ED pathology, both at the level of eating behavior, interpersonal problems and personality dysfunctions, especially if PD comorbidity is present.

In this paper we describe MIT-ED procedures for treating non-underweight ED and the protocol for an ongoing pilot randomized controlled trial aimed at establishing preliminary evidence for applying MIT-ED to non-underweight ED and warrant future empirical testing in larger samples.

Materials and Methods

Aims and hypotheses

The study is a pre-registered (*MICBT for Non-underweight Adults With Eating Disorders*; Protocol 0000781) pilot randomized clinical trial to generate preliminary evidence for the acceptability and effectiveness of weekly MIT-ED combined with specific CBT elements focused on ED symptoms in a group of adults diagnosed with ED. Specifically, we will investigate in a sample of non-underweight adults presenting with ED whether MIT-ED integrated with CBT techniques for ED symptoms compared to CBT-E, is i) feasible, ii) well-tolerated and iii) preliminary effective in reducing eating disorders symptoms and other symptomatology and is associated with improved emotion regulation. The study is defined according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement and guidelines (Chan *et al.*, 2013).

Study design

A parallel-group randomized controlled trial design will be used in order to compare CBT-E (n=10) condition to MIT-ED (n=10). Patients in both conditions will receive 20 weekly sessions of either CBT-E or MIT-ED. As the study is focused on

acceptability and feasibility in a ‘real-life’ setting, a formal power calculation for sample size was not conducted, with the aim to use the current study to establish sampling parameters for a future trial.

The primary outcome is ED symptomatology as assessed with the Eating Disorder Examination Questionnaire (EDE-Q6) (Fairburn & Beglin, 1994). Other assessed ED outcomes are eating disorder attitudes, clinical impairment and binge eating pathology. Secondary outcomes are anxiety, depression and global psychological symptoms.

Exploratory outcomes will be emotion regulation variables, specifically understanding, processing, regulating and describing emotions. Outcomes will be measured at baseline, after 10 sessions, at the end of the treatment, and in the following 3, 6, 12, 18 and 24 months after treatment completion. In order to explore the therapy process, two full psychotherapies per each study arm will be randomly selected, audio recorded and later analyzed.

Methods

Two therapists will be involved in the trial: one CBT-trained, the other trained in both CBT and MIT. Both therapists will be supervised throughout the trial. The CBT-E arm will be supervised by a head of an *Associazione Disturbi Alimentari* (ADA) center, the MIT-ED arm will be supervised by one of the developers of MIT, also a trainer of the *Società Italiana di Terapia Comportamentale e Cognitiva* (SITCC). A blinded research assistant will manage psychometric test administration and liaise regularly with the clinical team.

Participants

Twenty consecutive participants will be recruited at the BLINDED SITE. All participants will be aged 18 years or over and treatment naive. They will be screened for a main diagnosis of ED in the past 6 months. Full inclusion and exclusion criteria are reported in Table 1.

All participants meeting inclusion criteria will be informed about the trial and will decide whether to take part. A regular ED-focused treatment will be offered to all participants excluded from the trial or who decline to participate. All participants will give written informed consent before participation. Drop-out rates from each arm will be reported for patients withdrawing during treatment and those lost to follow-up. Treatment is delivered in a private center; therefore, participants are paying for their care, and there were no financial incentives to participate in the trial as opposed to other care package.

Measures

Primary, secondary and exploratory outcomes of the present study will be assessed using the following psychometric measures.

Primary outcome

Eating Disorder Examination Questionnaire (EDE-Q6, Fairburn & Beglin, 1994): a self-report measure assessing eating disorders symptoms and behaviors over the past 4 weeks, providing a measure of the range of severity of ED.

Secondary outcomes

Eating Attitude Test (EAT-26, Garner & Garfinkel, 1979): a self-report Measure for identifying the presence of “eating disorder risk” based on attitudes, feelings and behaviors related to eating. It assesses general eating behavior and risky behaviors.

Clinical Impairment Assessment Questionnaire (CIA 3.0): a self-report measure assessing the severity of psychosocial impairment due to eating disorder features over the past 28 days (Bohn and Fairburn, 2008).

Binge Eating Scale (BES, Gormally *et al.*, 1992): a self-report measure of behavioral, cognitive and emotional features of objective binge eating (OBE). *State-Trait Anxiety Inventory* (STAI): a self-report measure of trait and state anxiety (Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983).

Beck Depression Inventory (BDI): a self-report measure of depression (Beck, *et al.*, 1961).

Symptom Check List (SCL-90): a measure of psychopathology symptoms and their intensity at a specific point in time.

Exploratory outcomes

Difficulties in Emotion Regulation Scale (DERS; Gratz & Roemer, 2004): a self-report scale measuring individual differences in the ability to identify, accept and manage emotional experiences. This measure identifies and quantifies emotional dysregulation that may underlie the disorders.

Structured Clinical Interview for DSM-5 Disorders (SCID-5; Michael B. First, Janet B.W. Williams) for assessing and defining DSM-5 Model for Personality Disorders.

Toronto Alexithymia Scale (TAS – 20; Taylor & Bagby, 1992) that assesses difficulties in understanding, processing, or describing emotions.

Working Alliance Inventory-Short Revised (WAI-SR Hatcher & Gillaspay, 2006) that measures the therapeutic alliance by assessing three main aspects of the therapeutic alliance: agreement on the tasks of therapy, agreement on the goals of therapy and development of an affective bond.

All measures will be administered at baseline, after 10 sessions, at the end of the treatment and in the following 3, 6, 12, 18 and 24 months after the treatment. The SCID-5 Interview will only be only administered at baseline. The WAI will be administered monthly. All measures will be carried out by a trained research assistant who will receive weekly supervision.

Table 1. Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
- ED diagnosed in the past 6 months	- Acute psychotic episode, psychotic symptoms, bipolar disorder, antisocial personality disorder
- Seeking treatment for eating disorder	- Suicidal ideation
- Able to provide written, informed consent	- Substance abuse
- BMI>18.5	- Previous psychological intervention for other eating disorders
	- Currently involved in other ongoing treatment

ED, eating disorders; BMI, body mass index.

Randomization/treatment allocation

Each participant will be randomized to one arm of the trial. Randomization will be administered by a colleague in the same treatment setting, not involved in the study, using a computerized randomization generator. The research team will be blind to the randomized allocation. Group allocation will remain concealed until the end of all assessments.

Procedure

Treatment-seeking participants at the BLINDED SITE will first receive an assessment screening visit. Once evaluated for inclusion/exclusion criteria, and informed written consent has been obtained, baseline measures about primary and secondary outcomes will be completed. Participants will then be randomized into two experimental conditions: MIT-ED (experimental treatment) and CBT-E (standard treatment). All participants in each experimental condition will first receive two initial standard sessions focused on engaging with treatment and on understanding the maintenance factors of the ED, before commencing the remaining treatment according to allocation. In both conditions participants will receive an assessment session by a researcher who is blind and independent. In both arms, a review session will be scheduled 2 weeks after the end of therapy to evaluate progress and to address any remaining issues.

Experimental treatment

Participants in the MIT-ED condition will receive 1 or 2 preliminary sessions focused on typical elements of CBT-ED, that is: psychoeducational training on eating behaviors, an introduction to tools such as: monitoring form, weight chart and assessment of frequency of eating behaviors such as hours of physical exercise, bodily checking, number of bingeing and purging episodes, starving and so on. Prior to treatment start, patients also have a meeting with a dietitian who writes and agrees with them on a nutritional plan which includes normalizing calory intake. This plan will be reviewed by the dietitian during treatment. After these 2 sessions, participants will receive a total of 20 weekly individual sessions.

At the beginning of each of the 20 sessions the therapist begins by reviewing the monitoring form with the patient, recording current weigh and then asking how much each of the ED mechanisms described in the preliminary sessions has been used. The dyad then discusses how certain behaviours from each diary entry contributed to ED maintenance or successfully counteracted it. For example, the therapist and patient discuss an entry where the patient fasted at lunch, which was followed by a dinner binge. At this point the therapist suggests simple strategies the patient can use for reducing maladaptive eating behaviors, for example through graded exposure to previously avoided foods, and promoting healthy eating behaviors. These will include teaching mindfulness techniques, or using attention-focused techniques (Dimaggio *et al.*, 2020; Ottavi *et al.*, 2021) such as changing environments after lunch in order to prevent bingeing. These techniques are also used in order to counteract the repetitive thinking found to be consistently present in ED (Palmieri *et al.*, 2018). All aspects of the protocol are consistent with other manualized deliveries of MIT, whereby the therapist suggests regulation strategies consistent with the poor awareness of mental states the patient usually displays at treatment onset (Dimaggio *et al.*, 2015).

At this point, the therapist will use information from homework in order to start constructing the MIT shared formulation of

functioning. For example, the therapist asks for details of relational antecedents, (including autobiographical episodes) of instances in which a patient failed to abstain from fasting. After collecting episodes focused on interpersonal relationships that precipitate disordered eating behaviors, the therapist works with the patient to form a shared understanding of the interpersonal antecedents of both their ED symptoms, and their interpersonal functioning. Once a shared understanding is reached, therapist and patient work together to develop healthier strategies for managing negative thoughts and feelings antecedent to disordered eating, based on a more nuanced understanding of the individual's psychological functioning. For example, at this point the patient learns that she tends to fast after experiencing social rejection derived shame, such as recalling memories where she was praised at school for having lost weight. Accordingly, the therapist can help the patient to develop self-regulation of shame and associated failure-related schema without resorting to food restriction, until she discovers that after she no longer thinks she deserves criticism she also does not have the urge to fast or calorie count.

Therapist and patient also develop new adaptive strategies for engaging in social interactions that meet basic relational wishes, such as attachment, personal worth, autonomy and group belonging (Dimaggio *et al.*, 2015; 2020). Throughout treatment experiential techniques, such as imagery and rescripting, chair work, and bodily exercises are used in order both to help patients improve awareness of mental states and break their maladaptive interpersonal schemas (Dimaggio *et al.*, 2020). In summary, MIT aims to improve individuals' capacity to make sense of their own affect and cognitions and become aware of being driven by maladaptive, rigid and biased schemas about self and others. Gradually, patients form a richer understanding of their mind and the mind of others and use this knowledge to manage social difficulties in more adaptive ways. In doing so they are better able to fulfil evolutionary selected wishes, such as being cared of, finding a place in the social hierarchy, explore their environment and develop autonomy.

Standard treatment

Participants in the CBT-E condition will receive 2 preliminary sessions focused on psychoeducational training on eating behaviors and an introduction to the protocol tools, (monitoring form, weight chart, transdiagnostic formulation and Eating Problem Check List (EPCL)). Each patient will then receive a total of 20 weekly individual sessions. Patients will set a meeting with a dietitian who writes and agrees with them on a nutritional plan which includes normalizing calory intake. This plan will be reviewed by the dietitian during treatment.

CBT-E treatment will consist of four stages. In the first stage, treatment will be focused on achieving a shared understanding of the patient's eating disorder and the related maintenance factors. In this phase the patient will be helped to regulate and stabilize his eating habits addressing their weight concerns. In the second stage, progress made is reviewed in detail.

In the third stage, sessions are focused on the central processes that maintain ED. In particular, this will involve addressing concerns about weight and body shape, cognitive and caloric dietary restriction, events and emotions that affect nutrition. From phase three onwards, clinical perfectionism, low global self-esteem, intolerance of emotions and interpersonal difficulties will also be addressed. During the fourth stage, procedures will be also implemented to minimize the risk of short- and long-term relapse.

Supervision and monitoring

Clinicians will receive weekly supervision as outlined above. In addition to supervision, 2 full psychotherapies will be audio-recorded and analyzed by another founder of MIT to assess adherence to the MIT component. In each experimental condition 2 treatment sessions will be recorded in order to analyze the therapeutic process. Session transcripts will then be analyzed in order to explore mechanisms of change.

Statistical analysis

In order to assess whether the MIT-ED leads to a reduction in eating disorder symptoms, we will use paired-sample t-tests to identify change within treatment arms, and group comparison across treatment arms (MIT-ED and CBT-E) using an ANOVA at treatment conclusion. Effect sizes will be reported using Cohen's *d*. ANCOVA will be used to correct for baseline symptomology. We will also calculate Reliable Change Index (RCI; Jacobson & Truax, 1991) and Clinically Significant Change (CSC; Jacobson & Truax, 1991) for each patient, from pre- to post- treatment and at appropriate follow-up points. Following from this, we will provide grouped percentages (CBT-E vs MIT-ED) for those individuals who reliably improved or had a clinically significant change. Intention-to-treat and per-protocol analyses will be used to determine treatment effects on all outcome measures, adjusting for pre-specified baseline covariates.

Discussion and Conclusions

There are a number of evidence-based psychological interventions for patients with EDs, particularly CBT-E, but poor or partial treatment response and dropout remain challenges. We considered that adding treatment components focusing on poor metacognition (the capacity to make sense of mental states and use psychological knowledge to promote emotion regulation; Dimaggio & Lysaker, 2010; Semerari *et al.*, 2003; 2014) and maladaptive interpersonal schemas (Dimaggio *et al.*, 2015; 2020) would offer adjunctive therapeutic options to address problematic eating behaviors. This trial will use MIT, an empirically supported treatment for personality disorder based on those principles, adding ED specific CBT techniques.

We hypothesize that MIT-ED will be acceptable to patients, evidenced by high session attendance and low dropouts (consistent with <10 drop-out rate in other MIT trials); Dimaggio *et al.*, 2017; Gordon-King *et al.*, 2018; Inchausti *et al.*, 2018, 2020; 2022; Popolo *et al.*, 2018; 2019; 2021). This would be lower than the average drop-out across evidence-based treatments (17.5%; Grenon *et al.*, 2019). It will also deliver preliminary evidence for effectiveness of MIT-ED in this setting. The main limitation of the pilot RCT is the pragmatic nature of our small sample, with only 20 patients randomized to either of the 2 arms. This may narrow our parameters to observe treatment specific effects. The small sample also narrowed our measurement battery, with a number of assessments omitted including interpersonal problems. If results are consistent with expectations future studies also assess whether interpersonal problems and presence of comorbid personality disorders impact upon treatment outcomes (Brugnera *et al.*, 2019; Eilsen *et al.*, 2022). If the treatment is effective, replication with larger samples and other ED based presentations will be warranted.

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