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Introduction

Psychological intervention is an evidence-based treatment option for patients with non-anorexic eating disorders (ED). Cognitive Behavioral Therapy (CBT) has proven effectiveness for treating a broad spectrum of ED diagnoses. For instance, CBT for Bulimia Nervosa (CBT-BN) is acceptable to service-users with 80 to 85% completion rates and effectiveness in reducing core features of BN and improving comorbid psychological problems (Fairburn, 1997; Fairburn et al., 1993; Anderson, 2001; Murphy et al., 2010). Gains on primary outcomes are also mostly maintained at long term follow-up (Fairburn et al., 1995, Wilson et al., 2002).

More recently, attention has been paid to transdiagnostic aspects of psychopathology, present across all ED diagnoses. Elements such as clinical perfectionism, low self-esteem, Intolerance of Emotions and underlying interpersonal Difficulties all have potential to impact on the maintenance of gains and are also risk factors for ED relapse if unaddressed in psychotherapy.

In particular, maladaptive perfectionism is considered to be a core transdiagnostic feature of ED (Halmi et al., 1977; Bruch, 1973; Garner, 1986; Bauer & Anderson, 1989; Casper, 1983; Davis, 1997; Davis, et al., 2000) and a precipitant risk factor in the development of ED (Bastiani et al., 1995; McLaren et al., 2001; Ruggiero et al., 2003; Vitousek & Hollon, 1990). In addition, numerous studies have identified low self-esteem as a risk factor for developing EDs and a maintain factor (Button et al., 1997; Button et al., 1996; Canals et al., 1996; Geller et al., 2000; Ghaderi & Scott, 2001; Lilenfeld et al., 1998; Neumark-Sztainer & Hannan, 2000; Rastam, 1992; Wichstrom, 1995; Fairburn et al., 1997; Fairburn et all., 1998; Fairburn et al., 1999). 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).

Intolerance of Emotions has been identified as a potentially transdiagnostic factor, albeit in a subgroup of patient with EDs (Meyer et al., 1998; Steinberg et al., 1990; Stice, 1994; Waller, 2002). These individuals present with difficulties in effectively coping with emotional states, both negative and positive. Emotion regulation is often arrived at via dysfunctional strategies such as self-harm or alcohol and substance misuse (Claes et al., 2001; Holderness et al., 1994; Paul et al., 2002).

Finally, with regard to Interpersonal Difficulties studies have shown that a dysfunctional family environment is associated with a higher risk of continuing with restrictive eating behaviors, particularly in younger patients, intensifying a need for a perceived sense of "control". Examples are dysfunctional food-related activities such as controlling food intake and calories, as a response to a perceived hostile interpersonal environment (Fairburn et al., 1999). Bulimia nervosa has also been associated with interpersonal sensitivity in social interactions, further associated with self-criticism and lowered mood (Steiger et al., 1999). In general, poor interpersonal functioning has also been

identified as a predictor of poorer treatment response (Agras et al., 2000a; Steiger, Leung, & Thibaudeau, 1993).
Given the importance of transdiagnostic elements, an enhanced form of CBT was developed, adding a therapeutic focus on these maintenance factors (CBT-E; Fairburn, 2008) to CBT-focused (CBT-f, Fairburn et al, 2003) which originally included psycho-education, nutritional re-education and overall clinical management for ED.

CBT-E has demonstrated acceptability and effectiveness for all forms of EDs (Cooper & Fairburn, 2011; Fairborn et al., 2003) including anorexia nervosa (Dalle Grave et al., 2013a; Dalle Grave et al., 2013b; Dalle Grave et al., 2014; Fairburn et al., 2013; Zipfel et al. 2014), bulimia nervosa (Poulsen et al., 2014; Wonderlich et al., 2014), and intransdiagnostic samples (Fairburn et al. 2009) both in adults (Fairburn et al, 2009; Fairburn et al, 2013) and in younger patients (Dalle Grave et al, 2013). In a direct comparison with interpersonal psychotherapy for adults (IPT), CBT-E was found to be more effective (Fairburn et al, 2015) in patients with EDs.

However, there remain challenges with implementing CBT-E (Fairburn et al. 2014; Le Grange et al., 2020; Frostad et al., 2018; 2021). First, dropout rates remain significant, affecting at least ¼ of patients, even in high quality trials (Linardon, et al., 2018).

Second, remission rates are also a cause for concern. For instance, Poulsen and colleagues (2014) reported that in a sample of patients with BN, after 5 months, only CBT-E 36% of patients remitted, although this was favorable compared to psychoanalytic psychotherapy (23.5% remitted; (Poulsen et al., 2014). Other studies suggest that approximately 37% of patients who received CBT-E were remitted at post-treatment, which increased to 50% at 4-month follow-up (Wonderlich et al., 2014). Another study highlighted that 55% of CBT-E treatment completers met criteria for remission at post-treatment (Allen et al., 2012).

Third, CBT-E in transdiagnostic samples appears to result in moderate to large decreases in binge eating behavior and 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 44% to 40% (for CBT- f and CBT-E, respectively, using completer data; Thompson-Brenner et al., 2016) of patients at post treatment. Rates were generally well maintained up to 19-month follow-up.

Finally, most studies have focused on eating behavior as the main outcome, while other elements such as social & interpersonal functioning and other comorbid symptom disorders have been less frequently investigated. Those outcomes have important implications for both relapse prevention and functional recovery, as many patients who have registered improved eating-related outcomes through treatment may still experience difficulties in quality of life and interpersonal relationships.

Linked to this, several transdiagnostic elements that may contribute to ED psychopathology are potentially underspecified in CBT-E. One transdiagnostic element 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 and the second are maladaptive interpersonal schemas about self and others. Recent evidence suggests metacognitive difficulties are present in ED. For instance, Aloi and colleagues (2020; 2021) reported poor awareness of emotions and poor emotion regulation in patients with binge eating disorder. Further, 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) that reduced capacity to identify own emotions and communicate them to others is present in all ED types. Overall, 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 this is in turn connected with poor emotion regulation and eating disorder symptoms. Therefore, interventions that increase metacognitive capacity may in turn lead to reductions in ED symptoms.
There are also significant associations between cognition, maladaptive patterns and dysfunctional eating behavior (Fairburn, 2008). In this regard, patients with EDs demonstrate negative individual patterns relating to the self, the world and others, alongside as autobiographical memories based characterized by paternal emotional inhibition and social isolation (Basile et al., 2020). From a therapeutic perspective, restructuring these interpersonal schemas is required to reduce ED severity and to improve therapeutic alliance (Gilbert & Leahy, 2009). For instance, Maher et al's (2022) review of 29 studies suggests that individuals with an ED diagnosis or high level of ED symptomology reported higher scores across all early maladaptive schemas (EMS) subscales. In particular, Unrelenting Standards were 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). Finally, experiences of childhood trauma have also been associated with more severe ED symptoms, further linked to "disconnection and rejection" (Meneguzzo et al., 2021).

Given the current status of CBT-E, and the potential for targeting transdiagnostic factors such as metacognition and interpersonal schemas as mechanisms of change in ED, we propose that Metacognitive Interpersonal Therapy (MIT; Dimaggio et al., 2007; 2015; 2020) is a candidate intervention to enhance treatment adherence and improve outcomes, particularly for those who have either struggled to engage with or not responded to CBT-E.

MIT (Dimaggio et al., 2007; 2015; 2020) is focused on a fine-grained understanding of personality pathology, incorporating consideration of metacognitive difficulties and maladaptive interpersonal schemas. Therefore, it could be combined with CBT-F to form a comprehensive approach to targeting ED pathology, both at the level of eating behavior and personality. MIT is an empirically supported intervention, with evidence for its effectiveness for personality disorders and other complex mental health conditions, across multiple settings and geographies (Dimaggio et al., 2017; Gordon-King et al., 2018; Inchausti et al., 2018; 2020; Popolo et al., 2018; 2019; 2021; Pasetto et al. 2021, Simonsen et al., 2022).

Method/Design

2.1 Aims and hypotheses

The study is a pilot randomized controlled trial that aims to evaluate the feasibility and effectiveness of weekly MIT in addiction to CBT-F in a group of adults diagnosed with ED. Specifically, we will investigate in a sample of non-underweight adults presenting with ED whether once compared to CBT-E, a treatment combining MIT and CBT-F is a) feasible, b) well-tolerated and c) potentially effective on eating disorders symptoms and other outcomes. The study is defined according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement and guidelines (Chan et al., 2013).

2.2 Study design

A parallel-group randomized controlled trial design will be used in order to compare CBT-E (n = 10) condition to combined MIT/CBT-F (n = 10). Patients in both conditions will receive 20 weekly sessions of either CBT-E or MIT/CBT-F.

Primary outcomes will be represented by ED and comorbid symptoms as assessed with the Eating Disorder Examination Questionnaire (EDE-Q6) (Fairburn & Beglin, 1994), which are expected to be

reduced after treatment. Other measures of ED and comorbid symptoms will still be considered primary outcomes. Secondary outcomes are anxiety, depression and global psychological symptoms. Lastly, exploratory outcomes will be difficulties in the emotional sphere such as understanding, processing, regulating or describing emotions.
Predictors, mediators and outcome variables will be measured at baseline, after 10 sessions with the exclusion of SCID-5 Interview, at the end of the treatment, and in the following 3, 6, 12, 18 and 24 months after the treatment. Two psychotherapies for each arm will be randomly selected, audio recorded and later analysed in order to explore the therapy process.

2.3 Methods

Patients will be assessed and treated by the *Centro di Trattamento Integrato - Disturbi Alimentari e Obesità* (*CTI-Disturbi Alimentari e Obesità*). Two therapists will be involved in the trial: one CBT-trained, the other trained in both CBT-F and MIT. Both therapists will be supervised throughout the trial. The CBT-E arm will be supervised by a certified Associazione Disturbi Alimentari (ADA) supervisor, the MIT/CBT-F 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 research assistant will manage the psychometric test administration and will liaise regularly with the clinical team.

2.4 Participants

Twenty consecutive participants will be recruited at the CTI Disturbi Alimentari e Obesità. 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. Inclusion and exclusion criteria are reported in Table 1.

Table1 Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Aged >18 years	Acute psychotic episode, psychotic symptoms, Bipolar I disorder; antisocial personality disorder
ED diagnosed in the past 6 months	Suicidal ideation
Seeking treatment for eating disorder	Substance abuse
Able to provide written, informed consent	Previous psychological intervention for other eating disorders
BMI > 18.5	Currently involved in other ongoing treatment

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 participating. 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, however there is no financial incentive to participate in the trial. The study protocol is written in accordance with the European Union Standards of good clinical practice and in accordance with the Declaration of Helsinki. The protocol has been approved by the Ethics Committee of the Department of Dynamic and Clinical Psychology of “La Sapienza” University (Rome) Prot. n. 0000781, 05/13/2022 - [UOR: SI000092 - Classif. VII/15]

2.5 Measures

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

- Eating Disorder Examination Questionnaire (EDE-Q6, Fairburn & Beglin, 1994): A self report measure assessing eating disorders over the past 4 weeks, providing a measure of the range of severity of eating disorder features.
- 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 behaviour and risky behaviours.
- Clinical Impairment Assessment Questionnaire (CIA 3.0): a self-report measure f 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 questionnaire of the 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 measures 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.
- 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 help in understanding emotional dysregulation that might 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 assess difficulties in understanding, processing, or describing emotions.
- Working Alliance Inventory-Short Revised (WAI,-SR Hatcher & Gillaspy, 2006) that measure the therapeutic alliance by assessessing 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.

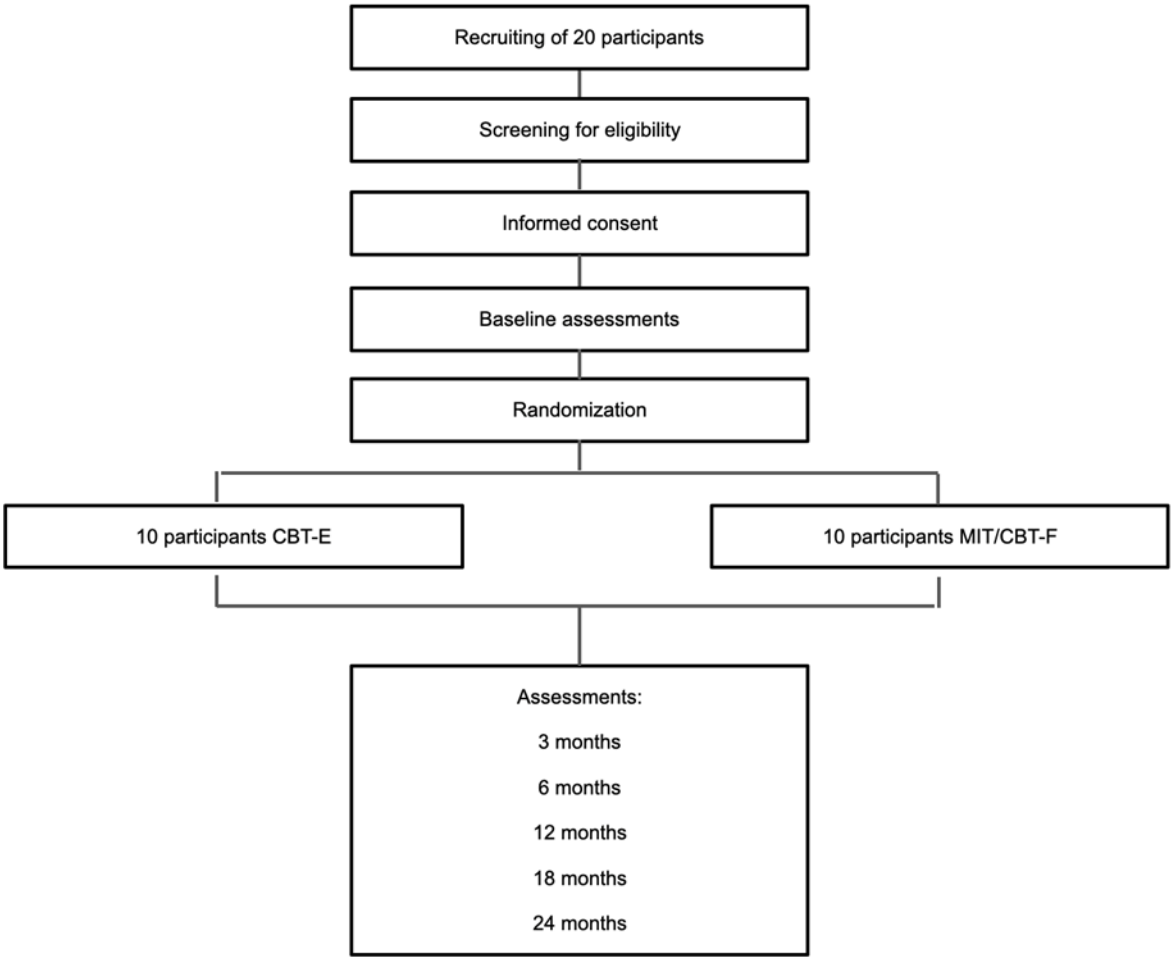
All the psychometric tests will be administered at baseline, after 10 sessions (with the exclusion of SCID-5 Interview which will be only administered…), at the end of the treatment and in the following 3, 6, 12, 18 and 24 months after the treatment. The WAI will be administered monthly. All measures will be carried out by the research assistant who will be trained and weekly supervised.

2.6 Randomization/treatment allocation

Each participant will be randomized in one of the two experimental conditions by allocation concealment. In particular, randomized-permuted blocks will be used. The research team will be also blind to the randomized allocation. Group allocation will remain concealed until the end of the assessment stage.

2.7 Procedure

Treatment-seeking participants at the CTI Disturbi Alimentari e Obesità will first receive an assessment screening visit. Once evaluated for inclusion/exclusion criteria, they will be informed about the study. If they wish to participate, they will be required to give written informed consent.



Tab.1. Flow chart of the study design

The researcher will ensure that the person is fully informed of the randomization process and their chances of receiving additional MIT sessions. Once informed and written consent has been obtained, baseline measures about primary and secondary outcomes will be completed.

Participants will then be randomized into two experimental conditions: CBT-F+MIT (experimental treatment) and CBT-E (standard treatment). All participants in each experimental condition will first receive two initial standard sessions mainly focused on investigating the compliance to the treatment and on understanding the maintenance factors of the ED.

2.7.1. Experimental Treatment: Participants in the CBT-F+MIT condition will receive a total of 20 sessions over 20 weeks. Specifically, 2 sessions will be based on CBT-F as usual only. During these sessions participants will receive psychoeducational training on eating behaviors and an introduction to the protocol tools, namely the monitoring form, weight chart, transdiagnostic formulation and Eating Problem Check List (EPCL).

These elements will be used at the beginning of the remaining 18 sessions, in order to monitor the regulations of eating behaviors as well eliciting narrative episodes. These materials will form the basis for the MIT-part of the session, in which therapists will seek to form with the patient a shared understanding of the psychological reasons underlying their ED symptoms and their maladaptive interpersonal functioning. Once a shared understanding is reached, patients and therapist will work to develop healthier strategies for managing negative thoughts and feelings antecedent to disordered eating. They will also develop new strategies for engaging in social interactions that meet their

relational basic wishes, such as attachment, personal worth, autonomy and group belonging (Dimaggio et al., 2015; 2020).

With MIT therapy, patients will be guided in to understand that perfectionism and the need for control they experience through ED are coping strategies developed within interpersonal patterns of interaction with significant others, where low self-esteem and emotive dysregulation play a central role.

Overall, 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. This enables the individual to form a richer understanding of the mind of the others and use this knowledge to react in more adaptive ways to social difficulties or evolutionary selected wishes (such as being cared of, finding a satisfying place in the social hierarchy, explore the environment and be autonomous). MIT also enables individuals to reflect on how these schemas may act as triggers for disordered eating behavior and develop more effective coping strategies in face of interpersonal stressors.

MIT sessions will be integrated within the CBT-F protocol (Fairburn; 2003) which will provide psycho-educational, nutritional re-education and management for ED. In particular, CBT aims to inform patients about the importance of self-control, the dangers of some restrictive behaviors such as self-induced vomiting. Moreover, CBT provides strategies to patients in order to monitor their usually dysfunctional behaviors and so increasing their awareness (i.e., food diary method) while reducing the availability of food and encourages activities that are incompatible with overeating. Patients will be trained in problem solving in order to change these feelings, as well as in increasing their self-awareness in order to recognize irrational thoughts about their body weight and shape. Additionally, they will be gradually exposed to foods that they had been avoiding [20].

2.7.2 Standard Treatment: participants in the CBT-E condition will receive a total of 20 CBT-E sessions over 20 weeks. This will include the standard CBT-E protocol outlined above, without the additional MIT elements.

CBT-E treatment will consist of four stages. In the first Stage, the 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 and so to address his weight concerns. In the second stage, progress made is reviewed in detail. In the third stage, the sessions will be focused on the central processes that are maintaining the psychopathology of the patient's eating disorder. In particular, this involves in addressing concerns about weight and body shape, cognitive and caloric dietary restriction, events and emotions that affect nutrition. in phase three and four clinical perfection, low global self-esteem, intolerance of emotions and interpersonal difficulties are also addressed.

Towards the end of the third stage and during the fourth stage, procedures will be also implemented to minimize the risk of short- and long-term relapse.

Each experimental condition will include up to 10 participants. In both conditions participants will receive an assessment session by a researcher who is blind and independent. In both arms, review session will be scheduled 2 weeks after the end of therapy to evaluate progress and to address any remaining or emerging issues.

2.7.3 Supervision and monitoring.

Clinicians will receive weekly supervision as outlined above. Besides supervision, several sessions audio-recorded sessions will be analyzed by another founder of MIT to assess adherence to MIT/CBT-F.

In each experimental condition all treatment sessions will be recorded. In order to analyze the therapeutic processes, sessions will be chosen at random for each of the two groups. Transcription of the sessions will be then analyzed in order to explore the process of change mechanisms.

3. Statistical analysis

As a feasibility study, analyses will be mainly focused on a descriptive method. However, in order to assess whether the experimental condition including MIT sessions leads to a reduction in eating disorder there will be also carry out an intention-to-treat and per-protocol analyses in order to determine treatment effects on all the outcome measures, adjusting for pre-specified baseline covariates. An exploratory repeated measures regression model, adjusting for baseline measures, will be adopted to assess the treatment effects on the outcomes and their effects over time. There will be also explored the sub-scales measures in order to assess whether there might be any treatment signals within sub-scales. Estimates of treatment differences and associated standard errors will be obtained from the mixed-effects models analyses. These will be run for intention-to-treat and per protocol analyses.

Exploratory linear multiple regressions, in which all predictors and covariates will be entered independently into the regression algorithm to avoid artificial inflation of estimated R2, these will be adopted to investigate the mediational effects of the putative underlying mechanisms of change. Finally, number of sessions received will be examined as a putative moderator.

Upon completion of the trial additional exploratory analyses will be run, from sub-samples of good and poor outcomes to identify mechanisms of change.

4. Discussion

Patients with EDs have a number of psychotherapeutic options, particularly CBT-E, but nonresponse, partial response and dropout remain challenges for treatment. We proposed 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 would offer adjunctive therapeutic options to address problematic eating behaviors. In this pilot RCT we considered these components from MIT as a bolt-on to a commonly used, empirically validated psychological intervention (CBT-E).

We hypothesize that the CBT-F+MIT arm will result as highly tolerable in terms of session attendance and dropouts. We expect possible <10-15% dropouts which would be above the average 17.51% found across evidence-based treatments (Grenon et al., 2019). Low dropout rate is a feature of existing MIT protocols for complex mental health problems such as personality disorders, psychosis, either as a solo treatment (Dimaggio et al., 2017; Gordon-King et al., 2018; Inchausti et al., 2018, 2020; 2022; Popolo et al., 2018; 2019; 2021; Simonsen et al., 2021) or combined with other treatments such as combining metacognition-based interventions with compassion focused practices (Cheli et al., 2022).

The main limitations of this pilot RCT are the small sample, with only 20 patients randomized to either of the 2 arms, possibly limiting scope to observe treatment specific effects. That said use of mixed effects modelling and confidence interval derived analyses may mitigate this problem. The trial will be an initial test of this new treatment combination. Further studies with larger samples and other ED based presentations will be warranted.

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