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## **A Stepped Care approach for the treatment of Binge Eating Disorder: main outcome analyses of a Randomized Controlled Trial**

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## Contents

Acknowledgements .....	1
Abstract .....	2
Preface .....	3
1. General Introduction .....	4
1.1 Stepped Care approach for Mental Disorders .....	5
1.2 Attachment Theory .....	6
1.2.1 Attachment in Childhood and its evaluation through the Strange Situation.....	9
1.2.2 Evaluating Attachment in adults: The Adult Attachment Interview .....	12
1.2.3 Evaluating the Attachment: the dimensional approach .....	15
1.2.4 Reflective Functioning (RF) .....	17
1.2.5 Attachment and Emotion Regulation.....	19
1.2.6 Dysfunctional Attachment Styles and Psychopathology .....	20
1.3 Binge Eating Disorder (BED).....	21
1.3.1 Treatments for BED.....	23
1.3.2 Eating Disorders, Attachment styles and Reflective Functioning .....	25
1.4 Individual CBT and the “Transdiagnostic Model” of Eating Disorders.....	26
1.4.1 Guided and Unguided Self-Help.....	28
1.5 Group Psychotherapies and group therapeutic factors.....	30
1.5.1 Attachment in Group Psychotherapies.....	33
1.6 Group Psychodynamic Interpersonal Therapy (GPIP) for BED.....	34
2. Stepped Care Study .....	38
2.1 Introduction.....	38

2.2 Methods.....	42
2.2.1 Participants.....	42
2.2.2 Measures .....	42
2.2.3 Interventions .....	44
2.2.4 Procedures.....	46
2.2.5 Data Analysis .....	47
2.3 Results.....	48
2.3.1 Preliminary analyses .....	48
2.3.2 Outcomes from Unguided Self-Help .....	49
2.3.3 Outcomes at Post-Group Treatment and Follow-Ups.....	49
2.4 Discussion.....	50
References.....	56
Table 1 .....	68
Table 2 .....	69
Table 3 .....	70
Table 4 .....	71
Table 5 .....	72
Figure 1 .....	73
Appendix: HLM Models.....	74

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## **Abstract**

Binge Eating Disorder (BED) is a common mental illness, with lifetime prevalence estimates of 3%. BED is usually associated with a higher occurrence of psychological difficulties (e.g. interpersonal problems), and is often comorbid with obesity, poor physical health and somatic diseases. However, due to high treatment costs or the lack of clinicians to treat all existing cases, most of the patients do not receive a specialized care. A possible solution is the wider adoption of stepped care programs, or models of healthcare delivery that use briefer treatments, distributed in different steps. A typical first step consists in self-help (i.e. books), a minimal-care and evidence-based intervention derived from cognitive behavioral therapy. A second step could be a group treatment, which is effective as the individual one and allow to treat more patients at once, thus reducing welfare burden.

The present dissertation examined the efficacy of a stepped care model for Binge Eating Disorder: a total of 135 patients first attended a 10-week program of unguided self-help (USH). After USH, 85 participants were later randomized to either a control no-treatment condition or Group Psychodynamic Interpersonal Psychotherapy (GPIP). Outcomes were evaluated up to 6 months after treatment. Results evidenced that USH reduced binge eating frequency and the core eating disorder psychopathology (i.e. over-evaluation of weight, shape, eating). In addition, patients randomized to GPIP experienced a further reduction in binge eating and a greater improvement in attachment avoidance, interpersonal problems and weight concerns.

Our findings provided preliminary evidence on the effectiveness of a stepped care approach for patients with BED, supporting its wider adoption and suggesting that this model could reduce welfare costs and potentially increase the percentage of treated patients. Further investigation should explore changes in other secondary outcomes (e.g. attachment states of mind, reflective functioning) not examined yet, as well as the potential moderating factors of treatment outcomes.

## **Preface**

The present dissertation was completed during my nine months research-stay at University of Ottawa, under the supervision of Dr. Giorgio A. Tasca (University of Ottawa, Canada) and Dr. Angelo Compare (University of Bergamo, Italy). The “Stepped Care” RCT was started within the Ottawa Hospital in 2013 and completed 3 years later, and involved several mental-health professionals, researchers, graduate and undergraduate students. During my visit, I re-checked all the entries, prepared the databases, run the analyses and wrote the manuscript on the main outcomes of the RCT itself. Dr. Tasca supervised step by step my work, revising and providing valuable suggestions on how to improve the manuscript.

## **1. General Introduction**

The following dissertation focused on the main outcome analyses of a Randomized Controlled Trial performed at the Ottawa Hospital, which tested the efficacy of a stepped care treatment for Binge Eating Disorder. The program was composed by unguided self-help (USH), followed by Group Psychodynamic Interpersonal Therapy (GPIP). All patients received USH, and were later randomized to either group therapy or waiting list.

A Randomized Controlled Trial (RCT) is a type of scientific experiment, considered the strongest research design for evaluating the efficacy of health care interventions (Altman et al., 2001). In a typical RCT, two groups of patients, namely the experimental and the control groups, are followed longitudinally. The experimental group receive the actual treatment (i.e. it is exposed to the independent variable), while the control group usually receive a placebo, a treatment as usual, no treatment at all, or enters in a waiting list (i.e. it is not exposed to the independent variable): the efficacy of the intervention (the primary goal of the RCT) is demonstrated comparing the post-treatment outcomes of the experimental arm with those of the control arm (Jadad, Enkin, & Jadad, 2007). Usually, patients are followed for several months after treatment (i.e. follow-up), to ensure the presence of long-lasting treatment effects. Other secondary goals are the evaluation of those factors that moderate or mediate the efficacy of the treatment itself (Jadad et al., 2007). One of the main characteristics of a RCT is the random assignment of participants to the study arms: in this way, any possible difference between the two groups (e.g. psychological characteristics of participants, environment characteristics) is due to chance, thus it is minimized and possibly equalized (Jadad et al., 2007; Viera & Bangdiwala, 2007). Finally, in this RCT we followed the “Consolidated Statement of Reporting Trials (CONSORT)”, which consists of a checklist and flow diagram that improve the reporting of clinical trials so that readers can assess validity based on standard criteria (Altman et al., 2001).

This chapter will introduce some of the most important topics related to the manuscript: after a short description of the stepped care approach, paragraph 1.2 will describe attachment theory (which is essential to understand group dynamics and how GPIP works). Then, key features (e.g. prevalence, comorbidities, evidence-based treatments) of Binge Eating Disorder will be reviewed. Finally, the last three paragraphs will focus on Cognitive-Behavioral Therapy for Eating Disorders,

on guided and unguided self-help, on group psychotherapies and their therapeutic factors, and on principles, techniques and previous results of Group Psychodynamic Interpersonal Therapy.

### **1.1 Stepped Care approach for Mental Disorders**

According to DSM-5, a mental disorder is a syndrome characterized by clinically significant disturbance in an individual's cognition, emotion regulation, or behavior, and is usually associated with significant distress in social, occupational, or other important activities (American Psychiatric Association, 2013). Mental disorders are extremely common: past prevalence studies on representative random samples from Europe and US found that the one-year or the lifetime prevalence of any mental disorder range from 18.5% to 25% (Alonso et al., 2004; Narrow, Rae, Robins, & Regier, 2002). However, only a little percentage of these individuals receive a treatment: as pointed out by “The Centre for Economic Performance’s Mental Health Policy Group” (2012), during 2007 in England only 10% of patients with depressive\anxious disorders and 15% of those with an eating disorder received a psychological treatment. High economic costs (e.g. insurances not covering private treatments), difficulties in accessing health care, lack of time among adult workers, stigma or other factors could explain these low percentages: however, untreated mental disorders lead to lower wages, employment rates and have “other negative social and economic consequences” (Golberstein, Eisenberg, & Downs, 2016; Smit et al., 2006): for example, Smit and colleagues (2006) found that the costs of mental disorders are similar to those of physical illnesses.

As such, health care systems are actively searching for better ways to i) deliver evidence-based treatments in a cost-effective manner, and ii) to reach as many patients as possible. A solution could be the adoption of stepped care approaches: the term refers to a model of healthcare delivery, that aims to increase the efficiency of welfare services adopting “briefer minimal interventions, within stepped care models” (Bower & Gilbody, 2005). Thus, a stepped care program would begin with the most cost-effective and least intensive treatment: for example, in the United Kingdom the National Institute for Health and Care Excellence (NICE) consider CBT-oriented guided self-help as a first-line intervention for individuals with specific disorders, such as Binge Eating or Bulimia Nervosa (NICE, 2017). If the first treatment is ineffective, then the program would move incrementally to more intensive therapies, such as Cognitive Behavioral or Interpersonal treatments (NICE, 2017). As such, stepped care approaches could help reaching and treating a



larger percentage of patients, improving the efficacy of welfare services and reducing the overall health care costs.

## **1.2 Attachment Theory**

Attachment is a well-known theory of personality development. It posits that the quality of early caregiving experiences influences how an individual perceives himself, the caregiver and significant others, and how he\she engages in subsequent relationships. The theory was initially developed by John Bowlby (1907-1990), a British psychiatrist and psychoanalyst, in the three volumes of *Attachment and Loss* (1969, 1973, 1980). Later, it was extended to adulthood, friendship and romantic relationships (Mikulincer & Shaver, 2007). Thanks to the contribution of several other authors, such as Mary Ainsworth, Mary Main and Peter Fonagy, Attachment theory provides one of the most ecological and scientifically sound framework to understand human normal and psychopathological development (Mikulincer & Shaver, 2007).

Bowlby's interest in child development started in the early '40s, when he published several reports on the disruptive effects in infants and young children of i) institutional\hospital care, and of ii) early experiences of prolonged separation from the caregiver (Bretherton, 1985). After these initial studies, and strongly influenced by ethology, evolutionary concepts, cognitive and control systems theories, Bowlby started developing the Attachment Theory in late '50s. At that time, the psychoanalytic theory of object relations considered the interpersonal relationships as "secondary acquisitions developed on the bases of gratification of primary drives" (Ainsworth, 1969): as such, some specific infant behaviors were difficult to explain using the psychoanalytic framework (Bretherton, 1985). For example, anxiety experienced by infants during a separation from their mothers was puzzling, especially if all their primary drives (e.g. hunger) had been gratified (Ainsworth, 1969; Bowlby, 1973). This led Bowlby first to investigate child and animal behaviors, and then to develop a rational theory on the innate tendency of an infant to form a bond with the caregiver.

Bowlby, in the first volume of his book "Attachment and Loss" (1969), defined Attachment as an instinctive, highly adaptable and cybernetically controlled behavioral system with the evolutionary function of protecting the infant from danger, increasing the survival chances of the child and, generally speaking, of the species.

The first main characteristic of Attachment theory is the search of proximity to attachment figures in case of danger, and the child's protest to separation from the caregiver (Bowlby, 1969). Attachment promotes survival of the infant "regulating behaviors designed to maintain or obtain proximity to and contact" with a caregiver (Bretherton, 1985). Indeed, from an evolutionary point of view, any infant mammal is defenseless for the first years of life, relying on the mother (or a caregiver, in the case of humans) to receive protection and comfort (primary attachment strategy; Bowlby, 1969). The Attachment behavioral system is strongly activated when the child is frightened, sick, wounded or when he perceives the environment as threatening, and is deactivated only when the caregiver is physically available and provides protection (e.g. holding the child; Bowlby, 1969). However, the Attachment system could be activated even by less extreme situations (i.e., separation from the caregiver), and assuaged by the simple knowledge that an attachment figure is available (Bretherton, 1985). Physical or psychological proximity to the caregiver promotes feelings of security and safety that encourage the child to continue searching for proximity in case of danger, thanks to feedback mechanisms (Bretherton, 1985). In adults, stressful events could activate the Attachment behavioral system, pushing them to search for proximity and support from the partner, parents or even friends (Mikulincer & Shaver, 2007). Finally, if the attachment figure is not available (physically or symbolically) when the Attachment behavioral system is activated, then the infant adopts a *secondary attachment strategy*: he/she can hyperactivate (e.g. increasing both the proximity-seeking attempts, and the demands of attentions or love), or deactivate/down-regulate the attachment system (e.g. blocking or weakening the proximity-seeking attempts, even if the sense of security was not achieved; Mikulincer & Shaver, 2007).

The second main characteristic of Attachment theory is the "secure base" behavior. When the child feels secure and perceives as safe the surrounding environment, he start exploring it using the attachment figure as a "secure base" where to return in case of danger (Bowlby, 1988). These "explorations" continue for the entire life, reaching increasingly far distances from the attachment figures (Bretherton, 1985). The secure base behavior was initially discovered by the American-Canadian psychologist Mary Ainsworth (1913-1999) using the "Strange Situation", a semi-standardized assessment protocol that allow to investigate the infant's response to brief separations (Ainsworth, Blehar, Waters, & Wall, 1978). The Strange Situation will be further explained in the next paragraph.

The Internal Working Models (IWM) of attachment figures and of the self are the third main characteristic of Attachment theory. Thanks to the continuous interactions with both the caregiver and other individuals, the child constructs “Internal Working Models of the external world and of the significant persons in it, including the self” (Bretherton, 1985). Thus, the child encode, process and store the actual experiences with attachment figures, developing specific cognitive-affective schemas that are used to interpret the present, appraise and guide behavior during new situations, and plan future actions (Bretherton, 1985). The Internal Working Models ultimately influence present and future interpersonal relationships, self-perception, and emotion regulation (Mikulincer & Shaver, 2007). The IWM tends to be relatively stable over time, due to fact that they become habitual and automatic (hence less accessible to awareness; Bretherton, 1992). In addition, relational patterns with others are characterized by reciprocal expectancies, that make more difficult any possible change (Bretherton, 1992). However, past studies evidenced that new relational experiences or life events (e.g. therapeutic intervention, a positive romantic relationship) could strongly affect and even change the Internal Working Models (Tasca, Ritchie, & Balfour, 2011).

Attachment tends to be organized only during specific sensitive developmental periods (i.e. from 9 months after birth, up to 5 years). As aforementioned, Attachment is an instinctive but not an inherited behavior: thus, this behavioral system has the potential to develop only if its adequately stimulated by a caregiver (Ainsworth, 1969). Early observational studies performed by Ainsworth, showed characteristic mother-infant interaction patterns even during the first months after birth (Bretherton, 1992). Newborns instinctively try to create a bond with their caregiver: in addition, they have a set of signaling behaviors (e.g. crying), that are implemented when the homeostasis of their organism is perturbed, such as in the case of hunger (Bowlby, 1969). However, the child start to express attachment behaviors (research of proximity and protest to separation) and to orient his actions in a more systematic way toward a discriminated person (i.e. the caregiver) only around 9 months, coinciding with the development of locomotion (Bretherton, 1985). Locomotion allows infants to walk away from the caregiver, which could put them in dangerous situations. Thus, from an evolutionary point of view, a system that “ensures that a child's explorations do not take it too far from a protective figure” can increase the survival of the child (Bretherton, 1985).

Finally, Attachment behavioral system is highly flexible and can adapt to changing environmental circumstances. In optimal circumstances (e.g. adequate and sensitive parenting), the infant develops the so called *secure* attachment style, characterized by good internal working models of both the self and attachment figures. On the contrary, dysfunctional early interactions or neglect during the sensitive developmental period can subvert the system from the optimal path of development. The individual adopts chronic secondary attachment strategies (i.e. hyperactivating and deactivating the attachment system) that leads to an *insecure* attachment style, negative IWMs, and possibly to an impaired psychosocial functioning of the infant and of the future adult (Bretherton, 1985; Mikulincer & Shaver, 2007).

### **1.2.1 Attachment in Childhood and its evaluation through the Strange Situation**

Mary Ainsworth provided one of the most important contributions to the Attachment theory thanks to her observational studies on infant-mother attachment, performed both in Africa and United States (Bretherton, 1992). However, these studies were methodologically limited (i.e. they did not allow to control for experimental variables), were expensive and took a large amount of time to be completed. Shortly after completing the “Baltimore Project”, Ainsworth developed the “Strange Situation”, a naturalistic laboratory procedure used to investigate reactions of 12-18 months old infants to separations and reunions with their caregivers (Bretherton, 1992). The Strange Situation is conducted in a standardized room with a one-way glass used to covertly observe the child, toys in the middle of the room, and 2 chairs (one for the mother and one for the “stranger”). The procedure is characterized by a series of 8 episodes, for a total length of ~20 minutes (Ainsworth et al., 1978).

The mother and the infant are initially introduced in the room: the child is free to explore the environment for few minutes and play with the toys. Later, an unfamiliar person (the “stranger”) enter in the room and starts playing with the child. The mother leaves briefly and then return: if necessary, she comforts the baby or pick him\her up, and tries to get the baby back to play. In the meantime, the stranger silently leaves the room. During the next episode, the mother leaves again the room, so that the child is left alone. Then, the stranger enters the room and tries to comfort the baby if necessary (or sits and waits for mother to return, if the infant can’t be comforted). Finally, the mother returns and comfort the baby if necessary (for a detailed explanation, see Ainsworth et al., 1978).

Initially, Ainsworth developed the procedure to better understand the effect of maternal absence on infant explorative behaviors (Bretherton, 1992). However, the reactions to the separations and reunions with the mother during the first experiments provided far more interesting information on the attachment styles of the child (Ainsworth et al., 1978). The interactive behaviors observed during the two reunion episodes were coded using an observation grid. The findings allowed to classify the child in one of three attachment styles, namely Secure, Insecure Avoidant, and Insecure Resistant/Ambivalent; each style was associated to a specific letter (B, A and C, respectively; Ainsworth et al., 1978). A fourth attachment behavior, called Disorganized/Disoriented (D), was later theorized by Main and Solomon (1990). Patricia Crittenden proposed also the A/C pattern, that accounts those attachment behaviors that combine the avoidant and ambivalent strategies (1985).

The main characteristics of an “optimally developed” Attachment behavioral system are the protest to separation, the search of proximity, and the “secure base” effect. As reviewed by Ainsworth and colleagues (1978):

- Infants classified as Secure (B; 65% of the infants) showed a prototypical reaction to the Strange Situation: they initially explored the new environment, using the caregiver as a safe base. They were distressed when the mother leaved the room (protest to separation), but were positive and happy when mother returned or, in case they cried, they stopped quickly after being hold by the caregiver.
- Infants classified as Avoidant (A; 21% of the infants) showed little to none distress during separations. They played with the stranger even when they were alone with him, and actively avoided or ignored the caregiver upon reunions.
- Infants classified as Resistant/Ambivalent (C; 14% of the infants) were intensely distressed during the separations (e.g. cried more compared to Secure ones). They showed few to none exploratory behaviors and avoided the stranger. When the mother returned, they cannot be settled and were ambivalent, showing attachment behaviors interspersed with angry/resistant behaviors (e.g. pushing the mother away).

The percentages reported above are based on the meta-analysis of Van Ijzendoorn and Kroonenberg (1988) on more than 2000 Strange Situation classifications.

Ainsworth (1978) suggested that infants develop a specific attachment style based on the behaviors (availability, sensitivity, and responsiveness) their mothers show towards them during the first years of life (“caregiver sensitivity hypothesis”). For example, caregivers of securely attached child are typically described as sensitive and responsive. Inconsistent primary cares (e.g. caregivers that sometimes meet the needs of the child, and sometimes ignore them) are associated with resistant\ambivalent attached infants. Finally, caregivers of avoidant attached child are described as unresponsive and emotionally detached: due to fact that his needs are not met, the child starts believing that the communication of his\her needs has no influence on the caregiver (Ainsworth et al., 1978). It’s worth noticing that the parental availability, sensitivity, and responsiveness are strongly influenced by parents’ own attachment patterns (Mikulincer & Shaver, 2007). The quality of infant attachment is also influenced by the personal/familiar/social context of parental caregiving (e.g. family economic problems), and the innate characteristics of the children (e.g. temperament) (Mikulincer & Shaver, 2007). These factors moderate the parental sensitive caregiving, which is still considered the most important predictor of infant’s attachment patterns (Mikulincer & Shaver, 2007).

The repeated interactions with caregivers are cognitively encoded in the Internal Working Models (i.e. mental representations of the self and the others): not surprisingly, infants that experience loving, sensible caregivers 1) will develop internal representations of supportive attachment figures, 2) will be able to establish intimate, caring relationships with others, and 3) will develop an authentic, solid sense of self-worth and self-competence (i.e. perceive themselves as valuable, lovable, active and competent; Mikulincer & Shaver, 2007). On the contrary, infants that experience unresponsive, unavailable attachment figures will experience intense distress, developing chronic secondary attachment strategies to “regulate the feelings of insecurity and worries about rejection or abandonment” (Mikulincer & Shaver, 2007). This will lead to 1) internal representations of attachment figures as non-supportive or rejecting, 2) problems in establishing intimate relationships, and 3) to a compromised sense of self-worth and self-competence (Mikulincer & Shaver, 2007).

All the attachment styles can be conceptualized as “organized strategies adaptive to the child’s environment” that allows the infant to deal with stressful events (i.e. separations from the caregiver, new environments, threatening events; Bakermans-Kranenburg, Van IJzendoorn, &

Juffer, 2005). This applies also to insecure attachment, which -even if dysfunctional- allows the child to cope with the external stressors. For example, Resistant/Ambivalent infants adopts a secondary attachment strategy characterized by a chronic hyperactivation of the attachment system, while Avoidant infants relies on a chronic deactivation of the attachment system (Mikulincer & Shaver, 2007). However, Main and Solomon (1990) described the case of some infants with apparently unorganized strategies and non-adaptive behaviors during the Strange Situation, such as “contradictory behaviors; undirected or misdirected movements and expressions; stereotypes and anomalous movements or postures; freezing or stilling behaviors; expressions of fear or apprehension regarding the parent; and clear indices of confusion and disorganization in the presence of the parent” (Bakermans-Kranenburg et al., 2005; Main & Solomon, 1990). These infants were difficult to classify in one of the three aforementioned attachment categories, so that Main and Solomon (1990) ended up defining a new attachment category, called “Disorganized/Disoriented” (D). As reviewed by Bakermans-Kranenburg et al. (2005), Disorganized attachment is associated with unresolved loss or trauma in parents, parental depression or marital discord, frightening parental behavior and the experience of maltreatments or even abuses.

### **1.2.2 Evaluating Attachment in adults: The Adult Attachment Interview**

As reviewed in the previous paragraphs, Attachment was initially developed as a theory of infant development. Both Bowlby and Ainsworth focused their work on infants and on normal and psychopathological development of Attachment behavioral system. In the 1980s, the theory had such a strong empirical base that some researchers started investigating a relatively new area, that is Attachment in adulthood (Mikulincer & Shaver, 2007).

Mary Main (1943 -) and her research group focused on the attachment styles of parents and their children (George, Kaplan, & Main, 1985). Main’s idea was that the “adults' current representations of their childhood relationships with parents” affected their parenting behaviors (Bartholomew & Shaver, 1998), and that these representations could have been used to predict the attachment patterns of their son (George et al., 1985). Main and colleagues started interviewing parents of infants whom attachment style was already known thanks to the Strange Situation, and then “searched for scorable features of the interview transcripts that could “postdict” their infants’ already known attachment classification” (Bartholomew & Shaver, 1998). These studies led to the

development of the Adult Attachment Interview (AAI; George et al., 1985). The AAI is a semi-structured, semi-clinical interview composed by 15 questions, that “surprise the unconscious” of the interviewees through a specific focus on the early attachment experiences of the adult. Noticeably, AAI can also be used with adolescents (Mikulincer & Shaver, 2007).

Interviewer starts asking for a general description of the family, and then poses open-ended questions about childhood relationships with parents. More in detail, interviewees are asked “for five adjectives to describe their relationship to each parent during childhood, and then for memories which support the choice of each adjective. They are asked whether they felt closer to one parent, and why; whether they had ever felt rejected during childhood; whether parents had been threatening with them in any way; why parents may have behaved as they did during childhood; and how these experiences may have affected the development of their personality. In addition, they are asked about any major loss experiences” (George et al., 1985).

The 1-2 hour long interview is tape-recorded and then transcribed verbatim: indeed, the raters classify the participant starting from the recorded discourse (George et al., 1985). The transcripts are rated using a complex scoring system that takes into account i) the interviewee’s actual description of the childhood experiences (e.g. if parents were loving, or abusive), ii) the way in which these experiences are qualitatively described, reflected and evaluated (Mikulincer & Shaver, 2007). Indeed, the psycholinguistic qualities of the discourse, such as its coherence, consistency and emotional organization, reflect the nature of an adult’s attachment representation (i.e. the “current state of mind with respect to attachment”; Van IJzendoorn, 1995). In other words, the patterns of attachment registered through the interview reflect the internal working models of the individual (Gullestad, 2003): as such, the AAI coding is based on the representation of attachment relationships within different memory systems (semantic, episodic, imaged, procedural and working memory; Gullestad, 2003).

AAI classifications are based on two main sets of 9-point rating scales, namely the parental behavior (separated for each parent) and the state of mind scales (Mikulincer & Shaver, 2007). The parental behavior scales investigate how each parent was loving, rejecting, neglecting, involving, or pressuring, and are scored based on both the rater’s clinical judgement and on what the interviewee said (Mikulincer & Shaver, 2007). The state of mind are rated through several subscales, labeled idealization, insistence on lack of recall, active anger, derogation of parents or



of attachment, fear of loss, metacognitive monitoring, and passivity of speech (Mikulincer & Shaver, 2016). The state of mind scales assess the so-called *Coherence of the discourse* during the AAI. Indeed, as stated by the linguistic philosopher Grice (1975), a rational (i.e. coherent) discourse is more likely achieved if it adhere to four conversational maxims: quality ("Be truthful and have evidence for what you say"), quantity ("Be succinct, and yet complete"), and relation ("Be relevant to the topic as presented"), and manner ("Be clear and orderly") (George et al., 1985). Thus, a coherent discourse is considered as an indicator of a secure attachment (George et al., 1985). After reviewing the transcript, the coder judges the overall coherence of the transcript as well as the interviewee's "coherence of mind", and then assign him to one of the three major categories, namely Secure\Autonomous (F), Insecure Dismissing (Ds), Insecure Entangled\Preoccupied (E) (Mikulincer & Shaver, 2007). In addition to being assigned to one of the other three categories, an interviewee can also be classified as Unresolved\Disorganized (U). Finally, the "cannot classify" (C\C) designation is assigned to those people with profiles that do not resemble any of the standard ones (Mikulincer & Shaver, 2007). As reviewed by George, Kaplan and Main (1985):

- Adults classified as Secure\Autonomous (F; 58%) have a coherent, collaborative discourse during the AAI. They are able to provide an objective, consistent description and evaluation of attachment-related experiences. There is no violation of the Grice's maxims (1975).
- Adults classified as Insecure\Dismissing (Ds; 23%) are incoherent and dismissing of their attachment-related experiences. They tend to normalize the relationship with their parents (e.g. "it was excellent"), but these statements are unsupported or contradicted by the episodes recounted. They violate the Grice's maxims of quality and quantity (e.g. transcript tends to be too brief).
- Adults classified as Insecure Entangled\Preoccupied (E; 19%) are incoherent, and appears too involved and preoccupied with their past attachment experiences. They may express anger, fear or passivity when discussing relationships with their parents. They often use long, complex sentences, violating the Grice's maxims of manner, relevance and quantity (e.g. transcript tends to be too long).
- Adults classified as Unresolved\Disorganized (U; 18% additionally coded) experience confusion and disorganization when discussing losses or trauma-related experiences (e.g. they could say that a dead person is still alive). Unresolved\Disorganized individuals may fit in any of the other three categories (F, Ds, E).

The percentages reported above are based on the recent review of Bakermans-Kranenburg and van IJzendoorn, (2009) on more than 200 studies presenting ~10.500 AAI classifications. As reviewed in the meta-analysis of van IJzendoorn (1995), the AAI has a good test-retest reliability (i.e. classifications tends to remain stable over time), and is “independent of differences between respondents in verbal and performance IQ, autobiographical memory not related to attachment, and social desirability”. There are no consistent gender differences in AAI classifications (Mikulincer & Shaver, 2007). Finally, van IJzendoorn (1995) evidenced that the Adult Attachment Interview has a good predictive validity: indeed, the accordance between AAI and Strange Situation classifications is around 75%, suggesting that most of the parents of securely attached infants are classified as Secure\Autonomous in the AAI, and vice versa. These findings support the hypothesis advanced by Bowlby (1973) and Main and colleagues (1985) of an intergenerational transmission of attachment patterns, as well as the hypothesis of the caregiver sensitivity (Ainsworth et al., 1978). Thus, it appears that the “parental representations of past and present attachment experiences affect the degree of sensitivity and responsiveness with which parents react to infant attachment signals”, influencing the trajectories of development of their Attachment behavioral system (Van IJzendoorn, 1995).

### **1.2.3 Evaluating the Attachment: the dimensional approach**

Attachment could be conceptualized using two different lines of research, namely the categorical and the dimensional one. The categorical approach holds that i) there are distinct and mutually exclusive attachment categories (i.e. styles), ii) attachment is an unconscious process, and finally that iii) individuals are unaware of their attachment styles (Mikulincer & Shaver, 2007). As reviewed in paragraph 1.2.1 and 1.2.2, Ainsworth (1978) theorized that infants fall in one of three main attachment categories (secure, avoidant, insecure\ambivalent), while Main (2002) classified adults as secure, dismissing or preoccupied. However, it's worth noticing that Ainsworth itself described infant-mother attachment also dimensionally, as “regions in a two-dimensional space” organized along two orthogonal dimensions of attachment avoidance on the vertical axis and attachment anxiety on the horizontal axis (Mikulincer & Shaver, 2007). Indeed, the second line of research suggest that attachment can be conceptualized continuously rather than categorically using two aforementioned dimensions (Brennan, Clark, & Shaver, 1998).

Interestingly, the categorical approach is commonly adopted by semi-structured interviews (such as the AAI) or laboratory procedures (such as the Strange Situation), which both evaluates “unconscious states of mind related to attachment in adults” (Tasca & Balfour, 2014), while the dimensional one is adopted by self-report measures: these questionnaires evaluate “consciously available information about one’s interpersonal relationships and affect regulation” (Tasca & Balfour, 2014). Brennan, Clark and Shaver (1998) suggest that the continuous approach results in a more powerful and precise assessment of attachment compared to their categorical counterpart. In addition, the continuous approach is less time-consuming compared to the AAI, which could be completed only after at least one hour\one hour and half. Finally, as noticed by Tasca and colleagues (2014), the two approaches tend to be poorly correlated, suggesting that they evaluate different aspects of attachment (i.e. conscious and unconscious ones).

One of the most widely-adopted dimensional questionnaires is the “Experience in Close Relationship Scale” (ECR; Brennan et al., 1998). The scale is composed by 36 items and evaluates romantic attachment. It was developed by Brennan and colleagues (1998) and is composed by two main dimensions, namely attachment anxiety and avoidance. Later, Fraley, Waller and Brennan (2000) revised the questionnaire using item-response theory, even if the resulting ECR-R seems not a significant improvement over the original version (Mikulincer & Shaver, 2007). During the last decades, other questionnaires were developed, such as the Attachment Style Questionnaire (ASQ; Feeney, Noller, & Hanrahan, 1994) or the Adult Attachment Scale (AAS; Collins & Read, 1990). The AAS is a 18-items self-report scale that evaluates 3 dimensions, namely discomfort with closeness, discomfort with depending on others (both measures of attachment avoidance), and anxious concern about being abandoned or unloved (a measure of attachment anxiety; Collins & Read, 1990). Noticeably, the scale was revised by Collins in 1996. On the contrary, the ASQ is a 40-items questionnaire composed by 5 subscales: lack of confidence (in self and others), discomfort with closeness, need for approval and confirmation by others, preoccupation with relationships, and viewing relationships as secondary (Feeney et al., 1994). Discomfort with closeness, lack of confidence and viewing relationships as secondary are measures of avoidant attachment, while preoccupation with relationships and need for approval and confirmation are related to the anxious one (Feeney et al., 1994). For a recent review on the various questionnaires that measure attachment, included their validity and reliability, see Ravitz and colleagues (2010).

### 1.2.4 Reflective Functioning (RF)

The concept of Reflective Functioning was initially developed by Peter Fonagy, a Hungarian-born British psychoanalyst (1952 -), in the early 1990s. While reading some AAI transcripts, Fonagy noticed a great variability in the interviewees' attempts to understand their own behaviors and those of others in terms of mental states (Katznelson, 2014). While investigating this observation, Fonagy further noticed that this phenomenon wasn't adequately captured by any of the scales of the AAI (such as the metacognitive monitoring scale). Therefore, inspired by the social biofeedback theory and the theory of the development of psychic reality (for more details, see Katznelson, 2014), he started working on a new scoring scale for the AAI, the so-called "Reflective Function" scale (RF; Fonagy, Target, Steele, & Steele, 1998).

Reflective Functioning is the active expression (i.e. operationalization) of those psychological processes that underlie the capacity to "mentalize" (Fonagy et al., 1998). RF, or Mentalization, was described by Fonagy as the capacity to i) perceive and understand themselves and others in terms of mental states (feelings, beliefs, intentions and desires), and to ii) reason (i.e. reflect) about one's own and others' behavior in terms of mental states (Fonagy et al., 1998). Thus, it is a concept partly related to those of empathy and metacognition (or "cognition about cognition"; Katznelson, 2014). Mentalizing skills are crucial for an adequate psychosocial functioning and quality of life. Indeed, thanks to a good reflective functioning the behavior becomes predictable: if an individual sees people's actions as meaningful (thanks to the attribution of thoughts and feelings), then these actions became predictable, which in turn increases the individual's mental and physical autonomy (Fonagy et al., 1998). In addition, RF promotes and maintain attachment security (as discussed later in this paragraph); it helps the child distinguish between appearance and reality (which could promote adaptive responses in front of traumas and maltreatments; e.g. "my parents were unloving but I am not unlovable"); enhances communication (i.e. a communication is effective only if the speaker bear in mind the point of view of the other); finally, Reflective Functioning encourages meaningful connections between the internal and external worlds (Fonagy et al., 1998).

RF is coded rating the level of reflection in specific passages of the Adult Attachment Interview, namely: i) those that permit the interviewee to demonstrate their reflective-self capacities (*permit questions*; e.g. "what did you do when you were upset as a child?"), and ii) those that demand a demonstration of RF capacities (*demand questions*; e.g. "why did your parents behave as they did

during your childhood?"; Fonagy et al., 1998). Passages in response to demand questions are fundamental to score the RF (Fonagy et al., 1998). Indeed, demand questions are weighted more than permit ones, so that non-reflective responses to permit questions carry less weight in comparison to non-reflective responses given to demand questions (Fonagy et al., 1998). The interviewee's responses to the various questions are rated taking into account 4 dimensions, namely: 1) how much the individual is aware of the nature of mental states; 2) how much he makes explicit efforts to understand mental states underlying behavior; 3) how much he recognizes the developmental aspects of mental states, and 4) how much he shows awareness of mental states in relation to the interviewer (Fonagy et al., 1998). Finally, the rater provides a global score on a 11-points Likert scale (from -1 to 9, with higher scores indicating higher RF competencies) combining the individual ratings to the various questions with an overall consideration of entire transcript (Katznelson, 2014). According to Fonagy and colleagues (1998):

- Individuals with a RF score of -1 systematically resists taking a reflective stance throughout interview: they show lack of participation, evasiveness or marked incongruences during the interview, and respond with hostile refusal to demand questions.
- Individuals with a RF score of 3 shows some evidence of consideration of mental states throughout the interview, but most of these references are not made explicit: for example, they can be too naïve/simplistic when interpreting the intentions of others, or over-analytical.
- Individuals with a RF of 5 shows a number of instances of reflective functioning: they clearly have a model of their own\parental mind, which may be simple but is relatively coherent, personal, and well-integrated.
- Individuals with a RF of 9 have an exceptional sophistication in the understanding of complex mental states: their transcripts show complex or elaborate causal reasoning, using mental states.

As reviewed by Katznelson (2014), RF scale scores are consistent over time, while the inter-rater reliability is generally quite high ( $r > .50$ ). In addition, scores are independent (i.e. not significantly correlated) from personalty characteristics, Intellective Quotient and gender (Katznelson, 2014). The RF scale is considered the strongest predictor of Attachment security, and has the highest discriminating capacity between secure and insecure states of mind among all AAI scales (Fonagy

et al., 1998). Not surprisingly, past literature evidenced lower mentalizing capacities in psychiatric patients, especially those suffering of Borderline Personality Disorders (Katznelson, 2014). The RF scale showed also a moderate to strong correlation with the classifications of infant attachment (obtained through the Strange Situation), suggesting that the RF competencies of parents can affect and predict the attachment status of their 12-18 months old infants (Katznelson, 2014). As reviewed in the previous paragraphs, Ainsworth and colleagues (1978) suggested that parents' sensitivity, availability and responsiveness can influence the attachment status of their child. However, the underlying mechanisms behind the transmission of attachment patterns are still unknown (Katznelson, 2014). Fonagy proposed that the mentalizing capacity of the caregiver (or the capacity to accurately perceive and reflect on the intentionality of their children's behavior) "allows to create a psychological and physical environment conducive to the development of a secure base for his\her infant" (Katznelson, 2014). Therefore, parents' RF could be the real mediator of attachment status of the infant and of his self-control and affect regulation competencies (Fonagy et al., 1998).

### **1.2.5 Attachment and Emotion Regulation**

The Attachment Behavioral System can be defined as an emotion regulation "device": as reviewed before, once triggered by perceived threats, it activates a set of behaviors aimed at attaining proximity, safety and comfort from the attachment figure. The infant, previously distressed, can now manage the threat together with his caregiver, and restore his\her emotional balance (Mikulincer & Shaver, 2007). The availability of the attachment figure contributes to shape the emotional regulation competencies of the child: repeated experiences with available and responsive attachment figures i) help the individual to cope with stressors and threats, and to maintain an adequate emotional balance as well as an overall state of positive emotion, to ii) promote healthy regulatory processes that allow to acknowledge, experience and express the emotions without distorting them or without being overwhelmed by feelings (Mikulincer & Shaver, 2007). On the contrary, unavailable attachment figures lead to i) higher levels of distress (due to fact that the child can't rely on the caregiver for protection and comfort) and to an increased frequency\intensity in the expression of negative emotions (such as anger), and to ii) poor coping skills and to the distortion or suppression of specific emotions or of entire emotional experiences (Mikulincer & Shaver, 2007).

### **1.2.6 Dysfunctional Attachment Styles and Psychopathology**

All the theories of personality development are initially based and subsequently developed starting from the observation of psychopathology: for example, foundations of psychoanalysis were laid down by Freud and Breuer during the “cathartical” treatment of a hysteric patient, Anna O. (Ellenberger, 1972). In the same way, John Bowlby started his research work on Attachment behavioral system investigating the causal antecedents of juvenile delinquency, as well as the psychosocial effects of maternal deprivation on children (Mikulincer & Shaver, 2007). After observing the disruptive effects of impaired early relationships with caregivers (e.g. neglect or separations), Bowlby later organized his ideas into a coherent theory of personality development.

Decades of empirical research have now evidenced that repeated experiences with loving, sensible and responsive caregivers, which are available when needed, lead to the development of a secure attachment in the infant. Thanks to the interiorization of positive Internal Working Models, these infants construct a stable, coherent and authentic sense of self-worth and self-efficacy, which provide the foundations for mental health during childhood, adolescence and adulthood (Mikulincer & Shaver, 2007). On the contrary, repeated experiences with neglectful, rejecting or unavailable caregivers lead to the development of attachment insecurity and to the interiorization of negative internal working models. Unable to construct an adequate sense of self-worth and self-efficacy, these infants (and the future adults) will rely on different secondary attachment strategies, which in turn increases the risk of developing mental disorders (Mikulincer & Shaver, 2007, 2012).

As recently reviewed by Mikulincer and Shaver (2012), the link between attachment insecurity and psychopathology is mediated by 3 main pathways, namely: 1) negative Internal Working Models (e.g. negative self-representation); 2) dysfunctional emotional regulation (e.g. problems in understanding, exploring and expressing their own and others’ feelings); 3) problems in interpersonal relationships.

Anxiously attached individuals have serious doubts about their self-worth and self-efficacy, due to repeated damaging interactions with unsupportive and inconsistent attachment figures: as such, “they are susceptible to rejection, criticism, and disapproval; suffer from self-criticism and destructive perfectionism”, and experience a sexual inhibition (Mikulincer & Shaver, 2007). These individuals have problems in the regulation of i) their negative emotions (experiencing intense distress even after a stressful event ceased), and of ii) in interpersonal relations. Even when they

have a partner, they continue having explicit and implicit negative views of them (“he\she is not really loving me”) and of humanity in general. Finally, these individuals experience a covert narcissism, “characterized by self-focused attention, hypersensitivity to other people's evaluations, and an exaggerated sense of entitlement” (Mikulincer & Shaver, 2012).

Avoidantly attached individuals maintain a defensive stance (e.g. “faking” security and exaggerating their self-sufficiency), due to repeated interaction with unavailable attachment figures: they block normal emotions and suppress doubts on self-worth i) using avoidant, deactivating strategies, and ii) trying to convince themselves and other that they’re self-sufficient and invincible (Mikulincer & Shaver, 2007). They will experience serious adaptive problems - such as a general decline in functioning- when facing highly demanding adversities; they’re reluctant on relying on other people, experience over-sexuality, a general inability to care for a partner, overt narcissism or grandiosity (i.e. denying past failures, vulnerabilities and negative aspects of the self) paired with high levels of perfectionism and self-criticism (Mikulincer & Shaver, 2007).

Finally, as reviewed by Mikulincer and Shaver (2007): attachment insecurity is not linked to specific mental disorders. Together with genetic and other psychosocial factors, it simply constitutes a general risk factor for the development of psychological disorders. Attachment insecurity is not sufficient by himself to induce psychopathology: however, reducing the resilience to stressors and the psychosocial resources of the individual, it can “act as catalysts of other pathogenic processes” (e.g. life events, traumatic experiences). Finally, attachment insecurity and psychopathology share a bidirectional causal pathway, so that attachment insecurity can be worsened by psychological disorders.

### **1.3 Binge Eating Disorder (BED)**

Binge Eating Disorder (BED) is a psychiatric disorder characterized by recurrent episodes of binge eating (i.e. over-eating), that occur at least once a week for 3 months (American Psychiatric Association, 2013). Binge eating episodes are associated with eating -generally while alone- much more rapidly than normal and even if the person is not hungry, until feeling uncomfortably full: afterward, the person feels disgusted, depressed or guilty. The binge episodes are accompanied by a sense of loss of control, but no compensatory behaviors (e.g. vomiting; American Psychiatric



Association, 2013). A higher frequency of binge episodes per week reflect a more severe level of BED.

BED was originally introduced in the appendix B of DSM-IV as a sub-category of eating disorders not otherwise specified (EDNOS), and it was considered a full diagnostic entity only after several studies demonstrated its clinical significance and validity (American Psychiatric Association, 2000, 2013; Tasca & Balfour, 2014). The DSM-5 considers BED one of the “Feeding and Eating Disorders”, a diagnostic macro-category that groups together Pica, Rumination Disorder, Avoidant/Restrictive Food Intake Disorder, Anorexia Nervosa and Bulimia Nervosa (American Psychiatric Association, 2013). Interestingly, BED and Bulimia Nervosa (BN) share some common characteristics, such as the over-eating episodes: however, BN patients show compensatory behaviors (e.g. dietary restrictions or vomiting), that are absent among BED ones, so that their presence is commonly used for differential diagnosis.

BED is considered the most common eating disorder, with recent worldwide prevalence estimates ranging from <1 to 4.7% (Cossrow et al., 2016; Keski-Rahkonen & Mustelin, 2016). DSM-5 reports twelve-months BED prevalence in the United States of 1.6% among females and of 0.8% among males (American Psychiatric Association, 2013). Lifetime prevalence estimates of BED ranges between 1 and 2%, but these percentages increase up to 3% when using the DSM-5 diagnostic criteria (Ágh et al., 2015). According to Ágh and colleagues (2015), BED is 1.5-6 times more prevalent among females, with the majority of patients developing the disorder between the ages of 12 and 25 years.

BED is associated with poor physical health and higher occurrence of somatic diseases, such as diabetes, hypertension and heart diseases (Ágh et al., 2015). This association is likely explained by obesity (Ágh et al., 2015), which is a highly prevalent condition among patients with BED (Hudson, Hiripi, Pope Jr, & Kessler, 2007; Kessler et al., 2013). Past evidence showed that the Health-related quality of life (HRQoL) is lower among patients with BED, compared to control subjects (Ágh et al., 2015). In addition, BED is associated with increased total health service use and higher healthcare costs, as well as with a resource utilization similar to that of other psychiatric conditions (Ágh et al., 2015).

Finally, BED is significantly related to distress, psychosocial impairment, and high rates of comorbid psychopathology (Hudson et al., 2007). Previous evidence showed that more than 80%

of community or treatment-seeking patients with BED meet the criteria for at least one other mental disease, such as anxiety or mood disorders (Grilo, White, & Masheb, 2009; Kessler et al., 2013). The DSM-5 (American Psychiatric Association, 2013) reports that depressive, anxiety and bipolar disorders (and in a lesser extent substance use disorders) are common comorbidities for BED, and that these comorbidities seem linked to the severity of binge eating.

### 1.3.1 Treatments for BED

Several evidence-based psychological and pharmacological treatments for BED exists.

The psychological treatments, provided in group or individual settings, include Cognitive Behavioral Therapy (CBT), Interpersonal Psychotherapy (IPT), and Dialectical Behavior Therapy (DBT).

The following descriptions are mostly based on the review of Iacovino and colleagues (2012):

- **CBT:** the rationale of this treatment suggest that patients with BED try to adhere to extreme eating restrictions, in order to control problematic eating patterns and concerns about shape and weight (Iacovino et al., 2012). However, patients with BED react negatively in case of even minor dietary slips, blaming themselves for their poor self-control competencies; this can lead to a temporary interruption of the eating restrictions, triggering a binge episode (Fairburn, Cooper, & Shafran, 2003). Therefore, the treatment focus on breaking the “diet-binge cycle” through the promotion of healthier eating patterns and weight-control behaviors, as well as improving shape and weight concerns.
- **IPT:** the interpersonal model of Binge Eating posits that dysfunctional social interactions lead to negative affects; however, patients with BED are unable to manage these emotions, so that they binge as a way to cope with negative affects. In addition, the model posits that BE could worsen interpersonal problems (i.e. the patient pursues social isolation), thus contributing to the maintenance of the disorder itself. The treatment aims at increase interpersonal skills, as well as help the patients to acknowledge and express painful affects (Iacovino et al., 2012). A sub-type of Interpersonal Treatment is **GPIP:** the rationale of this treatment is based on the model of Cyclical Relational Patterns (CRP). According to it, dysfunctional interactions induce negative mood which, in turn, trigger binge eating (considered a dysfunctional coping strategy). In addition, these negative interactions i)

generate and perpetuate cyclical relational patterns, and ii) support negative interpersonal representations of self and others (i.e. negative Internal Working Models; Tasca, Balfour, Ritchie, & Bissada, 2006). The treatment focus on increasing the interpersonal competencies of the patients, mitigating their dysfunctional CRPs.

- **DBT:** The rationale of this treatment is based on the affect regulation model of binge eating. According to it, patients with BED binge in response to intolerable emotional experiences. In addition, the temporary relief induced by this behavior reinforce the binge eating itself. The treatment aims at increasing the emotional regulation skills of the patients, focusing on four main areas: mindfulness, distress tolerance, emotion regulation and interpersonal effectiveness (Iacovino et al., 2012).

It's worth noticing that all these treatments are effective: recent meta-analyses found that, regardless the rationale, all group or *bona fide* psychotherapies for EDs led to better outcomes (i.e. reduced binge eating) at post-treatment when compared to wait-list control conditions, suggesting that common therapeutic factors (e.g. alliance, goal consensus, expectations) are more relevant than specific techniques and therapeutic ingredients (Grenon et al., in submission; Grenon et al., 2017). IPT and CBT evidenced also a good long-term efficacy at 4 years post-treatment, with “long-term recovery, partial remission, clinically significant improvement and significant reductions in associated psychopathology” (Hilbert et al., 2012). At the moment, CBT is the most investigated treatment for BED and its efficacy has been evidenced in so many studies (and subsequent meta-analyses) that it is now considered the first-line intervention (Brownley, Berkman, Sedway, Lohr, & Bulik, 2007; Vocks et al., 2010). Finally, all BED treatments relies on the so called “affect regulation model”, which posits that binge episodes are triggered by increases in negative affects; thus, binge eating is a coping strategy that can alleviate negative emotions “by using food for comfort and distraction” (Haedt-Matt & Keel, 2011). The model suggest that Binge Eating “becomes a conditioned response that is maintained through negative reinforcement” (Haedt-Matt & Keel, 2011). However, a recent meta-analysis suggested that greater negative affects (NA) both precede and follow a Binge Episode, in contradiction with the affect regulation model (which suggest that higher NA lead to a Binge Episode, which consequently lower NA intself; Haedt-Matt & Keel, 2011). Authors proposed that binge may probably result in an

immediate “reduction in negative affect that is quickly replaced with an increase in negative affect” (Haedt-Matt & Keel, 2011).

Other commonly used and evidence-based psychological treatments are the **(Un)Guided Self-Help**, and the **Behavioral Weight Loss Treatment** (Iacovino et al., 2012). Self-Help interventions are based on self-help manuals, and adopt CBT techniques to reduce binge frequency (Iacovino et al., 2012). Self-help, low-cost treatments can be provided without (i.e. unguided) or with (i.e. guided) specialist care. In case of guided self-help, regular meetings with a therapist are scheduled: the therapist provide the rationale of the treatment and encourage adherence and goal pursuit (Iacovino et al., 2012). Finally, Behavioral Weight Loss Treatments for BED focuses exclusively on weight loss, combining a restriction in caloric intake with increased physical activity (Iacovino et al., 2012).

As regards pharmacotherapy, a recent meta-analysis (Reas & Grilo, 2014) on 22 studies evidenced that pharmacological treatments (i.e. antidepressants such as SSRIs, or antiepileptics such as Topiramate) yielded superior results at post-treatment, in comparison to placebo. Medications reduced binge eating frequency, a number of secondary outcomes (e.g. depression) and -in a less extent- weight (Reas & Grilo, 2014). Reas and Grilo (2014) noticed that, even if significant, these outcomes were generally modest (i.e. most of the patients were not in remission), while most of the studies reviewed were methodologically limited (i.e. no long term follow-ups, or small sample sizes). Finally, a combined approach (pharmacotherapy + psychotherapy) did not lead to better outcomes (Reas & Grilo, 2014).

### **1.3.2 Eating Disorders, Attachment styles and Reflective Functioning**

As reviewed by Tasca and Balfour (2014), Eating Disorders are strongly associated with attachment insecurity, with prevalence ranging from 70 to 100% among various ED samples. A recent meta-analysis found that ED patients experience higher levels of insecure attachment relative to healthy controls, with a large effect size (8 studies;  $ES = 1.13$ ); in the same way, individuals with ED experience lower parental care (measured through self-report instruments) relative to Healthy Controls, and this effect size was moderate (25 studies;  $ES = 0.51$ ) (Caglar-Nazali et al., 2014). Similarly, Kuiper and Bekker in their meta-analysis (2012) performed on 10 studies found that attachment insecurity was more frequent in ED patients compared to a non-clinical population; interestingly, no significant correlations between specific insecure attachment

styles and specific ED diagnoses or symptoms were found. Previous studies suggested that attachment insecurity could contribute to the development or maintenance of EDs through maladaptive perfectionism or problematic affect regulation (Tasca & Balfour, 2014). For example, both Ivanova and colleagues (2015) and Lo Coco and colleagues (2016) found that affect regulation mediates the relationship between interpersonal problems and binge eating in a sample of patients with BED.

As regards Reflective Functioning, Kuiper and Bekker (2012) reviewed 3 studies suggesting that EDs (especially AN) seem associated with lower RF, compared to healthy controls. Patients with ED reports also higher rates of childhood trauma, abuse, and loss, which are directly linked to the development of attachment insecurity, to worse psychopathological outcomes and to the development of disorganized mental states (Tasca & Balfour, 2014).

#### **1.4 Individual CBT and the “Transdiagnostic Model” of Eating Disorders**

Cognitive Behavioral Therapy (CBT) is a widely-adopted and effective psychotherapy, considered the gold standard for several mental disorders (e.g. depression; Butler, Chapman, Forman, & Beck, 2006). CBT was originally developed by Aaron T. Beck (1921 - ) and colleagues for the treatment of Major Depressive Disorder: Beck found that depressed patients, in front of specific situations, experienced streams of negative thoughts about themselves, the world and the future, which led to negative affects and subsequently to dysfunctional responses or behaviors (Beck & Greenberg, 1984). These automatic thoughts are strongly influenced by “fundamental beliefs” that develops during the childhood (e.g. "I'm incompetent or unlovable" Beck & Greenberg, 1984).

The main objective of a CBT treatment is modifying the dysfunctional thoughts, substituting them with more reality-oriented ones: thus, the therapist teach the patient to monitor these thoughts, and to recognize the association between specific cognitions, negative affects and behaviors (Beck & Greenberg, 1984).

As regards Eating Disorders, the most up-to-dated CBT theory, namely the “Transdiagnostic Model”, was developed by Fairburn and colleagues (2003) to explain the maintaining factors of Bulimia Nervosa; later, it was extended to other EDs. Indeed, the CBT rationale for the treatment of BED explained in section 1.3.1, is largely based on the Transdiagnostic Model. The model posits that the core psychopathology of any ED is the “over-evaluation of weight, shape, eating

and their control” (Fairburn et al., 2003): this over-evaluation leads to the behavioral symptoms of eating disorders (i.e. binge eating, extreme weight-control behaviors such as dietary restraints, over-exercise, self-induced vomiting, and use of laxatives) (Fairburn et al., 2003). In addition, it interacts with other four additional maintaining processes, namely:

- Clinical perfectionism, or the over-evaluation of the striving for, and achievement of, personally demanding standards, despite adverse consequences (Fairburn et al., 2003). Clinical perfectionism is applied to several aspects of life; within the model, it is directly related to the core psychopathology (Fairburn et al., 2003).
- Core low self-esteem, or the “unconditional and pervasive negative view of themselves” (Fairburn et al., 2003). These evaluations are part of the identity of the patients, and limit the possibility of change (e.g. due to a sense of hopelessness). According to the Transdiagnostic model, the core low self-esteem is directly related to the core psychopathology, and with clinical perfectionism (Fairburn et al., 2003).
- Mood intolerance, or the inability to cope with negative mood states (e.g. anger or anxiety). ED patients do not try to cope nor accept their negative mood states, but rather adopt dysfunctional and impulsive mood-modulating behaviors, such as some ED behaviors (e.g. binge eating or self-induced vomiting), self-injury, and substance use (Fairburn et al., 2003). Fairburn *et al.* (2003) suggest that mood intolerance is directly related to the core psychopathology, and with both core low self-esteem and clinical perfectionism.
- Interpersonal difficulties, or problems in “establishing and maintaining supportive personal, family, and social relationships” (Tasca, Presniak, et al., 2011). According to the model, this well-known maintaining factor interact with and influence the other three (Fairburn et al., 2003).

Fairburn proposed also a transdiagnostic treatment which is suitable for all EDs: available in 2 versions (i.e. 20 sessions for most of the patients, and 40 sessions for those significantly underweight), this individual CBT treatment has four stages (Fairburn, Cooper, & Shafran, 2002). This treatment model combines psychoeducation and various cognitive-behavioral techniques, and aim at improving both the maintaining factors and core eating disorder psychopathology (Fairburn et al., 2002).

Interestingly, the Transdiagnostic Model was recently tested by Tasca and colleagues (2011) in a population of treatment-seeking ED patients ( $N = 1451$ ) using a structural equation modeling approach. The authors found that the model of the core and additional maintenance factors of Fairburn *et al* (2003) fit the data well, thus supporting its existence among ED patients.

#### **1.4.1 Guided and Unguided Self-Help**

As reviewed in section 1.1, in England only 15% of patients with a diagnosis of Eating Disorder receive a psychological treatment (Centre for Economic Performance, 2012): therefore, large part of the patients are unable to access specialized interventions. A possible solution is to deliver Self-Help treatments, which are brief, minimal-care, and evidence-based interventions derived from cognitive behavioral therapy (Traviss-Turner, West, & Hill, 2017). Basically, all Self-Help programs are delivered through books, computer programs, or audio-video materials, and aim at reducing ED symptoms by teaching patients skills to cope with, overcome and manage their difficulties (Perkins, Murphy, Schmidt, & Williams, 2006). Thus, they widely rely on psychoeducation and on CBT techniques. As reviewed by Perkins and colleagues (2006), Self-Help interventions have a number of advantages, such as i) allowing to deliver low-cost treatments with minimum delay, ii) allowing patients to work “in their own time and at their own pace”, iii) empowering the patients, i) reinforcing and consolidating learning (due to fact that ED patients suffer often of deficits in attention and concentration), and finally v) allowing the patients to re-start the treatment whenever they want, without no extra costs (Perkins et al., 2006). Adding self-help to a treatment as usual seem also to reduce the total societal costs (e.g. costs due to the use of health and non-health-care services) of patients with BED more than 400\$ over 12 months following the intervention (Lynch et al., 2010).

Self-Help treatments are defined Guided (GSH) if they include direct support from a health professional, which could monitor the patient’s progress, provide support and encouragement (Perkins et al., 2006); otherwise, these approaches are defined Unguided (USH) or “pure” self-help (Traviss-Turner et al., 2017). Both GSH and USH can be provided alone, or in adjunction with other psychological or pharmacological treatments; interestingly, studies comparing GSH and USH found no differences in outcomes between the 2 groups, both at the end of the treatment and at follow-up (Perkins et al., 2006). In addition, both approaches seem to be more effective when used among patients with BED, which experience less dropout and better outcomes during and

after a self-help treatment, compared to other EDs (Beintner, Jacobi, & Schmidt, 2014; Traviss-Turner et al., 2017). Finally, it should be noted that a problem in studies on self-help is drop-out rate, which seem to vary between 1 and 88% (Beintner et al., 2014).

As regards the efficacy, over the last decade several meta-analyses and systematic reviews were published: Perkins and colleagues (2006) meta-analyzed 12 randomized controlled trials (RCT) and 3 controlled trials on the efficacy of USH and GSH interventions in ED patients: both treatments moderately improved binge eating and a number of secondary symptoms (e.g. interpersonal functioning) in the short term. Additionally, the authors found no differences between self-help and other psychotherapies (e.g. CBT), as well as between USH and GSH, on several outcomes. However, these comparisons were probably underpowered, being based on a small number of studies (Perkins et al., 2006). A recent meta-regression on 30 RCTs (Traviss-Turner et al., 2017) showed that GSH significantly reduced binge episodes and eating psychopathology compared with controls; in addition, diagnosis of BED was an important predictor of outcome (i.e., patients with BED seem to respond in a better way to self-help treatments compared to other eating disorders). Traviss-Turner and colleagues (2017) also found that longer self-help treatments did not lead to better outcomes (i.e. there was no significant dose–response effect).

A commonly-used self-help manual for Binge eating is “*Overcoming Binge Eating*” (2013): written by Fairburn (the author of the “Transdiagnostic Model”; see section 1.5), the book has been used in most of the self-help studies performed to date (see for example Perkins et al., 2006; Traviss-Turner et al., 2017). The book is organized in two parts: the first provide psychoeducation (e.g. what is binge; differences between binge eating, eating disorders and obesity; psychosocial and physical correlates of binge eating), while the second offer the actual self-help program (Fairburn, 2013). The program has 6 steps, rooted in CBT techniques, and usually lasts 12 weeks. After each week, patients complete a summary sheet where they report for example their weight, the number of “good days” (whose definition change from step to step), and the number of binge episodes (Fairburn, 2013).

1. “Getting Started”: during the first step, patients start to self-monitor their eating behaviors, and to weight themselves weekly. The monitoring record is used for the entire length of the self-help program.



2. “Regular Eating”: in the second step, patients establish a pattern of regular eating (e.g. having three meals per day, plus two snacks), and tries to stop the extreme weight-control behaviors, such as vomiting or the misuse of laxatives. Patients receive also advices on how to consume meals, and on shopping or cooking.
3. “Alternatives to Binge Eating”: during this step, patients start using alternative activities (e.g. going out for a walk, exercising) when they have the urge to binge. Patients are encouraged to keep always with them a list of alternative activities (to check whenever they feel the urge to binge).
4. “Problem solving and Taking Stock”: in the fourth step, patients learn and practice how to solve in efficient way problems that could precipitate binge episodes, such as stress. Problems and their solution are also recorded in the monitoring record. In addition, during this step patients review their overall progress in detail.
5. “Dieting and Related Forms of Avoidance”: during this step, patients start to deal with dysfunctional forms of dieting, as well as with other forms of food avoidance.
6. “What next?”: in the final step, patients assess again their situation, and learn strategies to prevent relapse (e.g. having realistic expectations, or knowing how to deal with setbacks) and to deal with other problems (e.g. excessive concern about weight and shape, or depression\anxiety).

### **1.5 Group Psychotherapies and group therapeutic factors**

From an historical point of view, group psychotherapy originated in the US at the beginning of the nineteenth century, thanks to the pioneering work of Joseph H. Pratt (1872-1956). The American physician led “classes” with Tuberculosis patients to alleviate the distress caused by their condition (Stricker & Widiger, 2003). Later, Trigant Burrow (1875-1950) and Samuel Slavson (1890-1981) contributed to the further development of group therapy, the formed conducting group therapeutic sessions with non-institutionalized patients, the latter founding the American Group Psychotherapy Association in the 1948 (Stricker & Widiger, 2003). In Europe, pioneers in this field were the psychoanalysts Jacob L. Moreno (founder of psychodrama; 1889-1974) and Wilfred R. Bion (1897-1979), who both started working in group settings in mid-1900 (Stricker & Widiger, 2003). After 30 years of research, group psychotherapy is actually considered an effective and evidence-based treatment for several mental disorders (such as ED; Grenon et al., 2017; Yalom & Leszcz, 2005). Indeed, most of the treatment-seeking patients experience interpersonal-related

issues, so that group format constitutes a good therapeutic choice for them (Marmarosh, Markin, & Spiegel, 2013). In addition, a previous meta-analysis on 23 studies suggested that group treatments have similar outcomes to individual therapy (Burlingame, Fuhrman, & Mosier, 2003).

Today, several group formats (i.e. structured, unstructured, online) and theories supporting group interventions (i.e. CBT or psychodynamic) exist (Marmarosh et al., 2013). However, all group psychotherapies share common background and techniques, helping clients to change through a complex interaction of several self- and other-focused factors (Yalom & Leszcz, 2005). Usually, therapists screen potential participants (e.g. including in groups only few patients with severe psychopathology) and determine who is appropriate for group therapy before it starts; in addition, they usually provide a pre-treatment group session to all participants, where they provide information on the rationale of the treatment (Marmarosh et al., 2013). According to Yalom and Leszcz (2005), group therapy could be described as a “dual process consisting of emotional experience and of reflection on that experience”. Within this context, change is induced through 11 interdependent therapeutic factors, namely 1) Instillation of hope, 2) Universality, 3) Imparting Information, 4) Altruism, 5) The corrective recapitulation of the primary family group, 6) Development of socializing techniques, 7) Imitative behavior, 8) Interpersonal learning, 9) Group cohesiveness, 10) Catharsis, and 11) Existential factors (for more information, see Yalom & Leszcz, 2005).

- **Instillation of hope**, or believing in the efficacy of a treatment, is a well-known therapeutic factor that can itself be effective to determine a change in the patient (Grencavage & Norcross, 1990; Snyder & Taylor, 2000). Indeed, high levels of expectations in the efficacy of the treatment are positively and significantly correlated with the therapy’s outcome (Yalom & Leszcz, 2005): noticeably, placebo effect is probably mediated by expectancies (i.e. hope) of the individuals on the efficacy of a treatment with no “active” therapeutic effect.
- **Universality** is the disconfirmation of the “feeling of uniqueness” of the individual about his symptoms. Indeed, due to their social isolations, patients have difficulties in sharing their experiences, thus exacerbating their sense of loneliness (Yalom & Leszcz, 2005). As such, sharing problems, fantasies and thoughts and noticing that they’re experienced by many others, help patients to overcome their sense of uniqueness (“we are in the same boat”) and subsequently improve their symptomatology (Yalom & Leszcz, 2005).

- **Imparting information** to patients is another key-feature of group psychotherapies: it is composed by two main components, namely Psychoeducation and direct advices. As regards the latter, members of the group regularly give advices and suggestion that help other members to better understand themselves. On the contrary, Psychoeducation is provided by group therapists, which offers to patients basilar information on the process of group psychotherapy (i.e. group dynamics), as well as on psychic functioning and the meaning of their symptoms (Yalom & Leszcz, 2005). Noticeably, Psychoeducation is considered an effective treatment for anxious and depressive disorders and a first-line psychological approach (i.e. gold standard) in psychotic and bipolar disorders (Donker, Griffiths, Cuijpers, & Christensen, 2009).
- Altruistic acts allow participants to help one another (i.e. offering support and reassurance): as such, **altruism** is fundamental for the development of an adequate sense of group's cohesion and, generally speaking, to ensure positive outcomes of the treatment (Yalom & Leszcz, 2005).
- Due to fact that group setting figuratively resemble a family (e.g. the therapist is seen as a parental, authoritative figure; strong emotions are involved), group treatments provide the opportunity to change and correct those dysfunctional and/or unsatisfactory relations that most of the patients had within their primary family (**corrective recapitulation of the primary family group**). In addition, group therapies allow members to i) **develop their socializing skills** thanks to the continuous interactions between participants, as well as to ii) learn from others and from the therapist through **imitative behaviors** (Yalom & Leszcz, 2005).
- **Interpersonal learning** is considered one of the most important therapeutic factors. As already mentioned in the previous paragraphs, psychological symptoms can be partially attributed to dysfunctional early interpersonal relationships. As such, the group could be conceptualized as a social microcosm, within which the members repeatedly display their maladaptive and dysfunctional behaviors. Yalom & Leszcz (2005) described group therapy as a “hall of mirrors”, due to fact that everyone can see in the others those problems they struggle with every day. Therefore, thanks to this therapy format each group member has the opportunity to reflect on and understand the meaning and the dynamics of their behavior. Finally, once the group is perceived as a “safe” environment, the patient can expose himself

to those emotional situations previously considered unmanageable, generating an emotional corrective experience (Yalom & Leszcz, 2005).

- **Group cohesiveness** (or the attractiveness of a group for its members) is a fundamental ingredient for the efficacy of each group therapy, regardless their theoretical orientation (Yalom & Leszcz, 2005). Higher levels of cohesiveness are positively and strongly associated to better therapy outcomes, and to reduced drop-out rates (Joyce, Piper, & Ogrodniczuk, 2007). Indeed, a cohesive group is characterized by high levels of acceptance, understanding and support, allowing its members to form meaningful relationships and express and explore more deeply themselves (Yalom & Leszcz, 2005).
- Finally, the latest therapeutic factors mentioned by Yalom and Leszcz (2005) are emotional **catharsis** (or the experience of relief from emotional distress, through the open expression of strong affects) and **existential factors** (or the confrontation within the group setting with existential facts, such as human mortality and the pursuit of the meaning of life).

### 1.5.1 Attachment in Group Psychotherapies

Attachment theory, reviewed in section 1.2, provide an interesting framework to understand both the dynamics of all types of group therapy, and the group therapeutic factors (listed in the previous paragraph). Indeed, participants' attachment styles influence the group process: when the individual interact with other members of the group, he\she rely on his previous attachment experiences to “manage group processes, meet internal needs, and cope with his emotions” (Marmarosh et al., 2013). Group dynamics automatically trigger in each participant his\her beliefs (i.e., the Internal Working Models of the self and of the others), which are used to interpret the new relationships within the group: these interpretations subsequently influence the individual's behaviors (e.g. if and how he\she empathize with others, or manage conflicts) (Marmarosh et al., 2013). As regards specific attachment styles:

- Securely attached individuals are generally well suited for group psychotherapy (e.g. they easily share their emotions, provide support to other members, tolerate conflicts, express their opinion on therapists), and can facilitate the group process (Marmarosh et al., 2013).
- Preoccupied members fear rejections and are generally distrustful of others, but they attempt to control their anxiety of loss and abandonment using hyperactivating strategies, such as showing high levels of emotional proximity to other members (Marmarosh et al.,

2013). They require frequent reassurance and seek out relationships: however, these behaviors ultimately lead other group members to keep the preoccupied individual at distance (Marmarosh et al., 2013).

- Dismissing individuals tend to avoid other members (sometimes even offending them with insensitive comments), to not express their emotions and to display a lack of empathy (i.e. not listening to others), insight, as well as a pathological narcissism (Marmarosh et al., 2013). As such, these patients have a higher risk of drop-out.
- Finally, disorganized members tend to withdraw from relationships and deactivate emotions (e.g. attachment needs) within the group, but they do not deny the need of others: in addition, they typically display a lack of assertiveness and higher levels of distrust compared to other insecurely attached individuals, so that they could be easily exploited by other members (Marmarosh et al., 2013).

As reviewed by Marmarosh and colleagues (2013), the group therapy allows participants to i) explore, in the here-and-now, their relational injuries which prevented them to “maintain closeness or tolerate distance” from attachment figures and/or significant others, ii) develop new capacities to cope with unacceptable emotions, and finally to iii) explain their symptoms (e.g. avoidance or anxiety), connecting them in a coherent way with early dysfunctional experiences. Over time (and if groups are well conducted) members start perceiving the group itself as a “safe base”, from where to start exploring their internal world (Marmarosh et al., 2013). Within this safe base, members can finally have corrective emotional experiences, which ultimately help them to regulate and understand emotions, and to potentially develop a secure attachment (Marmarosh et al., 2013). Finally, the role of the group leader (i.e. the therapist) is to facilitate this process of change, using for example empathic attunement, facilitating mentalization, identifying and challenging transference phenomena, or providing feedback and insight of participants’ feelings (Marmarosh et al., 2013).

### **1.6 Group Psychodynamic Interpersonal Therapy (GPIP) for BED**

Group Psychodynamic Interpersonal Therapy (GPIP) is an evidence-based therapy specifically developed by Dr. George Tasca for the treatment of Binge Eating Disorder (Tasca, Ritchie, et al., 2006). GPIP integrates psychodynamic, interpersonal and attachment theories, and posits that patients with BED engage in repetitive maladaptive interpersonal interactions to avoid feelings of

abandonment and rejection: these interactions perpetuate “cyclical relational patterns, and reinforce negative introjects or internal working models” (Tasca, Ritchie, et al., 2006). Thus, in order to overcome binge eating, GPIP focuses on challenging the patients’ dysfunctional CRPs, and on building and reinforce new relational patterns (Tasca, Mikail, & Hewitt, 2005).

GPIP relies on a modified version of the Malan’s model of the two triangles (Triangle of Conflict, and Triangle of Person; Malan, 1979) to understand symptoms from a psychodynamic point of view (Tasca et al., 2005). In the GPIP redefinition of the Triangle of Conflict (renamed as Triangle of Adaptation), each individual has attachment needs, considered “the primary movers of thoughts, behaviors and emotions” (Tasca et al., 2005): if these needs are unmet, the individual experience anxiety or other negative affects such as anger; finally, the individual adopt defense elements (i.e. dysfunctional relational styles) as a solution to maintain self-esteem and self-concept and to avoid unwanted experience of negative affects (Tasca et al., 2005). Noticeably, the defense elements are always interpersonal. The triangle of Person (renamed in Triangle of Object Relations) consists of parallel relationship patterns between i) *past* relationships with Self and Others (i.e. parents), ii) *current* relationship with Self and Others and iii) the current relationship with the Therapist/group (Tasca et al., 2005). Thus, attachment constitutes one the main theories that inspired GPIP.

The Cyclical Relational Patterns (CRPs) are problematic interpersonal relations that are perpetuated by the individuals during their everyday life and during the group therapy interactions (Strupp & Binder, 1984). They incorporate specific aspects of client's behaviors, such as Acts of Self (e.g. cognitions, perceptions, needs), Expectations of others, Acts of Others and Introjects (for a review, see Tasca et al., 2005). According to GPIP, CRPs should be conceptualized taking into account the "defense elements" of the Triangle of Adaptation: the individual adopt dysfunctional relational styles (i.e. CRPs) to regulate his\her negative affects (which originate from unmet attachment needs), or to banish them from awareness (Tasca et al., 2005). Thus, the cost for a temporary relief is the development of psychological symptoms. The therapist could use the CPRs to make sense of the patients' interpersonal behaviors, and understand their needs, affective states, defenses, and their expectations of others. The final objective of GPIP is helping clients to have more rewarding interpersonal patterns: to achieve this goal, within the group setting the therapist point out the CRPs to the clients, which in turn can deeper the understanding of their behavior and even lead to a change in their self-concept (Tasca et al., 2005).

Finally, GPIP relies on the interpersonal theory and circumplex models of personality: according to the interpersonal construct of the self-system (Sullivan, 1953), the individual develops both the Introject (i.e. the relationship with themselves) and the concept of self during early interactions with parental figures (Tasca et al., 2005). During their lives, individuals try to avoid any unfamiliar social interaction (which could lead to feelings of insecurity and anxiety), thus creating "an interpersonal world that is familiar and predictable", even if dysfunctional (Tasca et al., 2005). As such, patients with BED engage in maladaptive interpersonal relationships because -according to the self-system construct- they constitute the only familiar interactions patients ever experienced. The interpersonal theory also suggests that interactions are complementary, so that the typical interpersonal behaviors of an individual evoke specific interpersonal responses from another (e.g. dominant behaviors tend to evoke submissive ones; Tasca et al., 2005).

As regards the treatment itself, GPIP is delivered in 16 sessions, each lasting 90 minutes, with a maximum of 8 or 10 participants per group. The treatment focuses both on relevant materials from the past of the patients, and on the actual interactions among group members and with the therapist (Tasca, Ritchie, et al., 2006). Prior to the start of the treatment, all clients attend a pre-group preparation session, during which their CPRs are assessed: in this way, the therapist explore, separately for each patient, how unmet attachment needs and negative affects lead to binge symptomatology (Tasca et al., 2005; Tasca, Ritchie, et al., 2006). In the early stage of the treatment, the therapist focus on understanding patients' CRPs; in the middle stage, therapist start challenging the CRPs "as they were expressed in the group interactions, with the intent of modifying the interactions in the group and outside of the group" (Tasca, Ritchie, et al., 2006). Finally, during the late stage, therapist reinforce the new clients' CRPs and their introjections, and help patients to better cope with losses and separations (Tasca, Ritchie, et al., 2006).

A previous randomized controlled trial evidenced the effectiveness of this treatment: in 2006, Tasca and colleagues investigated the efficacy of GPIP compared to group Cognitive Behavioral Therapy (GCBT) and a control group (i.e. waiting list). A total of 135 patients were randomized to one of the three conditions. Results showed that the two treatments led to similar outcomes (i.e. reduced days binged and ED psychopathology) at post treatment, and these improvements were maintained at twelve-month follow-up (Tasca, Ritchie, et al., 2006). Both GCBT and GPIP

reduced symptomatology, compared to the control condition. Finally, GPIP reduced depressive symptoms and improved self-esteem, compared to GPIP and wait list.



## **2. Stepped Care Study**

### **2.1 Introduction**

Mental disorders are extremely common syndromes among general population, with lifetime prevalence estimates of 25% in Western societies (Alonso et al., 2004). However, only a little percentage of patients receive a treatment, even if untreated mental issues lead to lower wages and employment rates and have several psychosocial consequences (Smit et al., 2006). As such, health care systems are actively searching for better ways to deliver evidence-based treatments in a cost-effective manner, and reach as many patients as possible.

A possible approach is stepped care: the term refers to a model of healthcare delivery, that aims to increase the efficiency of welfare services and reduce economic burden adopting briefer minimal interventions, distributed in different steps (Bower & Gilbody, 2005; Ho, Yeung, Ng, & Chan, 2016). Thus, a stepped care program would begin with the most cost-effective, least intensive and time consuming treatment (Ho et al., 2016; Loeb, Wilson, Gilbert, & Labouvie, 2000): for example, in the United Kingdom the National Institute for Health and Care Excellence (NICE) consider CBT-oriented guided self-help as a first-line intervention for individuals with specific disorders, such as Binge Eating (NICE, 2017). If the first treatment is ineffective, then the program would move incrementally to more intensive therapies, such as group Cognitive Behavioral or Interpersonal treatments. This would allow to use in a more efficient way the available healthcare resources (Bower & Gilbody, 2005). Indeed, a group treatment allows more people to be treated while using fewer resources, and is effective as individual therapies (Burlingame et al., 2003; McRoberts, Burlingame, & Hoag, 1998). Stepped care models have been used for the treatment and prevention of anxious, depressive and substance use disorders (Ho et al., 2016). However, there is little evidence supporting the use of stepped care in specific eating disorders such as Binge Eating, despite its potential to make treatment more widely available and more cost effective.

Binge Eating Disorder (BED) is a serious mental illness characterized by persistent and recurrent episodes of over-eating accompanied by a sense of a loss of control (i.e., binge eating), significant distress over binge eating, but no compensatory behaviors (e.g. vomiting; American Psychiatric Association, 2013). BED is considered the most common eating disorder, with recent worldwide prevalence estimates ranging from <1 to 4.7% (Cossrow et al., 2016; Keski-Rahkonen & Mustelin, 2016). BED is associated with poor physical health and higher occurrence of somatic diseases,

such as diabetes and hypertension (Ágh et al., 2015). This association is likely explained by obesity (Ágh et al., 2015), which is a highly prevalent condition among patients with BED (Hudson et al., 2007; Kessler et al., 2013). BED is also significantly related to distress, psychosocial impairment, and high rates of comorbid psychopathology (Hudson et al., 2007). Indeed, more than 80% of community or treatment-seeking patients with BED meet the criteria for at least one other mental disease, such as anxiety or mood disorders (Grilo et al., 2009; Kessler et al., 2013).

A known risk factor for the development of BED is childhood adversity (i.e. abuse, neglect, or loss; Smolak & Murnen, 2002). Little is known about why negative experiences in childhood may result in BED for some. Attachment theory (Bowlby, 1969), with its focus on childhood experiences on adult functioning, provides a potential explanation. According to attachment theory, early interactions with a caregiver become encoded in the implicit memory system, which then develops into internal working models of attachment (Tasca & Balfour, 2014). Over time, these internal working models become the bases “for consistent ways in which children and adults interact with the world, experience themselves and others, and regulate affect” (Tasca & Balfour, 2014). Thus, dysfunctional interactions during infancy and childhood could possibly lead to impaired internal working models and an insecure attachment state. Classified as dismissing (i.e. avoidant) or preoccupied (i.e. anxious; Tasca & Balfour, 2014), insecure attachment is characterized by reduced affect regulation and dysfunctional interpersonal relationships (Ivanova et al., 2015). Indeed, interpersonal problems are a key aspect of BED: these patients, in order to avoid feelings of rejection or abandonment, engage in repetitive, maladaptive interpersonal interactions that perpetuate cyclical relational patterns (CRPs), and reinforce negative internal working models (Tasca & Balfour, 2014; Wilfley, MacKenzie, Welch, Ayres, & Weissman, 2000). Therefore, from a psychodynamic point of view, binge eating symptomatology is triggered by interpersonal problems, and this relationship is partially explained by higher levels of negative affect (Ivanova et al., 2015). Given the importance of maladaptive interpersonal relationships in maintaining this disorder, a group therapy format could represent the best choice for patients with BED. Indeed, groups act as a social microcosm in which interpersonal patterns can be observed in vivo, with immediate feedbacks from therapists and group members (Yalom & Leszcz, 2005). Past research evidenced the efficacy of Group Psychodynamic Interpersonal Psychotherapy (GPIP) in the treatment of BED (Grenon et al., 2017; Tasca, Ritchie, et al., 2006). This manualized treatment proved its efficacy in a randomized controlled trial: GPIP was more effective than a control

condition and as effective as a Group Cognitive-Behavioral Therapy (GCBT) in reducing days binged and a number of secondary outcomes (i.e. depression, interpersonal problems, eating psychopathology; Tasca, Ritchie, et al., 2006). Therefore, several lines of evidence suggested that the improvement of dysfunctional interpersonal relationships could lead to better outcomes among these patients (Grenon et al., 2017; Tasca, Ritchie, et al., 2006).

Another commonly used treatment for BED is CBT, which focuses on “identifying relationships among thoughts, feelings, and behaviors, and to reduce negative emotions and undesirable behavior patterns by changing negative thoughts about oneself and the world” (Brownley et al., 2016). In this regard, the transdiagnostic cognitive-behavioral model of eating disorders (ED) suggests that cognitive distortions (i.e. overvaluation) about the patients’ own shape and weight are the core psychopathological features of all EDs (Fairburn et al., 2003; Murphy, Straebl, Cooper, & Fairburn, 2010). According to the transdiagnostic model, patients with BED try to adhere to several, extreme dietary rules (Murphy et al., 2010). However, they react negatively to even minor dietary slips, considered the results of poor self-control competencies (Fairburn et al., 2003). This can lead to a temporary interruption of the dietary restraints, triggering a binge episode (Fairburn et al., 2003). As a result, patients renew their efforts to control eating behaviors, shape and weight, which in turn increase the risk of further binge eating episodes (Murphy et al., 2010). Recent meta-analyses suggested that CBT is an effective treatment for BED (Brownley et al., 2016; Peat et al., 2017). In addition, evidence has shown that patients with EDs respond to simple, non-specialist treatments, such as self-help books (Carter & Fairburn, 1998). For example, Fairburn (2013) wrote “*overcoming binge eating*”, a self-help book composed of a psychoeducational (which provides the rationale for the program) and a CBT section. A recent meta-regression on 30 RCTs showed that guided self-help for EDs is effective in reducing binge episodes and eating disorder psychopathology, compared with both waiting list and other active treatments (Traviss-Turner et al., 2017). Finally, Perkins and colleagues (2006) in their Cochrane review evidenced no differences on several outcome measures between guided and unguided self-help for EDs: these findings are particularly relevant, given that in “real world” applications it would be far more common to administer a self-help treatment with minimal interventions from health care professionals.

There is a growing interest in evidence-based, cost-effective interventions for BED. In a recent review, Ágh and colleagues (2015) showed that BED is associated with increased healthcare utilization and healthcare costs. For example, Grenon and colleagues (2010) found that the total healthcare cost of women with BED was more than 1/3 higher compared to a matched healthy control group. These factors, in addition to the high prevalence of this mental disease (Cossrow et al., 2016; Keski-Rahkonen & Mustelin, 2016), suggest that specialist resources to treat all existing cases of BED will unlikely be available in the future (Carter & Fairburn, 1998). Moreover, treatments for BED are moderately effective, so that more than half of those with BED abstain from binge eating after receiving specialized therapy (Brownley et al., 2016; Grenon et al., 2017; Peat et al., 2017). However, not everyone with BED may require an expensive and difficult-to-access specialized treatment, suggesting the usefulness of a stepped care approach. In addition, this approach could lead to better outcomes. Fairburn and colleagues' (2003) transdiagnostic cognitive-behavioral model of the maintenance of eating disorders proposes that in some people, the core eating disorder maintaining processes (i.e. overvaluation of the body shape and weight) may also be joined by one or more of the four additional maintenance processes: clinical perfectionism, core low self-esteem, mood intolerance, and interpersonal difficulties. They theorized that for some individuals, a CBT intervention that does not target these additional maintaining processes may be less effective (Fairburn et al., 2003). Thus, a second step of treatment using GPIIP may be necessary to target the additional maintenance processes for those who do not respond to self-help alone.

The main aim of this Randomized Controlled Trial (RCT) was to investigate the efficacy of a stepped care approach for the treatment of patients with BED. All participants received unguided, CBT-oriented self-help. At the end of this first step, they were randomized to either GPIIP or no treatment control, with follow-ups at 3 and 6 months post-treatment. We tested two hypotheses: first, that unguided self-help (USH) will significantly reduce binge episodes (considered the main outcome of this study) as well as eating psychopathology, in accordance with the transdiagnostic cognitive-behavioral model (Fairburn et al., 2003); second, that GPIIP will further reduce binge episodes and significantly improve a number of secondary outcomes (e.g. eating psychopathology, interpersonal, and attachment related problems), in accordance with the treatment's rationale and previous findings (Tasca, Ritchie, et al., 2006).

## **2.2 Methods**

### **2.2.1 Participants**

Participants in the first part of the study, the unguided self-help (USH), were 135 individuals who met DSM-5 (American Psychiatric Association, 2013) diagnostic criteria for BED. After USH, the 85 participants who remained in the study were randomly allocated to either Group Psychodynamic Interpersonal Therapy (GPIP; N = 39) or to a no-treatment control condition (N = 46). All demographic characteristics for those in USH and then GPIP and control are reported in Table 1. Exclusion criteria included: non-English speaking, pregnancy (current or planned within next year), enrolment in other psychotherapies/weight loss programs (current or planned within next year), or comorbid bipolar, psychotic and substance dependence disorders.

### **2.2.2 Measures**

#### **Diagnosis**

The Structured Clinical Interview for DSM–IV Axis I Disorders (SCID-I/P; First, Spitzer, Gibbon, & Williams, 1996) is a semi-structured interview to diagnose lifetime or current Axis I mental disorders in accordance with DSM-IV-TR (2000). The interview was administered at pre-USH by expert clinical psychologists to investigate the presence of BED and other comorbidities. The interview was slightly modified to account for the new DSM-5 diagnostic criteria for BED. The inter-rater reliability of BED diagnosis between two independent judges on a random sample of 10% of participants was good,  $\kappa = 0.81$ .

#### **Binge Eating Frequency**

Number of binge eating episodes in the past 28 days were evaluated by experienced psychologists blind to the allocation of participants in the study using items from the Eating Disorders Examination (EDE; Cooper & Fairburn, 1987). The EDE is a semi-structured interview to assess the psychopathology and symptoms of eating disorders (Grilo, Masheb, Lozano-Blanco, & Barry, 2004). Using a calendar recall method, the EDE allows one to evaluate key behavioral aspects of eating disorders, such as the frequency of objective binge episodes, and the number of days during which these occurred (Grilo et al., 2004). Abstinence was defined as zero binges in the past 28 days. Improvement was defined as not meeting DSM-5 criteria for BED or having zero to three binge episodes in the past 28 days. In this study, the inter-rater agreement on frequency of binge

eating in the past 28 days between two independent judges at pre-USH was high, with an intra-class correlation coefficient ( $\rho$ ) = 0.91.

### **Depressive symptoms**

The Center for Epidemiologic Studies Depression Scale (CES-D; Radloff, 1977) is a 20-item self-report measure of depressive symptoms. The items are rated in a 4-point Likert-type scale, with higher total scores indicating greater depressive symptoms. A total score  $\geq 16$  suggest significant levels of depressive symptomatology. In this study, the mean coefficient alpha across all time points was 0.92, while the average mean inter-item correlation coefficient across all time points was 0.36. Inter-item correlation coefficients in the range of 0.15-0.50 are suggestive of a good internal consistency of a scale (Clark & Watson, 1995).

### **Interpersonal Problems**

The Inventory of Interpersonal Problems (IIP64; Horowitz, Rosenberg, Baer, Ureño, & Villaseñor, 1988) is a 64-item self-report scale that assesses types of interpersonal problems and provides an overall measure of interpersonal distress. Items are rated in a 5-point Likert-type scale, with higher total scores indicating greater interpersonal problems. In this study, mean coefficient alpha for the total score was 0.96, while the average mean inter-item correlation was 0.24.

### **Attachment**

The Experiences in Close Relationships Scale (ECR; Brennan et al., 1998) is a 36-item self-report measure of attachment styles. ECR measures two dimensions of attachment, namely Attachment Avoidance and Attachment Anxiety. Items are scored on a 7-point Likert-type scale, with higher scores indicating higher attachment avoidance or attachment anxiety. Each of the subscales is composed by 18 items. In this study, mean alpha coefficients were 0.96 and 0.94 for Attachment Avoidance and Attachment Anxiety scales, respectively. The average mean inter-item correlation coefficients were 0.58 for Avoidance, and 0.45 for Anxiety.

### **Eating pathology**

The Eating Disorder Examination – Questionnaire (EDE-Q; Fairburn & Beglin, 1994) is a 28-item self-report measure of eating disorder psychopathology. Items are rated on a 6-point Likert-type scale. Derived from the EDE interview (Cooper & Fairburn, 1987), the EDE-Q is composed by 4

subscales: Restraint (5 items) measures dietary restraint, Eating Concern (5 items) measures concern about eating, Shape Concern (8 items) measures preoccupation with one's body shape, and Weight Concern (5 items) measures preoccupation with one's body weight. In this study, mean alpha coefficients ranged from 0.67 to 0.82 for the subscales, while the average mean inter-item correlation ranged from 0.33 to 0.41.

### **Adherence to the treatment manual**

The Tape Rating Instrument for Psychotherapy of Eating Disorders (TRIPED; Olmsted, Isaacs, Bemis, & Garner, 1988) is a 30-items scale used to evaluate the quality of a psychotherapeutic session. The TRIPED includes five scales: among them, one assesses adherence to psychodynamic therapy (7 items) and was used to examine therapist adherence to the manuals. Items on the adherence scales are rated on a 7-point Likert-type scale, with higher mean item ratings indicating greater therapist adherence. The TRIPED was evaluated by two judges who rated three recordings from the early (week 3), middle (week 9), and late (week 14) stage of GPIIP. One judge previously received 30 hours of training, and the second judge was trained for this study. In the present study, the mean alpha coefficient for Psychodynamic Therapy Adherence scale was 0.85, while the average mean inter-item correlation was 0.49. In this study, the inter-rater reliability was evaluated by means of intra-class correlation coefficient (ICC) using a two-way random effects model. The ICC between two independent judges on a randomly selected week for each therapist was good,  $\rho = 0.77$ .

### **2.2.3 Interventions**

#### **Unguided Self-Help**

All participants attended a 10-week program of Unguided Self Help (USH). The USH was based on Fairburn's CBT-oriented and evidence-based self-help program for binge eating described in his book, *Overcoming Binge Eating* (2013). The book was provided to each participant for the study. In addition, participants received a typed version of the six steps of the book (pages 144-204), which was used as the manual for the USH. The manual was slightly edited to make it more specific to BED. In addition, participants received email reminders to indicate what step they should be on during a given week, and they received a link to a short online video that reminded them of the content of the current week's step and encouraged them to remain on track. A

participant could email or telephone the study research coordinator for technical help, but received no other contact with a mental health professional. In this way, the USH was delivered as it might be in a primary care setting with minimal guidance. The USH program follows six steps: (1) Getting started: Self-monitoring, weekly weighing; (2) Regular eating: Establishing a pattern of regular eating; (3) Alternatives to binge eating: Substituting alternative activities; (4) Problem solving and taking stock: Practicing problem solving and reviewing progress; (5) Dieting and related forms of avoidance: Tackling the three forms of dieting and other forms of avoidance eating; and (6) What next? Preventing relapse.

### **Group Psychodynamic Interpersonal Psychotherapy**

Post-USH, participants were randomized to one of two study conditions: GPIP or no treatment control. Those assigned to GPIP received a pre-group preparation plus 16 weekly 90-minute sessions GPIP, an empirically-tested and manualized treatment for BED (Tasca, Ritchie, et al., 2006). At the core of the treatment model is an assessment and intervention of the client's Cyclical Relational Pattern (CRP). The CRP is based on Strupp and Binder's (1984) individual therapy model that include four interpersonal elements: Acts of Self (representing behaviors, cognitions, feelings), Acts of Others (important others' behaviors towards the self), Expectations of Others (assumptions and predictions of others' behaviors, cognitions, and feelings). Each of these interpersonal elements each influence each other in an interactive feedback loop and define an intrapersonal element indicating a sense of self or Introject. The CRP is the basis of maladaptive interpersonal patterns and means of coping that may underlie binge eating. GPIP is consistent with attachment models of eating disorders (Tasca & Balfour, 2014) and the interpersonal model of binge eating (Wilfley et al., 2000). The individual pre-group preparation session (specifically outlined in the GPIP manual) was conducted by a psychologist who was not one of the group therapists. The pre-group preparation gave a rationale for the treatment and assessed the client's CRP. The potential impact of each participant's CRP in group therapy interactions was discussed in the pre-group preparation. This information about each patient's CRP was given to the group therapist before the start of the therapy. In the early stage of GPIP, the therapist focused on understanding participants' CRPs, its role in maintaining binge eating and related emotional and interpersonal distress, and on helping to develop a cohesive working group. In the middle stage, therapists challenged patients' CRPs as they were expressed in the group interactions, with the



intent of modifying the interactions in the group and outside of the group to help to reduce interpersonal distress, negative affect, and binge eating. In the late stage therapists focused on loss and separation as universal stressors, and new CRP patterns and accompanying self concepts were reinforced.

#### **2.2.4 Procedures**

Eligible participants were recruited from a regional centre for the treatment of eating disorders in a public hospital of a medium sized urban center in Canada. Some participants self-referred responding to media advertisements (e.g. local newspapers, newsletters, websites) between November 2012 and September 2014. Participants were initially screened by telephone by a Research Coordinator, who provided preliminary information on the study and assessed exclusion criteria and frequency of binge eating.

A total of 337 individuals were referred to the study and screened by phone. Qualified participants were subsequently invited to an interview with a member of the study team to assess for binge eating, exclusion criteria, comorbid disorders, medications, medical problems, personal and psychiatric history. In addition, participants underwent the Structured Clinical Interview for DSM-IV (SCID-I/P), which was used to establish a current diagnosis of BED, and participants completed the psychometric battery and the EDE interview. Of 337 individuals who were referred, 165 were excluded after the telephone interview for not meeting inclusion criteria or not being interested in the study, 22 were excluded after completing the SCID due to not meeting criteria for BED, and 15 dropped out of the study prior to starting USH. As a result, 135 participants started the USH: 85 completed the 10-week program, 47 dropped out during USH, and 3 dropped out of the study after USH. The 85 individuals who continued with the study were re-assessed before being randomized to either control ( $n = 46$ ) or treatment ( $n = 39$ ) conditions. In GPIP, 26 completed the entire group therapy and 13 dropped out (although 6 of the drop-outs continued to provide data at post-treatment). Of those in the control condition, 35 provided post control data and 11 dropped out of the study and did not provide further data. Analyses with 6-months post-treatment data included 28 participants in GPIP and 28 participants in the control condition. Figure 1 shows a CONSORT diagram illustrating participants' flow during each phase of the study.

Participants in the control condition waited 16 weeks without treatment. After the 6 months' follow-up period, these individuals were offered group therapy but these group therapy data were

not used in this study. All group therapy sessions were videotaped for supervision and for the assessment of therapist adherence to the manual: in total, 5 GPIP groups were formed (not including those offered to control condition participants after the study). Groups were conducted by five therapists: three Ph.D. psychologists, one psychiatrist and one social worker (mean age = 41.4; SD = 9.53). Four of the therapists were women, and all had least three years of experience in providing group therapy and therapy of eating disorders. Each therapist attended a 2-day training workshop that focused on the GPIP manualized treatment. Therapists received individual and group supervision weekly by a senior psychologist with more than 20 years' experience in group therapy, supervision, and treatment of eating disorders.

Participants received a reimbursement for travel expenses (i.e. parking costs or bus fare) but no other inducements. After participants received a complete description of the study, written informed consent was obtained from each participant prior to their enrollment. The study was approved by the local research ethics board and registered at [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) (registration number: NCT01837953).

### **2.2.5 Data Analysis**

To test hypothesis 1, that USH will have a positive effect on the outcome variables, we used paired-sample *t*-tests on pre- and post-USH data. Differences between dichotomous paired variables (presence\absence of abstinence from binge eating) were investigated through McNemar's test. For these data we adopted an intention-to-treat approach using the last observation carried forward method (Montori & Guyatt, 2001). Effect sizes for repeated measurements were assessed using Cohen's *d* (Cohen, 1988), and interpreted as small > .20, medium > .50, or large > .80.

To test hypothesis 2 that compared to the no-treatment control condition GPIP will result in greater change in the primary and secondary outcomes, we evaluated change in the outcome variables across four time points (pre-, post-, 3 months post-, and 6 months post-treatment). Pre-scores or pre-outcome status were included in the models to control for any differences between conditions on outcome variables at baseline. Initially, we assessed for dependence in the data with three-level hierarchical linear models (repeated measurements at level 1 nested within individuals at level 2, nested within groups at level 3) with intra-class correlation coefficients (ICC) by the method suggested by Tasca and colleagues (2009). Dichotomous variables (e.g. presence\absence of abstinence from or improvement in binge eating) were analyzed using hierarchical generalized

linear models (HGLM) with population-average model estimates. For HGLM models of dichotomous outcomes, ICCs to assess dependence in the data was computed using the method suggested by Snijders and Boskers (1999). An examination of the ICCs showed that less than 1% of the variance ( $ICC < .01$ ) for each outcome variable was accounted by the group level, indicating very small and ignorable dependence in the data (Kenny, Kashy, & Bolger, 1998). The only exception was for frequency of binge eating which had an  $ICC = 0.37$ . Due to ignorable dependence in most of the outcome data, we adopted two-level hierarchical linear models with repeated measurements at level 1 nested within individuals at level 2. However, for analyses of frequency of binge eating we ran two level models setting the Type I error rate at  $p = 0.003$  to adjust for possible inflation due to dependence in these data. Baseline values at pre-treatment, or pre-outcome status in the case of HGLM analyses, were grand centered at level 2 (see Appendix for all the models). Parameters were estimated using a full maximum likelihood approach, while model fit was evaluated using likelihood-ratio tests (Kutner, Nachtsheim, Neter, & William, 2005). In case of HLM analyses, effect sizes for the treatment effect were assessed and reported using pseudo- $R^2$  (Tasca, Balfour, Presniak, & Bissada, 2012). The HLM and HGLM models allow one to estimate reliable parameters for each individual without imputing missing data if the data are missing at random. This essentially results in an analysing an intent to treat sample. To evaluate if data may be missing at random we ran several pattern mixture models testing if patterns of dropping out or of having any missing data in the second phase of the study were significantly related to outcomes (Gallop & Tasca, 2009). All analyses were performed using Hierarchical Linear Modeling software, version 7 (Raudenbush, Bryk, Cheong, Congdon, & du Toit, 2011) and Statistical Package for Social Science (SPSS) version 23.0. All statistical tests were 2-sided; a  $p$  value  $\leq 0.05$  was considered statistically significant for any a priori hypothesis.

## **2.3 Results**

### **2.3.1 Preliminary analyses**

Preliminary analyses found no violations of univariate normality assumptions for all continuous variables, except for frequency of binge eating. This variable was slightly positively skewed at post-USH. A square root transformation of both pre- and post-USH data corrected the non-normality. However, analyses run with and without transformed variables gave similar results, thus we used non-transformed data for ease of interpretation (Tabachnick & Fidell, 2007). We also

found few outliers (from a minimum of 1 to a maximum of 4) at any time points for frequency of binge eating. The extreme scores were brought into range, as suggested by Tabachnick & Fidell (2007). Finally, the mean item rating in the TRIPED Psychodynamic Therapy Adherence scale was  $3.25 \pm 0.78$ , suggesting an adequate adherence to the manual by therapists, across the 3 evaluated sessions.

### **2.3.2 Outcomes from Unguided Self-Help**

We tested hypothesis 1 by analyzing changes between pre- and post-USH (Table 2). Of the 135 who began USH, 47 (34.82%) did not complete the treatment (Figure 1). Analysing the intent to treat sample, we found a significant decrease in frequency of binge eating in the past 28 days ( $p < 0.001$ ), with a medium effect size,  $d = 0.59$ . At pre-USH, none of the participants was abstinent of binge eating. After the self-help treatment, 9.6% of participants were abstinent and 30.4% improved (0-3 binges in the past month). Both of these changes were significant, according to McNemar's test ( $p < 0.001$ ).

We also found a significant decrease in EDEQ subscales ( $p \leq 0.001$ ), attachment avoidance ( $p = .047$ ) and attachment anxiety ( $p = .037$ ), but the effect sizes were all small ( $d = 0.175$  to  $0.325$ ). Changes in all other variables pre- to post-USH were not statistically significant and effects were small (see Table 2).

### **2.3.3 Outcomes at Post-Group Treatment and Follow-Ups**

Means and standard deviations for all outcome variables, across the four time points (pre-, post-, 3 months post-, and 6 months post-treatment) are reported in Table 3. Table 5 shows the frequencies and percentages of participants in control and treatment groups with 0 (abstinent), and with 0 to 3 binges (improved), across all time points.

Our second hypothesis was that GPIP following USH would result in better outcomes than the control condition following USH. Of those who started GPIP ( $n = 35$ ), 26 completed indicating a drop-out rate of 25.7%. Drop-out from the control condition was 23.9%. We first tested if the data may be missing at random with two pattern mixture models (Gallop & Tasca, 2009). There were no significant effects of these missing data patterns on any variable and so we proceeded on the assumption that the data were missing at random. Next, we evaluated linear changes in outcome variables across the 4 time points (pre-, post-, 3 months post-, and 6 months post-treatment),

controlling for each dependent variable's baseline values and modeling the effect of condition (i.e. treatment versus control at level 2; see Appendix Model 1). Table 4 shows the effect of condition on the linear parameter estimates for each variable.

The 2-level hierarchical generalized linear models showed a significant effect of the condition on both dichotomous variables, namely abstinence from binge eating,  $p = 0.040$ ; OR = 0.61 (95% CI = 0.39 – 0.98), and improvement in binge eating,  $p = 0.039$ , OR = 0.67 (95% CI = 0.46 – 0.98). Odds ratios indicate that compared to the control condition more than 1\3 of individuals in the treatment condition changed their binge eating behavior status (e.g., from non-abstinent to abstinent or from non-improved to improved) from pre- to 6 months post-treatment. However, we found no significant effect of condition on the linear change in frequency of binge eating in the past 28 days from pre- to 6 months post-treatment.

There was a significant effect of condition on several secondary outcomes. Compared to individuals in the control condition those in GPIP showed greater improvement from pre- to six months post-treatment in: attachment avoidance ( $p < 0.001$ ), interpersonal problems ( $p = 0.023$ ), and weight concerns ( $p = 0.038$ ) each with a medium effect size (Table 4). However, the conditions were not significantly different on linear change in other secondary outcomes: depression, attachment anxiety, dietary restraint, eating concerns, and shape concerns.

## **2.4 Discussion**

The present randomized controlled trial investigated the efficacy of a stepped care program for patients with Binge Eating Disorder. Participants first received unguided self-help, and were subsequently randomized to waiting list or Group Psychodynamic Interpersonal Psychotherapy. Results evidenced that both USH and GPIP were effective, and changes persisted up to 6 months after treatment. To the best of our knowledge, this is the first study to demonstrate that a stepped care model can improve both primary symptoms (i.e. binge eating) and a number of secondary ones (i.e. interpersonal problems, attachment avoidance and weight concerns) in treatment-seeking patients with BED.

As regards unguided self-help, the 10-week long treatment significantly reduced binge frequency and eating disorder psychopathology, as well as increased the percentage of patients abstinent or improved from binge eating. Findings were in accordance with previous meta-analyses (Beintner

et al., 2014; Perkins et al., 2006; Traviss-Turner et al., 2017). Self-help is a cost-effective, low intensity and time-saving treatment, usually delivered using specific manuals (such as “overcoming binge eating”; Fairburn, 2013) and based on two principles, psychoeducation and Cognitive-Behavioral Therapy techniques. As such, this treatment focuses exclusively on those symptoms identified by CBT as the core pathology of eating disorders (“over-evaluation of weight, shape, eating and their control”; Fairburn et al., 2003): indeed, our results clearly showed an improvement only in binge eating behaviors, and in the four EDE-Q subscales, a self-report questionnaire specifically developed to assess the core attitudinal features of eating disorders (Fairburn & Beglin, 1994). Based on our results and on previous findings (Perkins et al., 2006), unguided self-help seem therefore a valid first-line intervention for all patients with BED, especially considering that it requires minimum involvement of mental health professionals: this situation is more similar to “real-world”, where therapists would hardly be available to provide treatment for all cases of EDs.

As regards Group Psychodynamic Interpersonal Therapy, this is the second RCT evaluating its efficacy (Tasca, Ritchie, et al., 2006): in the first trial, GPIP was as effective as Group CBT in treating binge eating disorder, and led to better results in several secondary outcomes, such as depression and self-esteem (Tasca, Ritchie, et al., 2006). The present study showed that GPIP was associated with significantly lower rates of binge episodes and weight concerns from pre- to 6-months post treatment, compared to the waiting list. Noticeably, patients started group therapy (or entered in waiting list) reporting a low number of binge episodes (~6 in the past 28 days; see Table 3) due to the effect of unguided self-help: USH also affected EDs core psychopathology, thus probably hampering the efficacy of GPIP on both domains. The treatment led also to significant changes in interpersonal problems and attachment avoidance (which is characterized by a minimization of emotional experiences), compared to waiting list. Attachment insecurity and relational problems are commonly-reported symptoms among EDs patients (Tasca & Balfour, 2014). It’s worth noticing that GPIP is a modified interpersonal treatment, strongly influenced by psychodynamic and attachment theory: it posits that binge eating is a coping strategy against negative affects, which in turn are caused by unmet attachment needs (Tasca, Ritchie, et al., 2006). In addition, GPIP theorizes that patients engage in Cyclical Relational Patterns (i.e. problematic interpersonal relations that are perpetuated by the individuals even during the group therapy interactions) to regulate negative affects. CRPs constitute the main focus of this therapy: therefore,

it's not surprising that from pre-treatment up to six months after GPIP, binge eating disorder patients developed better emotional regulation skills and experienced a reduced number of interpersonal problems, compared to waiting list. Finally, according to the transdiagnostic model of eating disorders (Fairburn et al., 2003) interpersonal difficulties are considered a maintenance factor of binge eating: thus, we argue that patients treated with GPIP could potentially experience a reduced risk of relapse over time, in accordance with our findings.

Taken together, our results support the use of Stepped Care for the treatment of Binge Eating Disorder. The efficacy of both unguided self-help and Group Psychodynamic Interpersonal Psychotherapy suggest that common therapeutic factors (e.g. alliance or expectations) are more relevant than specific techniques and therapeutic ingredients (Grenon et al., in submission). From a clinical point of view, patients seeking help from healthcare psychotherapy (i.e. in hospital settings) generally experience long waiting times before entering in treatment: therefore, delivering unguided self-help once they're put in the waiting list could reduce binge and core EDs psychopathology, at least in some specific clusters of individuals. Later, therapists could deliver a specialized group treatment (i.e. GPIP or GCBT) to those patients who are still in need, so that to reduce attachment anxiety, interpersonal problems and other secondary symptoms which are directly linked to an increased risk of relapse in the future.

This study has some limitations. First, the drop-out rates for USH were high, with more than one third (34.82%) of those who started the treatment deciding to not continue it. However, Beintner and colleagues (2014) in their review on self-help found a considerable variability (from 1% to 88%; median 25%) in dropout rates across different studies. We suppose that USH is associated with higher dropout due to its general characteristics (i.e. absence of any professional that could monitor the patient's progress, provide support and encouragement): future studies should explore new ways to increase the probability to complete a self-help therapy. Second, the treatment and the control groups had different scores in several variables, as well as different percentages of comorbid anxiety disorders (see Table 1 and 3). Analyses were controlled for pre-scores, however these differences could have affected the results as well as reduced the effect sizes between the two groups. Third, our sample was composed mainly by highly educated Caucasian women, thus additional research in different populations and in people with lower education is necessary. Finally, all participants who were willing to continue after self-help entered in the second step for

ethical reasons (i.e. were randomized to GPIP or waiting list), while a typical stepped care model assumes that only patients who are not improved should receive a second, more intensive treatment. One could argue that the present RCTs provided something similar to a sequential treatment. However, the latter is usually defined as an intensive approach where two equally effective therapies (e.g. pharmacotherapy and psychotherapy) are used in a sequential order (Fava, Ruini, & Rafanelli, 2005), while in our study a low-intensity treatment such as USH was followed by group psychotherapy, as provided by a stepped care model.

Concluding, our findings add to the knowledge of the efficacy of stepped care approach for the treatment of a common and impairing Eating Disorder, such as BED. Future studies should investigate i) predictors of response to treatment, and ii) changes in other secondary outcomes such as Reflective Functioning and Attachment States of Mind, and their moderating effect on treatment outcomes: for example, Maxwell and colleagues (2017) found significant increases in Reflective Functioning or Coherence of Mind at six months post-GPIP among treatment-seeking women with BED, while higher RF scores at pre-treatment were associated to greater decreases in binge eating over time (Maxwell et al., 2017).



### **3. General Discussion**

Stepped Care approaches are increasingly popular models of healthcare delivery, that allow to reduce mental health costs (Crow, Agras, Fairburn, Mitchell, & Nyman, 2013; Ho et al., 2016). Due to their efficacy, the National Institute for Health and Care Excellence of United Kingdom recommends to adopt Stepped care models while treating several psychiatric disorders (NICE, 2017); in addition, these models have been successfully tested with “depressive and anxious disorders, obsessive-compulsive disorder, posttraumatic stress disorder, chronic fatigue syndrome, nicotine dependence, and alcohol use disorders” (Ho et al., 2016).

However, there is limited understanding on their efficacy in the treatment of EDs: to the best of our knowledge, only one study was published to date, showing that a stepped care approach was more cost-effective than CBT among patients with Bulimia Nervosa (Crow et al., 2013). Therefore, the overall goal of the present dissertation was to provide preliminary evidence on the effectiveness of a stepped model of care in the treatment of Binge Eating Disorder.

#### **3.1 Brief review of findings**

In our study, patients first attended an unguided self-help program (USH; Step 1) and were later randomized to a control condition or to Group Psychodynamic Interpersonal Psychotherapy (GPIP; Step 2). Participants were followed up to 6 months after treatment. Results evidenced that USH reduced binge eating frequency and the core eating disorder psychopathology: through the psychoeducation and the cognitive-behavioural techniques provided in the book “*Overcoming Binge Eating*” (Fairburn, 2013), patients learned to manage their binge eating symptoms and to decrease their over-evaluation of shape and weight (Fairburn et al., 2003). In addition, participants randomized to GPIP experienced a further reduction in binge eating and a greater improvement in attachment avoidance, interpersonal problems and weight concerns, which constitutes some of the most commonly-reported symptoms among individuals with BED (Fairburn et al., 2003; Ivanova et al., 2015; Tasca & Balfour, 2014). We suppose that both specific ingredients of GPIP (e.g. the focus on Cyclical Relational Patterns; Tasca et al., 2005) and common factors of group psychotherapy (e.g. expectations, group cohesiveness or interpersonal learning; Yalom & Leszcz, 2005) contributed to the observed findings.

### **3.2 Implications for the treatment of Binge Eating Disorder**

The results of this dissertation have implications for the treatment of Binge Eating Disorder: first, in line with recent meta-analyses (Beintner et al., 2014; Perkins et al., 2006; Traviss-Turner et al., 2017), Unguided Self-Help proved to be an effective treatment. Thus, even with minimal external interventions (e.g. email reminders), USH induced significant changes in eating behaviors and in the core eating psychopathology. These findings are similar to those observed by Grenon and colleagues in their meta-analysis (in submission), which evidenced similar outcomes between bona fide (e.g. Cognitive Behavioral Psychotherapy) and non-bona fide treatments (e.g. Self-Help; Grenon et al., in submission). Authors speculated that non-bona fide interventions may deliver common therapeutic factors (e.g. expectations, imparting information on the disease, universality; see paragraph 1.5), potentially explaining their relative effectiveness (Grenon et al., in submission). The present results suggest a wider adoption of Unguided Self-Help, especially if combined with a time-saving, cost-effective treatment with a group format.

Second, GPIP proved again its efficacy in the treatment of Binge Eating Disorder (Tasca, Ritchie, et al., 2006). As reviewed in the Introduction, group treatments are effective as individual ones (McRoberts et al., 1998), and they probably constitute one of the best options available to welfare states to treat in a cost-effective way as many patients as possible. Thus, a wider adoption of psychotherapies with group formats, within the context of a stepped care model, is strongly suggested.

### **3.3 Conclusions**

The results of this dissertation evidenced the incremental value of adding a second more intensive step of treatment for Binge Eating Disorder, and suggested that this model of healthcare delivery could minimize the impact on the patients' and providers' time and maximize efficiency and resource allocation. As reviewed in the Introduction, several adverse outcomes are associated with BED (e.g. higher incidence of psychiatric comorbidity, obesity, health issues, interpersonal problems and social impairment): however, few patients receive specialized, manual-based, empirically tested psychological treatments, due to financial considerations, stigma, feelings of shame, or not knowing where to go for help. Thus, a stepped care approach involving self-help could reduce some of these barriers, and make treatment for eating disorders more cost effective, widely available, and acceptable to patients.

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## TABLES

Table 1. Demographic characteristics of the participants.

Table 2. Paired sample t-tests between Pre and Post Self-Help scores on the main outcome variables.

Table 3. Mean, Standard Deviation and Sample Size of the main outcome variables at Pre-GPIP, Post-GPIP, 3 Months and 6 Months follow-ups in both treatment and control groups.

Table 4. Beta values,  $t$  values,  $p$  values for the effect of condition on the linear parameter estimates for each variable.

Table 5. Frequencies of Binge Eating episodes at Pre-GPIP, Post-GPIP, 3 Months and 6 Months follow-ups in both GPIP and control groups.

**Table 1**

<b>Demographics</b>	<b>Self-Help (N = 135)</b>	<b>Control Group (N = 46)</b>	<b>Treatment Group (N = 39)</b>
Females (%)	88.9	87	84.6
Mean age (SD)	41.87 (12.73)	42.98 (12.80)	44.97 (12.70)
Mean BMI (SD)	35.68 (8.06)	37.49 (9.31)	34.83 (7.25)
Mean years (SD) of eating disorder	18.06 (12.87)	19.87 (12.06)	19.30 (14.94)
Co-morbid mood disorder (%)	9.7	7.7	5.9
Co-morbid anxiety disorder (%)	16.5	10.3	26.7
White (%)	91.1	89.1	94.9
Married (%)	35.8	37.8	33.3
Employed full- or part-time (%)	76.6	80.5	61.6
Completed university or college (%)	50	56.5	43.6
Median family income (thousands)	80+	80+	50-59

*Notes:* BMI = Body Mass Index.

**Table 2**

	<b>Pre Self-Help</b>	<b>Post Self-Help</b>	<b><i>N</i></b>	<b><i>t</i> values</b>	<b><i>p</i> values</b>	<b>Cohen's <i>d</i></b>
<b>Binge eating episodes in 28 days</b>	13.30 (6.87)	9.01 (8.32)	135	6.715	<.001	0.588
<b>Depression</b>	17.99 (10.87)	17.41 (10.74)	135	0.767	.445	0.066
<b>Interpersonal Problems</b>	82.12 (34.89)	78.77 (36.32)	132	1.967	.051	0.172
<b>Attachment Avoidance</b>	3.44 (1.30)	3.36 (1.28)	132	2.006	.047	0.175
<b>Attachment Anxiety</b>	4.11 (1.29)	4.0 (1.29)	132	2.112	.037	0.184
<b>Restraint</b>	2.18 (1.35)	1.81 (1.42)	135	3.411	.001	0.294
<b>Eating Concern</b>	2.87 (1.36)	2.35 (1.52)	134	4.559	<.001	0.396
<b>Weight Concern</b>	4.04 (1.06)	3.72 (1.15)	135	3.642	<.001	0.316
<b>Shape Concern</b>	4.48 (1.03)	4.12 (1.25)	135	3.723	<.001	0.325



Table 3

	Pre-treatment		Post-treatment		3 months follow-up		6 months follow-up	
	<i>N</i>	<i>M</i> ( <i>SD</i> )	<i>N</i>	<i>M</i> ( <i>SD</i> )	<i>N</i>	<i>M</i> ( <i>SD</i> )	<i>N</i>	<i>M</i> ( <i>SD</i> )
<b>Binge eating episodes in past 28 days</b>								
Control	43	5.84 (6.61)	31	5.90 (7.15)	31	7.55 (8.74)	28	6.28 (6.11)
Treatment	38	6.13 (5.96)	32	6.09 (5.95)	27	4.91 (6.46)	28	5.50 (6.13)
<b>Depression</b>								
Control	39	14.81 (9.61)	30	16.87 (10.75)	32	15.81 (10.60)	25	19.92 (12.52)
Treatment	37	16.29 (8.42)	31	14.36 (9.60)	28	16.89 (14.67)	24	14.10 (12.01)
<b>Interpersonal Problems</b>								
Control	39	64.72 (31.49)	30	70.53 (39.69)	30	66.42 (30.45)	25	81.06 (45.01)
Treatment	37	88.41 (36.59)	29	88.28 (32.18)	26	73.19 (39.38)	24	70.76 (35.89)
<b>Attachment Avoidance</b>								
Control	38	2.82 (1.24)	30	3.21 (1.32)	30	3.20 (1.49)	25	3.48 (1.61)
Treatment	36	3.50 (1.31)	28	3.45 (1.43)	26	3.08 (1.30)	24	3.19 (1.49)
<b>Attachment Anxiety</b>								
Control	38	3.58 (1.23)	30	3.93 (1.28)	30	3.64 (1.21)	25	3.94 (1.20)
Treatment	36	4.06 (1.32)	28	3.92 (1.36)	26	3.77 (1.24)	24	3.88 (1.26)
<b>Restraint</b>								
Control	38	1.41 (1.50)	30	1.66 (1.45)	30	1.40 (1.37)	25	1.80 (1.66)
Treatment	36	1.74 (1.48)	27	1.58 (1.49)	26	1.68 (1.52)	24	1.58 (1.50)
<b>Eating Concern</b>								
Control	38	1.80 (1.41)	30	1.99 (1.49)	30	1.78 (1.22)	25	2.09 (1.68)
Treatment	36	2.22 (1.56)	28	2.27 (1.55)	26	1.81 (1.53)	24	2.09 (1.52)
<b>Weight Concern</b>								
Control	38	3.13 (1.08)	30	3.70 (1.16)	30	3.69 (1.19)	25	3.38 (1.24)
Treatment	36	3.86 (0.96)	28	3.69 (1.26)	26	3.14 (1.65)	24	3.01 (1.75)
<b>Shape Concern</b>								
Control	38	3.48 (1.33)	30	3.93 (1.13)	30	3.82 (1.44)	25	3.72 (1.29)
Treatment	36	4.14 (1.09)	28	3.89 (1.42)	26	3.57 (1.66)	24	3.31 (1.65)

Notes: Missing data due to drop outs from treatment or the control condition.

**Table 4**

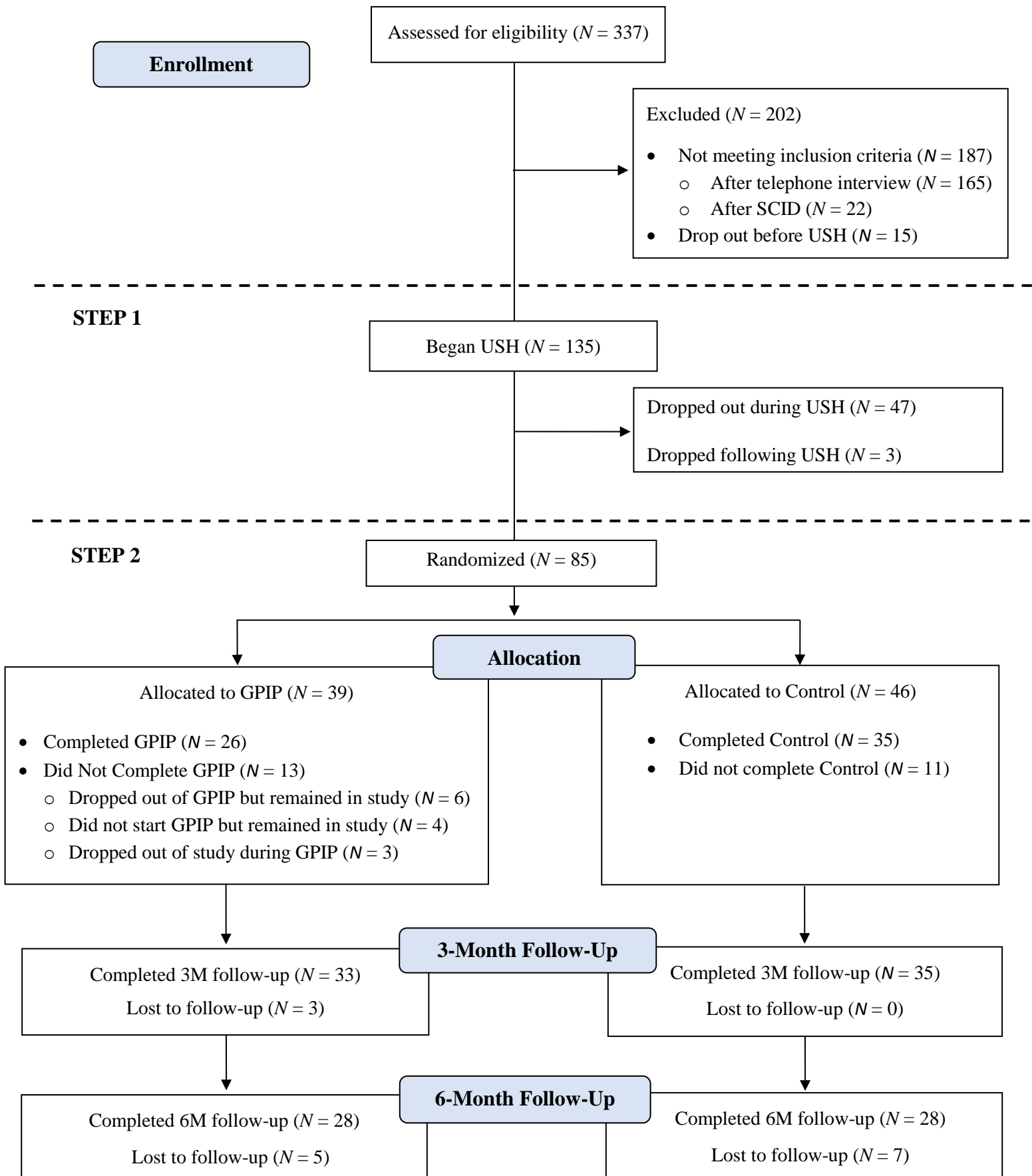
	<b>Beta</b>	<b>SE</b>	<b>t values</b>	<b>df</b>	<b>p</b>	<b>Effect Sizes</b>
						<i>OR (95% CIs)</i>
<b>Abstinence from binge eating</b>	-0.490	0.235	-2.087	82	0.040	0.61 (0.39, 0.98)
<b>Improvement of binge eating</b>	-0.395	0.188	-2.102	82	0.039	0.67 (0.46, 0.98)
						Pseudo $R^2$
<b>Binge eating episodes in 28 days</b>	0.451	0.464	0.973	82	0.334	0.013
<b>Depression</b>	0.615	1.045	0.588	82	0.558	0.018
<b>Interpersonal Problems</b>	5.967	2.584	2.310	82	0.023	0.085
<b>Attachment Avoidance</b>	0.303	0.084	3.618	80	<0.001	0.179
<b>Attachment Anxiety</b>	-0.026	0.088	-0.291	80	0.771	0.003
<b>Restraint</b>	0.103	0.117	0.877	80	0.383	0.003
<b>Eating Concern</b>	-0.009	0.118	-0.078	80	0.938	0.001
<b>Weight Concern</b>	0.246	0.117	2.114	80	0.038	0.093
<b>Shape Concern</b>	0.160	0.115	1.394	80	0.167	0.047

**Table 5**

	Pre-treatment		Post-treatment		3 months post		6 months post	
Per-protocol data								
	<i>N</i>	Abstinent (%)	<i>N</i>	Abstinent (%)	<i>N</i>	Abstinent (%)	<i>N</i>	Abstinent (%)
Control	43	10 (23.3)	31	10 (32.3)	31	5 (16.1)	28	6 (21.4)
Treatment	38	3 (7.90)	32	3 (9.40)	27	7 (25.9)	28	7 (25.0)
	<i>N</i>	Improved (%)	<i>N</i>	Improved (%)	<i>N</i>	Improved (%)	<i>N</i>	Improved (%)
Control	43	21 (48.8)	31	17 (54.8)	31	14 (45.2)	28	11 (39.3)
Treatment	38	16 (42.1)	32	15 (46.9)	27	17 (63.0)	28	16 (57.1)
Intention-to-treat data								
	<i>N</i>	Abstinent (%)	<i>N</i>	Abstinent (%)	<i>N</i>	Abstinent (%)	<i>N</i>	Abstinent (%)
Control	43	10 (23.3)	46	13 (28.3)	46	8 (17.4)	46	10 (21.7)
Treatment	38	3 (7.90)	39	6 (15.4)	39	9 (23.1)	39	8 (20.5)
	<i>N</i>	Improved (%)	<i>N</i>	Improved (%)	<i>N</i>	Improved (%)	<i>N</i>	Improved (%)
Control	43	21 (48.8)	46	24 (52.2)	46	23 (50)	46	20 (43.5)
Treatment	38	16 (42.1)	39	18 (46.2)	39	24 (61.5)	39	22 (56.4)

**Figure 1**

**CONSORT diagram**



## Appendix: HLM Models

<b>HLM Model 1 (Conditional 3-level model)</b>
--

### Level-1 Model

$$Y_{tij} = \pi_{0ij} + \pi_{1ij} * (\text{Time}_{tij}) + e_{tij}$$

### Level-2 Model

$$\pi_{0ij} = \beta_{00j} + \beta_{01j} * (\text{Pre.Score}_{ij}) + r_{0ij}$$

$$\pi_{1ij} = \beta_{10j} + \beta_{11j} * (\text{Pre.Score}_{ij}) + r_{1ij}$$

### Level-3 Model

$$\beta_{00j} = \gamma_{000} + \gamma_{001}(\text{Group.Mean}_j) + \gamma_{002}(\text{Condition}_j) + u_{00j}$$

$$\beta_{01j} = \gamma_{010} + u_{01j}$$

$$\beta_{10j} = \gamma_{100} + \gamma_{101}(\text{Group.Mean}_j) + \gamma_{102}(\text{Condition}_j) + u_{10j}$$

$$\beta_{11j} = \gamma_{110} + u_{11j}$$

<b>HLM Model 2 (Unconditional 2-level model)</b>
--

**Level-1 Model**

$$Y_{ti} = \pi_{0i} + \pi_{1i} * (\text{Time}_{ti}) + e_{ti}$$

**Level-2 Model**

$$\pi_{0i} = \beta_{00} + \beta_{01} * (\text{Pre.Score}_i) + r_{0i}$$

$$\pi_{1i} = \beta_{10} + \beta_{11} * (\text{Pre.Score}_i) + r_{1i}$$

<b>HLM Model 3 (Conditional 2-level model)</b>
--

**Level-1 Model**

$$Y_{ti} = \pi_{0i} + \pi_{1i} * (\text{Time}_{ti}) + e_{ti}$$

**Level-2 Model**

$$\pi_{0i} = \beta_{00} + \beta_{01} * (\text{Condition}_i) + \beta_{02} * (\text{Pre.Score}_i) + r_{0i}$$

$$\pi_{1i} = \beta_{10} + \beta_{11} * (\text{Condition}_i) + \beta_{12} * (\text{Pre.Score}_i) + r_{1i}$$

<b>HGLM Model 4 (Unconditional 2-level model)</b>
---

**Level-1 Model**

$$\text{Prob}(Y_{ti}=1|\pi_i) = \phi_{ti}$$

$$\log[\phi_{ti}/(1 - \phi_{ti})] = \eta_{ti}$$

$$\eta_{ti} = \pi_{0i} + \pi_{1i} * (\text{Time}_{ti})$$

**Level-2 Model**

$$\pi_{0i} = \beta_{00} + \beta_{01} + \beta_{02} * (\text{Pre.Status}_i) + r_{0i}$$

$$\pi_{1i} = \beta_{10} + \beta_{11} + \beta_{12} * (\text{Pre.Status}_i) + r_{1i}$$



## HGLM Model 5 (Conditional 2-level model)

### Level-1 Model

$$\text{Prob}(Y_{ti}=1|\pi_i) = \phi_{ti}$$

$$\log[\phi_{ti}/(1 - \phi_{ti})] = \eta_{ti}$$

$$\eta_{ti} = \pi_{0i} + \pi_{1i} * (\text{Time}_{ti})$$

### Level-2 Model

$$\pi_{0i} = \beta_{00} + \beta_{01} * (\text{Condition}_i) + \beta_{02} * (\text{Pre.Status}_i) + r_{0i}$$

$$\pi_{1i} = \beta_{00} + \beta_{01} * (\text{Condition}_i) + \beta_{02} * (\text{Pre.Status}_i) + r_{0i}$$