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Original article

Night Eating Syndrome in Individuals with Obesity: Psychopathological Features, Emotional Dysregulation, and Comorbid Eating Behaviors

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SUMMARY

Objective

This study aimed to explore the clinical and psychological characteristics of Night Eating Syndrome (NES) in individuals with obesity, focusing on comorbidity with other dysfunctional eating behaviors and difficulties in emotional regulation.

Methods

A cross-sectional study was conducted on 995 adults with obesity. Participants were assessed for NES, grazing, carbohydrate craving, sweet and junk food consumption, psychiatric disorders, depressive symptoms, and emotion regulation difficulties using validated clinical interviews and psychometric instruments, including the DERS, BDI-II, and SCL-90-R. Group comparisons were performed between individuals with and without NES.

Results

Individuals with NES reported significantly higher rates of psychiatric comorbidity, grazing, and junk food consumption. Although no significant differences emerged in general psychopathological symptoms and depression severity, patients with NES demonstrated greater difficulties in emotion regulation, particularly in goal-directed behavior, impulse control, and access to effective regulation strategies. These impairments may compromise adherence to behavioral and nutritional goals, further hindering therapeutic outcomes.

Conclusions

Patients with obesity and NES represent a clinically vulnerable subgroup characterized by emotional dysregulation and comorbid maladaptive eating behaviors. These findings underscore the importance of incorporating comprehensive psychopathological assessments, with a specific focus on emotional functioning, into tailored treatment strategies for this population.

Key words: night eating, emotion dysregulation, grazing, junk food, obesity, night eating syndrome

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Introduction

Night Eating Syndrome (NES) was described in the DSM-5 (American Psychiatric Association, 2013) within the category "Other Specified Feeding or Eating Disorder". NES is frequently associated with elevated body mass index (BMI) [1] and its clinical features include recurrent nocturnal food intake, evening hyperphagia - defined as the consumption of more than 25% of daily caloric intake after the evening meal and diminished morning ap-

petite [2,3]. The prevalence of NES in the general population is about 1-2%, increasing to approximately 15-25% in individuals with obesity [4], and ranging widely from 6% to 64% among those seeking bariatric surgery [5]. NES is most likely to develop during a stressful life period, and depending on age and gender, with an increased presentation in young adults and women during the perimenopause transition [6]. There is consensus regarding the robust association between night eating and an evening chronotype, independent of body weight, with affected individuals typically exhibiting a circadian delay in both food intake and overall functioning [7,8]. It was reported that an association between NES and psychopathology, including increased rates of depression, impaired quality of life, and psychological distress [9]. Research indicates that mental stress and psychiatric symptoms often precede the onset of NES and contribute to the maintenance of its symptoms [10]. Hyperphagia during the night may reflect a failure in the emotional regulation mechanisms that typically function throughout the day [9], and impaired emotion regulation strategies are pivotal in people with feeding and eating disorders (FEDs) [11]. In particular, food intake during the evening and nighttime is accompanied by feelings of shame and sadness [12], and recently, a relationship between NES and bedtime digital addiction has been observed [13].

In the obesity field, NES is concerning as over the long-term eating at night may contribute to adverse health outcomes, including weight gain and impaired metabolic function [14].

Individuals with NES present various medical comorbidities, such as diabetes, with an increased risk of diabetes-related complications [15,16]. Psychiatric comorbidity, particularly depression, and global mental distress are prevalent among individuals with moderate to severe obesity, and these issues may predispose them to NES [17-19]. Notably, researchers have observed numerous dysfunctional eating patterns associated with obesity [17,20,21] and although people with NES were most likely to endorse emotional eating [22], to our knowledge, dysfunctional emotion regulation strategies have not yet been investigated. Whereas NES has been extensively studied, its features and possible comorbidity with other eating patterns that are characteristic of individuals with obesity require further investigation [23]. In particular, grazing is conceptualized as the repeated consumption of small or modest amounts of food, occurring at least two to three times per day and persisting over an extended period. This pattern entails the ingestion of quantities exceeding what the individual perceives as appropriate for themselves, yet it remains distinct from uncontrolled eating, which is characterized by a subjective loss of control (LOC) during the intake of either a subjectively or objectively large amount of food. Grazing is not driven by hunger or satiety signals, is typically unplanned, and the amount consumed is not predetermined at the initiation of the episode. grazing was defined as “unplanned and repetitious eating of small amounts of food with an accompanying sense of a lack of control over this eating [24].

Carbohydrate craving is defined as an intense, often recurrent desire or urge to consume foods rich in carbohydrates, which may occur independently of energy needs or physiological hunger and is frequently associated with affective or neurobiological drives [25].

Sweet eating has been described as an eating behavior in which at least 50% of the daily intake is derived from simple carbohydrates and may be precipitated by emotional factors (e.g., stress). The definition explicitly excludes the consumption of artificial sweeteners, which are classified as ultra-processed foods (UPFs) [26].

Junk food refers to the predominant consumption of UPFs (i.e. high in fat, salt, cholesterol, and sugar, and characterized by the addition of industrial ingredients that cannot be replicated in home cooking [27]), a pattern commonly observed in individuals with obesity and associated with adverse physical, psychological, and social consequences [28].

The simultaneous presence of eating behaviors, such as grazing and craving for junk food and sweets, as well as possible relationships with emotional dysregulation and depressive symptoms, makes a detailed investigation crucial to identify useful elements for clinical evaluation and treatment in this population. Therefore, this study aimed to explore the characteristics of NES in a sample of individuals with obesity, specifically analyzing the psychopathological dimensions of depression and emotion regulation, and the comorbidity with other dysfunctional eating behaviors, such as grazing, carbohydrate craving, sweet eating, and junk food.

Methods

Participants

A total of 995 adults with obesity (281 males and 714 females; mean age = 43.96 years, SD = 12.2; mean BMI = 39.43 kg/m^2, SD = 7.5) who were seeking bariatric surgery and referred for the preoperative psychosocial evaluation were included in this cross-sectional study. Eligible participants were aged 18 years or older and had a body mass index (BMI) of ≥ 30 kg/m2. Exclusion criteria were a history of cognitive impairment and the presence of any condition affecting the ability to complete the assessment. Written consent was obtained from all participants before data collection.

Measures

Sociodemographic and clinical information was collect-

ed, including age of obesity onset, weight and dieting history, family history of obesity, and medical comorbidities.

Body Mass Index (BMI) was computed as weight in kilograms divided by height in meters squared (kg/m^2). Weight and height measurements were taken with participants wearing their usual street clothes.

Psychiatric and NES diagnoses were established with semi-structured clinical interview conducted by a trained psychiatrist, in accordance with DSM-5-TR diagnostic criteria (American Psychiatric Association, 2022), and it was supplemented by clinical documentation when available.

A psychiatrist with training relevant to the obesity field performed the psychosocial-behavioral evaluation.

Specifically, for NES, clinical ascertainment followed the DSM-5-TR criteria for Other Specified Feeding or Eating Disorder (OSFED), using operational definitions based on frequency, timing, and awareness of night eating episodes.

A comprehensive semi-structured interview [29], developed based on the existing literature on dysfunctional eating behaviors in obesity [30] was used to assess grazing, carbohydrate craving, sweet eating, and junk food consumption, which were defined as we detailed in the introduction and briefly as follows.

Grazing is the repetitive, unstructured consumption of small amounts of food, typically not driven by hunger or satiety cues [31].

Carbohydrate craving is characterized by a selective craving for carbohydrates, experienced as a compulsive need to eat that specific food, independent of physiological hunger [32].

Sweet eating is the continuous consumption of sweet foods, leading to the phenomenon of sugar addiction by activating the hedonic liking and food reward circuits [33].

Junk food is an unrestrained and persistent intake of ultra-processed foods (UPFs) [27].

A battery of psychometric instruments was administered to evaluate the key psychopathological constructs relevant to the study.

Emotion regulation strategies were assessed using the Difficulties in Emotion Regulation Scale (DERS) [34,35]. The questionnaire contains 36 items rated on a 5-point Likert scale ranging from 1 (*Almost never*) to 5 (*Almost always*). The instrument assesses five key dimensions: (1) non-acceptance of emotional responses (*Non-Acceptance*); (2) difficulty pursuing goals when experiencing negative emotions (*Goals*); (3) impulse control issues under emotional distress (*Impulse*); (4) lack of emotional awareness (*Awareness*); (5) limited perceived access to effective emotion regulation strategies (*Strategies*); and (6) lack of emotional clarity (*Clarity*). In our sample, most subscales demonstrated acceptable to good internal consistency (non-acceptance, $\alpha = 0.78$; goals, $\alpha = 0.76$; impulse, $\alpha = 0.78$; strategies, $\alpha = 0.81$; clarity, $\alpha = 0.67$); the *Awareness* dimension has been excluded from the analyses due to the poor reliability ($\alpha < 0.60$) [36].

To assess general psychological distress, we used the Global Severity Index (GSI) of the Symptom Checklist-90-Revised [37,38]. The GSI represents the overall level of psychological symptom severity and is derived from the average rating of all 90 items. It represents a global indicator of distress, assessing the intensity and breadth of reported symptoms across various domains. Higher scores indicate greater psychological discomfort. In the present study, the GSI demonstrated excellent internal consistency (Cronbach's $\alpha = 0.97$). Beck Depression Inventory - II [39,40] is a widely used self-report instrument designed to assess the severity of depressive symptoms. The questionnaire consists of 21 items, each rated on a 4-point scale, reflecting the intensity of depressive symptoms experienced over the past two weeks; it includes two main dimensions of depression: cognitive-affective symptoms (e.g., sadness, pessimism, self-criticism) and somatic-performance symptoms (e.g., fatigue, changes in sleep and appetite, work difficulties). Higher total scores indicate greater levels of depressive symptomatology. The Cronbach's alphas in the present sample were 0.85 and 0.63 respectively for the cognitive-affective and somatic-performance dimensions, respectively.

Statistical analysis

All analyses were performed with SPSS for Windows 27.0. Categorical variables were reported as frequencies and percentages, while continuous variables were summarized using means and standard deviations. Normality was assessed, and given that skewness and kurtosis values were within acceptable limits (i.e., below 4), parametric analyses were conducted. Group comparisons were performed to examine sociodemographic, clinical, and psychological differences between patients who reported night eating and those who did not. Independent samples *t*-tests were used for continuous variables and chi-square tests (χ^2) for categorical data. Cohen's *d* was calculated to estimate effect sizes. Occasional missing values were imputed by calculating, for each participant, the mean score of the subscale and then replaced. Statistical significance was set at $p < 0.05$.

Results

Sociodemographic and Psychopathological Differences

The sociodemographic and psychopathological differences between patients who reported night eating and those who did not are detailed in Table I. Overall, no

between-group differences emerged in key sociodemographic variables, i.e., sex, age, years of education, and marital status. Regarding clinical variables, no differences were found in BMI, family history of obesity, presence of medical comorbidities, and obstructive sleep apnea. However, participants who reported night eating showed higher prevalence of psychiatric disorders than patients who did not report night eating (χ^2, 1 = 5.931; p = . 020). Moreover, participants in the night eating group reported more Grazing (χ^2, 1 = 5.419; p = . 020) and junk food (χ^2, 1 = 12.958; p < . 001) compared to those without NES.

TABLE I. *Sociodemographic and Psychopathological Differences between groups.*

Variables, *N (%)*	Total Sample (*n* = 995)	Night Eating Group (*n* = 168)	No Night Eating Group (*n* = 827)	*t* or χ	*p*-value
Age, *M(SD)*	43.96 (12.2)	44.24 (12.1)	43.90 (12.2)	*t*(993) = -0.325	.745
Sex				$\chi^2(1) = 0.085$	.778
	Male	281 (28.2)	49 (29.2)	232 (28.1)	
	Female	714 (71.8)	119 (70.8)	595 (71.9)	
Marital Status				$\chi^2(3) = 2.703$	.440
	Single	289 (29.0)	47 (28.0)	242 (29.3)	
	Married	556 (55.9)	93 (55.4)	463 (56.0)	
	Divorced or separated	125 (12.6)	26 (15.4)	99 (12.0)	
	Widowed	24 (2.4)	2 (1.2)	22 (2.7)	
Years of education				$\chi^2(2) = 1.104$	.576
	8	721 (72.8)	117 (70.1)	604 (73.3)	
	13	152 (15.3)	30 (18.0)	122 (14.8)	
	18	118 (11.9)	20 (11.9)	98 (11.9)	
Body Mass Index, Mean (SD)	39.43 (7.5)	38.88 (7.3)	39.54 (7.6)	*t*(993) = -1.038	.299
Obesity onset				$\chi^2(3) = 2.061$	.560
	Childhood	344 (34.7)	55 (32.7)	289 (34.9)	
	Adolescence	186 (18.8)	30 (17.9)	156 (18.9)	
	Adulthood	463 (46.5)	82 (48.8)	381 (46.2)	
Parents with obesity				$\chi^2(1) = 1.532$	.216
	Yes	584 (58.8)	106 (63.1)	478 (57.9)	
	No	409 (41.2)	62 (36.9)	347 (42.1)	
Psychiatic disorders				$\chi(1) = 5.931$	**.020**
	Yes	260 (26.2)	56 (33.3)	204 (24.7)	
	No	734 (73.8)	112 (66.7)	622 (75.3)	
Medical comorbidities				$\chi^2(1) = 2.363$	.124
	Yes	509 (51.3)	95 (56.6)	414 (50.3)	
	No	483 (48.7)	74 (43.4)	409 (49.7)	
Number of medical comorbidities				$\chi^2(5) = 8.668$	.123
	0	483 (48.6)	74 (44.0)	409 (49.6)	
	1	285 (28.7)	47 (28.0)	238 (28.8)	

TABLE I. *Follows from the previous page.*

Variables, *N (%)*	Total Sample (*n* = 995)	Night Eating Group (*n* = 168)	No Night Eating Group (*n* = 827)	*t* or χ	*p*-value
	2	127 (12.8)	21 (12.5)	106 (12.8)	
	3	78 (7.9)	20 (11.9)	58 (7.0)	
	4	14 (1.4)	5 (3.0)	9 (1.1)	
	5	6 (0.6)	1 (0.6)	5 (0.6)	
Obstructive Sleep Apnea Syndrome				$\chi^2(1) = 1.933$	.198
	Yes	75 (7.5)	17 (10.1)	58 (7.0)	
	No	920 (92.5)	151 (89.9)	769 (93.0)	
Grazing				$\chi^2(1) = 5.419$	**.020**
	Yes	651 (65.4)	123 (73.2)	528 (63.8)	
	No	344 (34.6)	45 (26.8)	299 (36.2)	
Carbohydrate craving				$\chi^2(1) = 0.003$	.959
	Yes	810 (81.4)	137 (81.5)	673 (81.4)	
	No	185 (18.6)	31 (18.5)	154 (18.6)	
Sweet eating				$\chi^2(1) = 3.066$	.080
	Yes	146 (14.7)	32 (19.0)	114 (13.8)	
	No	848 (85.3)	136 (81.0)	712 (86.2)	
Junk Food				$\chi^2(1) = 12.958$	< . 001
	Yes	490 (49.2)	104 (61.9)	386 (46.7)	
	No	505 (50.8)	64 (38.1)	441 (53.3)	
Life-course Weight Pattern				$\chi^2(2) = 1.506$	.471
	Weight gain	562 (56.5)	102 (60.7)	460 (55.6)	
	Weight cycling	324 (32.6)	50 (29.8)	274 (33.1)	
	Weight stability	109 (11.0)	16 (9.5)	93 (11.2)	

Psychopathological differences

Psychopathological between-group differences are reported in Table II. We found statistically significant differences in the emotion regulation, as measured by the DERS subscales. Participants with night eating reported higher scores on the total DERS score (*t*, 993 = -2.523; *p* = . 012; *d* = -0.21) as well as on the DERS subscales of Goals (*t*, 993) = -2.592; *p* = . 010; *d* = -0.22), Impulse (*t*, 993 = -2.010; *p* = . 045; *d* = -0.17), and Strategies (*t*, 993 = -2.661; *p* = . 008; *d* = -0.23), indicating greater difficulties in pursuing goals when experiencing negative emotions, maintaining emotional control in stressful situations, and accessing effective emotion regulation strategies when needed, compared to patients who did not report night eating.

Discussion

In our sample of individuals with moderate to severe obesity, we found that 17% were affected by NES, which can be considered a relatively high prevalence.

Our findings highlighted different psychopathological characteristics in individuals with obesity and NES, as compared to those without. To begin with, this population exhibited a higher prevalence of clinically diagnosed psychiatric disorders, underscoring the clinical relevance of comprehensive psychiatric evaluations in patients with obesity, beyond the assessment of eating behaviors alone [41]. Furthermore, we found more comorbid dysfunctional eating behaviors, in particular compulsive consumption of junk food and grazing. This evidence supports the hypothesis that patients with NES are vulnerable to eating patterns characterized by loss of control and impulsivity,

TABLE II. *Psychopathological differences between groups.*

Variable, *M(SD)*	Total Sample (*n* = 995)	Night Eating Group (*n* = 168)	No Night Eating Group (*n* = 827)	*t*-test	*p*-value	Cohen's *d* [a]
BDI_Cognitive component	6.82 (6.2)	7.18 (6.2)	6.75 (6.2)	*t*(993) = 0.830	.407	-0.07
BDI_Somatic component	6.17 (3.7)	6.67 (3.7)	6.10 (3.6)	*t*(993) = 1.931	.054	-0.16
BDI_Total Score	13.00 (8.8)	13.85 (8.9)	12.82 (8.77)	*t*(993) = 1.387	.166	-0.12
SCL-90_GSI	0.67 (0.5)	0.71 (0.5)	0.66 (0.5)	*t*(993) = 1.162	.246	-0.10
DERS_Non-acceptance	12.30 (4.8)	12.60 (5.1)	12.18 (4.8)	*t*(993) = 1.046	.296	-0.09
DERS_Goals	9.99 (3.6)	10.60 (3.6)	9.86 (3.6)	*t*(993) = 2.592	**.010**	-0.22
DERS_Impulse	10.60 (4.1)	11.20 (4.3)	10.46 (4.0)	*t*(993) = 2.010	**.045**	-0.17
DERS_Strategies	14.10 (4.9)	15.00 (5.2)	13.91 (4.8)	*t*(993) = 2.661	**.008**	-0.23
DERS_Clarity	14.10 (2.6)	14.10 (2.8)	13.93 (2.6)	*t*(993) = 0.896	.370	-0.08
DERS_Total Score	76.7 (16.4)	79.60 (17.6)	76.13 (16.1)	*t*(993) = 2.523	**.012**	**-0.21**

Note. BDI = Beck Depression Inventory II; SCL-90_GSI = Symptom Checklist-90_Global Severity Index; DERS = Difficulties in Emotion Regulation Scale.
[a] Cohen's d values indicate the effect size and direction of the difference between Night Eating Group (coded as 1) and No Night Eating Group (coded as 0). Negative values indicate that group 1 (Night Eating Group) scored higher on average than group 0 (No Night Eating Group).

consistent with their underlying impairments in impulse control and behavioral regulation [42].

Consistent with our findings, NES was previously associated with increased odds of consuming fast food [43]. Moreover, beyond the hedonic properties of UPFs, these foods are often high in sugars and unhealthy fats which may induce postprandial fatigue, making them seemingly ideal choices for both coping with negative emotional stimuli and facilitating sleep onset [44]. Reduced sleep duration has also been correlated with specific food, triggering a vicious cycle of hedonic eating[45].

Grazing can be conceptualized along a spectrum of severity, with higher levels predicting more severe FEDs, such as binge eating, and has been associated with decreased mental health-related quality of life[46]. The co-occurrence of grazing and NES, as the pattern observed in our study, identifies a more severe clinical phenotype, marked by heightened psychopathological burden and potentially poorer treatment outcomes [47].

Although no significant differences emerged regarding the overall psychopathological symptomatology measured via the SCL-90-R, we found important differences in emotion regulation domains.

Specifically, individuals with NES reported greater difficulties in pursuing goals when experiencing negative emotions, controlling impulses in stressful situations, and effectively using strategies to regulate emotions.

The difficulties of goal-directed behavior when experiencing negative emotion are relevant, as this impairment predicts maladaptive coping strategies focused on problem-solving and low tolerance of stress. Such difficulties may stem from the heightened arousal typically associated with negative affect, which tends to monopolize attentional resources. As a result, individuals with obesity and NES may battle to adhere to behavioral and nutritional goals when these are misaligned with their emotional state, ultimately compromising therapeutic outcomes [48,49].

The finding of impaired control over impulsive behaviors triggered by negative emotions is reasonable, considering the characteristics of the disorder. Indeed, many patients engage in secret night eating, often following a day of food restriction, making it difficult for them to resist the urge to eat – typically when they are alone, experiencing negative affect, and out of sight of family members, due to feelings of shame about their eating behavior [50].

Finally, compared to the group with obesity alone, individuals with NES demonstrated lower confidence in their ability to regulate emotions, reflecting a belief that emotions, once activated, are difficult to manage. This emotional dysregulation may contribute to compulsive night eating behaviors and potentially undermine both the belief in the efficacy of treatment and the motivation to seek help [51,52].

Contrary to our expectations, the severity of depressive symptoms was not associated with NES, a finding that diverges from what has been reported in the existing literature [53]. We hypothesize that this discrepancy may be due to the fact that our sample consisted of individuals with obesity, suggesting several possible explanations. Obesity is known to have a bidirectional relationship with depression, sharing a common etiological platform

that may have limited the ability to distinguish between the groups with and without NES in terms of depression [54]. Further, non-depressed men and women with obesity have been found to score significantly lower in the recognition of most basic and mixed emotions, regardless of the presence of eating disorders, and may also fail to recognize depressive symptoms [55].

In sum, our results are consistent with previous evidence indicating that emotional dysregulation plays a central role in the onset and maintenance of NES [56], suggesting that interventions targeting specific domains of emotion dysregulation may be particularly beneficial in the treatment of these patients. The impairment of goal-directed behavior appears to be a key issue in this population, which requires support not only in recognizing and regulating emotions but also in adhering to a nutritional plan, given the ongoing need to make food-related decisions aimed at weight loss [57]. We believe that psychoeducational interventions targeting this deficit may effectively achieve both objectives [58,59].

Though there is an established link between emotional eating and NES, it is not surprising that night eating may compromise weight loss treatments, as individuals may require a certain amount of food to achieve relaxation and facilitate sleep. Moreover, it is plausible that such individuals might opt for UPFs, which are linked to the obesity epidemic, to fulfill this need. Hence, NES may hinder effective weight loss management [60], even after bariatric surgery [61]. Accordingly, NES was initially identified in individuals who struggled to achieve successful weight reduction [2].

Furthermore, considering the inconclusive evidence on the efficacy of specific pharmacological treatments for NES, such as serotoninergic drugs [3], and that some patients may not tolerate antidepressants [62], we propose the improvement of a specific focus on emotions within psychoeducation approaches – in addition to the other known therapeutic strategies such as relaxation techniques, light therapy [63], and psychotherapy [10].

It is important to acknowledge the limitations of the present study. Maladaptive eating behaviors in obesity are not yet standardized constructs; however, they were assessed through a clinical interview based on relevant literature and conducted by psychiatrists with expertise in obesity. Another limitation concerns the potential overlap between Binge Eating Disorder and NES, as the former may partly mask the latter [64]. In addition, although beyond the scope of our original hypothesis, it would have been important to address circadian rhythms, insomnia, and sleep duration which are intrinsically related to NES. Moreover, given the cross-sectional design and the small effect sizes observed (Cohen's d), clinical implications should be interpreted cautiously, highlighting the need for further longitudinal studies to better clarify causal relationships and the direction of the observed associations.

Nonetheless, the study benefits from several strengths, including a large sample size, clinical assessments conducted by a physician with expertise in obesity and eating disorders, and the use of validated psychometric instruments.

Above these limitations, this study contributes to a clearer understanding of the clinical and psychological profile of individuals with obesity and NES, highlighting the importance of integrating comprehensive psychopathological assessments – particularly those addressing emotional functioning and maladaptive eating behaviors – into therapeutic strategies for this population.

Conclusions

This study highlights that NES represents a clinically relevant condition among individuals with moderate to severe obesity, characterized by higher rates of psychiatric comorbidity, maladaptive eating behaviors – particularly grazing and junk food consumption – and significant impairments in emotion regulation. Difficulties in goal-directed behavior, impulse control, and access to effective regulation strategies may compromise adherence to nutritional and behavioral goals, ultimately impacting treatment outcomes.

These findings underscore the importance of incorporating comprehensive psychopathological and emotional assessments into clinical practice, with tailored psychoeducational interventions targeting both emotional regulation skills and adherence to nutritional plans. Addressing these domains may improve the management of NES and enhance the overall effectiveness of obesity treatment programs. Further longitudinal research is warranted to clarify causal relationships and to evaluate the efficacy of integrated therapeutic approaches in this vulnerable population.

Conflict of interest statement

The authors declare no conflict of interest.

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None.

Authors contribution

E.B. and R.M.Q. designed the study; E.B., E.B., P.G., performed data collection; R.M.Q, computed statistical analysis.and wrote the first draft of results; E.B. wrote the first draft of the manuscript; P.G., A.S, C.N., andG.D.L. revised the manuscript. All authors agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All authors have read and approved the final version of the manuscript.

Ethical consideration

The study was approved by the Ethical Review Board of

the University of Rome Tor Vergata, Rome, Italy, on May 19, 2011, and was carried out in accordance with the 1964 Helsinki Declaration.

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