



Trabajo Original

Valoración nutricional

The influence of the aesthetic body shape model on adolescents with eating disorders

La influencia del modelo estético corporal en los trastornos de conducta alimentaria en la adolescencia

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Abstract

Introduction: the relevance of sociocultural factors with respect to etiology, development and treatment of eating disorders has been supported by many studies.

Objectives: the aims of this study were: a) to analyze the different effects of the aesthetic body shape model on adolescents with anorexia nervosa (AN) vs bulimia nervosa (BN); b) to analyze possible differences, regarding that body shape model, between patients with purging behaviors vs non purging types of patients; and c) to explore the relationship between the influence of the aesthetic body shape model and other clinically relevant variables such as body dissatisfaction, eating attitudes and personality traits.

Methods: the sample comprised 104 adolescents suffering from AN and BN. The Questionnaire of Influences on the Aesthetic Body Shape Model (CIMEC-40), the Body Shape Questionnaire (BSQ), the Eating Attitudes Test (EAT-40) and the Millon Adolescent Clinical Inventory (MACI) were applied.

Key words:

Anorexia nervosa. Bulimia nervosa. Adolescence. Aesthetic body shape model. Body dissatisfaction.

Palabras clave:

Anorexia nerviosa.

Adolescencia, Modelo

Bulimia nerviosa.

estético corporal

Insatisfacción

corporal.

Results: the aesthetic body shape model of thinness influenced 77.9% of this sample, this influence being higher in the case of BN patients. In addition, that influence was stronger in the purging-type patients than in the non-purging type. Moreover, there was a significant and positive correlation among the influence of the aesthetic body shape model, body dissatisfaction and severity of eating symptoms. Finally, there seems to exist some personality traits more vulnerable to be affected by sociocultural factors.

Conclusions: in view of these results, it is necessary that psychotherapeutic approaches take into account the influence of sociocultural factors and body dissatisfaction mainly in the case of adolescents with BN.

Resumen

Introducción: la relevancia de los factores socioculturales en la etiología, el desarrollo y el tratamiento de los trastornos de la conducta alimentaria ha sido apoyada por varios estudios.

Objetivos: los objetivos del presente estudio fueron evaluar las diferencias en la influencia del modelo estético corporal en adolescentes diagnosticadas de anorexia nerviosa (AN) y bulimia nerviosa (BN), y explorar la relación existente entre la influencia del modelo estético corporal y otras variables clínicamente relevantes, como la insatisfacción corporal, la presencia de conductas purgativas, las actitudes hacia la comida y los rasgos de personalidad.

Método: la muestra se compuso de 104 adolescentes con diagnóstico de AN y BN. Los instrumentos de evaluación utilizados fueron el Cuestionario de Influencias sobre el Modelo Estético Corporal (CIMEC-40), el Body Shape Questionnaire (BSQ), el Test de Actitudes Alimentarias (EAT-40) y el Inventario Clínico para Adolescentes de Millon (MACI).

Resultados: los resultados obtenidos indican que la mayoría de la muestra está influenciada por el modelo estético corporal de delgadez. En cambio, las pacientes con BN están significativamente más influenciadas por el modelo estético que las pacientes con AN, provocando en las pacientes con BN una mayor insatisfacción corporal y propiciando la aparición de síntomas bulímicos, sobre todo de tipo purgativo. Por otro lado, parecen existir rasgos de personalidad más susceptibles a la influencia de los factores socioculturales, que pueden mediar entre la influencia del modelo estético, la insatisfacción y la aparición de síntomas.

Conclusiones: a la vista de los resultados, se requiere que las medidas de intervención psicoterapéuticas se adapten a la mayor influencia de los factores socioculturales y de insatisfacción corporal en la BN durante la adolescencia.

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INTRODUCTION

The aesthetic body shape model of thinness in our cultural context brings a message of thinness as synonymous of beauty and success (1). Sociocultural influences (e.g., media) are an important outlet for the model of thinness. Several studies have reported a relative increase of publications about diets, weight loss, diet products and physical exercise in the last decades (2,3). Other studies show that weight and body measurements of models and celebrities have been decreasing over time (4,5). These findings suggest that currently we are immersed in a culture of thinness, the body shape model being increasingly slim. Despite media are an important transmitter of body models, they are not the unique factor involved. Several studies highlight the relevance of family and peers in the transmission of this body model of thinness (6).

Body dissatisfaction refers to the discomfort caused by the negative self-evaluation of a person with respect to their own weight and body shape (7). Previous studies have reported relevant data about the relationship between the interiorization of thinness ideal and the increase of body dissatisfaction and symptoms of eating disorders (ED), mainly in adolescents (8,9). Adolescence is a period of life in which frequent concerns about physical appearance arise, so dissatisfaction and eating behavior disturbances emerge in order to compensate that dissatisfaction thus reaching a thinness ideal (10). A recent meta-analysis supports the hypothesis that media enact a thinness ideal that causes body dissatisfaction (8).

The direct relationship between interiorization of thinness ideal and disordered eating behaviors has been supported by many studies (11,12). Those studies based on interventions on the aesthetic body shape model have showed prospectively that decreasing of internalization of thinness ideal is associated to reduction of ED symptoms (13).

These findings add data about the relevance of sociocultural factors (e.g., the influence of the aesthetic body shape model) with respect to etiology, development and treatment of ED. In this regard, those factors must be taken into account when designing treatment programs in ED. Nevertheless, studies on this field have several limitations. First of all, most of those studies have been developed in general population and the analyses have been focused on risk factors for ED regardless of the severity of symptoms. Thus, it is recommended to evaluate the influence of the aesthetic body shape model not only in risky populations but also in clinical samples. The majority of studies have been focused on how the thinness ideal influences the risk for ED but there is a shortage of research about the differences with respect to the degree of the thinness ideal interiorization comparing subtypes of ED. Bearing in mind the status of art in this field of study, in the current one we have analyzed differences between anorexia nervosa (AN) and bulimia nervosa (BN) and other variables have been included (purging behaviors, eating attitudes and personality traits). Based on clinical observations and previous research, these variables have been reported to be relevant in order to distinguish the different subtypes of ED. Specifically, following the Diagnostic and Statistical Manual of Mental Disorders (4th ed. text rev), the presence of purging behaviors is the variable to distinguish between BN purging-type and BN nonpurging-type (American Psychiatric Association [APA], 2000). In the Diagnostic and Statistical Manual of Mental Disorders (5th ed.) these purging behaviors, along with the presence of episodes of bingeing, remain relevant to establish differences between AN restrictive-type and AN purging-type (APA, 2013). Eating attitudes have been identified as important to improve the knowledge about clinical variability of ED patients (14). With regards to personality, there are several studies reporting significant differences when comparing AN and BN (15-17).

The current study aims: a) to evaluate the different effects of the aesthetic body shape model on adolescents with anorexia nervosa *vs* bulimia nervosa; b) to analyze possible differences, regarding that body shape model, between patients with purging behaviors *vs* non purging types of patients; and c) to explore the relationship between the influence of the aesthetic body shape model and other clinically relevant variables such as body dissatisfaction, eating attitudes and personality traits.

METHODS

PARTICIPANTS

A non-probabilistic-intentional sample comprised of 104 patients, aged 13-18 (M = 15.47, SD = 1.43) was studied. There were seven males (6.7%) and 97 females (93.3%). Patients received treatment in the Eating Disorders Unit-Child and Adolescent Psychiatry (EDU-CAP) of the Hospital Clínico Universitario Lozano Blesa in Zaragoza, Spain (HCU-LB), between January 2008 and June 2012. The inclusion criteria were: a) to have a diagnostic of AN (n = 66) or BN (n = 38) following the DSM-IV-TR criteria (18); and b) to have undergone the evaluation protocol consisting of several questionnaires. Regarding the exclusion criteria, they were: a) the existence of neurological disorders; b) the presence of mental retardation; and c) to suffer from ED not otherwise specified.

The sample demographic characteristics are summarized in table I. There were 66 patients with AN and 38 with BN. Within the AN group, 75.75% (n = 50) were of the restrictive-type while

Table I. Sex, age, weight and BMI by
groups (n = 104)

	Group		
	AN	BN	
Sex (n)			
Males	6	1	
Females	60	37	
Age (years)			
Mean (SD)	15.27 (1.50)	15.82 (1.24)	
Weight (kg)			
Mean (SD)	46.34 (6.81)	54.09 (9.17)	
BMI (kg/m²)			
Mean (SD)	17.68 (1.88)	20.76 (2.85)	

AN: anorexia nervosa; BN: bulimia nervosa; SD: standard deviation; BMI: body mass index.

24.24% (n = 16) were of the purging type. In the case of the BN group, 86.84% (n = 33) were of the purging type and 13.15% (n = 5) were of the non-purging type. Considering the different diagnostics and the clinical interview, these data show that 47.11% (n = 49) had purging behaviors (e.g., vomits, laxatives abuse diuretics or enemas) while 52.88% (n = 55) were non-purging types. In this case, patients showed other pathological behaviors such as compulsive physical exercise, hyperactivity, skipping meals, etc.

INSTRUMENTS

- Clinical interview to diagnose ED following the DSM-IV-TR criteria (18). It was developed by a psychiatrist and a clinical psychologist, both members of the EDU-CAP.
- Questionnaire of the Influences on the Aesthetic Body Shape Model (CIMEC-40) (19). This instrument explores the interiorization degree of influences promoted by social factors with respect to the thinness ideal. The CIMEC-40 comprises 40 items (with three possible responses) which evaluate five areas: discomfort related to body image, influence of advertisements, influence of verbal messages, influence of social models and influence of social contexts. This questionnaire was developed and validated in Spanish population and it shows adequate psychometric properties, with an internal consistency (Cronbach's alpha) of 0.93. The cut-off point is set at 23 and higher scores indicate greater influence of social models. CIMEC-40 is considered as a valid and reliable instrument to evaluate the influence of social factors on the thinness ideal.
- Body Shape Questionnaire (BSQ) (20). This instrument was adapted by Raich et al. (1996) (21) in Spanish population. It aims to evaluate body dissatisfaction related to body self-perception. BSQ comprises 34 items with six possible responses and it explores four factors: body dissatisfaction, fear of gaining weight, feelings of law self-esteem related to appearance and desire to lose weight. BSQ has sown high reliability (Cronbach's alpha between 0.95 and 0.97).
- Eating Attitudes Test (EAT-40) (22). It was adapted for Spanish population by Castro, Toro and Guimerá (1991) (23). This instrument is a screening test to detect individuals at risk for ED, assessing fears of gaining weight, drive for thinness and restrictive eating patterns. It comprises 40 questions with six possible responses, which correspond to three subscales: diet and concerns about food, perceived social pressure and eating discomfort, and psychobiological disturbances. Higher scores indicate more ED symptoms. The Spanish version of the EAT-40 shows adequate psychometric properties with a Cronbach's alpha of 0.93.
- Millon Adolescent Clinical Inventory (MACI) (Millon, 1993) (24). It was adapted for Spanish population by Aguirre (2004) (25). MACI is a self-reported questionnaire, which comprises 160 items (to answer as true/false). It was designed to be applied individually for ages ranging from 13 to 19 years.

After being adapted for Spanish population, specific scales were established by age and sex, in all cases with adequate psychometric properties. It evaluates 12 personality profiles, seven clinical syndromes and eight scales of expressed concerns. In the current study MACI was used to evaluate the participants' personality profiles. In accordance with the aims of this study, we focus on the 12 personality profiles:

- 1. Introversive.
- 2A. Inhibited.
- 2B. Doleful.
- 3. Submissive.
- 4. Dramatizing.
- 5. Egotistic.
- 6A. Unruly.
- 6B. Forceful.
- 7. Conforming.
- 8A. Oppositional.
- 8B. Self-demeaning.
- 9. Borderline tendency.

PROCEDURE

The patients' evaluation process started by means of individual diagnostic interviews and was completed with a protocol including the following questionnaires: CIMEC-40, BSQ, EAT-40 and MACI. This is an *ex post facto* study which included patients who sought treatment in the EDU-CAP of Hospital Clínico Universitario Lozano Blesa (Zaragoza, Spain) between January 2008 and June 2012. Patients met the above mentioned inclusion criteria. Access to patients' clinical data aimed the objective of this research exclusively and it was done after obtaining the patients' and parents' informed consent. During data collection, any data which could have identified patients were removed, thus ensuring the anonymity and confidentiality of those patients who were included in the database.

RESULTS

GENERAL DESCRIPTION OF THE RESULTS OBTAINED REGARDING CIMEC

First of all, a descriptive and exploratory analysis of the scores on CIMEC was performed. Those scores were classified based on the cut-off point (\geq 23) established by the authors of the instrument (19). This cut-off point permits to explore differences between individuals influenced by the aesthetic body shape model and those who are not influenced by that model. The frequencies of patients influenced were analyzed establishing different sample subgroups. In order to make those subgroups, initially patients were classified as AN patients or BN patients based on the diagnostic. Secondly, patients were classified as purging-type patients (including AN and BN purging types) and non-purging type patients (AN restrictive type and BN non-purging type). Overall, 77.9% of participants were influenced by the aesthetic body shape model (scores on CIMEC-40 \geq 23) while 22.1% were not (scores on CIMEC-40 < 23). Figure 1 shows the percentage of patients influenced by the aesthetic model and those not influenced considering the diagnostics of AN and BN. In case of AN, these percentages were 68.18% and 31.82%, respectively. With regard to BN, the percentages were 94.74% and 5.25%, respectively. A significant association was found between the influence of the aesthetic body shape model and the diagnostic of AN or BN (X² [1] = 9.873, p < 0.05).

Figure 2 shows the frequency of patients influenced by the aesthetic model considering the presence of purging behaviors. In case of patients with purging behaviors, 95.91% are influenced by the aesthetic model while in non-purging patients the percentage was 61.82%. A significant association was found between the influence of the aesthetic model and to have (or not) purging behaviors (X^2 [1] = 17.494, p < 0.05).

These results show that the thinness aesthetic model influence is more relevant in BN than in AN. In addition, the presence of purging behaviors (regardless of the diagnostic) increases the percentage of patients influenced by the aesthetic model.

COMPARISON BETWEEN AN AND BN PATIENTS WITH REGARDS TO CIMEC-40 SCORES

After ensuring that variables fitted a normal distribution and they were independent, the parametric t-test for independent variables based on the Welch's equation was applied. Equality of variances was not assumed due to the result of the homoscedasticity Levene test (W_(1,102) = 7.225, p < 0.05), which showed that variances of the two diagnostic subgroups were no equal. As a result of the t-test, BN patients seem to be more influenced by the aesthetic model than AN patients ($t_{(1.95,284)} = -4.899$, p < 0.001). The Cohen's d was 0.9583, which indicates a large effect size (26). The mean scores on the CIMEC-40 were 33.45 and 48.76 for AN and BN, respectively. In addition to the significant difference between the two subgroups, it must be noted that both AN and BN patients scored above the cut-off point of 23. Table II shows the results obtained by means of the t-test. To summarize, there is a significant difference between AN and BN regarding the CIMEC scores, the greatest influence by the aesthetic model showed by BN patients.



Figure 1.

Influence of the aesthetic body shape model (CIMEC-40) on patients with AN and BN (%) (AN: anorexia nervosa; BN: bulimia nervosa).



Figure 2.

Influence of the aesthetic body shape model (CIMEC-40) in purging type patients vs non-purging type patients (%).

Table II. Differences between AN and BN with respect to the aesthetic body shape model (CIMEC-40)

				t-test			
		n	Mean	SD	df	t	р
	AN	66	33.45	18.12	95.284	-4.899	0.000
CIMEC-40	BN	38	48.76	13.49			
	Total	104	39.05	18.09			

SD: standard deviation; df: degrees of freedom.

COMPARISON BETWEEN PURGING AND NON-PURGING TYPE PATIENTS WITH REGARDS TO CIMEC SCORES

Again, after ensuring that variables fitted a normal distribution and they were independent, the parametric t-test for independent variables based on the Welch's equation was applied. Equality of variances was not assumed due to the result of the homoscedasticity Levene test ($W_{(1,102)} = 9.822$, p < 0.05), which showed that variances of the two subgroups were no equal. As a result of the t-test, significant differences between the two subgroups (purging *vs* non-purging) were found ($t_{(1,97,277)} = 5.406$, p < 0.001) (Table III). In this case, the Cohen's d was 1.05, which indicates a large effect size (26). In sum, adolescents with ED purging types are more influenced by the aesthetic body shape model than those with ED non-purging types. While the mean score on CIMEC obtained by the purging subgroup was 47.92, it was 31.15 in the case of the non-purging subgroup. In both purging and non-purging subgroups the mean score on CIMEC-40 was higher than the above mentioned cut-off point.

CORRELATIONS AMONG CIMEC-40, BSQ, EAT-40 AND MACI

The Pearson's correlation coefficient was used in order to evaluate the relationship among the aesthetic body shape model (as assessed by CIMEC-40), body dissatisfaction (BSQ), eating attitudes (EAT-40) and personality profiles (MACI). Table IV sums up the results. With respect to the relationship between the influence of the aesthetic model and body dissatisfaction, a significant and positive correlation was found (r = 0.849; p < 0.001), so a greater influence of the model is related to greater body dissatisfaction.

A significant and positive correlation between the aesthetic model and eating symptoms was also found (r = 0.620; p < 0.001). Those adolescents with more interiorization of the aesthetic model tend to show more severe eating symptoms with more pathological eating attitudes. Finally, the possible relationship between the aesthetic model and specific personality profiles was analyzed. As a result, significant and positive correlations were found between the aesthetic model and the following personality

 Table III. Differences between purging and non-purging patients with respect to the aesthetic body shape model (CIMEC-40)

				t-test			
		n	Mean	SD	df	t	р
	Purging	49	47.92	13.04	97.277	5.406	0.000
CIMEC-40	Non purging	55	31.15	18.39			
	Total	104	39.05	18.09			

SD: standard deviation; df: degrees of freedom.

Table IV. Correlation coefficients among CIMEC-40, BSQ, EAT-40 Y MACI considering the whole sample

		CIMEC-40	
BSQ	0.849†		
EAT-40	0.620†		
MACI	Introversive	0.292*	
	Inhibited	0.303 ⁺	
	Doleful	0.502 ⁺	
	Submissive	-0.053	
	Dramatizing	-0.439†	
	Egotistic	-0.568†	
	Unruly	0.035	
	Forceful	0.109	
	Conforming	-0.488†	
	Oppositional	0.442 [†]	
	Self-demeaning	0.593†	
	Borderline	0.392 ⁺	

*p < 0.01; †p < 0.05. CIMEC-40: Questionnaire of Influence of the Aesthetic Body Shape Model; BSQ: Body Shape Questionnaire; EAT-40: Eating Attitudes Test; MACI: Millon Adolescent Clinical Inventory. profiles: introversive (r = 0.232; p < 0.05), inhibited (r = 0.303; p < 0.01), doleful (r = 0.502; p < 0.01), oppositional (r = 4.442; p < 0.01), self-demeaning (r = 0.593; p < 0.01) and borderline (r = 0.392; p < 0.01). Other significant and negative correlations between the aesthetic model and the following personality profiles were found: dramatizing (r = -0.439; p < 0.01), egotistic (r = -0.568; p < 0.01) and conforming (r = -0.488; p < 0.01). In case of submissive, unruly and forceful profiles, no significant correlations were found. Summing up, these results show that specific personality profiles are related to a great influence of the aesthetic model (introverted, inhibited, doleful, oppositional, self-demeaning and borderline), while other profiles (dramatizing, egotistic, and conforming) are less related to the interiorization of the aesthetic model.

DICUSSION

The objectives of this study were: a) to evaluate the different effects of the aesthetic body shape model on adolescents with anorexia nervosa *vs* bulimia nervosa; b) to analyze possible differences, regarding that body shape model, between patients with purging behaviors *vs* non purging types of patients; and c) to explore the relationship between the influence of the aesthetic body shape model and other clinically relevant variables such as body dissatisfaction, eating attitudes and personality traits. Despite lots of studies have identified a significant influence of sociocultural factors on ED symptoms, there is a shortage of research based on clinical samples aimed to evaluate the different influence of the aesthetic model on different diagnostic categories.

Analyzing the extent of the influence of the aesthetic body shape model in our sample of ED patients, the results indicate that the majority of adolescents (79.9%) are influenced by the current thinness ideal. These results are similar to others which have concluded that the interiorization of that aesthetic model is a relevant predictor of ED symptoms (11,12,27). In addition, our results support that the influence of the aesthetic model is a risk factor for ED (28).

With regards to the differences between AN and BN, our results show that BN patients are more influenced by the aesthetic model than AN patients. This finding is in accordance with others which state that the influence of the aesthetic model is a predictor of suffering from BN but not AN (29), and with other studies indicating that sociocultural pressures to be thin correlate to bulimic symptoms (30).

Regarding the differences between purging (vomits, laxatives, diuretics, etc.) and non-purging types of ED, those patients with purging behaviors appear to be more influenced by the aesthetic model when comparing with non-purging patients. These results support the idea that the aesthetic model pressure and dissatisfaction predict unhealthy behaviors to control weight such as use of laxatives or vomits (31).

Bearing in mind our objective (to explore the relationship between the influence of the aesthetic body shape model and other clinically relevant variables), we found that body dissatisfaction is related to the aesthetic body shape model positively. The influence of the aesthetic body shape model is associated to higher levels of body dissatisfaction, thus promoting eating behavior disturbances mainly as bulimic symptoms in our sample. These results seem to be in accordance with previous research which has reported that thinness ideal is a relevant predictor of body dissatisfaction and ED (32). In our case, BN patients show the highest risk of thinness ideal interiorization and body dissatisfaction, thus leading to eating behavior disorders.

Our data support that the severity of ED symptoms (as measured by EAT-40) is linked to a greater influence of the aesthetic model. This finding is similar to the results reported by Martínez, Toro y Salamero (1996), who state that a stronger presence and interiorization of thinness-related cultural influences are associated with more eating symptoms.

Finally, our results support the existence of a positive correlation between the influence of the aesthetic model and the following personality profiles: inhibited, introversive, doleful, self-demeaning, oppositional and borderline. On the contrary, the correlation is negative with respect to profiles such as dramatizing, egotistic and conforming. These results suggest that specific personality traits might predispose adolescents to be influenced by sociocultural factors, thus increasing the influence of the current aesthetic body shape model. The Millon's evolutionary theory considers four basic polarities to describe different personality prototypes. These four polarities are: a) survival strategies-existence (the pleasure-pain polarity); b) adaptation (the active-passive polarity); c) replication (the self-other polarity); and d) processes of abstraction (the thought-feeling polarity). By means of these polarities, Millon built a classification system of personality prototypes. A personality prototype may be strong, weak or neutral with respect to the specific elements of polarities (Millon and Davis, 1998). Our results indicate that those personality traits, which correlated positively with the influence of the aesthetic model (inhibited, introversive, doleful, self-demeaning, oppositional and borderline), share a lack of capacity to experience pleasure (disbalance in the pleasure-pain polarity). More research is necessary to understand the nature of the relationship between personality and the current aesthetic model influence. Nevertheless, our data are similar to those reported in other studies indicating that some personality traits (e.g., perfectionism) are important and might predispose to ED through a higher susceptibility to sociocultural factors (33-35). There are other studies reporting that ED are not the direct result of a premorbid personality. The thinness ideal and body dissatisfaction would precede other psychological factors such as personality traits (36-38). It is necessary to extend the research on personality traits and their relationship with the aesthetic model influence not only with respect to some profiles (e.g., perfectionism) but including others such as those mentioned in this study.

The current study has some limitations. First, the use of self-reported instruments increases the probability of false responses (positives or negatives). Second, a control group was not included, so it was not possible to compare our results with a non-clinical sample. Third, this is a cross-sectional study. New longitudinal studies would be necessary to explore the temporal relation among sociocultural factors, personality traits, body dissatisfaction and ED.

Summarizing, the influence of the aesthetic body shape model is a relevant variable in ED patients as it is shown by the results of this study. All patients are influenced by that model but more clearly in case of BN patients. This influence would cause more body dissatisfaction, thus leading to bulimic symptoms, especially purging behaviors (vomits, laxatives or diuretics). Other aspect to be taken into account refers to the fact that some personality traits seem to be more susceptible to the influence of sociocultural factors and the aesthetic model influence, body dissatisfaction and ED symptoms. Previous research has reported differences between AN and BN with respect to personality (15,39,40), so further studies would be necessary to explore whether different diagnostics might influence on the degree of the aesthetic model relevance, dissatisfaction and purging symptoms.

A relevant contribution of this study refers to the thinness ideal influence and body dissatisfaction in ED and their implication in AN and BN. To sum up, intervention programs (prevention, treatment) must take into account the influence of sociocultural factors and body dissatisfaction in BN, thus adapting therapeutic programs to different diagnostics of ED in adolescents.

ETHICAL APPROVAL

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

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