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ORIGINAL ARTICLE

Body image-related cognitive fusion and disordered eating: the role of self-compassion and sad mood

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Abstract

Purpose The extent to which body image-related thoughts are endorsed and drive behaviors, a process known as Body Image-Related Cognitive Fusion (BI-CF), is an important contributor to disordered eating. Moreover, negative mood and negative self-referential processes (e.g., low self-compassion) have been reportedly associated with disordered eating; however, their associations with BI-CF are not known. The aim of this study was to investigate, among young adults, the association between (1) BI-CF and disordered eating attitudes and behaviors (2) BI-CF and self-compassion, and (3) whether sad mood influences BI-CF.

Method Participants completed online questionnaires that assessed BI-CF, self-compassion, negative affect, cognitive reactivity and disordered eating ($N=601$). A subsample ($n=51$) underwent an in-lab session in which they were exposed to a validated psychological sad mood induction task followed by the assessment of BI-CF.

Results 67.8% of variation in disordered eating was accounted for by BI-CF while controlling for covariates. Self-compassion was the strongest predictor of BI-CF levels, irrespective of other eating disorder or depression risk factors ($p<0.001$). Increases in sad mood did not influence levels of BI-CF.

Conclusion The endorsement of body image-related thoughts seems to play an important role in disordered eating. Compassionate self-responding may have positive influences on reducing negative body image-related thoughts. Furthermore, BI-CF appears to be a relatively stable phenomenon, irrespective of change in mood state. Results offer implications for the improvements in prevention and intervention models targeted towards disordered eating through self-compassion and cognitive defusion.

Level of evidence Part I: Level V, cross-sectional descriptive study. Part II: Level I, experimental study.

Keywords Disordered eating · Cognitive fusion · Self-compassion · Eating disorders · Cognitive vulnerability · Body image

Introduction

Eating disorders (EDs) result from complex interactions between biological, psychological, and social factors [1]. Among the different factors that have been suggested to play an important role in disordered eating, the process of body image-related cognitive fusion (BI-CF) has gained interest in vulnerability models [2–4].

The process of cognitive fusion results from an entanglement between thoughts, feelings, and behaviors, whereby individuals experiencing distressing thoughts and beliefs may become entangled (overly identified) with these thoughts. In a state of cognitive fusion, individuals may react to thoughts as though they are literal truths, resulting in difficulty disconnecting from them [5]. These thoughts are not necessarily reflective of reality and lead to unpleasant internal experiences, which may guide behaviors attempted at reducing distress [5]. This disconnect from reality and attempt to control behaviors and over-identification with thought processes is known to reflect psychological inflexibility, which is partly driven by cognitive fusion [6, 7]. BI-CF is a type of cognitive fusion centered around body image. For example, an individual may experience reoccurring negative body image-related thoughts that they strongly

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endorse and believe to be true. Importantly, negative body image-related thoughts alone may not result in disordered eating, yet research shows that the extent to which body image-related thoughts are endorsed and drive behaviors is an important contributor to ED vulnerability [2, 4]. Furthermore, BI-CF may partly explain the observation that while high rates of body dissatisfaction are observable within the general population, rates of EDs are not as high in comparison [3]. This discrepancy suggests an additional implication of intermediary factors that may take into account the vulnerability conveyed by body dissatisfaction and shame in the development of disordered eating [4, 8, 9]. As such, individuals may be unaccepting of their body image, but only some may identify with body image-related distressing thoughts to the extent that they would engage in disordered eating behaviors as a result [3]. In addition, BI-CF correlates positively with ED symptoms [3, 4]. Notably, while clear gender differences have been observed in the prevalence of disordered eating, most research on BI-CF has been conducted in solely female and Portuguese samples (e.g., [2, 6]). Thus, the evidence regarding gender disparities in BI-CF remains limited, especially in North American samples (e.g., [2, 9, 10]).

Mood states (i.e., affective state) can influence the type of thoughts individuals might experience in relation to themselves, consequently affecting eating behaviors [11–14]. Previous research has highlighted that mood is a factor that must be considered when studying ED development [14]. Cognitive distortions have been shown to be associated to disordered eating and influenced by mood [13, 15], yet no study has tested whether BI-CF is modifiable by mood. Mood changes can have an impact on the intensity of BI-CF an individual may experience, which can have implications for disordered eating.

The ability to be self-compassionate can lead to healthier strategies for dealing with unwanted thoughts, emotions, and feelings pertaining to body image [16, 17]. Self-compassion has been associated with positive mental health outcomes, such as greater life satisfaction and lower depression [18]. Researchers have found that self-compassion is negatively associated with psychological inflexibility, disordered eating, body dissatisfaction and *general* cognitive fusion [16, 19, 20]. Although self-compassion has been investigated in relation to body dissatisfaction and psychological flexibility, no research has incorporated both self-compassion and cognitive fusion specifically related to *body image*. Understanding the role of self-compassion in BI-CF may have implications for mindfulness and acceptance-based types of psychological interventions such as Acceptance and Commitment Therapy, which targets disordered eating. This framework aims to cultivate adaptive cognitive tendencies, such as psychological flexibility, through cognitive defusion [7].

The discrepancy between high rates of body dissatisfaction and relatively low rates of EDs can be modelled through the continuum theory of EDs. The continuum represents a risk gradient, where so-called "normal" eaters and clinical ED cases fall at opposite extremes [21]. Although two separate continuums may exist for restrictive vs. binge eating disorders, evidence suggests the presence of symptoms at varying degrees in the general population, whereby behavioral, cognitive and affective processes, self-esteem, and self-concept differences are determining factors that influence positioning along the continuum [21, 22]. The current study investigated the associations between affective and self-referential processes (i.e., mood and self-compassion) and BI-CF, an important cognitive process in the understanding of positioning along the ED continuum—in the general population.

The sequence of the research presented in this article is twofold; Part I was completed using self-report data collected online. Part II involved an in-lab testing session. In part I, the aim was to test the extent to which the identification with thoughts relating to one's body image (BI-CF) is associated with disordered eating and lower self-compassion while controlling for other risk factors. In part II, the aim was to test whether increases in sadness would predict increases in BI-CF, using a laboratory mood induction task.

Method: *Part I*

Participants

The first part of the study included 601 English-speaking adults ($M = 23.80$ years, $SD = 7.34$; 85.5% females). Participants were recruited through Concordia University's online participant pool system targeting undergraduate students (80.90%) and social media platforms (e.g., Facebook, Instagram, and Craigslist; 19.10%).

Measures

Prior to responding to self-report measures, participants answered questions about demographic information (e.g., age, ethnicity, and work status), gender and a question regarding ED history.

Disordered eating

The Disordered Eating Questionnaire (DEQ) [23] is based on the Diagnostic and Statistical Manual of Mental Disorders-4th edition text revision. The DEQ assesses frequency of disordered eating symptoms per week within the past 3 months. Section A-18 items measures the frequency of engaging in different disordered eating behaviors (e.g.,

limited the amount of food or calories consumed; 1 = *never* to 6 = *more than once a day*). Section B-6 items measures the frequency of body-and food-related worries and intrusive thoughts (e.g., felt uneasy seeing your body in a mirror; 1 = *not at all* to 7 = *very much*). Section C assesses height and weight. The original validation study revealed a one-factor structure including all section A items (with the exception of 4 items encompassing purging behaviors), and section B items. Answers on these items were averaged into a mean score, with higher scores indicating greater ED symptoms. The present study showed high internal consistency (α = 0.95).

Body image-related cognitive fusion

The Cognitive Fusion Questionnaire-Body Image [2] (CFQ-BI) contains 10 items (1 = *never true* to 7 = a*lways true*) adapted from the original 28-item questionnaire [24] that assesses tendency to endorse and identify with pervasive thoughts related to body image (i.e., the severity of BI-CF; my thoughts relating to my body image cause me distress or emotional pain; I over-analyze my physical appearance or body shape to the point, where it is unhelpful to me). Such pervasive thoughts can be defined by the extent to which they can interfere with functioning of daily activities. The average across all items represents the CFQ-BI score, where a higher mean represents more BI-CF. The CFQ-BI original validation study demonstrated superior psychometric properties (α = 0.96). The present study showed excellent internal consistency (α = 0.97).

Self-compassion

The Self-Compassion Scale [18] contains 26 items (1 = *almost never* to 5 = *almost always*) that assess self-compassion. Self-compassion subscales include Self-Kindness, Common Humanity and Mindfulness (e.g., I try to be loving towards myself when I'm feeling emotional pain, I try to see my failings as part of the human condition, when something upsets me I try to keep my emotions in balance, respectively). Self-deprecating subscales include Self-Judgment, Isolation, and Over-Identified (e.g., I'm disapproving and judgmental about my own flaws and inadequacies, when I fail at something that's important to me, I tend to feel alone in my failure, when something upsets me I get carried away with my feelings, respectively). These six subscales compose the three components of self-compassion and their opposite (self-kindness vs. self-judgment; common humanity vs. isolation, and mindfulness vs. over identification). Higher mean scores reflect higher self-compassion. The scale has good reliability and good convergent validity [18]. Our study presented high internal consistency (α = 0.93).

Cognitive reactivity

The Leiden Index of Depression Sensitivity questionnaire [25] contains 34 items that assess cognitive reactivity to sad mood. The participants are asked to imagine feeling moderately sad and report the intensity to which the items apply to them (0 = *not at all* to 4 = *very strongly*). There are six subscales: Hopelessness/Suicidality (e.g., When I feel down, I more often feel hopeless about everything), Acceptance/Coping (e.g., When in a sad mood, I am more creative than usual), Aggression (e.g., In a sad mood, I do more things that I will later regret), Perfectionism/Control (e.g., When I feel sad, I go out and do more pleasurable activities), Risk Aversion (e.g, When I feel sad, I am less inclined to express disagreement with someone else) and Rumination (e.g., When I am sad, I have more problems concentrating). Higher total scores reflect higher cognitive reactivity. The scale can discriminate well between individuals with a higher vulnerability of depression and healthy individuals [25]. The original validation study showed good psychometric properties [25]. Internal consistency in the present study was excellent (α = 0.91).

Affect

The Positive and Negative Affect Schedule [26] contains 20 items that assess how one feels in the present moment using positive and negative affect items (e.g., interested, afraid, distressed; 1 = *very slightly or not at all* to 5 = *extremely*). Higher average scores represent higher positive or negative affect on respective scales. The original validation study showed good psychometric characteristics [26]. The present study demonstrated good internal consistency (α = 0.85).

Procedure

Informed consent was obtained prior to participation. Upon completion, participants had the choice between 0.5 participant pool credits (exclusively for undergraduate students) or the chance to win a 50$ Amazon gift card. The original sample contained 648 participants; however, the final sample included 601 participants. The criteria for exclusion consisted of missing values on more than 2 items on the questionnaires or missing information on other key variables (gender, BMI and ED history).

Statistical analysis

All analyses were performed using IBM SPSS Statistics Version 25.0 [27]. Data were analyzed with descriptive

statistics, bivariate correlations and linear regression analyses.

Results: *Part I*

Data quality was ensured by screening all minimum and maximum across measures. Assumptions of linear regression were met. There were no visible outliers across outcome measures after examining standardized *z*-scores ($z < |3|$) [28]. Significant associations were found between the measures ($p < 0.001$; Table 1). The sample consisted of students (87.9%) and non-students (12.1%); Non-Hispanic White (62.9%), Asian (9.5%), Middle Eastern or Arab (8.3%), Black, Afro-Caribbean or African American (3.2%), Latino or Hispanic American (3.7%) and Other (12.4%). The average Body Mass Index (BMI) was 23.39 (Range: 15.14–46.37, $SD = 4.18$). Females had higher levels of disordered eating ($t(596) = 3.97$, $p < 0.001$), BI-CF ($t(596) = 3.72$, $p < 0.001$) and cognitive reactivity scores ($t(596) = 2.13$, $p = 0.003$) relative to males. Males had higher levels of self-compassion ($t(596) = 2.80$, $p < 0.001$) than females. Thirteen percent of the sample ($n = 78$) reported a history of or a current ED.

Hypothesis 1

A linear regression was conducted to determine the predictive value of BI-CF on disordered eating mean scores while controlling for the effects of age, gender, BMI and lifetime ED presence (Fig. 1). The overall model accounted for 67.8% of the variance in disordered eating scores, $F(5, 595) = 254.12$, $p < 0.001$. Whereas being female, having a higher BMI, lifetime ED and CFQ-BI scores were all predictive of ED symptoms, the standardized β coefficients showed that CFQ-BI was the strongest predictor ($p < 0.001$) (Table 2).

Table 1 Bivariate associations between questionnaire mean scores (Pearson correlations)

Measures	DEQ	SCS	CFQ-BI	LEIDS-R
DEQ	–	–	–	–
SCS	−0.49	–	–	–
CFQ-BI	0.80	−0.59	–	–
LEIDS-R	0.45	−0.53	0.49	–
PANAS-n	0.37	−0.34	0.39	0.43

All correlations significant at $p < 0.001$

DEQ disordered eating questionnaire, *SCS* self−compassion scale, *CFQ−BI* cognitive fusion questionnaire−body image, *LEIDS−R* leiden index of depression sensitivity−revised. *PANAS−n* PANAS negative affect

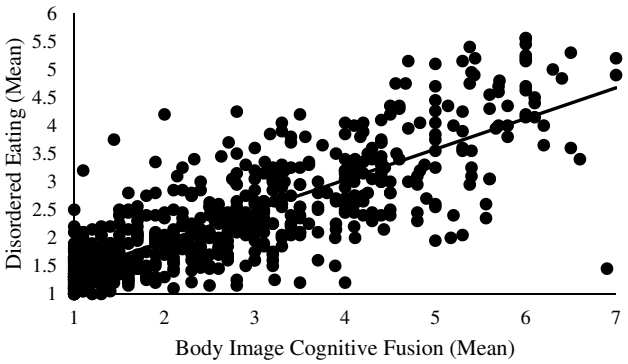

Fig. 1 Association between BI-CF (CFQ-BI mean scores) and disordered Eating (DEQ mean scores)

Hypothesis 2

Linear regression analysis was conducted to determine the predictive value of self-compassion on BI-CF while controlling for age, gender, BMI and ED presence, as well as negative affect and cognitive vulnerability to depression. The overall model accounted for 47.2% of the variance in CFQ-BI scores ($F(7, 593) = 77.68$, $p < 0.001$; Table 3). Although being female, having a higher BMI, a lifetime history of EDs, negative affect and greater cognitive vulnerability to depression were all predictors of higher levels of BI-CF, the standardized β coefficients showed that lower self-compassion was the strongest predictor ($p < 0.001$).

Method: *Part II*

Participants

83 participants were recruited for part II (laboratory session). After conducting a screening for depressive symptoms (see below), 32 individuals were excluded. The

Table 2 Linear regression analysis of disordered eating predictors

	Unstandardized coefficients		Standardized coefficients	*t*	*p*
	b	*SE*	*β*		
Constant	0.28	0.17	–	0.172	0.864
Gender	0.17	0.07	0.06	2.47	0.014
Age	< 0.01	< 0.01	< 0.01	− 0.14	0.890
BMI	0.03	< 0.01	0.14	5.85	< 0.001
ED history	0.38	0.08	0.13	5.07	< 0.001
CFQ-BI score	0.49	0.02	0.72	28.03	< 0.001

ED history eating disorder in present or past, *CFQ−BI* cognitive fusion body−image questionnaire

Table 3 Linear regression analysis of BI-CF predictors

	Unstandardized coefficients		Standardized coefficients	*t*	*p*
	b	*SE*	*β*		
Constant	1.72	0.52	–	3.33	0.001
Gender	0.33	0.13	0.08	2.63	0.009
Age	0.01	0.01	0.03	0.98	0.325
BMI	0.05	0.01	0.15	5.04	< 0.001
ED history	0.82	0.14	0.19	5.90	< 0.001
LEIDS-R	0.01	< 0.01	0.18	4.82	< 0.001
PANAS-n	0.31	0.07	0.15	4.40	< 0.001
SCS	− 0.81	0.10	− 0.38	− 10.56	< 0.001

Gender and ED lifetime presence were dummy coded, such that being male, and no lifetime presence coded as 0. BMI: one statistical outlier (z=8), was removed from analysis

ED history eating disorder in present or past, *LEIDS−R* leiden index of depression sensitivity−revised, *PANAS−n* PANAS negative affect, *SCS* self−compassion scale

final sample consisted of 51 participants (90.2% female; M_{age} = 23.35 years SD = 6.43), where 10% had a history of or current ED.

Measures

Depressive symptoms

The Centre for Epidemiological Studies-Depression scale [29] is a 20-item well-validated and reliable self-report questionnaire for use in the general population that measures symptoms of depression within the past week (e.g., I felt depressed; 0 = *rarely* to 3 = *mostly felt a certain way over the last week*). Item responses are summed, where higher scores represent higher depressed symptoms (positive items reversed scored). A score of 16 or higher on the Centre for Epidemiological Studies-Depression scale suggests the presence of possible depression [30]. Internal consistency in the present study was α = 0.91.

Mood change

The sad item of the Visual Analog Mood Scale [31] was used to track mood states. A neutral face is presented on one end and a sad face is located on the polar end of the unidimensional scale. The participant draws a mark somewhere along the line that best represents their current mood [32].

Procedure

The laboratory session took place at Concordia University. Informed consent was obtained from participants prior to participation. Participants first filled out the Centre for Epidemiological Studies-Depression scale and the Visual Analog Mood Scale to measure pre-induction mood states. During the negative mood induction, participants listened to music and were asked to recall a time when they felt sad [11, 33, 34]. The mood induction consisted of a six-minute music exposure to induce low mood (i.e., sadness), presented through headphones. The music selected was a slowed down version, at half speed, of an orchestral song by Prokofiev; "Russia Under the Mongolian Yoke". This is a standardized, commonly used, validated method in depression research to transiently lower mood experimentally [11, 33, 34]. Following the music task, participants filled out the Visual Analog Mood Scale post-induction and the CFQ-BI (time 2). Participants were debriefed and given compensation.

Statistical analysis

Paired sample t tests were conducted to study changes in sadness pre- and post-mood induction and changes in CFQ-BI scores. Linear regression analysis was conducted to test whether change in sadness predicted changes in CFQ-BI.

Results: *Part II*

No outliers were detected. Regression analysis assumptions of normally distributed residuals and linearity were violated. Transformations were not successful; therefore, non-transformed data was used and results were compared with non-parametric statistics [28].

Manipulation check

The mean score pre-mood induction increased from 8.40 (SD = 16.83) to 27.98 (SD = 26.21) post-mood induction, $t(50) = 5.85$, $p < 0.001$, $d = 0.88$. There was no difference between CFQ-BI mean scores at baseline and after the mood induction, $t(29) = 0.13$, $p = 0.895$, $d = 0.01$.

Hypothesis 3

A linear regression was carried out to determine the influence of change in sadness on change in CFQ-BI scores while controlling for age. Change in sadness ($\beta = 0.09$, $t = 0.59$, $p = 0.555$) and age ($\beta = 0.16$, $t = 1.09$, $p = 0.281$) were not significant predictors of changes in BI-CF (adjusted $R^2 = 0.01\%$, $F(2,48) = 0.60$, $p = 0.555$). A regression analysis with the addition of baseline depressive symptoms (Centre for Epidemiological Studies-Depression scale) did not change these results. A non-parametric correlation further confirmed the lack of association between sadness change and BI-CF change ($r_\tau = 0.136$, $p = 0.396$).

Discussion

The role of BI-CF in the development and severity of disordered eating has been supported by past research [3]. Our objective was to investigate the contributing mechanisms for positioning along the continuum theory of EDs in a community sample. Specifically, the goal was to investigate this continuum in the context of BI-CF by confirming associations between BI-CF and disordered eating [3], as well as to extend research on BI-CF by investigating the associations with self-compassion and sad mood while controlling for other cognitive vulnerability markers and ED risk factors.

The results uphold previous findings on the association between BI-CF and disordered eating, in turn, providing support for the first hypothesis; individuals experiencing higher BI-CF also experience more disordered eating behaviors and thoughts [2, 3]. Disordered eating is a maladaptive strategy resulting from intrusive and persistent body image-related thoughts that are regarded by the individual as factual [3–5]. Notably, the present study found that BI-CF was the strongest predictor among other ED risk factors (e.g., ED history). Interestingly, females had higher BI-CF than males—a finding in line with previous research conducted in Portuguese samples (e.g., [9]). The present study was conducted with a North American sample, which reinforces the universal phenomenon of BI-CF [7].

Our study introduced self-compassion as a predictor variable of BI-CF. The results provided support for the second hypothesis; individuals who display higher self-compassion experience lower BI-CF. While other risk factors for psychopathology such as negative affect and cognitive vulnerability to depression also predicted BI-CF, self-compassion was the most robust predictor. Although the directionality and predictive influences of the associations are limited by a cross-sectional design, the findings may suggest that self-compassion reduces the impact of unwanted thoughts associated with BI-CF. The ability to be kinder towards oneself may be a more adaptive strategy for dealing with such upsetting and persistent thoughts regarding body image and may help reduce the impact of disturbing thoughts on behaviors by supporting more flexible thinking [17]. Given that self-compassion involves aspects of psychological flexibility, such as mindful awareness of self-referential thoughts and emotions and non-judgment/acceptance, self-compassion may be relevant to reduce cognitive entanglement to negative thoughts related to body image, thus, helping individuals dissociate their thoughts from their actions. In this sense, self-compassion may have strong implications for Acceptance and Commitment Therapy and in other compassion-focused based therapies by reducing BI-CF. By targeting the reduction of an intermediary process (i.e., BI-CF), perhaps therapies will be more guided in targeting the reduction of ED symptoms [20].

To examine BI-CF in relation to mood, we studied whether CFQ-BI is sensitive to mood change. Based on previous research that has indicated the effects of mood on self-referential cognitive processes [11, 12, 35], we hypothesized that BI-CF may be sensitive to negative affect (sadness) and would reactivate negative thinking patterns associated to body image, reflected in higher CFQ-BI scores following negative mood induction. While the validated negative mood induction was effective and yielded an effect size similar to other mood induction studies [11], BI-CF did not change. This seems to have been the first study to explore the effects of changes in sadness on BI-CF and showed that BI-CF appears to be a phenomenon independent of mood state.

Limitations and future directions

In part I, the majority of the sample consisted of students and, although there were significant differences between males and females for each variable (i.e., disordered eating, BI-CF and self-compassion), the sample contained more females. Yet, the observed gender differences may provide direction for future studies on BI-CF in males. In addition, ED information was based on self-report rather than a clinical diagnosis and the design of the present study prevented the differentiation of those with current vs. past EDs. Furthermore, the cross-sectional design prevented analysis of the directionality of the observed relations between BI-CF, self-compassion, and disordered eating. Longitudinal studies should evaluate the predictive power of self-compassion on BI-CF.

In part II, we excluded individuals with high levels of baseline depressive symptoms. The relatively high rate of excluded individuals was unexpected and may indicate that the Centre for Epidemiological Studies-Depression scale detected an unforeseen construct in the sample. Perhaps the recruitment information revealed the general nature of the study and, in turn, attracted individuals more likely to engage in disordered eating or present other relevant comorbid conditions, such as depression [36]. In addition, part II only contained one condition; the negative mood induction. Although this is common practice in mood induction studies [11, 12], it would be recommended for future studies to include a neutral mood condition. Furthermore, change in CFQ-BI mean scores was measured using baseline scores from part I, which were collected on a different day than the CFQ-BI at time 2 (post-mood induction). Thus, the time elapsed between both assessments on the CFQ-BI varied among participants.

Despite these limitations, our study provided evidence, in a community sample, that BI-CF is positively associated with disordered eating irrespective of other ED risk factors, and that higher levels of self-compassion was the strongest predictor of BI-CF. While greater levels of BI-CF were also associated with negative affect and a greater cognitive vulnerability to depression, our findings suggest that BI-CF is a relatively stable phenomenon insensitive to mood changes.

Conclusion

The current findings contribute to the research on disordered eating and the importance of targeting BI-CF in therapy. Early ED detection is crucial and screening for BI-CF severity may aid in the detection of the vulnerability to disordered eating. Our findings on the roles of self-compassion and BI-CF in disordered eating offer contributions to therapies that target psychological inflexibility, such as Acceptance and Commitment Therapy. Acceptance and Commitment Therapy targets the reduction of psychological inflexibility, which is suggested to be driven by cognitive fusion [7]. The observed association between self-compassion and BI-CF suggests that therapies can focus on heightening self-compassionate responding in individuals at risk for disordered eating in attempt to produce psychologically flexible thinking patterns associated with body image. Targeting the reduction of BI-CF through a healthier coping strategy can be beneficial for individuals experiencing ED symptoms.

What is already known on this subject?

Previous research has shown that BI-CF is associated with ED symptoms and acts as an important mediator in various associations (e.g., shame and disordered eating). However, it is important to understand the factors that can increase vulnerability to BI-CF, such as the role of self-compassion and sad mood.

What does this study add?

We are the first to study to show (1) the link between BI-CF and self-compassion while controlling for other risk factors in young adults (2) experimentally the effects of mood on BI-CF. We also confirm the predictive value of gender in BI-CF in a North American sample. Our results can have implications for future research on the Acceptance and Commitment Therapy model.

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Data availability The data sets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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 (Concordia University Ethics Review Board Committee; certification number: 30010256) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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