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Running Head: EFFECTIVENESS OF PEER-FACILITATED PREVENTION

Effectiveness of Peer-led Eating Disorders Prevention:

A Replication Trial

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Portions of this study were presented as work in progress at the 39th Annual Meeting of the Association for Behavioral and Cognitive Therapies, Washington, D.C. and at the 2006 International Conference on Eating Disorders, Barcelona, Spain

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Abstract

The aim of this study was to replicate and extend results of a previous trial that investigated the effectiveness of two peer-led eating disorders prevention interventions on reducing eating disorder risk factors in undergraduate women (Becker, Smith & Ciao, 2006). In order to extend findings from the previous study by allowing for investigation of differential response, we randomly assigned a larger sample of both higher- and lower-risk sorority members (N = 188; age M = 18.64, range = 18-21; 20% minority) to either a cognitive dissonance (CD) or a media advocacy (MA) intervention under naturalistic conditions. Interventions were delivered by trained sorority peer-leaders and consisted of two 2-hour group sessions. Participants completed questionnaires assessing eating disorder risk factors at pre-treatment, post-treatment, 7-week follow-up, and 8-month follow-up. Results indicate that both interventions reduced thinideal internalization, body dissatisfaction, dietary restraint, and bulimic pathology at 8-months, although higher- and lower-risk participants responded somewhat differently. Both CD and MA generally appeared effective for higher-risk participants; only CD, however, appeared to benefit lower-risk participants. Results further support the viability of using peer-leaders in dissonancebased prevention.

Key Words: eating disorder, dissonance, peer-led, sorority, prevention

Effectiveness of Peer-led Eating Disorders Prevention: A Replication Trial

Although full syndrome eating disorders (EDs) occur in a minority of college women, sub-clinical eating pathology, which is associated with negative affect and body dissatisfaction, appears common (Mintz & Betz, 1988). Research also indicates that body dissatisfaction may predict onset of an ED (McKnight Investigators, 2003) and that as many as 30% of collegiate women with partial syndrome EDs may go on to develop full syndrome EDs (Taylor et al., 2006). Because of the frequency of body image concerns among college women, coupled with the potential development of EDs, it appears constructive to target ED prevention and body image concerns in this population.

Early ED prevention programs, particularly didactic psychoeducational ones, had little effect on reducing ED risk factors (Stice & Shaw, 2004). Recently, however, researchers have developed programs with improved efficacy. For example, Stice and colleagues developed a cognitive dissonance-based prevention program that has produced consistent reductions in ED risk factors in various populations (Stice, Mazotti, Weibel, & Agras, 2000; Matusek, Wendt, & Wiseman, 2004; Stice, Shaw, Burton, & Wade, 2006; Becker, Smith, & Ciao, 2005; 2006). Dissonance theory suggests that if individuals act in ways that contradict their beliefs then they typically will change their beliefs to align with these actions (Festinger, 1954). Cognitive dissonance ED prevention (CD) aims to change beliefs about the thin-ideal of feminine beauty by having participants actively speak against this ideal. Internalization of the thin-ideal has been related to ED pathology (Stice, 2002; Stice, Ziemba, Margolis, & Flick, 1996). Thus, decreasing thin-ideal internalization via CD should lower participants' ED risk.

To date, 12 studies conducted by five labs have investigated either the efficacy or effectiveness of CD (see Stice & Presnell, 2007 for summary). Overall, this research indicates that CD produces significant reductions in thin-ideal internalization, body dissatisfaction, dietary restraint, bulimic pathology and negative affect. It should be noted, however, that in the largest, most well-controlled CD trial, effects showed some signs of fading at 12-months (Stice et al., 2006). Despite this, CD remains one of the most rigorously tested ED prevention programs. CD also is one of very few programs to yield positive results which have replicated in multiple labs.

In a previous effectiveness trial, we investigated the viability of administering CD using undergraduate peer-leaders (PLs) (Becker, Smith & Ciao, 2006). In this study, new members in a sorority system were randomly assigned to receive peer-led CD or a more passive peer-led media advocacy (MA) intervention. MA presented similar content to CD, but eliminated the active, supposedly dissonance producing activities in an effort to investigate the importance of these activities. Results indicated that although both interventions reduced dieting, eating pathology, thin-ideal internalization, and body dissatisfaction at post-treatment and 7-week follow-up, only CD maintained these decreases at 8-month follow-up. These results are promising from a dissemination standpoint in that they suggest that trained undergraduates can deliver CD. This is important because many social systems that might wish to employ CD may not have sufficient clinical providers to implement it. Moreover, at the collegiate level many relevant social systems (e.g., sororities, athletics) are drawn to peer-led programs because such programs serve a dual purpose of addressing an important issue (i.e., prevention of EDs) and creating leadership opportunities for students. Peers also may play a significant role in body image (Shroff & Thompson, 2006). Given that the above study is the only study to date to explore the delivery of an efficacious ED prevention program using PLs, replication appears important.

The purpose of this study was to determine if the results from our earlier trial would replicate with a larger sample. We also sought to investigate the differential effectiveness of

peer-led CD for higher- and lower-risk sorority members. Sorority members often are perceived to be at higher-risk for EDs as compared to college women generally. Data supporting this belief, however, are equivocal (Allison & Park, 2004; Cashel, Cunningham, Landeros, Cokley, & Muhammad, 2003). Also, data from our previous trials indicate that individual sorority members fall along a continuum of risk, with some reporting minimal body image concerns. Given that sorority leaders, in our experience, want to implement programs with all members regardless of individual risk status, it seemed important to investigate differential response to peer-led CD and MA. Because MA is easier to administer than CD, a second evaluation of peer-led MA was warranted. Finally, although it would have been ideal to include a no-treatment control group in this study, the effectiveness nature of this research means collaborating with a social system that is unwilling to repeatedly include a no-treatment control condition. Thus, this was not possible.

We hypothesized that CD and MA would produce positive results through 7-week follow-up. We also expected CD to yield effects at 8-months, whereas positive results for MA would largely fade by 8-months. With regards to risk status, based on an earlier trial which explored the differential efficacy of CD and MA in high- and low-risk sorority members when administered by a doctoral level provider (Becker, Smith, Ciao, 2005), we hypothesized no differences between high-risk and low-risk members' responses to the two interventions.

Method

Participants

New members entering a local university sorority system over two consecutive years participated in this study (see Table 1 for demographics). Of the 211 new members who initially accepted sorority membership, 188 participated (see Figure 1).

Procedure

Overview and Participant Flow. The study took place during the 2nd and 3rd years of the Sorority Body Image Program (SBIP) for new members. Although program participation was semi-mandatory (i.e., all new members participated unless granted an excused absence by their sorority) participation in the study, which included completing baseline and follow-up measures, was optional. Both the study and program were approved by sorority presidents, Greek Council, the Counseling Center, and Student Affairs as well as the Institutional Review Board. Approximately 30% of female students on campus join to a sorority. Of the 211 women who received sorority bids over the two years of the study, seven did not pursue membership and 16 received excused absences from the first program session (e.g. for class, athletic event; Figure 1). Of the remaining 188 members, 100% participated in the study, and comprise the base study sample. Because this study investigated prevention, not treatment, we excluded members who met DSM-IV ED criteria, as in our previous trials, based on responses to the Eating Disorder Examination-Questionnaire (EDE-Q) diagnostic questions. Of the 188 members, six from CD (6.4%) and nine from MA (9.6%) were excluded for this reason. Of the remaining 173 members, 90.5% in CD and 91.6% in MA completed session two, 87.3% in CD and MA completed 7-week follow-up, and 74.5% of CD and 71.3% of MA completed 8-month follow-up.

At the start of the SBIP, new sorority members attended a meeting in which we explained the history of the SBIP along with the difference between the semi-mandatory program and the optional study. Members then completed baseline questionnaires before breaking up into smaller intervention groups. Each of the six CD and six MA groups was led by unpaid PLs. Groups were run simultaneously each year, and all seven campus sororities¹ coordinated schedules to allow their members to participate. Undergraduate research assistants (RAs) stratified members by

sorority before randomizing them into 12 groups (ensuring approximately equal representation from each sorority in the groups), which were then blindly randomized to condition.

Interventions. CD and MA consisted of two 2-hour group sessions administered by 3-4 PLs. Both interventions included asking members to a) commit to participate in the session, b) collectively identify and analyze the thin-ideal, c) watch a 7-minute video on media use of digital enhancement, and d) discuss before-and-after photos showing \$100 of digital editing.

Cognitive Dissonance. During the remainder of session one, participants a) individually brainstormed and wrote costs of pursuing the thin-ideal, b) collectively listed these costs and discussed the unattainability of the thin-ideal, and c) received "homework" asking them to stand in front of a mirror in the privacy of their own room, wearing as little clothing as possible, and list their positive qualities, both physical and emotional. In CD session two, participants a) reviewed the mirror assignment, b) completed role plays in which PLs acted as a friend who embraced the thin-ideal while small groups of participants attempted to persuade PLs against this pursuit, c) shared personal examples of a time when they felt pressure to pursue the thin-ideal, d) described how they would respond to that pressure now, e) developed a top-ten list of ways that sorority members can resist the thin-ideal, and f) selected a self-affirmation homework exercise (e.g., making a pact with a friend to stop negative body talk, accepting a compliment).

Media Advocacy. In session one, MA groups viewed a second video regarding the portrayal of women in advertisements, with intermittent opportunities for group members to discuss the video. In MA session two, group members a) addressed the influence of media in perpetuating the thin-ideal, b) discussed strategies for resisting pro-thin-ideal media messages and identified costs associated with pursuit of the thin-ideal, c) viewed and discussed a video highlighting ED health risks, and d) made a list of strategies to resist media messages.

The Study. New members who agreed to participate in the study completed a consent form and baseline questionnaires during the large group orientation session (February 2005 or February 2006). Members were informed they could pretend to fill out the questionnaires and submit a folded blank questionnaire and blank consent form to reduce coercion. Members generated their own ID numbers so that we could not link data to particular members. Postintervention measures were administered at the end of the second session in small groups and at 7-week and 8-month follow-up². We collected follow-up data at weekly sorority meetings or during individual time slots if participants decided to not attend their meeting.

Peer-facilitator Training. PLs, who had previously been a participant in either CD or MA, were recruited through an information session. Members were asked to self-screen and not serve as PLs if they believed they had significant ED concerns; referrals for ED treatment were provided to any interested member. Facilitators completed two 4.5-hour training sessions, which were led by a licensed psychologist (CB) and sorority RAs, all of whom had prior experience as PLs. PLs trained in "teams" of three to four, with three teams attending each training session. We trained six teams in each intervention per year. PLs received an intervention protocol, and each team led one slightly abbreviated session while the other two teams served as participants in order to simulate a real session. Thus, altogether each team led each session once and participated in each session twice. After each mock session, PLs received 30-minutes of supervision aimed at increasing adherence and developing group leadership skills.

Sessions were audiotaped to assess PLs adherence to the protocol. Each tape was rated by two trained RAs (kappa range = .66 to 1.0 with 97% - 100% agreement between raters, kappa M = .87). All groups during both years of the program evidenced acceptable adherence to protocol. Measures

Dependent variables included thin-ideal internalization, body dissatisfaction, dietary restraint, and bulimic pathology. Due to the unfunded effectiveness nature of this study, we were limited to self-report measures to assess these constructs. In order to compare results of this study to previous trials, we employed similar measures as those used in Becker et al. (2006). Thin-ideal internalization was assessed by the Ideal Body Stereotype Scale – Revised (IBSS-R; Stice & Agras, 1998). This ten item measure assesses belief about the ideal appearance characteristics of women. Body dissatisfaction was assessed by the Body Shape Questionnaire (BSQ; Cooper, Taylor, Cooper, & Fairburn, 1987), which measures the degree of unhappiness with body appearance over 28 days using a 6-point likert scale. Restraint was assessed by the restraint subscale of the EDE-Q (Fairburn & Beglin, 1994), which assesses eating behaviors and attitudes from the past 28 days. We also used a bulimic composite score derived from the diagnostic items on the EDE-Q to assess ED pathology. Internal consistency for all measures was good (IBSS-R α = .86, EDE-Q restraint α = .84, EDE-Q bulimic α = .79, BSQ α = .97). Statistical Analysis

Analyses were conducted intent-to-treat using full information maximum likelihood estimation. One way analysis of variance (ANOVA) revealed no significant baseline differences between groups for age or BMI (see Table 1 for demographics). Similarly, we found no baseline differences for dependent measures. Skewed BSQ, EDE-Q restraint and bulimic composite data were normalized for statistical analyses using a logarithmic transformation.

Members were determined to be high- or low-risk based on level of body dissatisfaction using a median split on baseline BSQ scores (Mdn = 85), a strategy we have used previously (Becker et al., 2005). Mean scores for low- (n = 88; M = 66.19, SD = 11.71) and high-risk members (n = 85; M = 114.59, SD = 23.93) were consistent with those in Becker et al. (low-risk M = 64.67, SD = 10.45; high-risk M = 113.21, SD = 24.31) and BSO scores differed significantly, t(171) = -18.24, p < .0001.

We conducted four planned 2 x 2 x 4 (group x risk status x time) repeated measures ANOVAs for each construct to examine differences by group and risk status over time. Partial eta-squared values are reported for effect sizes. Post-hoc ANOVAs (risk status X time) were conducted within CD and MA independently to explore significant time by group by risk status interactions. To control for multiple unplanned post-hoc comparisons, we used a Bonferroni correction on the post-hoc analyses, resulting in a significance level of p < .008.

Results

Table 2 presents the means by group and risk status on all dependent measures at each assessment period. To facilitate comparison with earlier studies, we included Cohen's d for within group effect size from baseline to 7-week and 8-month follow-up. Because we did not have a no-treatment group, we include six month effect sizes from the assessment only condition in Stice et al. (2006). Stice et al. employed a high-risk sample; thus, we also include one month waitlist effect sizes from Becker et al. (2005) which had a mixed-risk sample.

Dietary Restraint. Analyses revealed a linear time effect and a risk status effect with high-risk members showing greater restraint (see Table 3 for statistics). We also found a time by group by risk status interaction, suggesting that high- and low-risk members reacted differently to CD and MA across time. Post-hoc analyses indicated that high- and low-risk members responded similarly to CD as indicated by a time effect and lack of interaction (Table 4). Highrisk members showed greater response to MA, however, as indicated by a time by risk status interaction (Table 4) and 8-month follow-up effect sizes (Table 2).

Thin-Ideal Internalization. We found a linear time effect for internalization (Table 3). Within group effect sizes indicated that all groups reduced internalization over time (Table 2), although internalization effects faded slightly at 8-months. Results also showed a risk status effect, with high-risk members showing greater internalization.

Body Dissatisfaction. We found a linear time effect, and a risk status effect. High-risk members had greater body dissatisfaction. We also found a time by risk status interaction and a time, group, and risk status interaction (Table 3). Post-hoc ANOVAs indicated that low- and high-risk members responded similarly to CD as indicated by a time effect. Members responded differently to MA, however, as indicated by a time by risk status interaction (Table 4). High-risk members showed significantly greater response to MA (Table 2).

Bulimic Pathology. This scale showed a time and a risk status effect, with high-risk member reporting greater bulimic pathology. We also found a time by risk status interaction and a time by group by risk status interaction (Table 3). Post-hoc ANOVAs indicated that both lowand high-risk members responded to CD as indicated by a time effect (Table 4). Although a time effect indicated that both low- and high-risk members improved in MA, high-risk members responded better over time, as indicated by an interaction.

Onset of New Cases. Two baseline asymptomatic members, one each from CD and MA, met criteria for EDNOS at 8-month follow-up. Three members (CD n = 1; MA n = 2) who were subthreshold baseline ED cases worsened during the study, but did not meet full ED criteria.

Discussion

Results from this study partially support those found in Becker et al. (2006). Members in CD evidenced 8-month reductions in ED risk factors (d range .28-.40) that were roughly comparable to those found in our previous trial (d range. 19 - .61). At the same time, results

contrast to our earlier trial in that effects for CD appeared to fade slightly from 7-weeks to 8months for all dependent variables except body dissatisfaction. In addition, overall effects for MA did not appear to decrease as markedly in the present trial as compared to Becker et al.

Although the study did not include a waitlist control group, examination of assessment only effect sizes from Stice et al. (2006) and Becker et al. (2005) provide support for the interpretation that CD had an effect on risk factors, particularly with respect to internalization, body dissatisfaction and bulimic pathology. The case is somewhat less clear for MA, depending on whether one compares assessment only effect sizes from Becker et al. (which are consistent in terms of being a mixed risk sample) or Stice et al. (which are a more similar time frame).

We also explored whether or not low- and high-risk members responded differentially to peer-led CD and MA. This is important for several reasons. Meta-analyses suggest that high-risk samples are associated with larger effect sizes (e.g., Stice & Shaw, 2004), suggesting that if one's goal is to maximize effects then one should use high-risk samples. Indeed, post-treatment assessment only within-group effect sizes for Stice et al. (2006) are consistently larger than equivalent waitlist effect sizes for Becker et al. (2005), likely because high-risk samples have greater regression to the mean and fewer problems with floor effects. This also is seen on Table 2, which lists follow-up assessment-only effect sizes for these studies. Many social systems, however, prefer to target both high- and low-risk members. Thus, researchers who study the dissemination of efficacious interventions under naturalistic conditions may find pressure to include mixed-risk samples, even when the efficacy work was completed only with high-risk populations. Given that few trials of CD have included mixed-risk populations, and given that this is only the second study to investigate peer-led CD, it seems important to determine whether both low- and high-risk members benefit. Results indicated that both low- and high-risk

members decreased thin-ideal internalization in response to both CD and MA. For the remaining three variables, we also found no significant difference in low- and high-risk members' response to CD. In contrast, while high-risk members benefitted from MA, low-risk members in MA evidenced a small but negative effect on three risk factors. One interpretation of this finding is that low risk members in MA evidenced regression to the mean, which was prevented by CD.

Overall, results support the use of peer-led CD in mixed-risk populations. Although effect sizes in this study are somewhat smaller than in the most well-controlled trial of CD (Stice et al., 2006), we view them as positive given methodological differences between the studies. As noted above, high-risk populations such as those used by Stice et al. typically yield larger effect sizes. This study, in contrast, relied on a mixed-risk sample along with a semi-mandatory design, which is not uncommon when prevention programs are moved into naturalistic conditions. Thus, participants may have been somewhat less motivated than in voluntary programs. Further, Stice et al. employed a 3-session version of CD and used diagnostic interviews, which may produce larger effect sizes (Stice, Fisher, & Martinez, 2004). Finally, this study used non-clinical, undergraduate group leaders. Though audiotapes indicated that adherence to the manual was very good, PLs lack helpful background when responding to individuals who are highly committed to the thin-ideal. In sum, given the real world elements included in the present study, we suggest that the results speak favorably about the utility of CD in naturalistic settings.

This study has a number of limitations, many of which are related to the effectiveness nature of this research. First, because the interventions are run within a single social system, there is risk for spillover effects. Being a member of a sorority system which collectively tries to reject the thin-ideal on an ongoing basis may eliminate some differential intervention effects. The fact that we did observe differential response, however, suggests that spillover effects are

not fully negating intervention effects, although they may be weakening them. Second, it would have been preferable to use structured interviews instead of self-report, and to not rely on self-report height and weight. Third, it is not clear to what degree results will generalize to other social systems, such as residential or more ethnically diverse sororities, or athletic teams. Fourth, the high level of study participation may indicate that members felt demand to participate and possibly respond in certain ways, despite attempts to reduce coercion. In speaking with members, however, our sense is that members feel that filling out the questionnaires is a minor issue given that they are expected to attend the sessions. They also value the confidentiality created by self-generated ID numbers. Fifth, because of the participatory nature of this research, RAs were not blind to the study hypotheses. The PL's who run the groups, however, are blind. The short follow-up is also major limitation. Finally, a no treatment control would strengthen this study. Despite these limitations, however, this study provides further support for the effectiveness of CD, and indicates that delivery with well trained endogenous providers is feasible.

References

- Allison, K.C., & Park, C.L. (2004). A prospective study of disordered eating among sorority and nonsorority women. *International Journal of Eating Disorders*, *35*(3), 354-358.
- Becker, C. B., Smith, L. M., & Ciao, A. C. (2005). Reducing eating disorder risk factors in sorority members: A randomized trial. *Behavior Therapy*, *36*(3), 245-253.
- Becker, C. B., Smith, L. M., & Ciao, A. C. (2006). Peer facilitated eating disorder prevention: A randomized effectiveness trial of cognitive dissonance and media advocacy. *Journal of Counseling Psychology* 53(4), 550-555.
- Cashel, M. L., Cunningham, D., Landeros, C., Cokley, K.O., & Muhammed, G. (2003).

 Sociocultural attitudes and symptoms of bulimia: Evaluating the SATAQ with diverse college groups. *Journal of Counseling Psychology*, 50(3), 287-296.
- Cooper, P. J., Taylor, M. J., Cooper, Z., & Fairburn, C. G. (1987). The development and validation of the body shape questionnaire. *International Journal of Eating Disorders*, 6(4), 485-494.
- Fairburn, C.G., & Beglin, S. (1994). Assessment of eating disorders: Interview or self-report questionnaire? *International Journal of Eating Disorders*, 16, 363-370.
- Festinger, L. (1957). A Theory of Cognitive Dissonance. Stanford: Stanford University Press.
- Matusek, J. A., Wendt, S. J., & Wiseman, C. V. (2004). Dissonance thin-ideal and didactic healthy behavior eating disorders prevention programs: Results from a controlled trial. *International Journal of Eating Disorders*, 36(4), 376-388.
- McKnight Investigators. (2003). Risk factors for the onset of eating disorders in adolescent girls:

 Results from the McKnight Investigators longitudinal risk factor study. *American Journal of Psychiatry*, 160(2), 248-254.

- Mintz, L. B., & Betz, N. E. (1988). Prevalence and correlates of eating disordered behaviors among undergraduate women. Journal of Counseling Psychology, 35(4), 463-471.
- Shroff, H., & Thompson, J. K. (2006). Peer influences, body-image dissatisfaction, eating dysfunction and self-esteem in adolescent girls. Journal of Health Psychology, 11, 533-551.
- Stice, E. (2002). Risk and maintenance factors for eating pathology: A meta-analytic review. *Psychological Bulletin*, *128*(5), 825-848.
- Stice, E., & Agras, W. S. (1998). Predicting onset and cessation bulimic behaviors during adolescence: A longitudinal grouping analysis. Behavior Therapy, 29(2), 257-276.
- Stice, E., Fisher, M. & Martinez, E. (2004). Eating disorder diagnostic scale: Additional evidence of reliability and validity. Psychological Assessment, 16, 60-71.
- Stice, E., Mazotti, L., Weibel, D., & Agras, W. S. (2000). Dissonance prevention program decreases thin-ideal internalization, body dissatisfaction, dieting, negative affect, and bulimic symptoms: A preliminary experiment. *International Journal of Eating Disorders*, 27(2), 206-217.
- Stice, E., & Presnell, K. (2007). The body project: promoting body acceptance and preventing eating disorders facilitator guide. New York: Oxford University Press.
- Stice, E., & Shaw, H. (2004). Eating disorder prevention programs: A meta-analytic review. Psychological Bulletin, 130(2), 206-227.
- Stice, E., Shaw, H, Burton, E., & Wade, E. (2006). Dissonance and Healthy Weight Eating Disorder Prevention Programs: A Randomized Efficacy Trial.
- Stice, E., Ziemba, C., Margolis, J., & Flick, P. (1996). The dual pathway model differentiates bulimics, subclinical bulimics, and controls: testing the continuity hypothesis. Behavior Therapy, 27, 531-549.

Taylor, C. B., Bryson, S., Luce, K. H., Cunning, D., Doyle, A. C., Abascal, L. B., Rockwell, R., Dev, P., Winzelberg, A. J., & Wilfley, D. E. (2006). Prevention of eating disorders in atrisk college-age women. *Archives of General Psychiatry*, 63, 881-888.

Demographic Characteristics

Table 1.

Variable	M (SD)	Range	n	%
Age (years)	18.64 (.63)	18-21		
BMI	22.01 (2.82)	16-31		
Ethnicity				
African American			1	1%
Asian			3	2%
Caucasian			129	75%
Hispanic			26	14%
Mixed/Other			5	3%
Not Reported			9	5%

Table 2.

Means, Standard Deviations, and Follow-up Effect Sizes for Dependent Measures

	Pre-tx	Post-tx	7W follow-up	8-month Follow-up	7W <i>d</i>	8M <i>d</i>	8M <i>d</i> B '06	6M <i>d</i> CD S'06	6M <i>d</i> AO S'06	1M <i>d</i> WL B'05
	M (SD)	M (SD)	M (SD)	M (SD)			ъ 00	3 00	3 00	В 03
Restraint	, ,	. ,	, ,	, ,					.25*	01*
CD (EDQR)	1.55 (1.34)	1.17 (1.12)	.95 (.94)	1.22 (1.04)	.52	.28	.19*	.61*		
High-risk _a	2.08 (1.45)	1.65 (1.14)	1.21 (.99)	1.68 (1.08)	.70	.31				
Low-risk _a	1.02 (.99)	.69 (.88)	.69 (.80)	.75 (.76)	.37	.31				
MA (EDQR)	1.59 (1.44)	1.39 (1.33)	1.07 (1.12)	1.36 (1.17)	.40	.18	.13*			
High-risk _b	2.30 (1.55)	1.98 (1.45)	1.36 (1.19)	1.51 (1.26)	.68	.56				
Low-risk _c	.91 (.93)	.83 (.91)	.79 (.99)	1.21 (1.06)	.12	30				
Intern									.17*	.14*
CD (IBSS-R)	3.47 (.47)	2.98 (.64)	3.15 (.72)	3.23 (.71)	.53	.40	.61	.59		
High-risk	3.61 (.44)	3.17 (.53)	3.37 (.65)	3.44 (.56)	.43	.34				
Low-risk	3.33 (.45)	2.79 (.69)	2.93 (.73)	3.03 (.78)	.66	.47				
MA (IBSS-R)	3.46 (.63)	3.09 (.80)	3.21 (.81)	3.14 (.76)	.34	.46	.14			
High-risk	3.60 (.74)	3.46 (.59)	3.49 (.66)	3.39 (.68)	.16	.30				

Low-risk	3.33 (.49)	2.74 (.82)	2.95 (.85)	2.92 (.77)	.55	.64				
Body Dis									.10*	.01*
CD (BSQ)	89.31 (29.98)	79.53 (28.76)	79.28 (30.33)	79.24 (24.65)	.33	.37	.36	.66*		
High-risk _a	112.78 (23.67)	98.91 (25.88)	97.51 (29.19)	93.92 (20.65)	.57	.85				
Low-risk _a	65.83 (11.43)	60.16 (15.36)	61.04 (18.14)	64.55 (19.00)	.32	.08				
MA (BSQ)	90.66 (31.43)	81.45 (31.13)	80.53 (29.89)	86.05 (26.29)	.33	.16	.12			
High-risk _b	116.53 (24.33)	103.56 (29.26)	93.37 (29.77)	96.46 (24.54)	.85	.82				
Low-risk _c	66.56 (12.10)	60.84 (13.97)	68.57 (24.83)	76.34 (24.29)	10	51				
Bul Path									.21*	11*
CD (EDQBN)	12.16 (7.84)	9.47 (7.05)	7.95 (6.33)	9.32 (7.31)	.59	.37	.44	.56*		
High-risk _a	17.25 (6.98)	13.72 (6.77)	11.38 (5.99)	12.91 (7.33)	.90	.61				
Low-risk _a	7.07 (4.75)	5.23 (4.22)	4.52 (4.58)	5.74 (5.30)	.55	.26				
MA (EDQBN)	12.49 (8.94)	10.73 (8.02)	8.14 (5.81)	9.44 (5.89)	.58	.40	.35			
High-risk _b	18.63 (7.77)	16.19 (7.35)	10.46 (5.81)	11.55 (5.64)	1.19	1.04				
Low-risk _c	6.63 (5.31)	5.53 (4.34)	5.93 (4.94)	7.42 (5.44)	.14	15				

Note: Cognitive Dissonance (CD) n = 88; Low-risk, n = 44; High-risk, n = 44. Media Advocacy (MA) n = 85; Low-risk n = 44; High-risk n = 41. All analyses intent-to-treat. EDQR = EDE-Q Restraint subscale. EDEQBN = Bulimic composite score. Intern = Thin-ideal Internalization. Body Dis = body dissatisfaction. Bul Path = Bulimic Pathology. To facilitate comparison with previous studies, unadjusted group means are reported and Cohen's d is calculated based on unadjusted means and standard deviations. B'06 = Becker et al., 2006; S'06 = Stice et al., 2006; B'05 = Becker, et al., 2005. AO = Assessment Only; WL = Waitlist Control. Note: * indicates that a different measure was used to assess this construct in the comparison studies (Becker et al., 2006; Stice et al., 2006; Becker et al., 2005) listed on this table.

Table 3. Results of Repeated Measures ANOVA from Pre-intervention to 8-month Follow-up_

Analysis	F	p<	η^2
Restraint ($df = 168$)			
Time	9.48	.002*	.05
Group	.93	.336	.00
Risk Status	50.05	*000	.23
Time x Group	.16	.695	.00
Time x Risk Status	10.25	.002*	.05
Time x Group x Risk Status	6.28	.013*	.03
Thin Ideal Internalization ($df = 169$)			
Time	18.18	.000*	1.00
Group	.102	.750	.00
Risk Status	32.55	*000	.16
Time x Group	.841	.360	.00
Time x Risk Status	1.54	.217	.01
Time x Group x Risk Status	.003	.956	.00
Body Dissatisfaction ($df = 169$)			
Time	14.10	.000*	.06

Group	1.62	.205	.00
Risk Status	185.17	.000*	.52
Time x Group	2.23	.138	.01
Time x Risk Status	30.73	.000*	.14
Time x Group x Risk Status	5.93	.016*	.03
Bulimic Pathology (<i>df</i> = 168)			
Time	26.13	*000	.13
Group	.583	.000*	.00
Risk Status	106.24	.000*	.39
Time x Group	.536	.470	.00
Time x Risk Status	8.41	.000*	.04
Time x Group x Risk Status	5.35	.020*	.03

Note: * indicates significant effect with significance level set at p < .05.

Table 4.

Results of Post Hoc Repeated Measures ANOVA					
Analysis	F	p<	η^2		
Restraint					
Cognitive Dissonance ($df = 86$)					
Time	7.26	.008*	.08		
Time x Risk Status	.29	.591	.01		
Media Advocacy ($df = 82$)					
Time	3.05	.085	.02		
Time x Risk Status	13.76	.000*	.11		
Body Dissatisfaction					
Cognitive Dissonance ($df = 86$)					
Time	17.91	.000*	.16		
Time x Risk Status	6.29	.014	.06		
Media Advocacy ($df = 83$)					
Time	2.05	.156	.02		
Time x Risk Status	25.52	*000	.23		
Bulimic Pathology					
Cognitive Dissonance ($df = 86$)					
Time	18.36	*000	.18		
Time x Risk Status	.19	.668	.00		

Media Advocacy (df = 82)

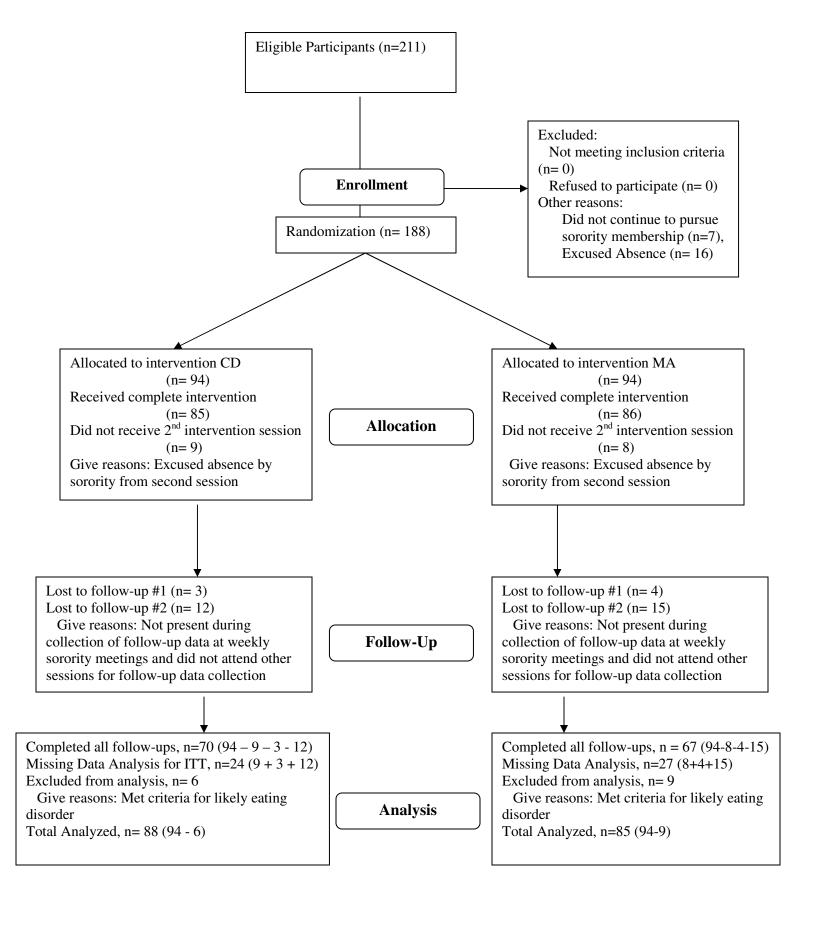
Time	8.93	.004*	.08
Time x Risk Status	12.65	.001*	.12

Note: * indicates significant effect with significance level set at p < .008.

Footnotes

- ¹ Campus sororities are non-residential and not affiliated with national sororities. Six campus sororities existed during the first year of data collection. During the second year, a new campus sorority was founded and this sorority also agreed to participate in the Sorority Body Image Program.
- ² On major limitation of the present study is the relatively short follow-up time period. There two primary reasons why we were limited to 8-months in the present study. First, because this study is built onto an annual program, we recruit peer leaders on an annual basis. Peer-leader training for the next year begins approximately nine months after the end of the program. A sizeable number of members choose to become peer leaders in the fall after they participate (i.e., close to 30 per year or 50-60 across both years, which is almost 1/3 of the sample). Thus, a not insignificant percentage of the sample is lost because they receive 10 more hours of exposure to the interventions via peer leader training. Second, a large percentage of students (over 35%) at our campus complete study abroad, and this number appears to be higher among sorority members. Thus, because a longer follow-up period runs into prime study abroad semesters, we lost another significant portion of students who could not be reached during this time period because this was an unfunded effectiveness study.

Figure 1: Consort Flowchart



Appendix A CONSORT Checklist of items to include when reporting a randomized trial

And topic TITLE & 1 How participants were allocated to interventions (e.g., "random allocation", "randomized", or "randomly assigned"). INTRODUCTION Background METHODS 3 Eligibility criteria for participants and the settings and locations where the data were collected. Interventions 4 Precise details of the interventions intended for each group and how and when they were actually administered. Objectives 5 Specific objectives and hypotheses. Outcomes 6 Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors). Sample size 7 How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules. Randomization - Sequence generation Randomization - 9 Method used to generate the random allocation sequence, including details of any restrictions (e.g., blocking, stratification) Randomization - John Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned. Randomization - Inplementation	PAPER SECTION	Item	Description	Reported
TITLE & ABSTRACT	And topic			
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Novigitions Dailo delline inclosion of italianam and italian. 0	Recruitment	14	Dates defining the periods of recruitment and follow-up.	8

Baseline data	15	Baseline demographic and clinical characteristics of each	9-10,
		group.	17-19
Numbers analyzed	16	Number of participants (denominator) in each group	9-10,21,
		included in each analysis and whether the analysis was by	22-25, 27
		"intention-to-treat". State the results in absolute numbers	
		when feasible (e.g., 10/20, not 50%).	
Outcomes and	17	For each primary and secondary outcome, a summary of	10-11,
estimation		results for each group, and the estimated effect size and its	18-23
		precision (<i>e.g.</i> , 95% confidence interval).	
Ancillary analyses	18	Address multiplicity by reporting any other analyses	24-25
		performed, including subgroup analyses and adjusted	
		analyses, indicating those pre-specified and those	
		exploratory.	
Adverse events	19	All important adverse events or side effects in each	None
		intervention group.	
DISCUSSION	20	Interpretation of the results, taking into account study	12-14
Interpretation		hypotheses, sources of potential bias or imprecision and the	
_		dangers associated with multiplicity of analyses and	
		outcomes.	
Generalizability	21	Generalizability (external validity) of the trial findings.	12-14
Overall evidence	22	General interpretation of the results in the context of current	10-14
		evidence.	