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Does Moderation Help? A Randomized Controlled Trial Of An Internet-Based Intervention For College Women At Risk For Eating Disorder Onset

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DOES MODERATION HELP? A RANDOMIZED CONTROLLED TRIAL OF AN INTERNET-BASED INTERVENTION FOR COLLEGE WOMEN AT RISK FOR EATING DISORDER ONSET

by

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NIMH Trial Preventing Eating Disorders & Reducing Comorbidities
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Does Moderation Help? A Randomized Controlled Trial of an Internet-based Intervention for College Women at Risk for Eating Disorder Onset

Dissemination science is a top clinical research priority (Insel, 2009). The National Institute of Mental Health (NIMH) has declared a vested interest in identifying high-impact, high-quality, and wide-reaching interventions for individuals with or at risk for a mental disorder (National Institute of Mental Health, 2008). Effective treatment and prevention interventions for mental disorders have been established; however, these evidence-based practices are not being implemented in routine clinical care, resulting in a devastating gap between those who are and are not receiving treatment (Beidas & Kendall, 2010; Drake et al., 2001; Proctor et al., 2009; Shafran et al., 2009). To address this deficit, researchers are increasing the demand that we translate interventions into disseminable mediums that are readily deliverable, rely less on specialists, and are effective for varied levels of risk and symptom profiles. Moreover, disseminable preventative interventions afford the opportunity to make a significant impact on high-risk populations by curbing the incidence or the worsening of clinical symptoms or disorders.

Eating disorders (EDs) affect approximately 5.9% of individuals in the United States (Hudson, Hiripi, Pope, & Kessler, 2007), and a significantly greater proportion exhibit subclinical symptoms or disordered eating behaviors and attitudes (Stice, Marti, Shaw, & Jaconis, 2009). EDs are associated with functional impairment and numerous medical and psychological comorbidities (Grilo et al., 2003; Herzog et al., 2000; Keel, Mitchell, Miller, Davis, & Crow, 1999; Strober, Freeman, & Morrell, 1997). Several risk factors for ED onset have been identified (Jacobi, Hayward, de Zwaan, Kraemer, &

Agras, 2004). Most EDs are manifested during the late high school and early college years (Hudson, et al., 2007; Lewinsohn, Striegel-Moore, & Seeley, 2000; Stice, et al., 2009), highlighting the need for heightened attention with this population. Given the high morbidity and protracted course associated with EDs (American Psychiatric Association, 2006), early intervention and prevention efforts are critical.

Internet-based interventions have been used for the treatment and prevention of EDs (Jones et al., 2008; Myers, Swan-Kremeier, Wonderlich, Lancaster, & Mitchell, 2004; Yager & O'Dea, 2008). The online platform makes these interventions well suited for universal (i.e., available to all) or targeted (i.e., for specific populations) delivery, as they are scalable, relevant, private, and cost-effective (Shaw, Stice, & Becker, 2009). In addition, internet programs are appealing to today's adolescent and young adult population, as internet use and online social networking is pervasive (Lenhart, Purcell, Smith, & Zickuhr, 2010). *Student Bodies*, an internet-based preventative intervention, has been effective in preventing EDs by reducing weight and shape concerns in college-age women at risk for onset (Taylor et al., 2006). Specifically, the cohort of *Student Bodies* users had 50% fewer ED cases at three-year follow-up than their control group counterparts. Given its success, our goal is to make *Student Bodies* widely disseminated across college campuses, as a means to reduce ED onset among students at high risk. Achieving this aim means specifying factors that maximize cost efficiency. Accordingly, the two highest costs associated with the intervention are running the program on a HIPAA-protected server and including a moderator to monitor the program's online discussion group. While the former is imperative for participant privacy, the clinical utility of the latter has yet to be determined.

The current study sought to determine whether the discussion group component of the *Student Bodies* program is necessary for eliciting clinically significant reductions in ED risk. It is possible that an unguided self-help intervention (in which participants receive session content but do not participate in a discussion group) is equally beneficial to a guided self-help (moderated) intervention. In this randomized controlled trial, college-age women at high risk for ED onset were assigned to a Discussion Group (DG) or No Discussion Group (NDG) condition as part of their participation in the *Student Bodies* intervention. The primary aim of this study was to assess changes in weight and shape concerns and negative affect following the 8-week intervention, as these key factors have been identified as significantly increasing risk for EDs. We hypothesized that the two conditions would be similarly efficacious, indicating that *Student Bodies* can be disseminated without the need for trained moderators and thereby allowing for the expansion of preventative resources. This investigation reflects the current research priority of exploring ways to facilitate dissemination and reduce the cost of efficacious interventions.

Methods

Participants

Participants were college-age women between the ages of 18 and 25, who were considered at high risk for ED onset. The study was conducted in the St. Louis, Sacramento, and San Francisco Bay areas. Participants were eligible for inclusion if they had a body mass index (BMI; weight in kilograms divided by height in meters squared) above 18, did not meet diagnostic criteria for a current clinical or subclinical ED as defined in the Diagnostic and Statistical Manual of Mental Disorders revised 4th edition

(American Psychiatric Association, 2000), and were not actively suicidal or psychotic, as determined by an interview using a modified version of the Structured Clinical Interview for DSM-IV Axis I Disorders (First, Spitzer, Gibbon, & Williams, 2002).

This study was approved by the Washington University and Stanford University institutional review boards.

Procedure

Participants were primarily recruited from nearby academic institutions. Interested individuals responded to campus and community flyers, email advertisements from university student groups, referrals from campus health centers, email or telephone contacts based on referrals from Volunteers for Health (a Washington University-specific research participant database), Facebook (an online social networking website), and word of mouth. Individuals provided informed consent prior to completing the study assessments. After completing a brief online or telephone screening questionnaire, potentially eligible participants were invited to complete an in-person semi-structured diagnostic assessment and self-report questionnaires, during which the following demographic variables were assessed: age, race/ethnicity, and parents' highest level of education (as a proxy measure of socio-economic status). Objective height and weight measurements were taken as well.

In order to participate in the study, individuals were required to have high weight or shape concerns, defined below. Women who also endorsed at least one of the following three criteria were invited to participate as well: 1) history of depression, 2) past teasing from a parent, teacher, or coach, or 3) engagement in low-frequency compensatory (e.g., purging; laxative abuse) behaviors (Jacobi et al., 2011). "High

weight or shape concerns" was defined as a score at or above 47 on the Weight and Shape Concerns Scale (WCS) (Jacobi, Abascal, & Taylor, 2004) or endorsement of the statement(s), "My weight is the most important thing in my life" or "I have an intense fear of gaining three pounds" on the WCS, irrespective of total score. All individuals in the study were considered "high risk;" however, those individuals who also endorsed one or more of the additional three criteria were considered "high, high risk."

All eligible individuals received the *Student Bodies* intervention. Study investigators randomized participants to one of two conditions: DG or NDG. Randomization was performed using random-number sequences in SPSS (SPSS Inc, Chicago, IL); participants were stratified by site and history of an ED. Before receiving access to the program, participants selected a non-identifying username and private password; usernames were stored in a password-protected database, accessible only to approved study investigators. Each week, participants received email prompts from the research team to log in to the program and complete the current week's session. At the beginning and end of the intervention, participants were encouraged to complete an online assessment battery, pre-programmed into the *Student Bodies* program.

Intervention

The *Student Bodies* intervention is an 8-week internet-based program primarily focused on reducing body weight and shape concerns, with one session released for viewing at the start of each week. Sessions are, on average, 21 pages in length. The program incorporates cognitive-behavioral therapy techniques into session content and includes weekly exercises and journal log prompts. Program content is designed to help participants create healthier behavior patterns around eating, exercise, sleep, mood, and

emotion regulation, as healthy routines are associated with improved mental health and hence increased body satisfaction. Users have unlimited access to the current week's session material and accompanying components; in addition, users may access previously-released content from already-completed sessions. Upon completion of the program, users are provided continued access to *Student Bodies* for nine months, so they may review the material for a booster session, as needed.

For those randomized to the DG condition, session content is accompanied by an asynchronous, moderated, online discussion group. This open forum allows participants to discuss reactions to the program material, support each other's progress in the program, seek advice, or ask questions in a safe, confidential, and anonymous environment. Postings to the discussion group are viewed by all cohort members; it is not possible for a participant to send private, personal messages to another individual participant. In the current study, there were four DG cohorts, comprised of 12-17 individuals and moderated by a psychiatrist associated with one of the participating academic institutions. The study moderator posted session-related questions to the group and commented on user responses to encourage continued dialogue and provide support. Moderator responsibility included logging in to the program and reviewing participant postings at least once each day. Full program details have been described previously (Taylor, et al., 2006).

Measures

Weight and Shape Concerns Scale (WCS): The WCS is a 5-item questionnaire that assesses disordered eating attitudes (Killen et al., 1996; Killen et al., 1994). Item responses are summed and divided by five, yielding a total score ranging from 0-100,

with higher scores indicating increased weight and shape concerns. A score of 47 was used as a criterion for high ED risk; this cut-off was based on a receiver operating curve analysis which showed good sensitivity, specificity, and predictive validity for identifying ED cases (Jacobi, Abascal, et al., 2004).

Center for Epidemiological Studies Depression Scale (CES-D): The CES-D is a 20-item questionnaire used to assess depressed mood and negative affect (Orme, Reis, & Herz, 1986). Responses are given on a 0-3 Likert scale. Four questions are reverse-coded, and then responses are summed to produce a total score ranging from 0-60; higher scores indicate worse mood. For a college-age population, a score above 14 indicates possible depression. This measure has demonstrated good internal reliability and consistency (Plutchik & van Praag, 1987).

Body Composition: BMI calculations were conducted from the height and weight measurements performed at baseline. Measurements were performed using a calibrated scale and portable stadiometer. Participants were weighed without shoes and while wearing loose clothing.

Adherence

Adherence data were tracked electronically and downloaded upon program completion from the online server. Adherence was quantified in three ways: 1) whether users ever logged on to the program; 2) amount of time spent using the program (in minutes); and 3) number of session pages viewed.

Analyses

Individuals who completed the assessments were included in the analyses in a modified intent-to-treat design (that is, assessment completers). Carry-forward imputation

of baseline values for missing post-intervention assessment data would not be appropriate, given the restricted number of assessment points. This design did not bias the analyses against those who did not complete the program, as these individuals were still retained in the analyses. Independent samples t-tests and chi-square analyses were used to examine baseline differences and program adherence between the DG and NDG conditions, as well as within-group change from pre- to post-intervention. Regression analysis was used to examine the effects of the DG on post-intervention assessment scores, controlling for baseline scores on the same measures. We specified separate regression models for WCS and CES-D. The interaction of DG condition by risk status was tested in a separate regression model; the interaction term was created by multiplying the main effect variables, centered on their respective baseline means. *P*-values less than 0.05 were considered statistically significant; all tests were two-tailed. All analyses were conducted using the SPSS version 18.0 software package (SPSS Inc, Chicago, IL).

Results

Of the 151 participants randomized, 111 (73.5%) completed posttest data and were included in the reported analyses. Fifty-two participants were randomized to the DG condition, and 59 participants were randomized to the NDG condition. There were no significant differences between conditions by site, BMI, in relation to the baseline demographic variables (age, race/ethnicity, and parent education), or in baseline scores on the WCS and CES-D. There were no significant differences between discussion group condition and post-intervention assessment completers compared to non-completers. The racial/ethnic breakdown of the sample was: 68.5% white, 8.1% African American, 7.2% Chinese; 4.5% Hispanic, 2.7% multi-racial, and 9.0% other. The mean BMI was 24.9

(SD=4.2); the median age was 21; and the median highest level of education obtained by a parent was the completion of "some graduate school."

Thirty-one women entered the study at "high risk" for an ED and 80 entered at "high, high risk." There were no significant differences between risk status groups by site, BMI, in relation to the baseline demographic variables (age, race/ethnicity, and parent education), or by discussion group condition. Compared to the "high risk" participants, participants at "high, high risk" had significantly higher WCS scores prior to ($t(96)=-2.8$; $p=0.007$) and following ($t(109)$; $=-2.5$; $p=0.01$) program completion. Similar results emerged for CES-D scores prior to ($t(96)=-3.8$; $p<0.001$) and following ($t(85)=-3.2$; $p=0.002$) program completion.

Change over time in outcome variables

At baseline, the mean (SD) WCS score was 53.0 (17.8) for the DG participants and 59.0 (16.9) for the NDG participants. Post-intervention, the mean (SD) WCS score was 46.0 (18.4) for the DG participants and 56.8 (19.3) for the NDG participants. Changes in mean WCS scores from pre- to post-intervention are shown in Figure 1. Within-group change from pre- to post-intervention was significant only for the DG condition ($t(44)=-4.6$; $p<0.001$). Compared to the NDG participants, DG participants scored 8.1 points lower at post-test on the WCS, controlling for baseline scores ($p=0.004$).

At baseline, the mean (SD) CES-D score was 15.2 (10.5) for the DG participants and 15.0 (11.0) for the NDG participants. Post-intervention, the mean (SD) CES-D score was 14.0 (7.7) for the DG participants and 16.0 (9.3) for the NDG participants. Changes in mean CES-D scores from pre- to post-intervention are shown in Figure 2. Within-

group change from pre- to post-intervention was not significant for either condition. A trend-level difference emerged between conditions in change in affect: DG participants scored 2.7 points lower on the CES-D, controlling for baseline scores, than the NDG participants (p=0.07).

There was no significant DG condition by risk status interaction on change in WCS or CES-D scores over the eight weeks of the intervention.

Adherence

Seventy-five (67.6%) participants logged in to the program. Of those users, the average number of minutes spent using the program was 374.2 (SD=331.0), equivalent to approximately six hours and 15 minutes of total use. Across the conditions, the average number of complete sessions viewed was four out of eight.

Individuals in the DG spent significantly more time using the program than did those in the NDG ($t(73)=-2.3$; p=0.02); the mean difference was approximately 2.9 hours of additional use. However, individuals in both conditions viewed equivalent numbers of session pages. Risk status was not associated with program use.

Discussion

Results of this study demonstrated greater reductions in risk for ED onset for those in the DG condition than those receiving session content alone. Specifically, DG participants endorsed decreased weight and shape concerns and decreased negative affect following program completion, to a greater extent than did their NDG counterparts. These findings suggest a clinically meaningful benefit to including the discussion group component with the *Student Bodies* program.

The lower WCS scores endorsed by the participants in the DG condition than the NDG condition suggest that the combination of the session content and the discussion group component was most effective in reducing risk for ED onset. Given the association between weight and shape concerns and heightened risk, results indicate that the discussion group component has clinical utility for participant improvement. While we hypothesized that the two conditions would be similarly efficacious in reducing weight and shape concerns, there are several reasons why the additional of the discussion group may have enhanced efficacy. It is possible that the open, confidential medium of the discussion group empowered individuals to share body shape concerns without feeling scrutinized over their actual body size, thereby prompting women to confront these issues and develop more healthy coping strategies. It may also be that belonging to a discussion group led women to feel accountable to the group members or the moderator, and thus motivated participants to remain active and involved. Recent studies also point to benefits of seeking interpersonal support from online groups for individuals with ED/body image concerns (Ransom, La Guardia, Woody, & Boyd, 2010), anorexia nervosa (McCormack, 2010), or bulimia nervosa (Wesemann & Grunwald, 2008).

The results regarding program adherence suggest that students in the DG condition took advantage of this feature of the intervention. Students in both groups spent equal time reading through session content, as evidenced by the equivalent number of pages viewed per session, but those in the DG condition spent more time logged in to the program overall. It is possible that the added time spent using *Student Bodies* was devoted to reading the discussion group postings and making comments to other cohort

members. However, we cannot rule out the possibility that these individuals spent more time reading the session content than those in the NDG condition.

It is worthwhile to highlight that WCS scores of both groups were lower at the end of the program than at the start, maintaining the previous findings that the *Student Bodies* program is effective in decreasing weight and shape concerns (Taylor, et al., 2006). However, it bears clinical relevance to note that the post-intervention WCS scores for both groups were above or narrowly below the cut-off score of 47, meaning that weight and shape concerns remained high in the sample. This finding is similar to past data from the *Student Bodies* program, which has demonstrated that participants' scores tend to decrease over time (i.e., reflecting improvements in body satisfaction), with more pronounced differences between intervention and control conditions emerging at long-term follow-up (Taylor, et al., 2006). Given that both conditions received the intervention in the current study, we would anticipate a similar pattern to emerge for the current study participants as well, with the hypothesis that, based on the current findings, those in the DG condition would endorse greater improvements than those in the NDG condition.

Given the potency of depression as a risk factor for the development of EDs (Jacobi et al., 2011), the changes in negative affect seen across conditions should be examined: while only of trend-level significance, results showed changes in the opposite direction for the two conditions. Though participants in the DG condition reported a decrease in negative affect (score of 14 or lower, which has been determined as clinically significant cut-off for college students), those in the NDG condition reported an increase in negative affect following completion of the intervention. One possible explanation for this finding is that students may experience increased negative affect as they become

more sensitive to and aware of their own body shape and weight concerns during their progress through the *Student Bodies* program; however, only those in the DG condition have an outlet through which they can confidentially share and "process" these concerns with others. While the privacy afforded from participating in an internet-based therapeutic program is an appealing feature of using an online intervention, participants in the NDG condition may not have felt compelled or have the available resources to establish healthy outlets in their environment for their negative mood. Hence, the added benefit of including the discussion group component with the program content may be partially due to its use as an avenue for coping with low mood.

Limitations of the study include the short duration of follow-up and the absence of a no-treatment control group. However, because the long-term efficacy of the intervention had previously been established through the comparison to a control condition, it was not necessary to replicate this design. However, the use of a high-intensity comparator (i.e., two active intervention conditions) allowed for careful examination of intervention differences. An additional limitation was the use of only one discussion group moderator. By not involving multiple individuals in the moderation, moderator-related factors may be a confounding variable in our results. It should be noted that we chose this approach to ensure moderation fidelity across cohorts, and a standardized protocol was followed throughout. Finally, the current study design does not allow for conclusion whether participation in an unmoderated discussion group would be equally beneficial to a moderated one. Until additional research is done, it is unknown whether 1) other moderators can be as successful; 2) what makes for successful

moderation; and 3) whether moderation is needed at all. It would be ideal to test these effects in future research studies.

The current study reflects the NIMH research priority of conducting translational science, with the goal of making effective interventions available for widespread use. While the aim of this study was to identify whether *Student Bodies* could be effective without the use of a moderated discussion group and thus could be more easily disseminated, results showed that there is an additive clinical benefit to including the discussion group component with the program content in reducing risk for ED onset. Accordingly, the costs of including a moderator are outweighed by the clinical utility of this program component, and on the whole, total staff effort and cost required to maintain the intervention are minimal, particularly as compared to conducting individual or group in-person treatment. In light of these findings, however, continued attention to facilitating the dissemination of *Student Bodies* is essential. Future work should aim to create a disseminable training manual for discussion group moderators. Such a tool would enable ease of program facilitation and the ability to train individuals with less specialized clinical experience (e.g., graduate students, university residential advisors) to monitor the groups. Moreover, moderator training could be pre-specified to address various populations such as particular racial/ethnic groups, thereby tailoring preventative resources to specific participant groups or risk/clinical profiles. Overall, this research provides continued evidence for the use of internet-based interventions for the prevention of EDs and supports the inclusion of the discussion group as a necessary component to the *Student Bodies* program.

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Figure 1: Change in WCS scores from pre- to post-intervention, by condition

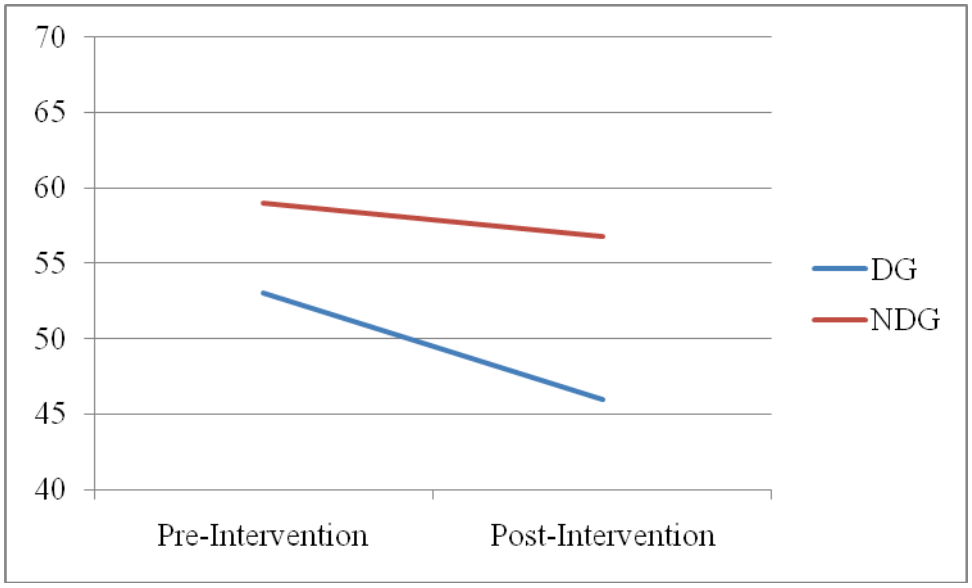

Figure 2: Change in CES-D scores from pre- to post-intervention, by condition