An Eating Disorder Randomized Clinical Trial and Attrition: Profiles and Determinants of Dropout

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ABSTRACT

Objective: This study sought to determine whether differential treatment effects in the targeted mechanisms of change and eating disorder (ED) symptoms are associated with patterns of attrition from a RCT.

Method: The main study was a RCT of a psychotherapy designed to alter the nonweight related self-cognitions as the means to promote recovery and health in a sample of 69 women with AN or BN. Four groups based on point of dropout were compared on demographic, self-cognitions and ED symptoms using logit and piecewise mixed effects modeling.

Results: Attrition was highest during treatment phase but no significant predictors were found. During the measurement phase, the direction and amount of change in self-cognition interrelatedness and body dissatisfaction differed according to point of dropout and treatment group.

Discussion: Attention to changes both in symptoms and mediating factors that occur during treatment and follow-up may help to identify those who are at risk for dropout and to develop strategies to promote RCT participant retention.

Keywords: eating disorders; RCT; attrition

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Introduction

Eating disorders (ED), particularly anorexia nervosa, account for the highest mortality rates among psychiatric disorders.[1,2] Psychotherapy has been the first-line approach for the treatment of ED, with demonstrated efficacy in bulimic samples and some indications of efficacy for the anorexic population.[3,4] However, treatment success remains limited and the development of effective interventions remains among the most important priorities in the field.[5] Randomized clinical trials (RCT) are considered the gold standard approach to establishing the efficacy of new forms of intervention. Yet the validity of findings from RCT in the ED field has been consistently threatened by high rates of attrition, and to date, studies focused on predictors of attrition have been limited.

The few studies that have examined ED RCT attrition have focused almost exclusively on drop out during the treatment phase of the study. Attrition that occurs during the postintervention follow-up phases has not been systematically addressed even though it has significant consequences on the result. Further, studies have been based on the assumption that pretreatment sources of individual difference account for the attrition, and therefore, the focus has been almost exclusively on the examination of group differences in baseline characteristics. The fact that findings from these studies have failed to converge raises an interesting question of whether individual differences in response to treatment may be important in explaining attrition patterns. The primary purpose of this study is to explore whether differential treatment effects in the targeted mechanism of change and ED symptoms are associated with patterns of attrition through the treatment and follow-up phases in an ED psychotherapy RCT.

Clarifying the Meaning of Attrition in Eating Disorder RCT

Although participant attrition is widely recognized as an important threat to the internal validity of ED intervention RCT, the concept lacks a clear and consistent definition in the literature. Shadish[6] define two types of attrition, treatment, and mea-

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surement attrition, and argue that the consequences of these types of attrition differ. Treatment attrition refers to the loss of participants during the intervention phase of the trial and this loss is of concern because it may be systematically linked to properties of the treatment. Participants who are withdrawn by the investigator should be included in the treatment attrition count since reasons for investigator exclusion are also likely to be correlated with properties of the treatments.

Measurement attrition refers to participants who fail to complete the postintervention data collection. Obviously, those lost to follow-up measurement cannot be included in the analysis, and consequently, pose the most significant threat to the validity of the study. Participants lost to follow-up measurement compromise the integrity of the randomization process and the assurance of unbiased treatment groups for comparison.[7,8] The intent-to-treat approach, as originally conceptualized, required postintervention measurement for all randomized participants and stable group assignment regardless of the withdrawal from treatment or deviations to the protocol.[9] Since that time, some have argued that intent-to-treat analyses produce unbiased results only when postintervention measurements are completed by all randomized participants.[10] This position is based on the argument that the last observation carried forward approach that fills in missing postintervention data by using the last available measurement, introduces significant but unknown degree of bias in the results by potentially distorting both the sample mean and covariance structure.[11] Sensitivity analyses, another approach to RCT data analyses, uses only cases that completed treatment and follow-up, and, then adjusts the test of significance by subtracting an estimate of the bias introduced by nonrandom assignment to the treatment group. Because the accuracy of the estimated bias is unknowable, group differences found using the intent-to-treat approach with all cases included in the follow-up measurements could be used to evaluate the reasonableness of the bias estimate.[10] Despite the recognized biases associated with intent-to-treat and sensitivity analyses related to the number of study dropouts and retrieved dropouts, reports of RCT often fail to include this information. Therefore, the degree of potential bias in the study results remains unknown.

The type of attrition reported in ED intervention RCT reports, meta-analyses, and reviews is inconsistent and frequently not defined. For example, in their meta-analysis comparing cognitive behavioral therapy to other forms of psychotherapy for BN and binge eating disorder, Hay et al.[4] state all RCT with attrition rates higher than 50% were excluded. Further, they reported that the attrition rates for 39 studies included in the meta-analysis ranged from 0 to 41.4%. Yet review of the original reports reveals that only treatment attrition was addressed. Cases lost during the postintervention data collection, measurement attrition, were not reported. Again based on review of the original reports for the 39 studies, measurement attrition for studies with immediate follow-up ranged between 0 and 34.2%, measurement attrition for studies with three-month postintervention follow-up ranged from 2.4% to 21.4%, and for studies with six month follow-up rates ranged from 0% to 55%. Finally, for studies with 12 and 18 month follow-up, measurement attrition ranged from 4.2% to 78.6%.

Reported attrition rates for RCT of treatments for AN are high and similarly reflect only treatment attrition.[12] McIntosh and colleagues defined treatment completion as attendance to at least 15 of 20 planned therapy sessions and reported a treatment attrition rate of 37.5%. Post-treatment data collection occurred after the last treatment session and no mention is made of the number of participants who completed these measures. In a pilot study comparing cognitive analytic therapy to educational behavioral therapy for AN, a 33% treatment attrition rate was reported but measurement attrition was not addressed despite the fact that one year postintervention outcome data was reported.[13] Similarly, Bachar et al. reported only treatment attrition for a RCT comparing the efficacy of self-psychological treatment and cognitive orientation treatment for women diagnosed with BN or AN.[14] One notable exception was the study by Dare et al. who explicitly reported the number of AN participants who completed and failed to complete the one-year follow-up data collection.[15] Other recently published RCT including one testing a maintenance treatment for weight restored person with AN and another testing treatments for EDNOS reported both treatment and measurement attrition rates (see Refs. 16 and 17).

Attrition Analyses in Eating Disorder RCT

Despite the high rates both of treatment and measurement attrition, empirical efforts to understand factors that contribute to attrition in ED RCT are limited. Studies completed to date have focused mainly on baseline differences between partici-

pants retained and treatment dropouts. This approach is recommended as a basic and important analytic approach necessary to provide an estimate of the direction of bias in the outcomes. In addition, the identification of group differences holds the potential for clarifying groups of persons who may be unable to utilize or tolerate the intervention, and hence, provides important information about the generalizability of the intervention to populations of persons with ED diagnoses. For example, Hoste reported differences between treatment dropouts (n = 9) and completers (n = 71) in a RCT of family-based treatment for adolescents with BN.[18] The control arm was individual supportive psychotherapy. Results showed that adolescents who dropped out from both conditions were less likely to be from intact families and had a significantly longer duration of illness.

Other reports addressing ED RCT attrition similarly address only baseline differences between treatment dropouts and completers and failed to include in their analyses persons who were withdrawn by the investigator (for an exception see Ref. 19). Findings show a diverse array of differences associated with dropout including higher levels of bulimic cognitions, body weight concerns, comorbid psychiatric disorders,[20] family background[21] self-conceptions related to problem solving abilities,[22] personality traits,[23] impulsivity, and treatment characteristics including longer treatments.[20] Although studies reveal a long list of correlates of treatment attrition, little convergence among the studies has been found.

A second recommended approach to attrition analyses is to identify conceptually or empirically identified predictors of patterns of attrition.[6] Few studies in the ED field have pursued this approach. In one notable exception, Halmi et al. used survival analyses techniques to explore predictors of patterns of attrition in a RCT comparing the efficacy of CBT, fluoxetine hydrochloride, and their combination in the treatment of AN.[24] Findings show that women with low self-esteem were much more likely to dropout of the trial during the treatment phase compared to those with high self-esteem (40% compared with 86% completion rate).

In this study, we extend the focus on the identification of patterns of attrition to determine whether differential treatment responses are predictive of patterns of attrition and retention in an ED psychotherapy RCT. The major aim of the RCT is to test the efficacy of a self-schema focused identity intervention program to reduce ED symptoms and improve health and well being in sample of young adult women with AN and BN.[25] The focus of the identity intervention program (IIP) is to alter the underlying array of self-related cognitions, referred to as self-schemas, as the mechanism underlying changes in ED symptoms and health. The intervention program is based on findings that show a highly interconnected collection of few positive and many negative self-schemas is predictive of ED symptoms in clinical and community-based samples and this effect is mediated through the availability of a fat self-schema.[26,27] In this study, a fat self-schema is defined as a semantically based organization of knowledge about the self-related to fat body weight/shape that is stored in long-term memory.[26,28] Rather than focusing on modifying the established fat self-schema as more traditional approaches to ED do, the aim of the intervention is to increase the number of distinct and separate positive self-schemas in behavioral domains unrelated to body weight and image.[29] Cognitive, behavioral, and social strategies are used to identify a meaningful and feasible possible self-goal and to transform the goal into an elaborated self-schema in the domain. Supportive psychotherapy (SPI) was used as the control treatment and both groups received nutritional counseling and medical monitoring. Participants were randomized to the treatment condition after completion of the preintervention data collection, which included measures of self-schema organization (the hypothesized mechanism of change) and ED symptom level. The treatment phase of the study was 20 weeks and postintervention follow-up data collection was completed at one, six, and 12 months. Three research questions were addressed in this secondary analysis study: (1) What demographic, baseline ED symptoms and self-schema properties predict time of dropout? (2) Were intervention-related changes in the organizational properties of self-schemas (e.g. valenced number and interrelatedness of self-schemas) predictive of patterns of dropout, (3) Were intervention related changes in ED symptoms predictive of patterns of dropout?

Method

Participants

Women 18–35 years who met the following criteria were recruited for participation: (1) not pregnant, (2) full or subthreshold AN or BN, (3) no psychotropic medication for at least two weeks prior to screening, and (4) no current psychotherapy. AN and BN were based on DSM-IV criteria. Subthreshold levels of the disorders were defined based on DSM-IV EDNOS and criteria defined

by Strober.[30] Exclusion criteria included: (1) symptom severity requiring inpatient treatment, (2) suicidality, (3) lifetime history DSM-IV psychotic disorders, or (4) concurrent DSM-IV Axis I disorder at threshold level. The Institutional Review Board approved the study.

Procedures

Participants were recruited through provider referrals, community and Internet advertisements. An initial phone screening was followed by a two-step eligibility assessment. First, informed consent, height and weight, the Beck Depression Inventory (suicide screen) and the Structured Clinical Interview for DSM-IV (SCID) were completed. The SCID was administered by 3 experienced and trained clinicians. SCID interviews and diagnoses were reviewed with the first author to confirm eligibility. The second screening step included a physical assessment, blood laboratory studies, and EKG.

Participants completed a battery of measures, including a 21-day measurement of ED behaviors using ecological momentary assessment methodology (EMA) before being randomized to the IIP (experimental) or SPI (control) treatment conditions. For a description of the treatment conditions see.[25] Research assistants blinded to the treatment condition administered pre and postintervention measures. Data collection sessions were individual face-to-face sessions held in the outpatient clinic of a university hospital. The Zajonc card-sorting task (administered first to avoid priming), the EDI and others measures not addressed in this report were completed in a fixed order, single 2-hour session. Two weeks later the participant was oriented to the EMA procedures in a 45-min session and the 21-day EMA period began. Postintervention measures were completed one, six, and 12 months after completion of treatment and participants were paid $50 at each data-collection point to defray transportation costs.

Measure

Self-Schema Number, Valence, and Interrelatedness

Zajonc's[31] card-sorting task was used to measure the number of valenced self-schemas and interrelatedness. This measure includes two tasks. First, participants were asked to list all descriptors that are important to how they think about themselves and to rate each descriptor according to (1) self-descriptiveness, (2) importance, and (3) valence. In keeping with previous research,[32–34] descriptors rated highly self-descriptive and highly important were identified as self-schemas. The number of positive (negative) self-schemas was determined by totaling the number of self-descriptors that meet the criteria for a self-schema and are rated positive (negative).

To measure interrelatedness among self-schemas, participants identify all other descriptors that would change if the targeted descriptor was "changed, absent or untrue of you." Responses were used to form a dependency matrix such that when descriptor A_j causes a change in descriptor A_i, a value of 1 is assigned. The total dependence of a descriptor was calculated by summing the row entries, and the total dependency of the schema was calculated by summing the dependencies across all characteristics. The sum was then normalized by dividing the total dependency by the total number of possible dependencies of the structure. Validity of the self-rating to identify self-schemas has been supported.[32,34] Stein showed retest reliability across a 12-month interval for the number of valence self-schemas and interrelatedness.[26]

Eating Disorder Attitudes and Behaviors

The EDI[35] consists of 64 items used to generate 8 subscale scores. Validity and retest reliability have been shown.[35,36] Three subscales, drive for thinness, body dissatisfaction and bulimia were used in our study. Cronbach's alpha coefficient (preintervention) were body dissatisfaction scale 0.89, bulimia scale 0.88 and drive for thinness scale 0.84.

Eating Disorder Behaviors

EMA methodology[37] was used to measure ED behaviors in vivo. A menu-driven computerized questionnaire programmed for use on a handheld computer measured 8 ED behaviors (e.g., self-induced vomiting, laxative use, diuretic use, diet pill use, excessive exercise, binge eating, food/calorie restriction, and fasting). Items were derived from the EDE[38] and the Questionnaire on Eating and Weight Patterns-Revised.[39] Participants carried the project-provided handheld computer for 21 days and recorded all episodes of vomiting, laxative, diuretic, diet pill use, exercise, and binge eating immediately after the behavior occurred. In addition, they were asked to complete four questions related to food/calories restricting behaviors and fasting before going to bed each night. All entries were automatically entered with a date and time stamp. Reliability of EMA is supported by studies that have shown that ED behavioral patterns are nonreactive to the approach. Studies demonstrating correspondence between EMA and EDE supports the validity.[40]

Statistical Method

All analyses were conducted under the intent-to-treat framework. Dropouts were classified into five groups. The first group, the treatment dropout group (n = 26), has only baseline data available and consists of women who dropped out during the treatment phase of the trial. The mean number of treatment sessions completed by this group was 6.4 (SD = 5.9). To maximize available power, we also chose to include in this group two participants who completed 20 weeks of treatment but failed to complete the one-month postintervention data collection. All analyses were completed a second time with these two participants excluded and results were unchanged. The second group, referred to as the completers (n = 23), completed all four data collection time points. The next two groups were those that dropped out in a monotone pattern, either after two or three of the four data collection time points (six month, 12-month postintervention). Those who completed the one-month postintervention data collection but dropped out prior to the six-month postintervention data collection will be referred to as one-month postintervention completers (n = 8) and those who dropped out prior to the 12-month postintervention data collection will be referred to as the six month postintervention completers (n = 7). The last group was the intermittent group; those that completed the preintervention time point but then missed a data collection before returning to complete another collection (n = 5). The intermittent group was included in the analyses to not add a source of bias, but their results were not presented because of the heterogeneity of the group.

Two-sample t tests were used to compare the means of continuous variables at baseline for those who were retained and those who dropped out during the treatment phase of the study. For variables that were categorical, chi square tests were used.

Descriptive statistics for the baseline values of covariates and the previous value of the outcome variables were conducted. Multinomial logit models compared dropout groups with the completers as the reference group for each predictor separately while adjusting for treatment type, age, and race. Continuous variables were standardized before being added to the model. The intermittent dropout group was excluded from this analysis due to lack of clarity in defining the previous value. Three dropout groups were included: treatment dropout group, the one-month postintervention completers, and the six-month postintervention completers. Each time of dropout had its own odds ratio estimate.

Piecewise linear mixed effects models were used to assess potential differences in estimated trajectories of the five dropout groups for five different outcome variables. These variables were number of positive self-schemas and number of negative self-schemas, drive for thinness, bulimia score, and body dissatisfaction. Two time contrasts were used in the model: (1) baseline to one-month postintervention and (2) one-month postintervention to end of protocol. These contrasts allow for the immediate treatment effect and the effect after treatment to be estimated separately. All statistical analyses were performed using PROC MIXED and PROC LOGISTIC in SAS version 9.1.3 (SAS Institute Inc., Cary, NC).

Results

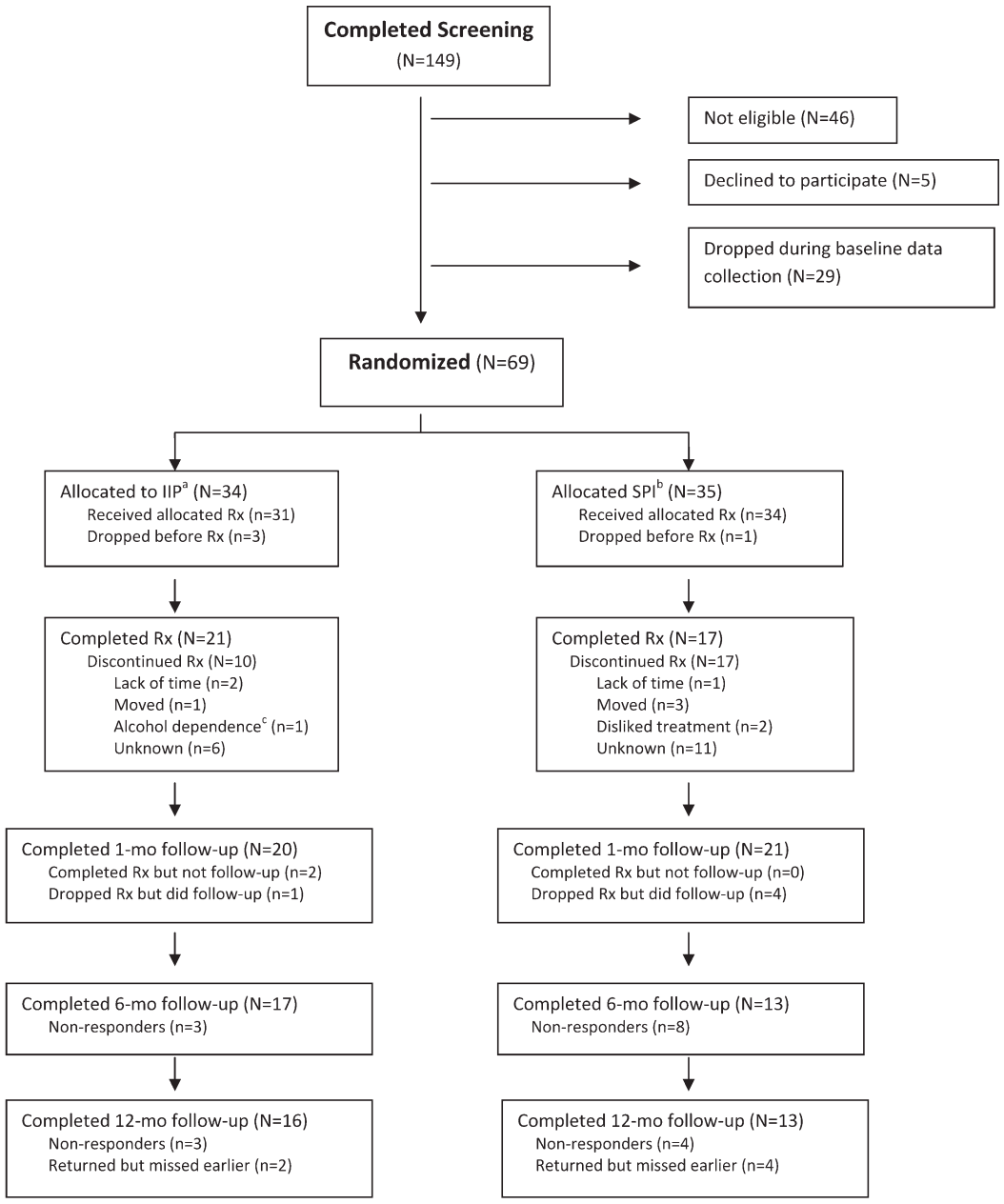
Description of Study Attrition

Figure 1 shows the pattern of attrition across the total study protocol. A total of 69 completed baseline data collection and were randomly assigned to a treatment condition (IIP n = 34 and SPI n = 35). Of the 69 participants, 45 (65%) met criteria for BN, 4 (6%) for AN, 18 (26%) for BN subthreshold, and 2 (3%) AN subthreshold. Four participants dropped out after being randomized but prior to any involvement in treatment (IIP n = 3, SPI n = 1), thus a total of 65 women initiated treatment. The total number of prescribed individual psychotherapy sessions was 20. A total of 21 out of the 31 women who began IIP treatment (68%) completed and 17 of 34 (50%) completed SPI. One participant was withdrawn from the IIP condition by the investigator because an alcohol abuse problem emerged during the course of treatment. In total, treatment attrition for the study was 39% of the 69 randomized participants.

Baseline Comparisons Between Study Completers and Dropouts

Two groups were compared using t tests and chi square tests, treatment dropout group (n = 26) and all participants who completed at least the one-month postintervention data collection (n = 38) excluding those in the intermittent dropout group. Results revealed that those in the treatment dropout group were not statistically different from those retained through the one-month postintervention data collection. As shown in **Table 1**, no differences were found between demographic characteristics or any of the baseline values of the other variables.

FIGURE 1. Participant flow chart.



[a]IIP=Identity Intervention Program
[b]SPI=Supportive Psychotherapy Intervention Program
[c]Investigator removed

Self-Schema and Eating Disorder Symptom Pattern Changes and Point of Study Dropout

Descriptive statistics showed that the rate of attrition was fairly balanced among the two treatment groups with the exception of dropping out after the one-month postintervention; only 25.0% of the dropouts at that time point were IIP (**Table 2**). Similarly, the average age was also higher for the dropouts at that time. Of the previous values of the outcomes, it appeared that earlier dropouts had higher scores for the drive for thinness and body dissatisfaction.

The multinomial logit models demonstrated that an increase of one standard deviation unit in interrelatedness between the one-month postintervention follow-up and six-month follow-up increases the odds of dropout after the six month postintervention 2.39 times relative to the completers after controlling for treatment, age, and race (**Table 3**). Education and diagnosis experienced quasi-separa-

TABLE 1. Baseline comparisons of demographic characteristics and variables of interest using two-sample t tests and chi square tests

	Dropped During Treatment	Completed Immediate Post Intervention	
	$N = 26$	$N = 38$	p-value
Demographics:			
IIP treatment	50.0%	50.0%	1.000*
White	73.1%	81.6%	0.419*
Age	23.6 (3.3)	23.9 (4.1)	0.678
Years of education	13.3 (4.9)	14.1 (5.4)	0.569
Household income	$61,263 (33,491)	$81,183 (134,390)	0.531
Baseline values			
Number of positive self-schemas	8.96 (6.3)	9.39 (5.4)	0.777
Number of negative self-schemas	4.08 (4.6)	3.55 (5.2)	0.675
Interrelatedness	0.17 (0.1)	0.21 (0.1)	0.134
Body dissatisfaction	15.4 (7.5)	16.2 (7.1)	0.705
Drive for thinness	14.4 (5.8)	13.7 (5.3)	0.638
Bulimia	11.3 (6.0)	10.8 (6.5)	0.732
Total number of ED behaviors	2.07 (1.2)	1.68 (0.8)	0.158

* Indicates a chi square test instead of a two-sample t test.

TABLE 2. Descriptive statistics on baseline values of covariates and the previous value of the predictors

	Did not complete Treatment	Completed Treatment		
	Treatment Dropouts	1-month Post Intervention Completers	6-month Post Intervention Completers	Completers
	$N = 26$	$N = 8$	$N = 7$	$N = 23$
Baseline covariates				
Treatment (IIP)	50.0%	25.0%	57.1%	56.5%
Age	23.6 (3.3)	25.9 (4.4)	22.9 (5.0)	23.6 (3.6)
Education (College)	96.2%	100%	100%	91.3%
Race (White)	73.1%	100%	71.4%	78.3%
Diagnosis (BN)	88.5%	100%	85.7%	87.0%
Positive Schemas	8.96 (6.3)	11.1 (7.8)	11.9 (5.0)	8.04 (3.7)
Negative Schemas	4.08 (4.6)	2.75 (2.9)	6.71 (8.9)	2.87 (4.3)
Interrelatedness	0.17 (0.1)	0.22 (0.1)	0.27 (0.2)	0.19 (0.2)
Body Dissatisfaction	15.4 (7.5)	18.1 (5.2)	13.0 (4.9)	16.5 (8.0)
Drive for thinness	14.4 (5.8)	15.5 (4.0)	11.9 (3.4)	13.7 (6.0)
Bulimia	11.3 (6.0)	13.3 (6.9)	7.71 (4.6)	10.8 (6.7)
Previous value				
Positive Schemas	8.96 (6.3)	12.1 (5.7)	14.6 (9.7)	8.83 (5.2)
Negative Schemas	4.08 (4.6)	1.13 (1.7)	2.57 (3.8)	1.43 (1.7)
Interrelatedness	0.16 (0.1)	0.27 (0.1)	0.28 (0.2)	0.21 (0.1)
Body Dissatisfaction	15.4 (7.5)	12.9 (3.7)	4.17 (6.6)	9.57 (9.0)
Drive for thinness	14.4 (5.8)	7.71 (4.9)	1.33 (1.2)	6.48 (6.6)
Bulimia	11.3 (6.0)	2.57 (3.3)	0.50 (0.8)	2.39 (4.2)

Mean (Std. Dev.) or Percent (%). Completers correspond to those that participated in each of the four time points.

TABLE 3. Adjusted odds ratios (ORs) for dropout relative to completers with 95% confidence intervals

	Treatment Dropouts	1-month Post Intervention Completers	6-month Post Intervention Completers
Previous value			
Positive Schemas	1.01 (0.67, 1.52)	1.08 (0.59, 1.97)	1.41 (0.82, 2.41)
Negative Schemas	1.31 (0.76, 2.27)	1.26 (0.62, 2.54)	1.75 (0.94, 3.24)
Interrelatedness	0.77 (0.41, 1.46)	1.38 (0.66, 2.92)	2.39 (1.03, 5.56)
Body Dissatisfaction	0.94 (0.50, 1.78)	1.10 (0.36, 3.23)	0.42 (0.13, 1.39)
Drive for thinness	1.46 (0.75, 2.82)	1.90 (0.64, 5.62)	0.09 (0.01, 1.15)
Bulimia	2.33 (0.86, 6.32)	1.00 (0.43, 2.31)	0.97 (0.23, 4.17)

Models are adjusted for treatment, age, and race. Other demographic factors were not included due to limited sample size. Completers correspond to those that participated in each of the four time points.

tion and could not be included in the models. No other significant comparisons were found, but a few trends were seen by comparing six-month postintervention completers to the completers. Those that had a one standard deviation unit increase in negative schemas between the one-month and six-month postintervention follow-ups had a 75% increase in odds of dropping out after the six month postintervention follow-up. For a decrease of one standard deviation unit in drive for thinness score between the one-month and six-month postintervention follow-ups, there was an 11 times increase in odds of dropping out at that same time frame relative to the completers.

Predicted Self-Schema and ED Symptom Patterns by Treatment and Dropout Groups

On the basis of the mixed effects model, the predicted trajectories for time of dropout were found to be significantly different for number of positive self-schemas. As shown in **Figures 2a** and **2b**, the SPI treatment group experienced a predicted decrease in the estimated number of positive self-schemas, but not for the IIP group. Furthermore, for the IIP group, a trend was found indicating group differences in baseline to one-month postintervention change in positive self-schemas (p = 0.052, **Table 4**). Although all IIP groups, appeared to have an increase in the number of positive self-schemas during that period, those who completed the total 12-month protocol had a greater increase compared to those who dropped out after completing the one-month and six-month postintervention data collection. No predicted trajectory differences were found for the IIP group, but the predicted slopes (one-month through 12-month positive self-schemas scores) for the SPI group were significantly different from one another (p = 0.003). Predicted scores show that participants randomized to the SPI condition that dropped out of the protocol after the six-month postintervention follow-up had an overall increase of 3.12 positive self-schemas while women in the SPI condition who completed the protocol on average had a decrease of 2.40 schemas across the postintervention measurement period.

Patterns of dropout in interrelatedness also found significant results. While there were no differences between the treatments, there were some differences detected within the IIP group (**Figs. 2c** and **2d**). The predicted trajectories were significantly different from one another at the initial difference, from baseline to one-month post, (p = 0.004) as well as from one-month post to completion ($p < 0.001$). Women in the IIP group who dropped out after the one-month postintervention session had the largest increase in self-schema interrelatedness from pre-intervention to one-month postintervention whereas the women in the IIP group who completed the six month postintervention session had a decrease in that self-structure property. However, for the six-month completers, interrelatedness increased across the measurement period where in the completers group, interrelatedness was unchanged.

Interesting patterns were also observed when comparing the predicted trajectories of the body dissatisfaction scores between the one-month postintervention and 12-month postintervention follow-ups (**Figs. 2e** and **2f**). The predicted trajectories for the pre-intervention to one-month postintervention follow-up for the IIP group were found to be different (p = 0.045), but the predicted slopes (one-month through 12-months) were borderline different (p = 0.052). Participants who dropped out after completing the one-month postintervention data collection reported the least amount of change in body dissatisfaction during the treatment period compared with those retained for the six and 12-month follow-up sessions. No difference was detected among the predicted trajectories in the SPI group.

No statistical difference was found in the patterns for number of negative schemas, bulimia, and drive for thinness. For those who completed treatment, the postintervention groups (completed one-month post only, completed one and six month post, and completed all three postintervention measurements) had a similar trajectory; there was the initial decrease at treatment implementation followed by a leveling off or gradual decease during follow-up.

Discussion

The purpose of this study was to investigate the effects of treatment related changes in the organizational properties of self-schemas and ED symptoms on patterns of attrition from an ED psychotherapy RCT. Two features of this study were notable and hold potential for extending our understanding of individual differences that contribute to study dropout. First, the study was unique in that it addressed treatment and measurement attrition and explored patterns of dropout over the complete follow-up course of the trial. Second, it extended beyond an exploration of baseline differences in demographic characteristics and

FIGURE 2. (a) **Predicted number of positive schemas by time of dropout in months for the IIP and (b) SPI treatment groups, respectively; interrelatedness (c, d); and body dissatisfaction score (e, f).**

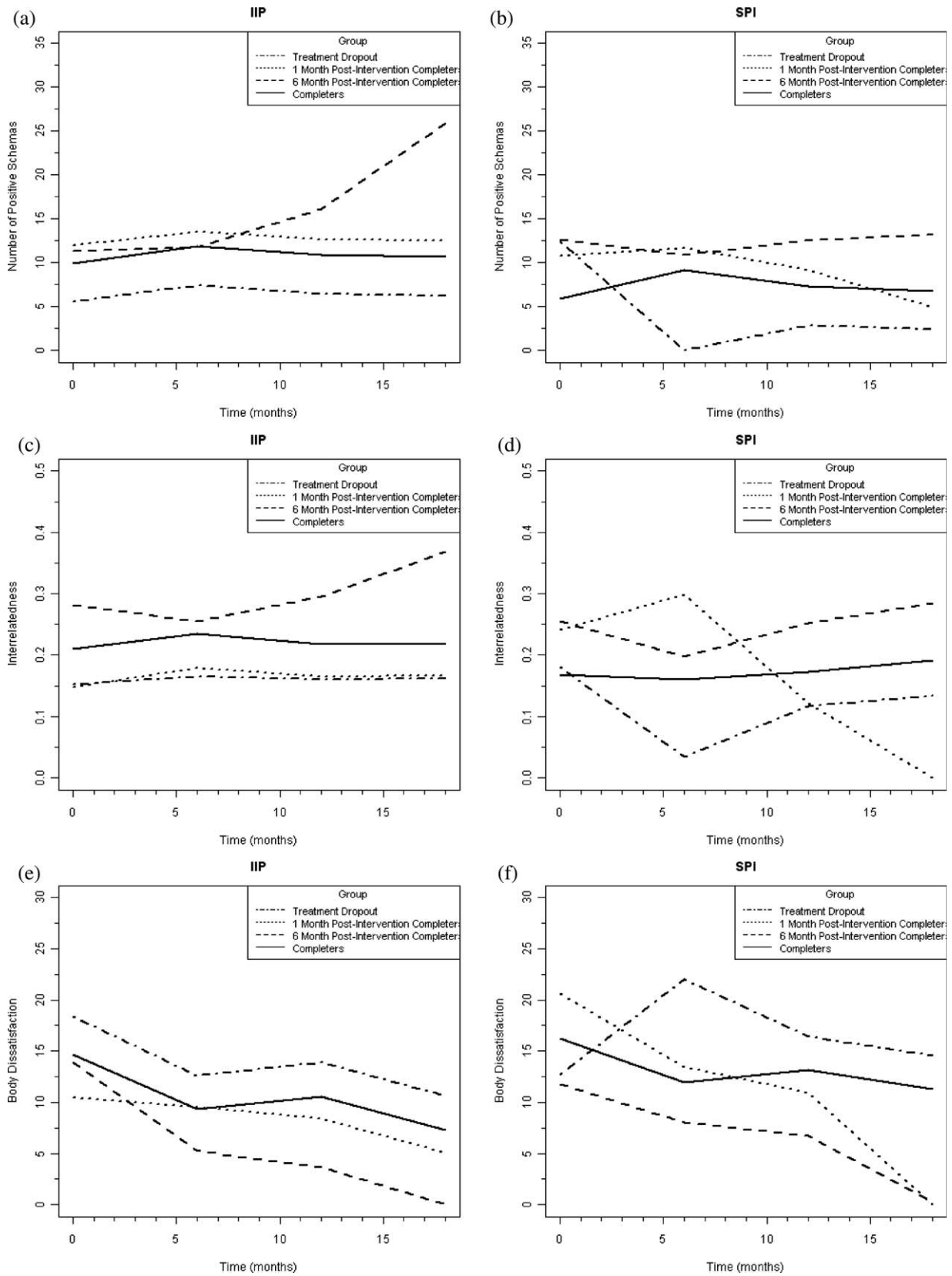


TABLE 4. Predicted differences between baseline and one-month post-intervention measures and predicted slopes from one-month post-intervention to twelve-month post-intervention

(a) Number of Positive Self Schemas	IIP	SPI		IIP	SPI	
Pattern	Diff (SE)	Diff (SE)	Diff *p*	Slope (SE)	Slope (SE)	Slope *p*
Treatment Dropouts (n=26)	NE	NE	NE	NE	NE	NE
1-mos Post-Intervention Completers (n=8)	1.50 (4.0)	0.83 (2.3)	0.884	NE	NE	NE
6-mos Post-Treatment Completers (n=7)	0.50 (2.8)	-1.67 (3.2)	0.612	1.12 (0.6)	0.26 (0.7)	0.308
Completers (n=23)	1.92 (1.6)	3.30 (1.8)	0.558	-0.10 (0.1)	-0.20 (0.1)	0.619
Pattern Difference (*p* value)	0.052	0.441		0.096	0.003	
(b) Interrelatedness	IIP	SPI		IIP	SPI	
Pattern	Diff (SE)	Diff (SE)	Diff *p*	Slope (SE)	Slope (SE)	Slope *p*
Treatment Dropouts (n=26)	NE	NE	NE	NE	NE	NE
1-mos Post-Treatment Completers (n=8)	0.03 (0.1)	0.06 (0.1)	0.801	NE	NE	NE
6-mos Post-Treatment Completers (n=7)	-0.02 (0.1)	-0.06 (0.1)	0.753	0.01 (0.0)	0.01 (0.0)	0.958
Completers (n=23)	0.01 (0.0)	-0.01 (0.0)	0.730	-0.00 (0.0)	0.00 (0.0)	0.545
Pattern Difference (*p* value)	0.004	0.873		<0.001	0.468	
(c) Body Dissatisfaction	IIP	SPI		IIP	SPI	
Pattern	Diff (SE)	Diff (SE)	Diff *p*	Slope (SE)	Slope (SE)	Slope *p*
Treatment Dropouts (n=26)	NE	NE	NE	NE	NE	NE
1-mos Post-Treatment Completers (n=8)	-1.00 (3.9)	-6.86 (2.4)	0.203	NE	NE	NE
6-mos Post-Treatment Completers (n=7)	-8.81 (3.1)	-3.67 (3.2)	0.244	-1.11 (0.6)	-0.78 (0.8)	0.731
Completers (n=23)	-5.81 (1.6)	-4.30 (1.7)	0.521	-0.17 (0.1)	-0.05 (0.1)	0.546
Pattern Difference (*p* value)	0.045	0.871		0.052	0.114	

Both differences and slopes given with standard errors (SE); slopes in units of change per month. Pattern difference *p* values correspond to differences between patterns of dropout within treatment groups; other *p* values represent differences between treatment groups within patterns of dropout. NE is not estimatable.

indicators of illness severity to explore the effects of treatment-related changes in illness symptoms and the theoretically predicted mediators of symptom change on dropout.

The first research question addressed in this study focused on the link between demographic characteristics, baseline levels of ED symptoms, self-schema properties, and pattern of participant dropout. We began this analysis by focusing on those who dropped out during the treatment phase of the trial since 63% of those who dropped out of the trial did so during the treatment phase. Consistent with the findings of other studies of attrition, no differences were found between treatment dropouts and those who completed at least the one-month post-invention data collection in demographic characteristics baseline levels of ED symptoms nor self-schema properties. Further, results of the logistic regression showed that neither self-schema properties nor ED symptoms distinguished treatment dropouts from protocol completers.

In this study, measurements of study outcomes and hypothesized mediators were completed at baseline, one, six, and 12-months postintervention. No measures were completed during treatment phase of the trial. Consequently, no information is available about the pattern of symptom or mediator change associated with dropout during this phase. Descriptive data shows that that those who were retained at least through the one-month post-treatment phase did report a decrease in ED symptoms and lower levels of ED symptoms at their last available measurement compared with the baseline level of the treatment dropouts. Although speculative, it may be that only those who experienced some positive effect were motivated to complete treatment, while those who experienced no relief fled. Capturing patterns of symptom and mediator change during treatment is difficult because dropout occurs throughout and would require multiple measurements to adequately capture the process for those terminating at different point. It addition, repeated measurements threaten the validity of study findings due to potential reactivity and practice effects.[41] Yet given the fact that studies that have focused on demographic and illness characteristics have failed to identify consistent predictors of treatment attrition, detailed information about symptom and mediator change that occurs during treatment may hold important potential for explaining the large rate of attrition during this phase of RCT.

The second research question addressed the relationship of treatment-related changes in the organizational properties of the self-concept and patterns of dropout. The overall goal of the experimental intervention was to increase the number of separate positive self-schemas, and thereby decrease the

overall level of interrelatedness among the self-schemas, as the means to reduce ED symptoms and increase emotional and behavioral involvement in adaptive, non-ED domains of functioning. Results suggest that changes in self-schema properties including the number of positive self-schemas and the overall level of interrelatedness among the self-schemas, which occurred during the intervention phase, as well as in the postintervention follow-up, were predictive of participant attrition.

Changes that occurred in the number of positive self-schemas during the interval between baseline and one-month postintervention data collection related to dropout pattern in both treatment groups, but the pattern of effects differed by group. When both treatment groups were combined, results showed no predictive relationship between changes in the number of positive self-schemas and point of dropout. However, examination of predicted trajectories of change in positive self-schemas by treatment group did reveal patterns of association. For the IIP group, a trend in the data suggests that the pattern of change in positive self-schemas during the pre to one-month post intervention interval was associated with measurement attrition and the specific point of dropout for this group. Women in the IIP group who completed the total 12-month protocol had a mean increase of approximately two self-schemas during the treatment phase. Women who dropped out after the one-month postintervention data collection, as well as those who dropped out after the six-month follow-up, had increases in positive self-schemas during the treatment phase, but these mean increases were smaller.

Interrelatedness refers to the extent to which the self-schemas are linked in memory such that activation of one aspect leads to activation of the total self-structure. Previous studies have shown that high interrelatedness among self-schemas is predictive of negative emotional and physical responses to stress and reliance on negative risk behaviors such as binge eating to avoid intense negative emotions associated with activation of the highly interrelated structure.[42,43] When the treatment groups were combined to examine the effects of changes in interrerlatedness of dropout pattern, results showed that an increase in interrelatedness during the follow-up period, particularly between the one-month and six-month period predicted dropout before the final 12-month follow-up session. Examination of the predicted change trajectories by treatment group, however, revealed that this effect was driven by those in the experimental IIP group. The level of interrelatedness among self-schemas changed during treatment and post-treatment intervals for those in the IIP groups and these changes also were associated with point of dropout. Women in the IIP condition who completed the study protocol reported the least amount of change in interrelatedness both during the pre to one-month post interval as well as during the postintervention measurement phase. Consistent with the total group analyses, women in the IIP group who dropped out after the six-month data collection were predicted to have an increase in level of interrelatedness during the measurement period.

When the interrelatedness findings are considered together with the positive self-schema results, these data provide preliminary evidence to suggest women in the IIP condition who are able to claim additional positive behavioral domains as self-definitional during treatment while generally maintaining the level of self-structure interrelatedness both during the treatment and follow-up phases may experience feelings of success and optimism that motivate them to sustain participation in the protocol. In contrast, women in the IIP group who reported an increase in positive self-schema and an increase in interrelatedness during the pre to one-month postintervention session, dropped prior to the six-month follow-up. Although the mechanisms underlying this more complex pattern are unknown, it is possible that an increase in interconnectivity in the context of holding many negative self-schemas increases negative affect and motivates a desire to disconnect from the protocol that may be experienced as the source. In this situation, it may be that the increase in the number of positive schemas was not sufficient to overcome negative affect associated with activation of a highly interconnected structure that includes many negative aspects of the self at baseline.[26,27] Finally, women in the IIP condition who dropped out during the final phase of the study, between the six and 12-month follow-up period simultaneously experienced a relatively smaller increase in positive self-schemas and a decrease in interrelatedness during the pre to one-month postintervention period. On the basis of the projected trajectory of interrelatedness scores, it appears that the change in interrelatedness was not sustained during the follow-up period and this corresponded to a loss of motivation to complete the protocol.

The control treatment, support psychotherapy, focused on identifying underlying problems contributing to ED symptoms, and enhancing relevant coping strategies. Although not the focus of this approach to intervention, changes in self-schema properties were related to study dropout. For all

participants randomized to the SPI condition, an overall decrease in the number of positive self-schemas during the pre to one-month postintervention interval was found and based on the predictive trajectories, the greatest predicted decrease was for SPI participants who dropped out during the treatment phase. Predicted trajectories show that women in the SPI group who dropped out after the six-month postintervention data collection were expected to experience a small increase in the number of positive self-schemas over the course of the measurement period. In contrast, those who completed the protocol experienced on overall decrease in positive self-schemas during this period. Although tentative, this pattern of findings suggest that breaking off involvement in a study with a treatment arm that lead to a decrease in positive self-schemas, may lead to a regaining of positive conceptions of the self. Whereas, continued involvement, even in the form of data collection sessions appear to continue to negatively impact the self-structure. No associations between changes in self-schema interrelatedness and dropout were detected for this group.

The final research question addressed the relationship between intervention related changes in ED symptoms and dropout pattern. The findings show that both groups experienced decreases in drive for thinness, body dissatisfaction, and bulimia scores during the treatment phase but few associations with study dropout were found. Only for the IIP group was there an association between point of dropout and treatment phase change in symptoms and this was for body dissatisfaction only. Women in the IIP group who were retained in the study for at least the six-month follow-up had a greater decrease in body dissatisfaction in the pre to one-month post intervention interval compared to those who dropped out after the one-month postintervention follow-up. A trend in the projected trajectories suggests that those who dropped out continued to experience a decline in body dissatisfaction during the measurement phase. Although there is no confluence of findings across the ED symptoms, the body dissatisfaction findings provide some suggestion that a decrease in symptoms that occur along with changes in self-schema properties interfere with completion of the trial. It is possible that a decrease in dissatisfaction with one's physical self along with the addition of new self-conceptions lead to involvements in other domains that diminish motivation or time to complete the final phase of the trial.

The interesting pattern of findings must be qualified by the limitations of this study. First and most importantly, the anticipated sample size for this study was not met and therefore some of the tests were underpowered to determine effect differences. Second, women with AN and BN who met criteria for another current Axis I disorder were excluded from the sample. Hence, the findings of this secondary analysis are generalizable only to this subset of women with an ED. Additional studies are needed to determine if a similar pattern of findings would be found in populations of women with co-morbid Axis I conditions. Finally, multiple models were run for this study and no multiple comparison corrections were made.

The limitations of this study along with the complex pattern of results found suggest that additional research is needed to clearly establish the effects that treatment related changes in self-schema properties and ED symptoms have on RCT attrition. However, the results of this study do lend initial support to the idea that changes in beliefs about the self, as well as in ED symptoms, that occur during treatment and continue through the follow-up phases are important to understanding RCT attrition. Clearly, attrition is a complex phenomenon with dropout at different points in the protocol stemming from different patterns of change. The findings of this study provide initial evidence to suggest that regardless of the focus of treatment, changes in the number of positive self-schemas and the overall level of interrelatedness of the total self structure occur during treatment and follow-up phases and these changes are predictive of point of attrition. Attention to treatment response from the earliest phases of intervention through follow-up may help to identify those at greatest risk of dropping and lead to strategies for promoting participant retention.

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