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Therapeutic Alliance in Two Treatments for Adults with Severe and Enduring Anorexia Nervosa

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ABSTRACT

Objective: The aim of this study was to investigate the strength and role of therapeutic alliance in a trial comparing Cognitive Behavioral Therapy for anorexia nervosa (CBT-AN) and Specialist Supportive Clinical Management for the treatment of severe and enduring AN (SE-AN).

Method: Participants were 63 adult females with SE-AN presenting to an outpatient, multisite randomized controlled trial conducted at two clinical sites. Participants completed measures assessing their perception of the quality of the therapeutic relationship, eating disorder (ED) symptomatology, and depressive symptomatology.

Results: Beyond the effect of early treatment change and treatment assignment, early therapeutic alliance was a significant predictor of Restraint and Shape Concern at follow-up (*ps* < .02). Late

therapeutic alliance was a significant predictor of weight change, depressive symptomatology, and ED symptomatology at end of treatment and follow-up (ps < .008), with the exception of Shape Concern at follow-up (p = .07).

Discussion: The results suggest that therapeutic alliance can be effectively established in the treatment of SE-AN and may be relevant for treatment response, particularly in late treatment, on some aspects of ED and depressive symptomatology. © 2013 Wiley Periodicals, Inc.

Keywords: therapeutic alliance; anorexia nervosa; cognitive behavioral therapy; specialist supportive clinical management

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Introduction

Severe and enduring anorexia nervosa (SE-AN), defined as meeting criteria for AN for at least 7 years, is a public health concern as it creates a substantial burden in terms of morbidity, mortality, suffering, and cost. 1-9 Although there is promising evidence for the efficacy of family-based treatment for adolescents with AN, 10 there is little evidence for an empirically supported and effective treatment for adults with SE-AN. 2 This may be due to high dropout rates in treatment studies related to the misalignment of treatment aims for recovery and patient readiness for change and recovery. 2,11

To address this dissonance in the treatment of SE-AN, Touyz et al. conducted a randomized controlled trial (RCT) with two treatments adapted to more closely align with the aims of patients with SE-AN such that weight gain was not a main goal of treatment. A retention rate of 85% was achieved at post-treatment, and significant improvements were reported on the majority of outcome measures. The authors postulated that the findings are related to a positive patient response to a broader focus of treatment. Although these findings are promising, more research is necessary to identify

and better understand factors that influence outcome in the treatment of SE-AN.

One possible factor is therapeutic alliance, which refers to the relationship bond that can develop between a client and therapist through collaborative work and mutual trust in establishing and reaching treatment goals. Therapeutic alliance has been shown to predict outcomes in therapy across a wide variety of disorders and treatment modalities. Therapeutic alliance has been shown to be effectively established in the treatment of adults and adolescents with eating disorders (EDs), yet its role in treatment outcome for ED populations has been mixed. To our knowledge, the role of therapeutic alliance in treatment outcome for adults with SE-AN has not been investigated.

The primary aim of this study is to fill this gap in the literature by comparing the strength and role of therapeutic alliance in a trial comparing Cognitive Behavioral Therapy for AN (CBT-AN) and Specialist Supportive Clinical Management (SSCM) for the treatment of SE-AN. We hypothesized that there would be no significant difference in strength of therapeutic alliance between the two interventions throughout treatment. We also hypothesized that both early and late therapeutic alliance would predict positive treatment outcomes (e.g., ED severity and depressive symptoms) at end of treatment and follow-up, with the exception of weight gain, as weight gain was not mandated in either treatment.

Method

This study is a secondary analysis of data from a RCT conducted at two clinical sites (the University of Sydney and St. George's Hospital, University of London) and a Data and Coordinating Center (the University of Chicago) comparing the efficacy of CBT-AN and SSCM for a cohort of adults with SE-AN. Specific treatment effects have been analyzed and are reported in the main outcome article. 12 In the RCT, participants received 30 \times 50-min individual treatment sessions provided over a period of 8 months in an outpatient setting.

Participants

Recruitment of participants occurred from July 2007 to November 2010 through advertising to clinics treating EDs, clinicians, and generic websites (see Supporting Information Fig. S1).

Participants were eligible for RCT if they met the *Diagnostic and Statistical Manual for Mental Disorders*, 4th Edition, Text Revision (DSM-IV-TR)²⁰ criteria for AN, excluding criterion D (amenorrhea); had an illness

duration of at least 7 years; were at least 18 years of age; and were female. Exclusion criteria included presenting with a current manic episode or psychosis; current alcohol or substance abuse or dependence; significant current medical or neurological illness (including seizure disorder), with the exception of nutrition-related alterations that are impacted by weight; current engagement in psychotherapy and being unwilling to suspend such treatment for the duration of their participation in the study; and plans to move beyond commuting distance for the study site in the following 12 months or not living within commuting distance to the study site.

In compliance with the Institutional Review Boards of all three sites, participants completed written informed consent prior to assessment.

Treatments

Participants were randomly assigned to either CBT or SSCM by a biostatistician in the Data and Coordinating Center at the University of Chicago, independent from either intervention sites. Randomization was conducted using Ephron's biased coin approach, stratified within sites by subtype of illness (restrictive and binge-purge) and psychiatric medication status. To minimize therapist effects, three clinical psychologists with prior experience treating EDs in adults acted as therapists for both the CBT and SSCM conditions. All therapists attended two 2day in-person workshops for training in the manualized treatments. All therapists treated pilot cases using each treatment before being assigned randomized cases and were supervised by senior clinicians throughout the duration of the trial. Treatment occurred in outpatient settings at the University of Sydney and St. George's Hospital, University of London. Both treatments involved 30 individual treatment sessions provided over 8 months.

Cognitive Behavioral Therapy-AN. CBT-AN is based on the protocol developed by Pike et al.21 that focuses on the cognitive and behavioral disturbances associated with the main features of AN, as well as more global issues related to the disorder, including motivational and schema-based work. CBT-AN has four phases of treatment. Phase I provides specific strategies for the start of treatment, addressing issues related to motivation, and orienting patients to the CBT process. Phase II then focuses on strategies for addressing weight gain, as well as cognitive distortions and behavioral disturbances associated with eating and weight for the patient. Phase III expands the focus of treatment to schema-based work that addresses relevant issues that are outside of the specific domain of eating and weight. Phase IV focuses on reviewing the therapy process, consolidating gains, and preparing the patient to continue the work of CBT-AN independently post-treatment. For this trial, CBT-AN was modified to reflect a shift in treatment goals. Specifically,

treatment goals were set collaboratively, and weight gain was encouraged but not identified as the primary focus of the treatment (although medical safety was monitored and required to remain in the study).

Specialist Supportive Clinical Management. SSCM combines features of clinical management and supportive psychotherapy.^{22,23} Supportive psychotherapy aims to assist the patient through use of praise, advice, and reassurance. Clinical management includes support and psychoeducation while fostering a therapeutic relationship with the intent of increasing adherence to treatment. Goals are set in a collaborative manner and "target" EDs and other symptoms to be a focus of therapy. Similarly to CBT-AN, SSCM was modified for this trial such that weight gain was not the primary treatment goal; instead, patients were encouraged to make changes to improve their quality of life and physical well-being. The rationale for this emphasis in treatment is that efforts to aid individuals in improving quality of life will further motivate and enable them to make progress on their core ED pathology as well.

Physical Assessment

To calculate body mass index $(BMI = kg/m^2)$, weight and height of the participants were measured by a trained research assistant using a calibrated digital or balance-beam scale and stadiometer, respectively. All patients were weighed in light indoor clothing, without shoes.

Measures

The Helping Relationships Questionnaire. The Helping Relationships Questionnaire (HRQ)²⁴ is an 11-item selfreport questionnaire measuring the quality of the therapist-patient relationship from the patient's perspective. The HRQ was administered at Week 2, mid-treatment, and end of treatment. Higher total scores reflect greater therapeutic alliance. Examples of questions include "I believe that my therapist is helping me" and "I feel I am working together with the therapist in a joint effort." Items for the HRQ are rated on a 6-point Likert scale ranging from -3 (strongly feel it is not true) to +3 (strongly feel it is true). Total scores, computed by summing all items, range from -33 to 33. Participant responses with missing items on the HRQ were excluded from analyses involving HRQ total scores. The HRQ has strong psychometrics and has been shown to correlate with treatment outcome. 25,26

The Eating Disorder Examination. The Eating Disorder Examination (EDE)²⁷ is a semistructured investigator-based interview measuring cognitive and behavioral symptoms related to ED. The EDE was used to generate DSM-IV-TR diagnoses for an ED and to assess the severity of ED symptomatology. Subscales include Weight

Concern, Shape Concern, Eating Concern, and Restraint. Global scores reflect the overall severity of ED symptoms. The EDE was administered at baseline, mid-treatment, end of treatment, and 6 and 12 months post-treatment. The EDE has demonstrated good reliability and validity. ^{28,29}

The Beck Depression Inventory. The Beck Depression Inventory (BDI)³⁰ is a 21-item self-report questionnaire designed to assess depressive symptoms. Higher total scores reflect greater depressive symptomatology. The BDI was administered at baseline, mid-treatment, end of treatment, and 6 and 12 months post-treatment. The BDI has good psychometric properties.^{31,32}

Data Analysis

The analyses were based on the intent-to-treat principle, with missing data imputed with the last observation carried forward. t-tests were used to compare participants receiving CBT-AN and SSCM on ratings of early, middle, and late treatment therapeutic alliance. A repeated-measures ANOVA was conducted to detect significant change in therapeutic alliance over time. Hierarchical multiple regressions were conducted to investigate the predictive utility of therapeutic alliance for weight change, depressive symptoms, and ED severity at end of treatment and follow-up. To test whether early and late treatment therapeutic alliance had any predictive value over and above the treatment received and to adjust for the possible effect of early treatment change, baseline values of outcome measures were included in the first step of the hierarchical regressions, with treatment assignment included in the second step, and therapeutic alliance score included in the third step. An alpha level of .05 was used to provide maximum power to identify potential predictors of outcome.

Results

A total of 63 participants were randomly assigned to CBT-AN (n=31) or SSCM (n=32). All study participants were female and ranged in age from 20 to 61 years ($M=33.4\pm9.6$), with a range of duration of illness of 7–49 years ($M=16.6\pm8.5$). The mean BMI for the sample was 16.2 (SD = 1.3, range = 11.8–18.5). The majority of participants met criteria for AN restricting subtype (n=47,74.6%). No significant differences on any baseline characteristics were found between treatment groups, sites, or group-by-site interactions.

No significant differences occurred between CBT-AN participants and SSCM participants in terms of therapeutic alliance ratings at Week 2 (t[61] = -.55, p = .59), mid-treatment (t[61] = .76, p = .45), and end of treatment (t[61] = .08, p = .95)

TABLE 1. Hierarchical regressions of early therapeutic alliance predicting change in psychosocial and eating disorder variables at end of treatment and follow-up

Hierarchical Regression Variable	Step		nd of Treatr	nent	12-Month Follow-Up						
		df	ΔR^2	ΔF	β	р	df	ΔR^2	ΔF	β	р
BMI model											
BMI Baseline	1	1, 61	.539	71.19	0.734	<.001	1, 61	.432	46.42	0.657	<.001
Treatment group	2	2, 60	.007	.873	082	.35	2, 60	.006	.598	075	.44
HRQ total score	3	3, 59	.000	.055	021	.82	3, 59	.003	.003	.005	.96
BDI model		,					,				
BDI Baseline	1	1, 61	.252	20.60	.502	<.001	1, 61	.250	20.29	.500	<.001
Treatment group	2	2, 60	.006	.475	.080	.49	2, 60	.001	.100	.037	.75
HRQ total score	3	3, 59	.002	.190	.050	.66	3, 59	.002	.128	041	.72
EDE Global Score model											
EDE Global Baseline	1	1, 61	.530	68.68	.728	<.001	1, 61	.486	57.71	.697	<.001
Treatment group	2	2, 60	.012	1.56	110	.22	2, 60	.025	3.02	− .157	.09
HRQ total score	3	3, 59	.008	1.08	094	.30	3, 59	.018	2.92	139	.14
EDE Restraint model											
EDE Restraint Baseline	1	1, 61	.090	6.04	.300	.02	1, 61	.145	10.38	.381	.002
Treatment group	2	2, 60	.044	.044	026	.84	2, 60	.026	1.91	163	.17
HRQ total score	3	3, 59	.053	3.65	232	.06	3, 59	.066	5.09	259	.02
EDE Eating Concern model											
EDE Eating Concern Baseline	1	1, 61	.571	81.27	.756	<.001	1, 61	.478	55.81	.691	<.001
Treatment group	2	2, 60	.028	4.25	169	.04	2, 60	.010	1.22	103	.27
HRQ total score	3	3, 59	.000	.068	023	.80	3, 59	.003	.386	.061	.54
EDE Shape Concern model											
EDE Shape Concern Baseline	1	1, 61	.452	50.36	.672	<.001	1, 61	.378	37.07	.615	<.001
Treatment group	2	2, 60	.036	4.24	190	.04	2, 60	.049	5.15	222	.03
HRQ total score	3	3, 59	.017	1.97	130	.17	3, 59	.065	7.50	257	.008
EDE Weight Concern model											
EDE Weight Concern Baseline	1	1, 61	.488	58.12	.698	<.001	1, 61	.459	51.80	.678	<.001
Treatment group	2	2, 60	.019	2.31	138	.13	2, 60	.018	2.10	135	.15
HRQ total score	3	3, 59	.003	.321	053	.57	3, 59	.019	2.27	142	.14

Note: Step 1 examines the main effect of baseline score. Step 2 examines the main effect of treatment type. Step 3 examines the main effect of therapeutic alliance score. BMI, body mass index; BDI, Beck Depression Inventory; HRQ, Helping Relationship Questionnaire; EDE, Eating Disorders Examination.

.94). A repeated-measures ANOVA indicated that there were significant differences in HRQ scores over the three time points in treatment (F[2, 124] = 32.53, p < .001), as mid-treatment (SSCM M = 20.8, SD = 7.8; CBT-AN M = 19.1, SD = 9.9) and end of treatment (SSCM M = 22.5, SD = 9.9; CBT-AN M = 22.3, SD = 9.0) therapeutic alliance scores were significantly higher than the Week 2 scores (SSCM M = 13.4, SD = 7.3; CBT-AN M = 14.4, SD = 6.4; p < .001).

Relationship between Therapeutic Alliance and Clinical Outcomes

The results of hierarchical regressions evaluating the relationship between the early and late therapeutic alliance and end of treatment and 12-month follow-up outcomes are displayed in **Tables 1** and **2**. A detailed discussion on differences in outcome by treatment is detailed elsewhere¹²; however, our models indicated that Eating Concern at end of treatment and Shape Concern at end of treatment and follow-up were more strongly predicted by CBT-AN (p < .04).

Early Treatment Therapeutic Alliance. Beyond the effect of treatment, early therapeutic alliance

significantly predicted the Restraint subscale ($\beta = -.26$, SE = .03, p = .02) and Shape Concern subscale ($\beta = -.26$, SE = .03, p = .008) at 12-month follow-up. Early therapeutic alliance did not significantly contribute to the models predicting BMI, BDI, or EDE Global score outcomes at end of treatment or 12-month follow-up (p > .05).

Late Treatment Therapeutic Alliance. Beyond the effect of treatment, late therapeutic alliance significantly predicted end of treatment BMI (β = .33, SE = .02, p < .001), BDI score (β = -.51, SE = .02, p < .001), EDE Global score (β = -.31, SE = .01, p < .001), and EDE subscales (ps < .004). Late therapeutic alliance also significantly predicted 12-month follow-up BMI (β = .27, SE = .15, p = .005), BDI score (β = -.30, SE = .18, p = .006), EDE Global score (β = -.27, SE = .02, p = .003), and EDE subscales (ps < .008), with the exception of the model predicting the Eating Concern subscale at 12-month follow-up (p = .07).

Discussion

This study aimed to examine the role of therapeutic alliance in the outcome of two treatments for

TABLE 2. Hierarchical regressions of late therapeutic alliance predicting change in psychosocial and eating disorder variables at end of treatment and follow-up

Hierarchical Regression Variable	Step		nd of Treatr	nent	12-Month Follow-Up						
		df	ΔR^2	ΔF	β	р	df	ΔR^2	ΔF	β	р
BMI model											
BMI Baseline	1	1, 61	.539	71.19	.734	<.001	1, 61	.432	46.42	.657	<.001
Treatment group	2	2, 60	.007	.873	082	.35	2, 60	.006	.598	075	.44
HRQ total score	3	3, 59	.101	16.91	.325	<.001	3, 59	.072	8.72	.274	.005
BDI model		,					,				
BDI Baseline	1	1, 61	.252	20.60	.502	<.001	1, 61	.250	20.29	.500	<.001
Treatment group	2	2, 60	.006	.475	.080	.49	2, 60	.001	.100	.037	.753
HRQ total score	3	3, 59	.260	31.89	512	<.001	3, 59	.092	8.23	304	.006
EDE Global Score model											
EDE Global Baseline	1	1, 61	.530	68.68	.728	<.001	1, 61	.486	57.71	.697	<.001
Treatment group	2	2, 60	.012	1.57	110	.22	2, 60	.025	3.02	一.157	.09
HRQ total score	3	3, 59	.095	15.36	310	<.001	3, 59	.070	9.85	267	.003
EDE Restraint model											
EDE Restraint Baseline	1	1, 61	.090	6.04	.300	.02	1, 61	.145	10.38	.381	.002
Treatment group	2	2, 60	.001	.044	026	.84	2, 60	.026	1.91	163	.17
HRQ total score	3	3, 59	.175	14.05	419	<.001	3, 59	.093	7.46	305	.008
EDE Eating Concern model											
EDE Eating Concern Baseline	1	1, 61	.571	81.27	.756	<.001	1, 61	.478	55.81	.691	<.001
Treatment group	2	2, 60	.028	4.25	169	.04	2, 60	.010	1.22	103	.27
HRQ total score	3	3, 59	.096	18.50	313	<.001	3, 59	.029	3.49	−.171	.07
EDE Shape Concern model											
EDE Shape Concern Baseline	1	1, 61	.452	50.34	.672	<.001	1, 61	.378	37.07	.615	<.001
Treatment group	2	2, 60	.036	4.24	190	.04	2, 60	.049	5.15	222	.03
HRQ total score	3	3, 59	.068	9.06	261	.004	3, 59	.092	11.24	303	.001
EDE Weight Concern model											
EDE Weight Concern Baseline	1	1, 61	.488	58.12	.698	<.001	1, 61	.459	51.80	.678	<.001
Treatment group	2	2, 60	.019	2.31	138	.13	2, 60	.018	2.10	135	.15
HRQ total score	3	3, 59	.090	13.19	303	.001	3, 59	.076	9.98	278	.003

Note: Step 1 examines the main effect of baseline score. Step 2 examines the main effect of treatment type. Step 3 examines the main effect of therapeutic alliance score. BMI, body mass index; BDI, Beck Depression Inventory; HRQ, Helping Relationship Questionnaire; EDE, Eating Disorders Examination.

adults with SE-AN. Early, mid, and late treatment therapeutic alliance was present, with no significant differences in patient ratings across treatment types. Adjusting for early treatment change and type of treatment, early treatment therapeutic alliance predicted treatment outcome in terms of Restraint and Shape Concern in follow-up, but not changes in other ED domains, depressive symptomatology, or weight. Late therapeutic alliance predicted treatment and follow-up outcomes for all evaluated domains, with the exception of Eating Concern at follow-up.

Consistent with our hypothesis, there were no significant differences in patient ratings of therapeutic alliance of the two treatments. Although CBT-AN and SSCM use unique intervention strategies to achieve therapy aims, both were able to promote moderate therapeutic alliance in early treatment, increasing to strong therapeutic alliance in late treatment, to relatively the same degree. The level of therapeutic alliance is also consistent with the use of the HRQ with other ED samples.¹⁸

Consistent with our hypothesis, therapeutic alliance was a predictor of some ED symptomatology. Specifically, Restraint and Shape Concern subscale scores at follow-up were significantly predicted by

early treatment therapeutic alliance, beyond the effect of baseline severity and treatment assignment. With the exception of Shape Concern at follow-up, all ED and depressive symptomatology assessed at end of treatment and follow-up were significantly predicted by late treatment therapeutic alliance. These findings may indicate that although early treatment therapeutic alliance is present for patients with SE-AN, the possible benefits of the therapeutic relationship to treatment outcome require more time to develop. More research is required to better understand how therapeutic alliance interacts with both treatment interventions to enact change in specific ED symptomatology, both during treatment and posttreatment.

Depressive symptomatology and changes in weight were not significantly predicted by early treatment therapeutic alliance for either treatment, but were predicted by late treatment therapeutic alliance. Although speculative, the failure of early therapeutic alliance to predict changes in weight and depressive symptoms may arise from the fact that changes in these domains are more resistant to change. As previously postulated, it is possible that such variables require a longer exposure to the

therapeutic relationship before positive change may be predicted. Future research should examine factors that affect these outcomes.

To our knowledge, this is the first study to examine the predictive role of therapeutic alliance in the outcome of two treatments for adults with SE-AN. Understanding the factors that promote positive treatment outcomes and improve retention provides greater insights on how to most effectively intervene for this population. There were several strengths to this study, specifically the strongest retention rate to our knowledge of a study of adults with AN, assessments with well-validated measures, and 12-month follow-up data. Yet limitations also warrant acknowledgement. Our sample sizes were moderate, yet sufficient to show differences in outcomes. It is of note that the number of analyses conducted increases the risk for Type I error. Finally, as the majority of the sample met criteria for restricting subtype, we were unable to explore the effect of therapeutic alliance on bingeing and purging outcomes for the SE-AN population. Future studies should explore the role of therapeutic alliance in the treatment of adults with SE-AN in larger samples.

In summary, consistent with previous findings from ED samples, therapeutic alliance can effectively be established in adults with SE-AN, with no significant differences occurring between those treated with CBT-AN and SSCM. Early therapeutic alliance significantly predicted some ED symptomatology, but not changes in weight or depression. Late therapeutic alliance predicted all ED and depressive symptoms, with the exception of Shape Concern at follow-up. Future research should examine other aspects of interventions that positively affect retention and outcome for adults with SE-AN.

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