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A Pilot Randomized Controlled Trial of Transdiagnostic Network-Informed Personalized Treatment for Eating Disorders versus Enhanced Cognitive Behavioral Therapy

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Abstract

Objective: Eating disorders (EDs) are serious mental illnesses with high mortality and relapse rates and carry significant societal and personal costs. Nevertheless, there are few evidenced-based treatments available. One aspect that makes treatment difficult is the high heterogeneity in symptom presentation. This heterogeneity makes it challenging for clinicians to identify pertinent treatment targets. Personalized treatment based on idiographic models may be well-suited to address this heterogeneity, and, in turn, presumably improve treatment outcomes.

Method: In the current randomized controlled trial (RCT), participants will be randomly assigned to either 20 sessions of Enhanced Cognitive Behavioral (CBT-E) therapy or Transdiagnostic Network-Informed Personalized Treatment (T-NIPT-ED) for EDs. Assessment of ED symptoms, clinical impairment, and quality of life will occur at pre-, mid-, posttreatment, and one-month follow-up.

Results: We will examine the acceptability and feasibility of T-NIPT-ED compared to CBT-E. We also will test the initial clinical efficacy of T-NIPT-ED versus CBT-E on clinical outcomes (i.e., ED symptoms, body mass index, and quality of life). Finally, we will test if the network-identified precision targets are the mechanisms of change.

Discussion: Ultimately, this research may inform the development and dissemination of evidenced-based personalized treatments for EDs and serve as an exemplar for personalized treatment development across the broader field of psychiatry.

Keywords

eating disorders; personalized treatment; network analysis; cognitive behavioral therapy; randomized controlled trial

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Introduction

Eating disorders (EDs) are chronic and debilitating disorders with high relapse rates and low rates of full recovery (Keel & Brown, 2010; Strober et al., 1997). At present, no empirically supported treatments exist for adults with anorexia nervosa (AN) or other specified feeding and eating disorders (OSFED), and the empirically supported treatment for bulimia nervosa (BN) and binge eating disorder (BED), cognitive-behavioral therapy for EDs (CBT-E), only has a 50% success rate (Kaidesoja et al., 2022; Keel & Mitchell, 1997; Steinhausen, 2009; Steinhausen & Weber, 2009). This low response rate may be due to the heterogeneity of these disorders, even within the same diagnosis (Levinson et al., 2018). For example, one individual with AN may restrict and fear high calorie foods and have co-occurring depression, whereas another individual with AN may have binge and purge episodes and meet criteria for an anxiety disorder.

Existing treatments developed based on ‘average symptom presentation’ inadequately address this heterogeneity in symptom presentation evidenced across individuals. For instance, CBT-E is predicated on the theory that shape and weight-related concerns are the central maintaining factors of eating disorders and therefore focuses primarily on this symptom (Fairburn, 2008). To address the wide range of symptom presentations, clinicians typically adapt evidence-based treatments relying on clinical judgment, although research has demonstrated that clinical judgment is flawed and that data-based decisions outperform even team-based clinician decisions (Fernandez et al., 2017). As a result, both the heterogeneity of symptoms, as well as the dependence on clinical judgment, can minimize the efficacy of ED treatment. Developing a personalized, data-driven treatment to assist in selecting which symptoms to target in treatment would help to minimize the reliance on clinical judgment and create a personalized treatment for the individual.

Personalized treatment can be developed using idiographic network analysis (NA; Epskamp et al., 2018). Idiographic NA is used to pinpoint core ‘trigger’ symptoms (e.g., shame, body dissatisfaction) that are theorized to maintain the disorder by modeling how symptoms interrelate and become mutually reinforcing. Idiographic NA uses intensive longitudinal data (i.e., ecological momentary assessment; EMA) to model how dynamic systems of symptoms interrelate with each other to maintain pathology within a single individual. For example, strength centrality provides a measurement of which symptoms are most interconnected to other symptoms, and thus have the largest potential to activate other symptoms in the network. Once these precision targets are identified, they can be directly addressed which should weaken the strength of the edges among symptoms (i.e., nodes). Psychological improvement would occur as a result of this decreased interconnectedness. This type of intervention, targeted at central maintaining symptoms, is theorized to produce the maximal change in the network of pathology as a whole, for that individual (Borsboom, 2017; Borsboom & Cramer, 2013). Existing research has demonstrated that using this modeling technique can help to conceptualize how psychiatric illness maintains itself in a wide range of disorders, including EDs, anxiety, depression, and post-traumatic stress disorder (Bringmann et al., 2018; David et al., 2018; Fisher et al., 2017; Howe et al., 2020; Levinson et al., 2020; Reeves & Fisher, 2020). These studies underscore the importance of using

idiographic networks to identify personalized symptom dynamics and select central targets for precision intervention planning.

Though research applying idiographic NA has suggested these models may inform treatment, scholarship testing this method against existing approaches remains limited. Referring to the National Institute of Health (NIH) stage model for testing behavioral interventions (Rounsaville et al., 2001a; Rounsaville et al., 2001b), the pilot study (Levinson et al., in press), represents testing at stage 1. This initial pilot study was an open series trial examining the feasibility and acceptability of T-NIPT-ED. Pilot data revealed that personalized, data-driven ED treatment was rated as highly acceptable with very low drop out (Levinson et al., in press). This completion rate of 83% is on par with trials of CBT-E which generally have attrition rates ranging from 20–54% (Atwood & Friedman, 2020). This study also indicated strong initial clinical efficacy on both ED symptoms and co-occurring symptoms with medium to large effect sizes (Levinson et al., in press). There were no significant differences between diagnoses (i.e., AN, BN, BED, OSFED; $p = .538$) or between those with an underweight body mass index (BMI) at baseline compared to those with a BMI of 18.5 to 30 ($p = .824$; Levinson et al., 2022). These results lend support to the utilization of personalized treatment for transdiagnostic EDs. The next steps in this research are to 1) compare transdiagnostic network-informed personalized treatment (T-NIPT-ED) for EDs to CBT-E, a current evidence-based treatment for EDs, and 2) identify the mechanisms driving treatment change. Testing the feasibility and acceptability of a randomized controlled trial comparing T-NIPT-ED to CBT-E will constitute stage II of the NIH stage model.

As such, the current study will recruit 80 adults with a current ED diagnosis and randomly assign participants to 20 sessions of either T-NIPT-ED ($n = 40$) or to CBT-E ($n = 40$) over 20 weeks. We aim to (a) examine the feasibility and acceptability of randomization to T-NIPT-ED compared to CBT-E for EDs, (b) test the initial clinical efficacy of T-NIPT-ED versus CBT-E on clinical outcomes (i.e., quality of life, and ED symptoms), and (c) examine if changes in NA-identified precision targets as well as in network structure (proposed mechanisms of change in T-NIPT-ED), are associated with changes in clinical outcomes.

We hypothesize that both conditions will be highly feasible and acceptable and that there will be no significant difference between the two conditions. Additionally, we hypothesize that T-NIPT-ED will produce significantly greater improvements in clinical outcomes than the CBT-E condition. We expect that more changes in precision targets and network structure (e.g., decrease in interconnectedness among symptoms) will be associated with better clinical outcomes (e.g., quality of life, improved ED symptoms), regardless of the condition. Finally, we hypothesize that greater target improvement (i.e., change in idiographic central symptoms as evidenced by network factor loading) will occur in the personalized treatment condition.

Method

Participants

We will recruit 80 adults with a current ED diagnosis from the community via social media and nationwide ED treatment centers.

Inclusion Criteria—Participants must be between 18 and 65 years old and meet criteria for AN, BN, BED, or OSFED as defined by the DSM-5 (APA, 2013). ED diagnoses must be active or in partial remission (e.g., for AN, weight restored but still experiencing significant ED cognitions or behaviors) based on DSM-5 criteria, which is assessed using the Structured Clinical Interview for DSM-5 (SCID-5; First et al., 2015).

Exclusion Criteria—Participants will be excluded if they endorse active suicidality, mania, or psychosis, assessed using the Mini-International Neuropsychiatric Interview 5.0 (MINI; Sheehan et al., 1998), or if they are currently medically compromised (e.g., fainting, BMI < 17.0). Further, participants will be excluded if they are currently in other specialized ED treatment, but are not excluded if taking psychotropic medication. Participants will be excluded if they engage in excessive substance use (determined by the Addiction Severity Index – Lite) that may interfere with treatment. Participants must have access to the internet to use a video conferencing platform for treatment delivery.

Procedure

All procedures occur via phone or a secure video conferencing platform. Recruitment methods will include recruiting from ED treatment centers' alumni lists, email, social media, and fliers. Participants will be screened by phone using semi-structured diagnostic interviews to determine initial eligibility (see assessments below). In session one, participants will complete more in depth semi-structured diagnostic interviews to confirm ED diagnosis and eligibility based on inclusion/exclusion criteria. Participants will complete self-report questionnaires at pre-, mid-, posttreatment, and one-month follow-up. Participants will be given instructions on how to complete EMA and will complete five questionnaires daily for 15 days at the beginning and end of treatment, which has been piloted previously (Levinson et al., 2021; Levinson et al., 2022). Participants will be asked to complete up to 15 additional days of EMA surveys if there is insufficient data for computation of contemporaneous network analysis. Participants will be randomized to one of two active treatment conditions: 1) T-NIPT-ED ($n = 40$), or 2) CBT-E ($n = 40$). The first two sessions of treatment are identical in both conditions; conditions diverge at session three. Randomization occurs following session two of the study. Following treatment, participants will complete a one-month follow-up assessment, which will include semi-structured diagnostic interviews and self-report questionnaires. Study sessions will be rated for adherence to the treatment protocol by trained independent raters. Therapists are clinical psychology doctoral students and postdoctoral fellows trained to provide both CBT-E and T-NIPT-ED and supervised by a licensed clinical psychologist. Participants will be compensated up to \$100 for completing assessments, broken down as follows: \$25 for initial mobile assessments, \$25 for posttreatment mobile assessments, and \$50 for initial diagnostic assessments and follow-up assessments. This trial is registered at

[Clinicaltrials.gov: NCT05195840](https://clinicaltrials.gov/ct2/show/study/NCT05195840). Procedures have been approved by the university's Institutional Review Board.

Transdiagnostic Network-Informed Personalized Treatment for EDs (T-NIPT-ED)—Treatment will include 20 sessions. Treatment begins with psychoeducation about network-informed personalized treatment and why it is important to personalize treatment. Idiographic NA from EMA data will be used to model the three to four most central symptoms to target with personalized treatment. Session one comprises semi-structured diagnostic assessments, and session two involves a clinical intake interview. Sessions 3–18 will involve targeting central symptoms with pre-selected evidence-based approaches (e.g., imaginal exposure for fear of weight gain, social exposures for social anxiety; see Levinson et al., 2021 for details on development of personalized treatment modules). Treatment will conclude with two sessions of relapse prevention. The T-NIPT-ED manual is available upon request to the senior author.

Enhanced Cognitive Behavioral Therapy for EDs (CBT-E)—Treatment will be 20 sessions and will be based on Fairburn (2008). Sessions one and two mirror those in T-NIPT-ED. Sessions 3–17 of CBT-E will include psychoeducation, self-monitoring, regular eating, and in-session weighing, challenging thoughts, and making adaptive behavioral changes. Therapist and client collaboratively determine which mindsets that maintain EDs to address, including overvaluation of weight and shape, overvaluation of control overeating, restriction and dietary restraint, perfectionism, and low self-esteem. Treatment will conclude with three sessions of relapse prevention.

Measures

Recruitment and Treatment Process

Demographics.: We will collect information about participants' age, sex at birth, gender, race, ethnicity, education status, and income level.

Structured Clinical Interview for DSM-5 (SCID-5).: The SCID-5 (First et al., 2015) is a semi-structured diagnostic interview to assess for ED psychopathology. We will administer the ED modules during the phone interview and session one. The SCID-5 demonstrates good interrater reliability, test-retest reliability, and convergent validity (Osório et al., 2019; Shankman et al., 2018).

Mini-International Neuropsychiatric Interview 5.0 (MINI).: The MINI (Sheehan et al., 1998) is a semi-structured clinical interview used in the current study to identify mania, psychosis, and active suicidality at time of screening. During session one, the full MINI is administered to assess psychiatric comorbidities (e.g., major depressive disorder, social anxiety).

Eating Disorder Diagnostic Inventory (EDDI).: The EDDI (Nobakht & Dezhkam, 2000) is a clinician administered interview assessing ED symptoms. The interview has content validity and excellent test-retest reliability (Nobakht & Dezhkam, 2000). This assessment will be used to confirm ED diagnosis.

Addiction Severity Index – Lite (ASI-Lite): The ASI-Lite (McLellan et al., 1997) is a clinical interview used to assess severity of substance use over the past 30 days as well as lifetime use. The ASI-Lite demonstrates validity and reliability comparable to that of the original ASI (Cacciola et al., 2007). This assessment will be used to determine ineligibility based on excessive substance use.

Treatment Information: During an unstructured intake interview, we will gather information about prior treatment experiences including dates of treatment, type of treatment, treatment providers, and current or past use of psychiatric medications.

Feasibility and Acceptability Assessment: Retention will be defined as completion of all active components of treatment. Satisfaction with treatment will be rated using an adapted version of the Client Satisfaction Questionnaire (CSQ; Larsen et al., 1979). Additionally, we will ask for open-ended responses about participants' experience in their treatment condition.

Primary and Secondary Treatment Outcomes—See Table 1 for all primary and secondary treatment outcomes.

Eating Disorders Examination Questionnaire Version 6.0 (EDE-Q): The EDE-Q (Fairburn & Beglin, 1994) comprises 28 items assessing ED cognitions and behaviors. The measure demonstrates excellent test-retest reliability and good criterion and convergent validity (Mond et al., 2004). The global scale of the EDE-Q will be used to assess global ED symptoms.

Eating Pathology Symptoms Inventory (EPSI): The EPSI (Forbrush et al., 2013) is a 45-item measure of ED symptoms which comprises eight subscales: body dissatisfaction, binge eating, cognitive restraint, purging, restricting, excessive exercise, negative attitudes towards obesity, and muscle building. The EPSI has excellent convergent and discriminant validity, test-retest reliability, and demonstrates invariance across demographics such as sex and weight (Forbrush et al., 2013).

Quality of Life Scale (QOL): The QOL (Flanagan, 1978) is a 16-item measure that assesses satisfaction with various domains of life. The QOL will be used to examine changes in quality of life between baseline, mid-treatment, post-treatment, and follow-up timepoints. The measure demonstrates good internal consistency, test-retest reliability, and construct validity (Burckhardt & Anderson, 2003).

Clinical Impairment Assessment (CIA): The CIA (Bohn et al., 2008) is a 16-item assessment of how ED related symptoms have affected functional impairment in the past 28 days and will be used to examine changes in functional impairment between baseline, mid-treatment, post-treatment, and follow-up timepoints. The measure has excellent internal consistency as well as construct validity and test-retest reliability.

Weight, Height, Weight Suppression, and Medical Status: We will collect weight and height in order to determine BMI. We will collect participants' height, weight, and highest

adult weight to calculate weight suppression. Weight suppression is defined as the difference between one's highest weight and current weight (Lowe et al., 2018). We will also ask about current medical complications of the ED such as bradycardia, dizziness, or chest pain to determine medically compromised status, to ensure participants are medically stable for participation in the trial.

Ecological Momentary Assessment (EMA): The EMA includes 56 items which assess daily ED cognitions and behaviors along with co-occurring pathology (e.g., shame, posttraumatic stress) and will be utilized to create a personalized network and determine precision targets in personalized treatment. More details on this assessment can be found in Levinson et al., 2021.

Data Analytic Plan

Computation of Idiographic Networks

The idiographic model will include the eight symptoms with the highest means and variances as has been done prior (Levinson et al., 2021). A contemporaneous network will be generated for each participant to identify the momentary (e.g., within seconds, accounting for lagged associations) relationships among ED and co-occurring (e.g., anxiety, depression) symptoms. Networks will be created using the *graphicalVAR* package in R (Wild et al., 2010). To our knowledge, there currently are no reliable ways to estimate stability in idiographic networks. Personalized treatment will target the top three or four central symptoms depending on treatment module length.

Missing Data and Descriptives

Missing data for pre-, mid-, posttreatment, and one-month follow-up assessments will be imputed as needed using multiple imputation in R (R Core Team, 2022). For idiographic networks, if the network does not converge due to missingness or adequate variability, participant EMA data will be imputed using the Kalman filter with the *na_kalman* function in the package *imputeTS* (Moritz & Bartz-Beielstein, 2017). Descriptive statistics will be calculated for all measures. Distribution diagnostics and outlier analyses will be performed based on standard recommendations (Field, 2017).

Analytic Plan for Primary Aims

Intention-to-treat analyses will be conducted using the full sample of participants who enrolled in the study for all aims. To test the feasibility and acceptability of the randomization to T-NIPT-ED for EDs compared to CBT-E, we will conduct confirmatory analyses to examine whether conditions have similar ratings of acceptability and satisfaction. We will examine retention rates (i.e., completion of all active components of treatment) in each condition and expect retention rates above 85% in both conditions. We will also examine compliance rates (i.e., completion of all components of the study) and expect compliance rates of greater than 70% in both conditions. Participant satisfaction will be rated, and we expect high satisfaction ratings for both conditions. To test initial clinical efficacy of T-NIPT-ED versus CBT-E on clinical outcomes, we will use ln(t+1) generalized linear mixed models to compare changes in primary outcomes (i.e., ED symptoms, quality

of life, clinical impairment) between conditions across time (pre-, mid-, posttreatment, one-month follow-up). Confirmatory analyses of time by condition interactions will be used to determine whether T-NIPT-ED results in greater change in primary outcomes than CBT-E. Demographic variables may be included as covariates if they differ between conditions.

To examine hypothesized target mechanisms for exploratory purposes, we will test whether changes in NA-identified precision targets and dynamic network structure (e.g., decreased interconnectedness among symptoms) are associated with change in clinical outcomes regardless of condition. With posttreatment EMA data, we will compute an idiographic network to compare to the pretreatment idiographic network using novel finite mixture models. We will compare factor loadings and node strength for idiographic networks using Loadings Comparison Test (Christensen & Golino, 2021) and test whether changes are associated with clinical outcomes. We will then use general linear mixed models to test whether changes in factor loading differ by treatment condition. We will examine whether change (i.e., difference score) in the top three to four central symptoms is associated with change in primary clinical outcomes. Change in precision targets will be examined from pretreatment to posttreatment. Models examining change in clinical outcomes will include the following timepoints: pre-, mid-, posttreatment, and one-month follow-up.

Power Analyses

Ability to calculate stable idiographic vector autoregressive models (VAR) models is determined by the number of time points and number of symptoms included in the model (Zhu et al., 2017). The Digital Phenotyping Power Calculator (Barnett et al., 2020) suggests that 13 symptoms and 70 assessment points allows for more than adequate power to compute idiographic networks. Models from our preliminary data with the same amount of time points converged with high stability in over 99% of cases. For analyses of clinical outcomes and change in network loadings, we calculated power by estimating at least medium effect sizes based on preliminary findings of a large effect size ($d = 1.00$) in our pilot research (Levinson et al., in press). We used the package SIMR in R which uses Monte Carlo simulations to estimate power for mixed effects models based on preliminary data (Green & MacLeod, 2019). To achieve .80 power with two groups to detect a medium effect size at $\alpha = .05$ with three assessment time-points (i.e., baseline, posttreatment, one-month follow-up), 66 participants (33 per condition) are needed. We will recruit a sample of 80 to have adequate power to detect medium effects and to account for potential drop-out from treatment (up to 15%). Given a sample size of 80, we may be limited in detecting a small effect between treatment conditions, should the effect exist. A small effect size between treatment conditions may still represent clinically meaningful differences in decreases in ED symptoms and improvement in quality of life for participants. Small effects may be more meaningful when considering the context, such as a small sample size. Thus, the current study is considered a pilot study given the lack of power to detect a significant small effect.

Conclusion

We propose a pilot randomized controlled trial of T-NIPT-ED compared to CBT-E and an assessment of dynamic mechanisms of change across treatment. We will test (a) whether

T-NIPT-ED for EDs versus CBT-E are feasible and acceptable, (b) comparative clinical efficacy of T-NIPT-ED versus CBT-E, and (c) if changes in NA-identified precision targets, as well as in dynamic network structure, are associated with changes in clinical outcomes regardless of treatment condition. The development of T-NIPT-ED, a personalized, data-informed precision treatment for EDs, has the potential to improve rates of recovery in ED through targeting central mechanisms.

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Public Significance

Current evidence-based treatments for eating disorders (EDs) result in low rates of recovery, especially for adults with anorexia nervosa. Our study aims to test the feasibility, acceptability, and clinical efficacy of a data-driven, individualized approach to ED treatment, Network-Informed Personalized Treatment, compared to the current evidence-based treatment for EDs, Enhanced Cognitive Behavioral Therapy. Findings have the potential to improve treatment outcomes for EDs by identifying and targeting core symptoms maintaining EDs.

Table 1.

Primary and Secondary Outcome Assessments

Outcome	Assessment	Time points
<u>Primary Outcomes</u>		
Treatment acceptability	Adapted Client Satisfaction Questionnaire	Post
Eating disorder symptoms	Eating Disorder Examination – Questionnaire Eating Pathology Symptoms Inventory	Baseline, mid, post, one-month follow-up
Quality of life	Quality of Life Scale	Baseline, mid, post, one-month follow-up
Clinical Impairment	Clinical Impairment Assessment	Baseline, mid, post, one-month follow-up
<u>Secondary Outcomes</u>		
Network dynamics	Mobile application assessment	Sessions 1–3, post

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