

The Reward Re-Training protocol: A novel intervention approach designed to alter the reward imbalance contributing to binge eating during COVID-19

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Abstract

Reduced exposure to social reward during the COVID-19 pandemic may result in both reduced reward response to day-to-day life activities and elevated reward response to substances or naturally rewarding stimuli (e.g., food). The combined hypo- and hyper-reward responses results in a reward imbalance, which has been noted as a relevant maintenance factor for eating disorders (EDs) characterized by binge eating. This registered report describes the protocol for a pilot randomized controlled trial (RCT) comparing supportive therapy to a novel treatment targeting reward imbalance (Reward Re-Training; RRT) for individuals with binge eating. Aims of the current study include to confirm feasibility and acceptability of RRT, to evaluate the ability of RRT to engage critical targets, and to provide preliminary estimates of efficacy in reducing ED symptoms at both posttreatment and 3-month follow-up. Sixty participants will be randomized to either RRT or supportive therapy. For both conditions, treatment will be delivered in 10 weekly group outpatient therapy sessions conducted remotely using videoconferencing software. Assessments will be conducted at baseline, mid-treatment, posttreatment, and 3-month follow-up to measure feasibility, acceptability, critical treatment targets (i.e., reward to day-to-day life activities, reward to palatable foods, social isolation, and loneliness), and ED symptoms.

KEYWORDS

binge eating, eating disorders, group therapy, reward

1 | INTRODUCTION

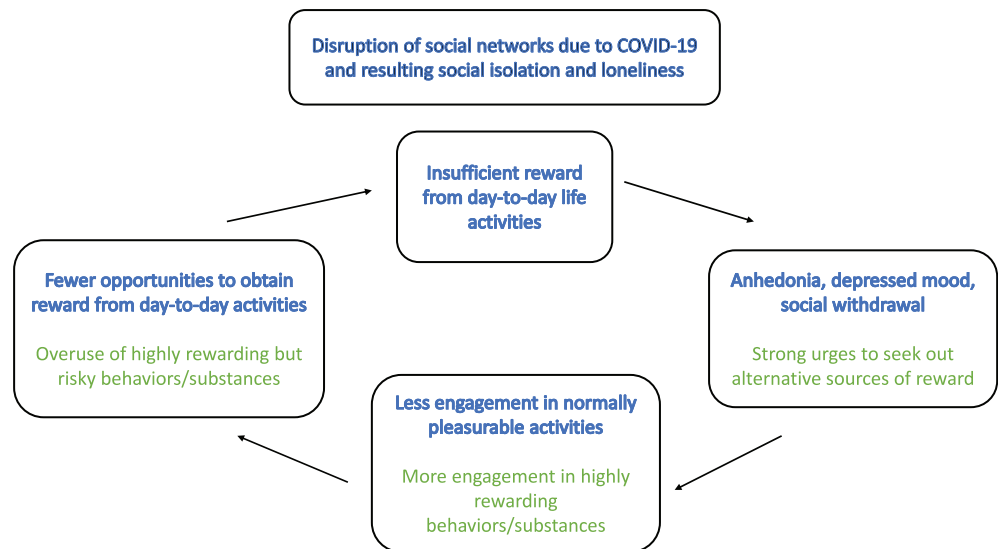
1.1 | Reduced social reward and hypo-reward response during the COVID-19 pandemic

Public health approaches to reducing the spread of COVID-19 such as social distancing, quarantine, and telework have produced sudden and widespread disruptions to social networks. These disruptions are likely

to increase social isolation (i.e., limited interactions with family, friends, romantic partners, or co-workers) and loneliness (i.e., an adverse emotional state characterized by lack of connection and intimacy) (Panchal et al., 2020). This is particularly concerning given the strong evidence that social isolation and loneliness are transdiagnostic risk factors for a range of mental health disorders including eating disorders (EDs), depression, and substance use disorders (Mushtaq, Shoib, Shah, & Mushtaq, 2014) and have a comparable or greater impact on mortality than other common risk factors such as obesity, physical inactivity, and smoking (Holt-Lunstad, 2018).

Clinical Trial Registration: NCT04661410.

FIGURE 1 Reward imbalance maintaining mental health conditions characterized by compulsive engagement in or use of highly rewarding stimuli despite adverse consequences (e.g., substance use disorders, eating disorders) [Color figure can be viewed at wileyonlinelibrary.com]



We have long understood that social interactions are among the most powerful sources of pleasure and reward in day-to-day life. Reduced exposure to sources of reward such as social interactions during the COVID-19 pandemic can lead to a hypo-reward response (e.g., low activation of dopaminergic cortico-striatal reward pathways) to conventionally rewarding stimuli (Hagerty & Williams, 2020) and reduce individuals' motivation to engage in typically pleasurable activities (Husain & Roiser, 2018). Motivation will often continue to worsen over time as any engagement in activities that does occur produces low levels of reward and is insufficiently reinforced (Husain & Roiser, 2018). Thus, a vicious cycle can develop such that day-to-day opportunities to experience reward become increasingly limited and anhedonia and depressed mood may begin or worsen. This cycle (depicted in blue text in Figure 1) has long been recognized as a maintenance factor for depression and disrupting this cycle is a key goal of effective treatment approaches for depression such as behavioral activation (Lejuez, Hopko, & Hopko, 2001).

1.2 | Reward imbalance (hyper- and hypo-reward response) and compulsive engagement in highly rewarding stimuli

A growing body of evidence suggests that insufficient reward from day-to-day life activities is a relevant maintenance factor for many mental health conditions beyond depression, in particular disorders characterized by compulsive engagement in highly rewarding stimuli despite adverse consequences (e.g., substance use disorders, EDs) (Garfield, Lubman, & Yücel, 2014; Tchanturia et al., 2012). When day-to-day life activities provide insufficient reward, these individuals are likely to seek out other stimuli that can immediately and powerfully activate neural reward pathways such as illicit substances or overindulgence in naturally rewarding behaviors such as palatable foods (Blum, Cull, Braverman, & Comings, 1996). A hyper-reward response (e.g., high activation of dopaminergic cortico-striatal reward pathways) to disorder

specific stimuli (e.g., highly palatable food, poker chips) may develop as individuals seek out larger quantities or more frequent exposure to a limited range of intensely stimulating sources of reward. We propose that these individuals may become stuck in a second vicious cycle (depicted in green text in Figure 1) whereby overreliance on one source of reward further reduces the ability to experience reward from day-to-day life activities, which subsequently drives continued engagement in highly rewarding but risky behaviors. Together, the two pathways in Figure 1 comprise what we have termed as reward imbalance. While reward imbalance is likely an important maintenance factor outside of the COVID-19 pandemic, the resulting disruptions to social networks are almost certainly exacerbating this cycle.

1.3 | Translating the concept of reward imbalance to the field of EDs

There is a strong and growing body of evidence supporting reward imbalance as an important maintenance factor for individuals with an ED characterized by binge eating (i.e., eating large amounts of food within a discrete time period accompanied by a sense of loss of control). Individuals with binge eating show clear evidence of both insufficient reward from day-to-day life activities (e.g., elevated rates of anhedonia) (Tchanturia et al., 2012) and hyper-reward response to palatable foods (Steward, Menchon, Jiménez-Murcia, Soriano-Mas, & Fernandez-Aranda, 2018). Recent studies suggest that momentary insufficient reward, such as decreases in positive affect (Schaefer et al., 2020) and momentary increases in boredom (Witt, 2015), predict greater risk for the near-time occurrence of a binge-eating episode. Collectively, these results provide preliminary support for reward imbalance as a maintenance factor for binge eating.

Individuals with EDs may also be particularly vulnerable to the disruption of social networks during COVID-19. Even before the pandemic, individuals with EDs were more likely to be socially isolated (Levine, 2012) and have worse quantity and quality of social

support (Tiller et al., 1997) compared to peers without an ED. Accordingly, there is emerging evidence suggesting an outsized impact of COVID-19 on ED symptoms (Shah, Sachdeva, & Johnston, 2020) likely due to the combination of heightened stressors, disrupted routines, and diminished social support paired with constant and easy access to palatable food within the home. These results suggest a clear and pressing need to develop treatment approaches for binge eating that target reward imbalance and address the unique challenges of the COVID-19 pandemic.

1.4 | Novel Reward Re-Training intervention and preliminary data

Prior to the COVID-19 pandemic, our team began to develop and pilot a novel treatment approach called Reward Re-Training (RRT) that is specifically designed to address reward imbalance for individuals with binge eating (Juarascio et al., 2020). RRT is distinct from traditional behavioral treatment approaches for EDs in that RRT does not directly attempt to reduce binge-eating episodes via commonly used behavioral treatment components such as regular eating and self-monitoring of food intake (Fairburn et al., 2009). Instead, RRT is designed to indirectly change binge eating by directly focusing on building a more rewarding life. RRT hypothesizes that reductions in binge eating will occur as life becomes more rewarding because individuals will no longer need to rely on binge eating as a primary source of momentary reward. RRT focuses on building sources of reward outside of food by (a) increasing sources of momentary reward, and (b) building a valued life that will provide sustained reward (see Table 1 for overview of skills).

We conducted a small ($n = 19$) trial comparing RRT to a wait-list control and found preliminary support for feasibility and acceptability (Juarascio et al., 2020). Furthermore, participants in the RRT treatment reported improvement in binge-eating symptoms, decreased reward from food, and increased reward from day-to-day life activities (Juarascio et al., 2020). However, despite the promise of our early pilot data, the use of a wait-list control as our comparison conditions suggests that additional pilot work is necessary to determine how RRT compares to a more active control condition and whether the effects of RRT are maintained over time.

1.5 | Current study

In a clinical trial, registered at clinicaltrials.gov (NCT04661410) and approved by Drexel University's IRB, we will conduct a pilot RCT that will randomize individuals with binge eating to receive either 10 sessions of RRT ($n = 30$) or supportive therapy ($n = 30$), both delivered as group-treatments via videoconferencing software. The specific aims of the current study are to confirm the feasibility and acceptability of RRT for EDs (Primary Aim 1), evaluate the ability of RRT to engage critical targets including reward to day-to-day life activities, reward to palatable foods, social isolation, and loneliness (Primary Aim 2), and provide preliminary estimates of efficacy in reducing ED symptoms at both posttreatment and 3-month follow-up (Primary Aim 3).

We hypothesize that RRT will achieve our established benchmarks for feasibility and acceptability, will produce significantly greater increases in reward to day-to-day life activities and decreases in reward to palatable foods, social isolation, and loneliness compared to supportive therapy, and will result in significant reduction of ED symptoms at posttreatment and 3-month follow-up. We will also evaluate the impact of RRT on secondary outcome variables including depression, substance use, and quality of life (Secondary Aim 1). The study is funded via NOT-MH-20-047 (Notice of Special Interest [NOSI] regarding the Availability of Administrative Supplements and Urgent Competitive Revisions for Mental Health Research on the 2019 Novel Coronavirus).

2 | METHOD

2.1 | Participants

Sixty participants will be recruited for this study (see description of power analysis in Statistical Methods). Recruitment methods will include advertisements in local media outlets and social media sites. Targeted recruitment methods will be used as needed to recruit under-represented participants (e.g., men, racial/ethnic minorities). Participants must: (a) be between age 18–65, (b) experience 12 or more binge-eating episodes (i.e., objective or subjective binge-eating episodes) in the last 3 months, (c) have a BMI equal to or greater than 18.5, (d) live in the United States, and (e) be willing/able to participate in remote treatment and assessments during scheduled times. Individuals will be excluded if they are (a) below a BMI of 18.5, (b) already receiving treatment for an ED, (c) require immediate treatment for medical complications as a result of ED symptoms, or (d) experiencing other severe psychopathology that would limit their ability to comply with the current study (e.g., severe depression with suicidal intent, active psychotic disorder, active substance use disorder). Current therapy for depression or for weight loss and medications that affect mood, eating, or weight will not be excluded for, but will be assessed at baseline and controlled for in statistical analyses as needed. Participants will be screened by phone to assess preliminary eligibility and eligibility will be confirmed during a baseline assessment described below.

2.2 | Study design

Participants will be randomized to one of two treatment conditions, RRT or supportive therapy, stratifying based on frequency of binge-eating episodes and compensatory behaviors in the month prior to treatment and depressive symptoms. For both conditions, treatment will be delivered in 10 weekly 90-minute group outpatient therapy sessions. Each group will consist of approximately 10 participants and two group therapists. Group therapists in both conditions will attend a training workshop and will receive group supervision with study investigators on a weekly basis. Group therapists will be assigned to only deliver one of the interventions to avoid

TABLE 1 Reward Re-Training (RRT) session topics

	Session title	Session description
Session 1	Introducing daily monitoring	<ul style="list-style-type: none"> Review the role of reward imbalance in maintaining binge eating Review RRT treatment rationale, to intervene on reward imbalance by increasing sources of reward outside of food <i>Homework:</i> Begin self-monitoring daily activities
Session 2	Introducing behavior change	<ul style="list-style-type: none"> Describe and provide examples of sources of momentary reward (e.g., productive tasks, healthy routine activities, immediately pleasurable activities, social activity) <i>Homework:</i> Pleasant event scheduling, or planning activities into daily schedule that provide momentary reward
Session 3	Smart goal setting	<ul style="list-style-type: none"> Introduce SMART goal setting model Discuss how to set goals that are specific, measurable, attainable, relevant, and time-bound <i>Homework:</i> Create individualized hierarchy of goals for activities that provide momentary reward
Session 4	Introduction to values	<ul style="list-style-type: none"> Introduce values and values-consistent activities as a way to build sources of sustained reward (e.g., meaning, fulfillment, life satisfaction) into daily life <i>Homework:</i> Complete worksheets to begin clarifying values
Session 5	Applying values to behavior	<ul style="list-style-type: none"> Apply SMART goal setting to values-consistent activities <i>Homework:</i> Begin planning values-consistent activities into daily schedule
Session 6	Barriers to living a valued life	<ul style="list-style-type: none"> Review common barriers to living a valued life (e.g., difficulty keeping values in mind, conflicting values) Problem solve and introduce skills for addressing barriers (e.g., visual reminders of values, integrating multiple values into an activity) <i>Homework:</i> Implement problem solving skills when experiencing barriers to values-consistent activity goals
Session 7	Shifting attention to positive momentary experiences	<ul style="list-style-type: none"> Discuss negative thinking biases and their impact on experiencing reward during activities Review cognitive skills to address negative thinking biases (e.g., noticing the enjoyable aspects or benefits of the activity) <i>Homework:</i> Practice shifting attention to positive momentary experiences
Session 8	Adding sources of reward to difficult activities and willingness	<ul style="list-style-type: none"> Discuss ways to make activities that are not pleasurable in the moment more enjoyable by pairing with a rewarding activity (e.g., listening to music while doing chores) Introduce psychological concept of willingness to move toward values even when difficult or distressing <i>Homework:</i> Try making difficult or distressing activities more enjoyable by adding sources of reward.
Session 9	Building a sense of self-efficacy	<ul style="list-style-type: none"> Discuss the importance of celebrating accomplishments for building self-efficacy and obtaining reward from difficult experience <i>Homework:</i> Spend time reviewing accomplishments from treatment
Session 10	Relapse prevention, recognizing accomplishments	<ul style="list-style-type: none"> Review key skills from treatment Create relapse prevention plan for end of treatment

contamination across randomized groups. Assessments will be conducted by trained assessors at baseline, mid-treatment (after Session 5), posttreatment (after Session 10), and 3-month follow-up. Study assessments and group therapy sessions will be conducted using an encrypted HIPAA-compliant version of Zoom videoconferencing software which our team is currently using in several NIH-funded clinical trials. Informed consent will be collected using an electronic consent form that participants will be asked to complete during the baseline appointment after reviewing the consent form jointly with a staff member.

2.3 | RRT treatment

See Table 1 for a detailed description of the RRT treatment by session. RRT includes evidence-based components of behavioral treatments for depression (e.g., pleasant event scheduling) and acceptance and commitment therapy (e.g., values clarity) (Hayes, Strosahl, & Wilson, 2009; Lejuez et al., 2001) to increase sources of reward outside of food. When choosing pleasant events, RRT specifically encourages individuals to prioritize activities that are social in nature given evidence that these activities tend to be produce more momentary reward than solitary activities

(Sun, Harris, & Vazire, 2019). Similarly, given that for most individuals, meaningful and fulfilling relationships are among the most important valued life domains (Stavrova & Luhmann, 2016), RRT particularly focuses on building valued life domains related to relationships (e.g., romantic relationships, family relationships, friendships). RRT also encourages the use of several cognitive strategies designed to enhance the ability to experience reward from conventionally rewarding activities (e.g., shifting attention to positive momentary experiences, building a sense of self-efficacy).

2.4 | Supportive therapy group

We considered several possible comparison conditions for the proposed trial (e.g., treatment-as-usual, self-help reading materials, a evidence-based treatment comparison such as CBT) before determining that a group-based supportive therapy condition was the best control condition for the current state of the research. Supportive therapy will allow us to control for many of the nonspecifics of therapy such as working with an empathetic provider and instilling hope and optimism. The group-nature of the supportive therapy condition will also allow us to better determine whether treatment gains were due to the content of RRT or if comparable gains can be achieved by simply increasing social connection and support via a group treatment. The supportive therapy condition will be based on existing manuals (Novalis, Virginia Singer, & Peele, 2019). As is typical for supportive therapy conditions, the group leader will be instructed to be nondirective and allow the patients to determine the focus of each session. The group leader will be encouraged to use reflective listening, elicit and validate affect, and offer empathetic comments. Group leaders will also be instructed to avoid any cognitive and behavioral techniques that could overlap with RRT.

2.5 | Measures

2.5.1 | Feasibility and acceptability (Primary Aim 1)

Assessment of feasibility will include percent of eligible patients enrolled, attrition, and study retention. We will use a feedback questionnaire (FQ) to obtain qualitative acceptability ratings, which will be modified from FQs used in our prior intervention development projects.

2.5.2 | Target engagement (Primary Aim 2)

We will use the Power of Food Scale (PFS) (Lowe et al., 2009) to assess reward response to palatable foods, and the Temporal Experience of Pleasure Scale (TEPS) (Rizvi et al., 2015) and Dimensional Anhedonia Rating Scale (Gard, Gard, Kring, & John, 2006) to measure anticipatory and consummatory experiences of pleasure in day-to-day life activities. The NIH Toolbox Social Relationship Scale (Cyranowski et al., 2013) will be used to measure social support, companionship, and social distress and better assess the impact of RRT on social isolation and loneliness as additional targets.

2.5.3 | Preliminary estimates of efficacy (Primary Aim 3)

We will use The Eating Disorder Examination (Cooper & Fairburn, 1987) semi-structured interview for the assessment of ED symptoms. We will use the total number of objective and subjective binge episodes in the last 28 days and EDE global scores as the primary outcomes. Remission status will also be evaluated at each assessment following the baseline assessment and will be defined as the absence of any binge episodes or compensatory behaviors in the 28 days prior to the assessment point and an EDE global score within 1 standard deviation of the community norm (EDE global <1.74) (Fairburn et al., 2009).

2.5.4 | Secondary outcomes (Secondary Aim 1)

We chose to use commonly-used and well-validated measures of depression (Beck Depression Inventory-II [Dozois, Dobson, & Ahnberg, 1998]), substance use (Alcohol, Smoking, and Substance Involvement Screening Test [Group, 2002]), and quality of life (Quality of Life Inventory [Frisch, Cornell, Villanueva, & Retzlaff, 1992]) to assess secondary outcome measures.

2.5.5 | Additional measures

We will measure the effect of public health approaches for reducing the spread of COVID-19 (e.g., social distancing, quarantine) on participant's behaviors, emotions, and social interactions at each assessment point (Changes to Your Life due to COVID-19 Inventory) (COVID-19 Survey for Workers, 2020). Although this measure was not included in the NIMH grant proposal or clinical trial registration, with NIMH guidance, we chose to include this measure because the changing social environment due to the COVID-19 pandemic may impact treatment outcomes. We plan to control for changes in participant's social environment in statistical analyses as needed.

2.6 | Statistical analyses

Power calculations were conducted to determine the sample size needed to achieve 80% power in simple mediation models. Under the assumption of a medium effect for intervention with the mediator and medium effect for the mediator on outcome controlled for intervention, the required sample size is 72 in total with 36 per intervention arm. Given our relatively small sample size ($n = 60$), our study is powered to detect large effect sizes. While we observed large effect sizes in our pilot trial of RRT compared to a wait list control, we anticipate that the effect sizes may be smaller in the current trial as supportive therapy is an active treatment condition. It is likely that we may be underpowered for formal tests of statistical significance in this preliminary study. We will rely on effect sizes for interpretation when underpowered.

Patterns of missing data will be examined. Likelihood-based estimation methods and multiple imputation models will be used to handle missing data. Baseline characteristics will be compared between treatment conditions using ANOVA (or nonparametric Kruskal Wallis test, as appropriate) for continuous variables and a chi-square test for categorical variables. Key baseline variables that differ by condition will be considered for use as covariates in the analyses described below.

2.6.1 | Feasibility and acceptability (Primary Aim 1)

We will use the following benchmarks to confirm feasibility and acceptability: (a) recruitment success: enrollment of 60 patients; (b) attrition: retention of >75% of patients through all assessments; (c) study retention: 90% attendance of all treatment groups; (d) satisfaction: patients express high satisfaction with RRT based on FQs.

2.6.2 | Target engagement (Primary Aim 2)

To evaluate the effect of each treatment condition on hypothesized targets, we will model the pattern of change in reward response to palatable food, day-to-day life activities, social isolation, and loneliness separately over time using multilevel models (Raudenbush & Bryk, 2002). The cross-level interaction between time and treatment condition will be used to determine the effect of treatment condition on the pattern of change in the hypothesized targets. We will conduct mediation analyses to determine whether temporally-precedent changes in the hypothesized targets mediate differences in the primary outcomes between the two treatment conditions. In particular, we will examine improvement in each hypothesized target from baseline to mid-treatment assessment predicting post-treatment outcomes and improvement at posttreatment predicting 3-month follow-up outcomes.

2.6.3 | Preliminary estimates of efficacy (Primary Aim 3)

To evaluate the effect of treatment condition on primary outcomes, we will use linear mixed effects models to model the pattern of change in binge-eating frequency and EDE global scores separately over time. The cross-level interaction between time and the treatment condition will be used to determine the effect of treatment condition on the pattern of change in the primary outcomes at posttreatment and at 3-month follow-up.

2.6.4 | Secondary outcomes (Secondary Aim 1)

We will use the same analytic approach described for Primary Aim 3 but will test the impact of treatment condition on secondary outcomes including depression, substance abuse, and quality of life.

3 | CONCLUSIONS

The current study will provide critical pilot data to determine whether RRT should be further tested as a treatment approach for binge eating in a fully powered clinical trial. If the current study finds that RRT demonstrates adequate feasibility and acceptability, produces clinically significant reductions in ED symptoms, and targets the hypothesized treatment mechanisms (e.g., decreased reward from food, increased reward from day-to-day life activities), this pilot data would highlight the role of reward imbalance in maintaining binge eating and suggest further testing to confirm the ability of RRT to modify reward imbalance and improve binge-eating symptoms.

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CONFLICT OF INTEREST

The authors declare no potential conflict of interests.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon request.

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