Bilateral stimulation versus standard care in the treatment of food anxiety in eating disorder patients: A pilot study

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Study Completed: 12/08/2023

Study Protocol and Statistical Analysis Plan

Background and Rationale

Regular eating is essential for eating disorder (ED) recovery; however, eating often evokes anxiety, fear, and distress. Bilateral stimulation (BLS), a component of eye movement desensitization and reprocessing (EMDR), has demonstrated efficacy in trauma treatment, but its effects on post-meal distress in ED populations have not been well studied. This pilot study evaluated whether BLS administered after eating could reduce emotional distress and ED-related symptoms.

Objectives

1. To assess whether BLS reduced food-related anxiety, depression, and ED symptoms compared to standard treatment (ST) alone.
2. To explore whether reductions in distress were associated with changes in weight, vital signs, or laboratory values.

Study Design

This was a pilot, non-randomized, two-arm clinical trial conducted in a virtual outpatient ED treatment setting. The intervention occurred across 4 consecutive sessions (4–12 weeks depending on appointment frequency). Assessments were conducted at baseline, during intervention sessions (intervention group only), and within one week post-treatment. Blinding was not feasible due to the nature of the intervention.

Participants

Eight adults (≥18 years) with DSM-5 diagnosed eating disorders (anorexia nervosa, bulimia nervosa, binge eating disorder, or OSFED) were recruited from the primary investigator's outpatient practice. Participants were medically stable and provided informed consent.

Inclusion criteria:

- Age ≥18 years
- DSM-5 ED diagnosis
- Medically stable (vital signs within defined ranges)
- Able to consent and participate voluntarily

Exclusion criteria:

- Age <18

- Certain non-ED diagnoses (e.g., pica, cyclic vomiting syndrome)
- Medical instability or acute suicide risk

Participants self-selected into standard treatment (ST; n=4) or standard treatment plus BLS (ST+BLS; n=4). One participant withdrew early and was analyzed within the control group.

Interventions

Standard Treatment (ST)

Participants continued outpatient care, including dietary counseling, food logging, and coping strategies.

Standard Treatment Plus Bilateral Stimulation (ST+BLS)

Participants completed sessions involving:

- Consumption of a meal (including a self-identified "fear food")
- Pre-intervention questionnaire assessing thoughts, emotions, and ED urges
- Researcher-guided BLS protocol, during which participants actively performed alternating bilateral tapping (e.g., shoulders, thighs, or feet)
- Three 20-second tapping rounds focusing on:
    1. Meal-related thoughts and emotions
    2. Desired thoughts
    3. Desired emotional states
- Post-intervention questionnaire and discussion

This protocol was repeated across 4 consecutive sessions over the course of 4-12 weeks depending on scheduled frequency of appointments.

Outcomes

Primary outcome:

- Change in self-reported anxiety and depressive symptoms immediately before and after BLS sessions (intervention group only)

Secondary outcomes:

- Change from baseline to post-treatment in anxiety, depression, and ED symptoms across both groups

Validated measures included:

- State–Trait Anxiety Inventory (STAI)
- Beck Depression Inventory-II (BDI-II)
- Eating Disorder Examination Questionnaire-Short (EDE-QS)

Statistical Analysis Plan

Descriptive statistics were used to summarize participant characteristics and outcomes. Within-session changes in the intervention group were assessed using pre–post comparisons. Between-group differences were evaluated descriptively. Due to the small sample size and pilot nature of the study, inferential statistical testing was limited and results were considered exploratory. Missing data were handled by analyzing participants with complete data for each outcome.

Changes in weight, vital signs, and laboratory values were planned to be assessed from baseline to end of treatment (4–12 weeks) and examined in relation to changes in psychological distress. However, these measures were not consistently collected due to the short study duration and logistical barriers, including limited access to clinical appointments and measurement tools (e.g., blind weight scales and home monitoring devices). As a result, insufficient data were available for analysis.

Ethics

This study was approved by the San Francisco State University Institutional Review Board (Protocol #2022-258). All participants provided informed consent. Participation was voluntary, and participants could withdraw at any time without consequence.

San Francisco State University
Informed Consent to Participate in Research

Bilateral Stimulation (BLS) potential use in treating patient's relationship with food and nutritional complications of eating disorders.

A. PURPOSE AND BACKGROUND

The purpose of this research is to explore new treatments for people with eating disorders. The researcher, Naia Riley Cook, is a graduate student at San Francisco State University completing her master's degree/honor's thesis in Family & Consumer Sciences with an emphasis in Nutrition.

You are being asked to take part in this study because you are one of my clients in eating disorder recovery. I will teach you how to use a coping skill called bilateral stimulation (BLS) which creates new connections between the two sides of the brain. This can reduce anxiety and help you feel more relaxed.

B. PROCEDURES

These are the steps that will happen if you agree to take part in this research project:

- On day one, you will complete three surveys about depression, anxiety, and eating disorder thoughts. Each survey takes about 10 minutes.
- There will be two groups and you will choose which one you want to be in.
    - Group One: Standard Treatment. This group will take the surveys at the start and end of four weeks and will continue treatment as per usual (meeting with your dietitian, following your meal plan, using coping skills that you already have).
    - Group Two: Intervention Group. This group will take the surveys before and after the four weeks and will also learn how to use bilateral stimulation (BLS). You will eat a meal in session, then I will lead you through BLS after the meal and ask you questions about your thoughts during the meal. You will tap your hands or feet side to side while I am talking and then take a short survey about how you feel. This will take place 1-2 times per week for 4 weeks.
- If you are part of the intervention group, I recommend you eat a "fear food" during the session to work on the thoughts you may have about those foods. A "fear food" is a food or food group that someone avoids out of fear for what might happen (examples: weight gain, feeling out of control, feeling extreme guilt and shame, choking/getting sick).
- After the meal you will be asked to complete a brief questionnaire about your thoughts and feelings during the meal and then write what you would have liked to think and feel about your food or body.
- I will lead you through 3-5 minutes of bilateral stimulation (BLS), which will include tapping the feet or hands side-to-side. I will ask you questions about how you felt during the meal and how you would have liked to feel.
- Then you will answer 2 questions about if your thoughts and feelings changed and add any notable comments (if applicable).

- The intervention group will follow this protocol for four weeks: eat 1-2 meals per week in session, answer questions, go through BLS, answer final questions. You will eat your other meals outside of sessions as per usual.
- After the four weeks, you will take the 3 surveys again about depression, anxiety, and eating disorder thoughts.
- Obtaining lab values and vitals are optional, though highly encouraged. If you are willing to get labs and vital signs taken, I request that you do this within 4 weeks of the start and 4 weeks of the end of the study (*see Section F. Costs for more details*).
- The total time commitment is 2 hours over the course of 4 weeks. This excludes the time spent eating the meal and the time spent obtaining labs and vitals as that is typically part of recovery and not exclusive to this project.

C. RISKS

There is a risk of discomfort or anxiety due to the nature of the questions asked; however, you can answer only those questions you choose to answer and can stop participation in the research at any time. There is a risk of loss of privacy. However, no names or identities will be used in any published reports of the research. Only the researcher will have access to the research data.

D. CONFIDENTIALITY

The research data will be kept in a secure location and only the researcher will have access to the data. All research data will be stored in an encrypted document on a password protected computer.

E. DIRECT BENEFITS

As this is a new study, there are no formerly identified benefits to the participant.

F. COSTS

If you choose to get labs tested, you may incur expenses for the doctor appointment and/or lab tests if it is not covered by insurance. Due to the potential cost and/or inconvenience of laboratory tests, you can decide not to get labs tested and still be eligible to participate in the research study with no consequences.

If you choose to do labs and vitals, this is what I am requesting: height, weight, blood pressure, heart rate, basic metabolic lab panel (blood glucose, sodium, potassium, phosphorous), complete blood count (white blood cell count, red blood cell count, hemoglobin, hematocrit, mean corpuscular volume), and liver function tests (ALT, AST, alkaline phosphatase). These labs have been chosen because changes in nutrition status over 4-12 weeks can be reflected in these particular lab values and will help me know if the study is effective at improving nutritional status.

I encourage you to discuss the potential cost for these lab tests with your doctor and your insurance provider. If your doctor considers these tests as routine/standard and is able to order them for you, then your insurance may cover the cost. However, it is important to note that your insurance may deny coverage if your primary care physician does not code the

order correctly or if the insurance determines there is no good clinical reason for the tests. Without insurance coverage, these tests can be very expensive ($3,000-5,000) and you will not be asked to do them if you do not have insurance, your insurance will not pay for them, or you do not want to get them tested.

The lab tests are encouraged but not required. If you do not wish to get the labs tested, there is an alternative to schedule a doctor's appointment to check weight, blood pressure, and heart rate or to test using an at-home scale and/or blood pressure cuff. You can use an at-home blood pressure cuff if you are supervised by myself or a doctor to make sure you take accurate measurements. If you do not have at-home devices, the average cost for a scale is $10-15 and blood pressure/heart rate cuff is $30-40.

You are still eligible to participate in the research study with no penalty if you decide not to get labs tested or not to test at home. There will be no other costs to you for participating in this research.

G. COMPENSATION

There will be no compensation for participating in this research.

H. ALTERNATIVES

The alternative is not to participate in the research. If emotional discomfort occurs, you will have access to your treatment team to discuss your experience.

I.. QUESTIONS

If you have any questions about the study, you contact the researcher by email at nutritionwithnaia@gmail.com. If you prefer anonymous contact, you can call from a blocked phone number to (415) 323-6942. You may contact the researcher's advisor, Professor Gretchen George at glgeorge@sfsu.edu .

Questions about your rights as a study participant, or comments or complaints about the study, may also be addressed to the Human and Animal Protections at (415) 338-1093 or protocol@sfsu.edu.

J. CONSENT

You have been given a copy of this consent form to keep.

PARTICIPATION IN THIS RESEARCH IS VOLUNTARY. You are free to decline to participate in this research, or to withdraw your participation at any point, without penalty. Your decision whether or not to participate in this research will have no influence on your present or future status at San Francisco State University.

Signature _____ Date: _____
Research Participant

Signature _____ Date: _____
Researcher