

AWARD NUMBER: W81XWH-18-1-0220

TITLE: Targeting Food Cue Reactivity and Satiety Sensitivity to Decrease Binge Eating and Weight

PRINCIPAL INVESTIGATOR: Kerri Boutelle, Ph.D

CONTRACTING ORGANIZATION: University of California, San Diego, La Jolla, CA

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14. ABSTRACT The purpose of the study is to compare a novel treatment, named Regulation of Cues (ROC), to Cognitive Behavior Therapy (CBT), to address binge eating and weight loss in veterans. The objectives of the study are: 1) to evaluate feasibility and acceptability of ROC and CBT and 2) to evaluate the efficacy of both treatments on reduction of binge eating and weight among 120 Veterans with subclinical or clinical Binge Eating Disorder (BED) with comorbid overweight/obesity (OW/OB). By the end of Year 4, 131 participants were randomized into treatment. All treatments were completed. All assessments were completed for Cohort 1-4. Due to the COVID-19 pandemic related delay in recruitment from Q3 Year 3 through Q1 Year 4, DoD approved one-year no cost extension (NCE) to complete the last Cohort 5 6-month follow-up assessments and related data entry, cleaning, and auditing. Statistical analyses of primary aims will be completed by Q4 Year 5 while secondary and exploratory aim analyses will most likely be completed after the NCE. No unanticipated problems involving risk to subjects or others have occurred since the study began. Regulatory documents, amendments to research protocols, adverse events, and protocol deviations were submitted in a timely manner and approved/acknowledged by local IRBs and DoD HRPO.									
15. SUBJECT TERMS binge-eating disorder, obesity, overweight, veterans, Regulation of Cues (ROC), Cognitive Behavior Therapy (CBT)									
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TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	4
2. Keywords	4
3. Accomplishments	4
4. Impact	7
5. Changes/Problems	8
6. Products	9
7. Participants & Other Collaborating Organizations	10
8. Special Reporting Requirements.....	16
9. Appendices	16

1. INTRODUCTION:

The objectives of the study are: 1) to evaluate feasibility and acceptability of a novel intervention, Regulation of Cues (ROC), and Cognitive Behavior Therapy (CBT), and 2) to evaluate the efficacy of both treatments on reduction of binge eating and weight loss among 120 Veterans with subclinical or clinical Binge Eating Disorder (BED) with comorbid overweight/obesity (OW/OB).

2. KEYWORDS:

binge-eating disorder, obesity, overweight, veterans, Regulation of Cues (ROC), Cognitive Behavior Therapy (CBT)

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Year 4 major goals include: 1) preparing and submitting regulatory documents and research protocols as needed, 2) completing participant recruitment, treatment, and assessments, and 3) completing data entry, auditing, analysis, and dissemination of results and treatment.

1. Preparation and submission of regulatory documents and research protocols as needed.

UCSD and VASDHS submitted and received approvals for amendments, annual IRB report for continuing review, and quarterly technical progress reports to local IRBs and/or DoD HRPO in a timely manner during Year 4. Therefore, 100% of goals stated in the approved SOW were met.

2. Completion of participant recruitment, treatment, and assessments.

The approved SOW states we planned to complete recruitment of study participants by Q4 Year 3. However, due to the delay in recruitment that was reported previously, we didn't meet 100% of the recruitment goal until Q2 Year 4. We randomized 131 participants into treatment by Q2 Year 4.

The approved SOW states we will complete treatment of final cohort of participants by Q2 Year 4. We didn't meet 100% of the goal until Q4 Year 4. Assessment staff continued to participate in weekly supervision to maintain competency and fidelity of assessments (100% of the SOW goal). The approved SOW states we will complete 6-month follow-up assessment with a final participant by Q4 Year 4. Eighty percent of the goal was met by Q4 Year 4.

3. Completion of data entry, auditing, analysis, and dissemination of results and treatment.

The approved SOW states we will complete data entry, auditing, data analyses and finalizing treatment materials for potential distributions within the VA and other active-duty mental health venues as appropriate by Q4 Year 4. All data were entered into database except cohort 5 6-month follow-up assessment data (80% of the SOW goal) and most of data entered into database have been cleaned and audited (70% of the SOW goal). No statistical analyses of primary, secondary, and exploratory aims have been completed by Q4 Year 4.

What was accomplished under these goals?

Preparation and submission of regulatory documents and research protocols:

1. *Submit amendments, adverse events, and protocol deviations as needed.*
UCSD submitted required documents in a timely manner and received approvals from local IRBs and DoD HRPO during Year 4. In January 2022 UCSD requested to add 3 questions to online screening to improve efficiency in determining subject eligibility for the study. Between 7/1/21 and 7/31/22 UCSD IRB underwent a rolling transition from the old legacy IRB system (eIRB system) to the new Quali system. In response, UCSD submitted an amendment request for a rollover to the new system to UCSD IRB, which was approved on 5/25/22. These amendments were reported and acknowledged by DoD HRPO in a timely manner. VASDHS did not have any required documents to submit during Year 4.
2. *Coordinate with sites for annual IRB report for continuing review.*
UCSD received an approval letter of a continuing review application from the UCSD IRB on 6/16/22, and DoD HRPO acknowledged the approval on 7/1/22. VASDHS received an approval letter of a continuing review application from VASDHS IRB on 8/29/22 in which VASDHS IRB stated that the study is no longer subject to the requirements of continuing review by the IRB in the future. VASDHS reported the approval to DoD HRPO on 9/20/22.

Training and certification of assessment staff and treatment staff:

3. *Maintain competency and fidelity of assessment and treatment staff throughout the study until the end of Year 4.*
The study continued to have weekly assessment meetings and treatment supervision to clarify or address staff questions and concerns and to maintain fidelity of assessment and treatment staff throughout Year 4.

Participant recruitment, treatment, and assessment:

4. Complete recruitment of study participants by the end of Year 3.

Due to the COVID-19 pandemic and changes in recruitment parameters for online recruitment on Facebook, we didn't complete participant recruitment until Q2 Year 4. We randomized 131 participants into treatment by Q2 Year 4.

5. Complete treatment of final cohort of participants by Q2 Year 4.

Due to the delay in recruitment, participants in the last cohort didn't complete treatment until Q4 Year 4.

6. Complete 6-month follow-up assessment with final participant by Q4 Year 4.

By the end of Year 4, cohort 1-4 participants completed all the assessments. The last 6-month follow-up assessments of cohort 5 participants are scheduled to be conducted between January and March 2023 (Q2 Year 5).

Data entry, cleaning, auditing, analysis and dissemination of results and treatment:

7. Enter, clean, and analyze all data and disseminate results and treatment by Q4 Year 4.

All the cohort 1-5 data except cohort 5 6-month follow-up assessment data were entered into database (80% of the SOW goal). We are currently cleaning and auditing these data (70% of the SOW goal).

What opportunities for training and professional development has the project provided?

Nothing to report.

How were the results disseminated to communities of interest?

Nothing to report.

What do you plan to do during the next reporting period to accomplish the goals?

Effective on 9/29/22, DoD approved NCE for 12 months (Year 5). During Q1 Year 5 we will continue entering, cleaning, and auditing cohort 1-5 data except cohort 5 6-month follow-up assessment data. We will schedule cohort 5 6-month follow-up assessments, which will be conducted between January and March 2023 (Q2 Year 5). UCSD and VASDHS will continue to coordinate preparation and submission of regulatory documents as needed in a timely manner.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to report.

What was the impact on other disciplines?

Nothing to report.

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology?

Nothing to report.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Nothing to report.

Actual or anticipated problems or delays and actions or plans to resolve them

Nothing to report.

Changes that had a significant impact on expenditures

Nothing to report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

Nothing to report.

Significant changes in use or care of vertebrate animals

Not applicable.

Significant changes in use of biohazards and/or select agents

Not applicable.

6. PRODUCTS:

- **Publications, conference papers, and presentations**

Journal publications.

Nothing to report.

Books or other non-periodical, one-time publications.

Nothing to report.

Other publications, conference papers and presentations.

Nothing to report.

- **Website(s) or other Internet site(s)**

Nothing to report.

- **Technologies or techniques**

Nothing to report.

- **Inventions, patent applications, and/or licenses**

Nothing to report.

- **Other Products**

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

1. Kerri Boutelle

PI (UCSD PI)

3.6 person month

Dr. Boutelle provided overall direction of the project, including development, coordination, implementation, and monitoring of program activities. She was responsible for all fiscal and administrative decision-making, and for all design, analyses, and manuscript planning. She was also responsible for the daily and monthly timeline for all operational features of the trial. Decisions to alter the design or implement critical problem-solving steps were determined by Dr. Boutelle with consultation from the SEC.

2. Niloofar Afari

Co-I (VA San Diego PI)

1.2 person month

Dr. Niloofar collaborated on design and implementation of the study, provided input on assessment tools, and oversight of recruitment at VASDHS.

3. David Strong

Co-I (UCSD Co-I)

0.60 person month

Dr. Strong assisted in refining recruitment, treatment, and assessment protocols. He contributed to the development of data collection protocols.

4. Saori Obayashi

UCSD Project Director

10.2 person month

Dr. Obayashi oversaw the execution of the project, coordinated across sites to prepare regulatory documents, hired and managed the study coordinator. She also ensured the study was conducted in a timely and appropriate manner.

5. Paige Awtrey

UCSD Project Coordinator

7.1 person month

Ms. Awtrey assisted Drs. Boutelle and Obayashi with recruitment, assessment and treatment protocols, and amendment request submission to UCSD IRB. She interviewed and managed undergraduate research assistants. Ms. Awtrey was also trained and certified on the interviews and many tasks which were used in the study

6. Keenan Adams (replaced Ms. Awtrey after her resignation from the study)

UCSD Project Coordinator

4.7 person month

Mr. Adams assisted Drs. Boutelle and Obayashi with recruitment, assessment and treatment protocols, and amendment request submission to UCSD IRB. He interviewed and managed undergraduate research assistants. Mr. Adams was also trained on many tasks which were used in the study.

7. Jacquelyn Felix-Wilson

UCSD Clinical Assessor and Interventionist

4.8 person month

Dr. Felix-Wilson was trained to be certified for interviews and tasks used in the study. She also assisted in interventions.

8. Kaylen Moline

UCSD Recruitment Coordinator

2.1 person month

Ms. Moline assisted in the development of recruitment protocols and materials. Ms. Moline has developed relationships with local physicians and community contacts to recruit study subjects. She has conducted the online recruitment for the study.

9. Angela Camodeca

VASDHS Research Associate

3 person month

Ms. Camodeca assisted in regulatory updates, recruitment, data entry and management, and served as liaison with UCSD.

10. Eastern Kang

UCSD Postdoctoral Fellow, Assistant Project Scientist

3 person month

Dr. Kang assisted in setting up the RedCAP online survey system which was used for data collection. Dr. Kang also assists in managing, combining, cleaning the baseline data.

11. Sally Nguyen

UCSD Undergraduate Research Assistant

2.2 person month

Ms. Nguyen was trained and assisted the project coordinator with assessment visits, administering surveys, measuring height and weight, entering data, and providing computer and other tasks.

12. Phuoc Vo

UCSD Undergraduate Research Assistant

2.2 person month

Ms. Vo was trained and assisted the project coordinator with assessment visits, administering surveys, measuring height and weight, entering data, and providing computer and other tasks.

13. Andre Hirakawa

UCSD Undergraduate Research Assistant

5.1 person month

Mr. Hirakawa was trained and assisted the project coordinator with assessment visits, administering surveys, measuring height and weight, entering data, and providing computer and other tasks.

14. Kaela Alagos

UCSD Undergraduate Research Assistant

2.6 person month

Ms. Alagos was trained and assisted the project coordinator with assessment visits, administering surveys, measuring height and weight, entering data, and providing computer and other tasks.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

1. Kerri Boutelle

New grants:

R01HD106991 (PI: Boutelle) 8/15/22 - 6/30/27 2.7 calendar months
NIH/NICHD Total Award:

Telehealth parent-only treatment for youth with autism spectrum disorder and overweight/obesity

This project is part of a larger center grant evaluating chronic disease risk among Latino families. The purpose of this project is to evaluate the efficacy of parent-based treatment for all caregivers compared to a health education control for Latino children with overweight or obesity.

Grants that received the NCE

W81XWH-18-1-0220 (PI: Boutelle) 9/30/2018 – 9/29/2023 (NCE) 2.7 calendar months
DOD USAMRAA (total)

Targeting Food Cue Reactivity and Satiety Sensitivity to Decrease Binge Eating and Weight

The major goals of this project are to evaluate the efficacy of a novel treatment, Regulation of Cues on reducing binge eating as well as assisting with weight loss, among Veterans with clinical and subclinical binge eating compared to cognitive behavioral therapy. Role: Co-I

R01DK114794 (PI: Boutelle) 9/1/2017-06/30/23 (NCE) 0.69 calendar months
NIH/NIDDK Funding Amount:

Behavioral Phenotype of Reward and Inhibition in Parent-Child Weight Loss

The objective of this application is to use innovative methodologies to collect critical data on aspects of cognitive functioning regarding reward and inhibition in children and parents participating in a weight-loss program over 18-months.

Grants that received the second NCE

R01DK108686 (PI: Boutelle) 7/2016-6/2023 .15 calendar months
NIH/NIDDK Total Award Amount (including indirect costs):

Effect of Treatment Dose on Childhood Obesity

The objective of this study is to conduct a fully powered randomized controlled trial comparing Guided Self Help treatment based on family based behavioral programs (gshFBT) with a family based behavioral treatment (FBT) in children across the overweight and obese weight spectrum.

R01DK106157 (PI: Rhee) 8/2016-7/2023 0 calendar months
NIH/NIDDK

Parent Training Program to Improve Outcomes in Childhood Obesity Treatment

The objective of this study is to evaluate the efficacy of a program that combines family-based behavioral therapy and comprehensive parenting training to standard family-based behavioral therapy on child BMI/BMI z-score outcomes. Mediators and moderators of child outcomes such as parenting style, parenting strategies, behavioral strategies, and child-level factors (like impulsive behavior and temperament) will be evaluated. Role: Co-I

2. Niloofar Afari

New grants:

1 IK2RX003634-01A2 (Wooldridge) 04/01/22-06/31/27 1.5 calendar months
VA RR&D (total)

Real-World Assessment of Daily Functioning in Veterans with Type 2 Diabetes

The primary objective of this study is to understand the within-person interplay between comorbid symptoms, social context, and daily activities among Veterans with T2D with a focus on physical activity behavior and other diabetes self-management behaviors. Role: Primary Mentor

Grant that was previously active and is in the No Cost Extension:

W81XWH-18-1-0220 (PI: Boutelle; Afari site PI) 9/30/2018 – 9/29/203 (NCE) 1.2 calendar months
DOD USAMRAA (total)

Targeting Food Cue Reactivity and Satiety Sensitivity to Decrease Binge Eating and Weight

The major goals of this project are to evaluate the efficacy of a novel treatment, Regulation of Cues on reducing binge eating as well as assisting with weight loss, among Veterans with clinical and subclinical binge eating compared to cognitive behavioral therapy. Role: Site PI

U01 DK082325-14 (PI: Buchwald; Afari site PI) 9/15/2008 – 06/30/2023 (NCE)

0.6 calendar months

NIH/NIDDK (total)

Washington State University Urologic Chronic Pelvic Pain Syndromes Discovery Center

This project is one of 6 Discovery Centers in the Multi-Disciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) Research Network. Role: Site PI

Grant that received the second NCE:

1R01DK106415 (PI: Afari) 6/01/16–12/31/22 (NCE) 3.6 calendar months
NIH/NIDDK (total)

An ACT-enhanced Weight Management and Fitness Program for Navy Personnel

The objective of this project is to conduct a randomized controlled trial to examine whether supplementing an existing weight management program (ShipShape) with acceptance & commitment training improves the weight loss in Navy personnel. Effectiveness will be measured by assessing % weight loss, changes in body fat %, BMI, physical activity, problem eating, quality of life, and pass rate for the Navy's body composition and physical fitness assessment in active duty service members.

3. David Strong

New grants:

T32CF4745 (PI: Jie Liu) 7/1/2022-6/30/2025 2.4 calendar months
UC Tobacco-Related Disease Research Program (TRDRP)

Enhanced Multicomponent Proactive Navigator-Assisted Cessation of Tobacco Use in Low-Income Patients.

Primary aims of this study are: 1) to compare the effectiveness of Enhanced Multicomponent Proactive Navigator-Assisted Cessation of Tobacco Use (EMPACT-Us) versus newly-enhanced usual care on improving engagement in tobacco treatments, quit attempts and biochemically verified cessation at 6 and 12 months post initial offerings; 2) to explore potential modification of the effectiveness of EMPACT-Us among low-income patients, sexual and gender minorities, racial/ethnic minorities and people with comorbid medical, substance use or mental health concerns; and 3) to evaluate implementation processes and fidelity, including acceptability and perceived feasibility by patients, clinic staff, and community stakeholders. Role: Co-I

R01HD106991 (PI: Boutelle) 8/15/22 - 6/30/27 0.6 calendar months
NIH/NICHD Total Award:

Telehealth parent-only treatment for youth with autism spectrum disorder and overweight/obesity

This project is part of a larger center grant evaluating chronic disease risk among Latino families. The purpose of this project is to evaluate the efficacy of parent-based treatment for all caregivers compared to a health education control for Latino children with overweight or obesity. Role: Co-I

Grant that was previously active and is in the No Cost Extension:

W81XWH-18-1-0220 (PI: Boutelle) 9/30/2018 – 9/29/2023 (NCE) 0.6 calendar months
DOD USAMRAA (total)

Targeting Food Cue Reactivity and Satiety Sensitivity to Decrease Binge Eating and Weight

The major goals of this project are to evaluate the efficacy of a novel treatment, Regulation of Cues on reducing binge eating as well as assisting with weight loss, among Veterans with clinical and subclinical binge eating compared to cognitive behavioral therapy. Role: Co-I

R01DK114794 (PI: Boutelle) 9/1/2017-06/30/23 (NCE) 0.5 calendar months
NIH/NIDDK Funding Amount:

Behavioral Phenotype of Reward and Inhibition in Parent-Child Weight Loss

The objective of this application is to use innovative methodologies to collect critical data on aspects of cognitive functioning regarding reward and inhibition in children and parents participating in a weight-loss program over 18-months. Role: Co-I

Grant that received the second NCE:

R01DK106157 (PI: Rhee) 8/2016-7/2023 (NCE) 0 calendar months
NIH/NIDDK

Parent Training Program to Improve Outcomes in Childhood Obesity Treatment

Parent training program to improve outcomes in childhood obesity treatment

The purpose of this application is to evaluate the efficacy of a program that combines family-based behavioral therapy and comprehensive parenting training to standard family-based behavioral therapy on child BMI/BMI z-score outcomes. Mediators and moderators of child outcomes such as parenting style, parenting strategies, behavioral strategies, and child-level factors (like impulsive behavior and temperament) will be evaluated. Role: Co-I

R01DK108686 (PI: Boutelle) 7/2016-6/2023 (NCE) 0.5 calendar months
NIH/NIDDK

Effect of Treatment Dose on Childhood Obesity

Primary aims of this study are to: 1) compare the effect of gshFBT and FBT on the target child's weight over the two years of the study; 2) evaluate the cost effectiveness of gshFBT as compared to FBT. The secondary aim of this study is to determine the extent to which the gshFBT and FBT affects parent BMI, parenting skills, and parent and child physical activity and dietary intake. The exploratory aim of the study is to evaluate moderators (e.g., gender, age, educational level, parent baseline BMI, child baseline BMI, executive functioning, parenting style) and mediators (e.g., parenting skills) of the gshFBT and the FBT treatment on child body size over time (BMI; BMiZ). Role: Co-I

Grants that ended in Year 4:

T29IP0584 (PI: Brouwer) 4/2019-3/2022 (NCE) 1.2 calendar months
Tobacco-Related Disease Research Program

Reducing disparities by integrating tobacco cessation into HIV care

The purpose of this project is to: 1) determine tobacco use patterns and barriers and facilitators to smoking cessation in PLWH; 2) explore physician and health system practices and attitudes regarding integration of tobacco cessation into the clinical care setting; 3) map smoking cessation interventions and combinations thereof that address the competing priorities and challenges of affected communities. Role: Co-I

T291R0770 (PI: Salem; Strong Co-I) 04/2019-03/2022 .36 calendar months
Tobacco-Related Disease Research Program Funding Amount:

Large Scale Analyses of Gene-Smoking Interaction on Cardiometabolic Traits

This project will assemble and perform a large scale GWAS of gene by smoking interaction (GxSMK) for quantitative cardiometabolic phenotypes (Aim 1), for incident cardiometabolic diseases (Aim 2), and mortality (Aim 3). Together, the aims have the potential to identify novel mechanisms underlying cardiometabolic disease biology, smoking associated morbidity and mortality, and role of smoking in health disparities. Role: Co-I

R21DA051356 (PI: Leas) 8/2020-7/2022 0.6 calendar months
NIH/NIDA Total Award Amount (including indirect costs):

The effect of switching on or off menthol use on cigarette consumption, dependence, nicotine exposure and quitting success

This study aims to: 1) compare quitting success between quit attempters who had switched on or off menthol cigarettes; 2) compare consumption, nicotine exposure, and dependence between adult smokers who switch on or off menthol cigarettes without successfully quitting; and 3) assess whether race, sex or age modify the effects of switching on or off menthol cigarettes on 30-day cigarettes abstinence, 12-month cigarette abstinence consumption, dependence, and nicotine exposure. Role: Co-I

T31CR2231 (PI: Strong) 7/2020-6/2022 1.2 calendar months
Tobacco-Related Disease Research Program Total Award Amount:

Feasibility and acceptability of a suite of tobacco cessation service for low-income populations

The main goal of this project is to design, evaluate and promote evidence-based tobacco cessation services that are responsive to the needs of a low-income, underserved and minority patient population.

What other organizations were involved as partners?

Nothing to report.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: None

QUAD CHARTS: See attached (page 19). We also attached Award Chart on page 17.

9. APPENDICES: None