

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
JOLLA CA 92093

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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 1, study start up tasks were completed and participant recruitment and assessment were initiated. Seventeen participants completed baseline assessments and are awaiting randomization, 6 participants are in the process of scheduling and completing baseline assessments, 3 participants screened out due to lack of binge-eating, and 5 dropped out of the study (2 due to unknown reasons, 1 due to multiple reasons such as lack of time, transportation issue, 1 due to future work schedule, and 1 due to lack of time). No individuals were randomized during Year 1 because treatment will commence on 11/7/19 (Q1 Year 2).									
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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 1 major goals include: 1) complete study start up, 2) begin participant recruitment, treatment, and assessment, and 3) begin data collection.

Study start up milestones:

1. *The SOW proposed to obtain study protocol approvals from local IRBs (UCSD and VASDHS IRBs) and VA R&D by 3/31/19. Approvals from UCSD and VASDHS IRBs and VA R&D were received on 7/11/18, 10/11/18, and 10/17/18, respectively.*
2. *The SOW proposed to obtain study protocol approvals from DoD HRPO by 3/31/19. UCSD protocols received an approval on 10/3/18, and VASDHS received an approval on 2/14/19, respectively.*
3. *The SOW proposed to hire and train research staff by 3/31/19. UCSD hired and began to train project director, coordinator, and other main research staff by 12/31/18.*
4. *The SOW proposed to train assessors and clinicians to competency for fidelity by 6/30/19. All assessors and clinicians were trained by 6/30/19 as planned.*
5. *The SOW proposed to maintain competency and fidelity of assessment and treatment staff throughout the study. The study has ongoing weekly assessment meetings to clarify or address staff questions and concerns and to maintain fidelity throughout the study.*
6. *The SOW proposed to purchase initial study supplies by 3/31/19. The purchase was finalized by 6/30/19.*

Participant recruitment milestones:

7. *The SOW proposed to consent and screen the first study participant by 6/30/19. The goal was accomplished by 5/2/19.*
8. *The SOW proposed to enroll and randomize 20-30 veterans between 9/30/19 (Q4 Year 1) and 12/31/19 (Q1 Year 2). Of note, the UCSD IRB definition of “enrollment” is the number of individuals who consented to participate in the study. Because the study is a clinical trial, we considered the number of participants “randomized” as enrolled since participants will screen out during the baseline assessments. By the end of Q4 Year 1, 31 veterans were consented. Of these, 17 participants had completed baseline assessments and were awaiting randomization, 6 participants were in the process of scheduling and completing baseline assessments, 3 participants were screened out due to not endorsing binge-eating, and 5 dropped out of the study (2 due to unknown reasons, 1 due to multiple reasons such as lack of time, transportation issue, 1 due to future work schedule, and 1 due to lack of time). No individuals were randomized during Year 1 because treatment will commence on 11/7/19 (Q1 Year 2).*

What was accomplished under these goals?

Study start up subtasks:

1. *Prepare Regulatory Documents and Research Protocol.* Coordination of regulatory documents between UCSD and VASDHS was completed during the Q2 Year 1. UCSD received their initial IRB approval on study protocols on 7/11/18 and DoD HRPO approved their protocols on 10/3/18. VASDHS received their initial IRB and R&D approvals on 10/11/18 and 10/17/18, respectively. DoD HRPO approved their protocols on 2/14/19. Eligibility criteria, exclusion criteria, and screening protocols were finalized on 11/5/18. Consent form and human subjects protocols were developed during the Q2 Year 1. Amendments to study protocols were implemented after local IRBs approved the amendments and DoD HRPO was informed during Year 1. UCSD IRB approved the annual continuing review application on 7/11/19. UCSD submitted the annual continuing review application to DoD HRPO on 7/10/19. VASDHS IRB approved the annual continuing review application on 9/16/19. VASDHS submitted the annual continuing review application to DoD HRPO on 10/10/19.
2. *Hire additional study staff as needed.* UCSD hired a project director, coordinator, and other main research staff during the Q1 Year 1 and additional student research assistants during the Q2 Year 1. VASDHS hired Ms. Jennifer Salamat as a project coordinator to replace Ms. Isabel Miller during the Q1 Year 1. However, Ms. Salamat transitioned out of the position during the Q4 Year 1. Mr. Michael Lee and Ms. Angela Camodeca were hired as Research Associates (both part-time) to replace Ms. Salamat.

3. *Train and certify assessment staff and treatment staff.* Assessment staff were trained and certified during the Q2 Year 1. ROC treatment staff were trained during the Q2 Year 1. Dr. Peterson trained CBT treatment staff on 5/20/19.
4. *Finalize treatment materials and assessment protocols.* Assessment measures and assessment protocols were finalized during the Q2 Year 1. ROC treatment materials and manuals were completed during the Q2 year 1. CBT treatment materials and manuals were completed during the Q3 Year 1.

Participant recruitment, treatment, and assessment subtasks:

5. *Recruitment, screening, and baseline assessment.* The VASDHS has been recruiting veterans receiving care at VASDHS directly through flyers and brochures, tabling, TV monitors at the medical center, prior research studies, and approaching veterans in waiting rooms and already-established educational or clinical groups. The VASDHS also receive referrals from providers and have approval to contact potentially eligible veterans through mailing. Veterans who were identified by UCSD as receiving care at VASDHS have been also referred to VASDHS. UCSD has been recruiting veterans from the community, through online marketing, prior research studies, tabling, UCSD medical charts, and paper flyers. We have been also exploring presentations to health care professionals for referrals to the study (i.e. Dr. Boutelle is scheduled to present grand rounds at the Naval Medical Center San Diego on January 24, 2020). Weekly recruitment meetings evaluate and implement recruitment efforts. Any amendments to improve recruitment have been reported to both the UCSD and VASDHS IRBs, as well as the DoD HRPO. UCSD has screened 164 veterans through the community during Year 1. The VASDHS has screened 182 veterans and referred 15 veterans to UCSD for further eligibility determination. The rate of recruitment at VASDHS has been slower than anticipated due to study staff turnover. However, the rate has been improving since Q4 Year 1 after the new staff have been trained and new methods have been implemented to recruit veterans for this study (e.g., tabling at VA hospital).

Baseline assessments began during the Q2 Year 1 and are ongoing. 21 baseline assessments were completed during Year 1. Of these, 3 participants were screened out due to not endorsing binge-eating.

6. *Conduct randomization and treatment.* No participants were randomized during Year 1. Randomization for the first cohort is scheduled on 10/31/19 one week prior to treatment start date of 11/7/19 (Q1 Year 2).

Data collection subtask:

7. *Enter and clean data and perform quality control measures.* Baseline assessment and data entry are ongoing. Data audits are regularly performed to ensure accuracy of data entry and to evaluate study protocols.

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

Dr. Boutelle presented and attended the International Conference on Eating Disorders (ICED) in New York in March 2019.

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?

We plan to continue recruitment and baseline assessments for the next cohort (projected start date April 2020 (Q3 Year 2) while conducting treatment with the first cohort. This will help recruit targeted number of veterans for the next cohort by the time the first cohort ends their treatment. UCSD and VASDHS will continue outreach efforts and continue to plan and implement additional strategies to improve recruitment.

The first cohort will end treatment in March 2020. Post-treatment and 6-month follow-up assessments for the first cohort will be conducted in April 2020 (Q3 Year 2) and September 2020 (Q4 Year 2), respectively. The second cohort will begin in April 2020 (Q3 Year 2) and post-treatment assessments will occur in September 2020 (Q4 Year 2) and 6-month follow-up assessments will occur in February 2021 (Q2 Year 3).

Drs. Boutelle and Peterson will lead weekly supervisions with treatment staff to ensure staff fidelity with treatment protocols and to resolve any issues that may arise. Assessment staff will continue to attend weekly meetings to ensure compliance with assessment protocols and to clarify any questions or concerns that may arise.

Data entry and auditing are ongoing, and data backup has been performed regularly (e.g., daily to weekly depending on the type of data).

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

Amendments to study protocols to decrease participant burden, to improve protocol and recruitment efficiency, to collect additional measurements of study targets, to improve recruitment and to reflect changes in study teams were implemented during Year 1 after local IRBs approved the amendments and DoD HRPO was informed.

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

The rate of recruitment at VASDHS has been slower than anticipated due to VASDHS study staff turnover. However, the rate has been improving since Q4 Year 1 after the new staff have been trained and new methods have been implemented to recruit veterans for this study (e.g., tabling at VA hospital). We plan to continue recruitment and baseline assessments for the next cohort (projected start date April, 2020 [Q3 Year 2]) while conducting treatment with the first cohort. This will help recruit targeted number of veterans for the next cohort by the time the first cohort ends their treatment. UCSD and VASDHS will continue outreach efforts and continue to plan and implement additional strategies to improve recruitment.

Changes that had a significant impact on expenditures

There was a delay in hiring research staff at VASDHS which led to under expenditure.

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 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 person month
Dr. Niloofar collaborated on design and implementation of the study, provided input on assessment tools, and directed the recruitment at VASDHS.
3. David Strong
Co-I (UCSD Co-I)
1 person month
Dr. Strong assisted in refining recruitment, treatment, and assessment protocols. He contributed to the development of data collection protocols.
4. Jennifer Salamat
VASDHS Project Coordinator
4 person month
Ms. Salamat organized study documents, IRB and R&D protocols, and initiated recruitment at VASDHS.
Funding support from VASDHS
5. Saori Obayashi
UCSD Project Director
7 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.
6. Georgia Potter
UCSD Project Coordinator
12 person month
Ms. Potter assisted Drs. Boutelle and Obayashi with the development of recruitment, assessment and treatment protocols, and amendment request submission to UCSD IRB. She interviewed and managed undergraduate research assistants. Ms. Potter was also trained and certified on the interviews and many tasks which were used in the study.
7. Kaylen Moline
UCSD Recruitment Coordinator
2 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.

8. Elena Kaltsas
UCSD Clinical Assessor
1 person month
Ms. Kaltsas was trained to be certified for interviews and tasks used in the study.
Ms. Kaltsas also assisted in refining recruitment, treatment, and assessment protocols.
9. Michael Lee
VASDHS Research Associate
2 person month
Mr. Lee recruited study participants and enter and manage data.
10. Angela Camodeca
VASDHS Research Associate
2 person month
Ms. Camodeca assisted in regulatory updates, recruitment, data entry and management, and served as liaison with UCSD.
11. Eastern Kang
UCSD Postdoctoral Fellow
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.
12. Karina Barajas
UCSD Undergraduate Research Assistant
2 person month
Ms. Barajas 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. Armand Yazdani
UCSD Undergraduate Research Assistant
1 person month
Mr. Yazdani 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. Grace Lee
UCSD Undergraduate Research Assistant
1 person month
Ms. Lee was trained and assisted the project coordinator with assessment visits, administering surveys, measuring height and weight, entering data, and providing computer and other tasks.
15. Rachel Steeley
UCSD Undergraduate Research Assistant
2 person month
Ms. Steeley 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

Grants that were previously pending and are now active:

W81XWH-18-1-0220 (PI: Boutelle) 09/30/2018 – 09/29/2022 3.6 calendar months
DOD USAMRAA Annual Direct Costs: \$582,528

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

The goal of this proposal is to evaluate the efficiency 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: PI

R01DK116616-01A1 (PI: Boutelle) 07/01/2018-04/30/2023 1.8 calendar months
NIDDK Annual Direct Costs: \$501,993

Targeting Emotional Eating and Weight Loss in Adolescents

The goal of this proposal is to evaluate the efficacy of a novel treatment targeting emotional eating on the target adolescent's weight compared to family-based therapy over the 18 months of the study. Role: PI

Grants in No Cost Extension (NCE) but not providing effort:

1 R40MC29452 (PI: Rhee; Boutelle Co-I) 04/01/2016-03/31/2020 (NCE) 0 calendar months
HRSA Annual Direct Costs: \$192,952

Using a Guided Self-Help Treatment Model for Childhood Obesity Management in the Primary Care Setting

The goal of this proposal is to test the effect of health coaches providing obesity treatment in the primary care setting compared to usual care (PCP providing obesity management with the help of clinical decision support tools in the electronic health record) on changes in child BMI/BMI z-score. Role: Co-I

2. Niloofar Afari

Grants that were previously pending and are now active:

T29IP0379 (PI: Anthenelli; Afari Co-I) 04/01/2019 – 03/31/2021 .24 calendar months
Tobacco-Related Disease Research Program \$200,000

Novel Pharmacotherapy Approaches in Smokers with Serious Mental Illness

The goal of this pilot trial is to combine novel dosing strategies for varenicline with acceptance & commitment therapy (a behavioral treatment that teaches smokers to better accept the internal discomforts of quitting) in smokers with serious mental illness. The project will also test whether one's nicotine clearance rate influences the incidence of adverse events with the different dosing strategies. Role: Co-Investigator

W81XWH-18-1-0220 (PI: Boutelle; Afari site PI) 09/30/2018 – 09/29/2022 1.2 calendar months
DOD USAMRAA \$65,002 site

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

Grants that were previously active and have been extended:

U01 DK082325 (PI: Buchwald; Afari site PI) 09/15/2008 – 06/30/2022 1.8 calendar months
NIH/NIDDK \$26,514 site

University of Washington 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

Additional active grant that has not been reported previously:

IK2 RX002807-01A2 (PI: Herbert; Afari Mentor) 04/01/2019 – 03/31/2024 1.2 calendar months
VA RR&D \$926,337 (total) (donated)

Mindful Action for Pain: An Integrated Approach to Improve Chronic Pain Function

The major goals of this project are to develop a novel mindfulness-based group intervention for chronic pain (Phase 1) and to compare this intervention to cognitive-behavioral therapy in a pilot randomized controlled trial (Phase 2). Role: Mentor

3. David Strong

New grants:

1R01CA234539 (PI: Pierce; Strong Co-I) 09/11/2018-08/31/2021 .6 calendar months
NCI Annual Direct Costs: \$286,681

The Role of ENDS use in changing rates of escalation and quitting of cigarette smoking in those under age 35 years in US population

In the Population Assessment of Tobacco and Health (PATH) Study, we will investigate whether ENDS use changes the pattern of escalation and early quitting in the United States. Role: Co-I

T291P0584 (PI: Brouwer; Strong Co-I) 04/01/2019-03/31/2021 .6 calendar months
Tobacco-Related Disease Research Program Annual Direct Costs: \$199,999

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

T291P0384 (PI: Mackey; Strong Co-I) 04/01/2019-03/31/2021 .6 calendar months
Tobacco-Related Disease Research Program Annual Direct Costs: \$199,999

Digital Surveillance to Identify ENDS Industry Mobilization and Influence

This project responds to TRDRP State and Local Tobacco Control Policy Research by assessing the impact of tobacco industry policy mobilization on the implementation of tobacco control laws proposed and enacted from 2015 to present. The specific aims of the project are to identify (Aim 1), collect (Aim 2), and characterize (Aim 3) “digital” policy mobilization and coordination between Electronic Nicotine Delivery System (ENDS) trade associations and retailers/vendors aimed at influencing public sentiment against California tobacco control programs and policies. Role: Co-I

T291R0770 (PI: Salem; Strong Co-I) 04/01/2019-03/31/2021 .6 calendar months
Tobacco-Related Disease Research Program Annual Direct Costs: \$199,999

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

HHSN271201600001C

(PI: Maklan; UCSD PI: Pierce; Strong Co-I) 04/01/2016-11/30/2024 1.8 calendar months
NIDA Contract Annual Direct Costs: \$172,752

PATH Study: Population Assessment of Tobacco and Health

The purpose of this contract is to conduct a large national longitudinal cohort study of tobacco product users 18 years or older in the U.S., and thereby to establish a regulatory-science framework to monitor and assess the behavioral and health impacts of provisions in the 2009 Family Smoking Prevention and Tobacco Control Act. Role: Co-I

Grants that were previously pending and are now active:

W81XWH-18-1-0220 (PI: Boutelle; Strong Co-I) 09/30/2018 – 09/29/2022 .6 calendar months
DOD USAMRAA Annual Direct Costs: \$582,528

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

The goal of this proposal is to evaluate the efficiency 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

R01DK116616-01A1 (PI: Boutelle; Strong Co-I) 07/01/2018-04/30/2023 .696 calendar months
NIDDK Annual Direct Costs: \$501,993

Targeting Emotional Eating and Weight Loss in Adolescents

The goal of this proposal is to evaluate the efficacy of a novel treatment targeting emotional eating on the target adolescent's weight compared to family-based therapy over the 18 months of the study. Role: Co-I

Grants that were previously active and have been closed:

1R01DA037217-01 (PI: Doran; Strong Co-I) 09/01/2014 – 05/31/2019 .6 calendar months
NIDA Contract Annual Direct Costs: \$125,016

Social Cognitive Theory and Nondaily Smoking, Escalation and Desistance

The purpose of this contract is to collect surveillance of tobacco use across a range of products, examine patterns of use and related social cognitive mechanisms thought to influence tobacco use among adult non-daily cigarette smokers. Role: Co-I

HHSN271201100027C

(PI: Maklan; UCSD PI: Pierce; Strong Co-I) 09/22/2011-06/30/2019 .6 calendar months
NIDA Contract Annual Direct Costs: \$441,041

PATH Study: Population Assessment of Tobacco and Health

The purpose of this contract is to conduct a large national longitudinal cohort study of tobacco product users 18 years or older in the U.S., and thereby to establish a regulatory-science framework to monitor and assess the behavioral and health impacts of provisions in the 2009 Family Smoking Prevention and Tobacco Control Act. Role: Co-I

Grants in No Cost Extension (NCE) but not providing effort:

1 R40MC29452 (PI: Rhee; Strong Co-I) 04/01/2016-03/31/2020 (NCE) 0 calendar months
HRSA Annual Direct Costs: \$192,952

Using a Guided Self-Help Treatment Model for Childhood Obesity Management in the Primary Care Setting

The goal of this proposal is to test the effect of health coaches providing obesity treatment in the primary care setting compared to usual care (PCP providing obesity management with the help of clinical decision support tools in the electronic health record) on changes in child BMI/BMI z-score. Role: Co-I

What other organizations were involved as partners?

Nothing to report.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: None

QUAD CHARTS: See attached (page 20). We also attached Award Chart on page 18.

9. APPENDICES: None