AWARD NUMBER: W81XWH-I8-1-0220

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, La Jolla, CA

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Kerri Boutelle

E-Mail: kboutelle@ucsd.edu

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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 3, 102 participants were randomized into treatment(22 participants in Cohort 1, 31 participants in Cohort 2, 29 participants in Cohort 3, and 20 participants in Cohort 4; 85% of the study goal). We started recruitment of Cohort 5 by the end of Year 3. Assessments were conducted per schedule for each cohort. Cohort 3 participants completed treatment and Cohort 4 participants completed 12 of 18 scheduled treatment sessions by the end of Year 3. 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. Data entry and cleaning are ongoing. The study continues to adapt to the restrictions caused by the COVID-19 pandemic by amending research protocols and minimized the impact on data collection and treatment.

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

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Unclassified	Unclassified	Unclassified	Unclassified	18	USAMRMC

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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 3 major goals include: 1) preparing and submitting regulatory documents and research protocols as needed, 2) continuing participant recruitment, treatment, and assessment, and 3) continuing data entry and auditing.

Preparation and submission of regulatory documents and research protocols:

1. *Submit amendments, adverse events, and protocol deviations as needed as stated in the SOW.* UCSD submitted required documents in a timely manner and received approvals/acknowledgement from local IRBs and DoD HRPO during Year 3. VASDHS did not have any required documents to submit during Year 3.

2. *Coordinate with sites for annual IRB report for continuing review as stated in the SOW.* UCSD submitted a continuing review application to the UCSD IRB, received an approval letter dated on 7/11/21, and received acknowledgement by DoD HRPO on 8/6/21. VASDHS submitted a continuing review application to VASDHS IRB, received approval on 9/21/21, and received acknowledgement by DoD HRPO on 9/24/21.

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 as stated in the SOW.* The study has ongoing weekly assessment meetings and treatment supervision to clarify or address staff questions and concerns and to maintain fidelity of assessment and treatment staff.

Participant recruitment, treatment, and assessment:

4. *Complete recruitment of study participants by the end of Year 3 as stated in the SOW.* The SOW planned to complete the recruitment of 120 participants by the end of Year 3. However, due to the COVID-19 pandemic and changes in recruitment parameters for online recruitment on Facebook, only 102 veterans (85%) were randomized. We engaged an online marketing company, BuildClinical, during Q3 Year 3 and the rate of recruitment and enrollment improved.

5. *Complete treatment of final cohort of participants by Q2 Year 4 as stated in the SOW.* Treatment is ongoing and 102 participants (22 participants in Cohort 1, 31 participants in Cohort 2, 29 participants in Cohort 3, and 20 participants in Cohort 4; 85% of target subjects) completed or were participating in treatment by the end of Year 3.

6. *Complete 6-month follow-up assessment with final participant by Q4 year 4 as stated in the SOW.* By the end of Year 3, Cohort 1 participants completed 6-month follow-up assessments. Cohort 2 participants completed post-treatment and 6-month follow-up assessments. Cohort 3 participants completed monthly surveys, mid-treatment interviews, treatment, post-treatment assessments, and began 6-month follow-up assessments. Cohort 4 participants completed baseline assessments, began treatment, completed 3 monthly surveys and mid-treatment interviews. Recruitment of Cohort 5 participants began at the end of Year 3 and treatment is scheduled to begin Q2 Year 4.

Data entry and auditing:

7. *Enter all data into the database by Q4 Year 4 as stated in the SOW.* Data entry and auditing are ongoing.

What was accomplished under these goals?

Preparation and submission of regulatory documents and research protocols:

1. *Preparation and submission of regulatory documents and research protocols.* UCSD submitted a continuing review application to the UCSD IRB, received an approval letter dated on 7/11/21, and received acknowledgement by DoD HRPO on 8/6/21. VASDHS submitted a continuing review application to VASDHS IRB, received approval on 9/21/21 and received acknowledgement by DoD HRPO on 9/24/21.

   Protocol deviation was reported to UCSD IRB on 1/20/21. On 12/28/20, a participant received extra $50 gift card for completing a post-treatment assessment visit due to a staff mistake in tracking on the electronic participant database. After communicating with an UCSD IRB staff on 1/11/2021, it was decided that no changes would be made to the participant's incentives in the future to limit impact on motivation to continue in the study.

   Another protocol deviation was reported to UCSD IRB on 1/20/21. The project Manager, who also conducts intervention, mistakenly sent an email to a participant that included an individual who is not part of the study team (with the same first name) disclosing participant's name and email address to the individual. The project manager sent an email to the individual who is not part of the study team, requesting to disregard the email and sent an email to the affected participant, apologizing the mistake, and explained the plan to prevent the same error from happening again in the future. The next morning, the project manager also called the participant, and the participant said they understand the situation and does not have further questions or concerns. After reporting the incident, UCSD IRB requested no further actions.

Training and certification of assessment staff and treatment staff:

2. *Maintaining competency and fidelity of assessment and treatment staff throughout the study.* The study has ongoing weekly assessment meetings and treatment supervisions to clarify or address staff questions and concerns and to maintain fidelity of staff throughout the study.

Participant recruitment, treatment, and assessment:

3. *Recruitment, screening, and baseline assessments.* In Year 3 UCSD prescreened 635 veterans through the community. The VASDHS prescreened 103 veterans and referred 30 veterans to UCSD for further eligibility determination. Ninety-four veterans consented to participate in the study. Thirty-four veterans were excluded from the study due to: lack of binge eating behaviors (n=29), wanting to gain weight (n=1), living outside San Diego, California (n=1), age (n=1), and behavioral concerns (n=2). Seven veterans will be considered in the future because they were unavailable for upcoming treatment (n=4), currently in active duty (n=1), or their unstable medication (n=2). Sixteen veterans dropped out of the study before or after baseline assessments due to: time conflict/too busy (n=3), unresponsive/unknown (n=9), and no longer interested in the study (n=4). We are continuing to work closely with the UCSD Environment, Health and Safety department and are conducting in-person and password protected HIPAA compliant zoom assessment meetings to keep participants safe while minimized the impact of the COVID-19 pandemic on data collection.

4. *Conduct randomization and treatment.* In Year 3, 52 veterans were randomized into Cohort 3 and 4 treatment (n=30 and n=22, respectively). However, 3 participants were excluded post-randomization due to refusal to participate in treatment components (n=1 in Cohort 3 and n=1 in Cohort 4) and not meeting the inclusion criteria at the second session (pregnancy; n=1 in Cohort 4). These participants would have been excluded if these issues were known prior to randomization. As a result, 29 Cohort 3 participants completed treatment on 3/29/21, and 20 Cohort 4 participants completed 12 of 18 treatment sessions by the end of Year 3. We continued treatment via password protected HIPAA compliant zoom meetings because it was considered unsafe to have a group of participants present in the same room during the COVID-19 pandemic. No Cohort 3 and 4 participants dropped out of the study during Year 3.

   No unanticipated problems involving risks to subjects or others have occurred since the study began. Adverse events that were not serious, unexpected, and unrelated to the study have been reported to the UCSD IRB and DoD HRPO at annual continuing reviews or quarterly technical reports.

5. *Conduct Study Assessments.* Cohort 1 participants completed 6-month follow-up assessments during Year 3. Cohort 2 participants completed post-treatment and 6-month follow-up assessments during Year 3. Cohort 3 participants completed baseline assessments, monthly surveys, mid-treatment interviews, post-treatment assessments, and began 6-month follow-up assessments by the end of Year 3. Cohort 4 participants completed baseline assessments and completed 3 monthly surveys by the end of Year 3. Cohort 5 participants began baseline assessments at the end of Year 3.

Data entry and auditing:

6. *Enter and clean data and perform quality control measures.* Baseline, monthly surveys, mid-treatment interviews, post-treatment, 6-month follow-up assessments, and treatment data entry are ongoing. Data auditing is regularly performed to ensure accuracy of data entry. All of data entry and cleaning are expected to be completed by Q4 Year 4.

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?

By the end of Year 4, we will complete Cohort 3 6-month follow-up assessments and Cohort 4 treatment, monthly surveys, post-treatment assessments, and 6-month follow-up assessments. We did not meet the recruitment goal by the end of Year 3 due to the challenges that arose, including the COVID-19 pandemic and changes made by Facebook and Instagram regarding recruitment parameters. Therefore, we will continue to recruit, randomize, treat, and conduct monthly surveys, mid-treatment interviews and post-treatment assessments with Cohort 5 participants during Year 4.

Drs. Boutelle and Peterson will continue 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 have.

UCSD and VASDHS will continue to coordinate preparation and submission of regulatory documents and research protocols 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

During Year 3, the rate of enrollment slowed down due to the challenges that arose, including the COVID-19 pandemic and changes made by Facebook and Instagram regarding recruitment parameters. UCSD IRB approved amendments to ask 3 eligibility questions during online screening to improve screening efficiency and to add a recruitment service, BuildClinical, to increase participant enrollment. In addition, UCSD IRB approved the amendment to have in-person treatment in the future, however, this will be adjusted based on the restrictions due to the pandemic. Using in-person and password protected HIPAA approved zoom meetings, we collected assessment measures that were proposed in the grant during Year 3 except psychophysiological task due to potential risks of handling food and social distancing concerns during COVID.

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

See above.

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

Nothing to report.

Significant changes in use or care of human subjects

Not applicable.

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.

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)
0.75 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
9.3 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 (replaced Ms. Gasparetto and Hammock after their resignation from the study) UCSD Undergraduate Research Assistant, UCSD Project Coordinator
6.5 person month
As an undergraduate research assistant, Ms. Awtrey was trained and assisted the project coordinator with assessment visits, administering surveys, measuring height and weight, entering data, and providing computer and other tasks. Upon graduation, she became a Project Coordinator to assist 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. Beatriz Gasparetto
UCSD Project Coordinator
10.2 person month
Ms. Gasparetto 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. Gasparetto was also trained on many tasks which were used in the study.

7. Kyndal Hammock
UCSD Project Coordinator
2.4 person month
Ms. Hammock assisted Drs. Boutelle and Obayashi with recruitment, assessment and treatment protocols, and amendment request submission to UCSD IRB. Ms. Hammock was also trained on many tasks which were used in the study.

8. Caley Bailey
UCSD Clinical Assessor
1.8 person month
Ms. Bailey was trained to be certified for interviews and tasks used in the study. She also assisted in interventions.

9. Jessica Willis
UCSD Clinical Assessor
2.7 person month
Ms. Willis was trained to be certified for interviews and tasks used in the study. She also assisted in interventions.

10. Kaylen Moline
UCSD Recruitment Coordinator
1.65 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.

11. Angela Camodeca
VASDHS Research Associate
8.4 person month
Ms. Camodeca assisted in regulatory updates, recruitment, data entry and management, and served as liaison with UCSD.

12. 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.

13. Carlota Conant
UCSD Undergraduate Research Assistant
3.6 person month
Ms. Conant 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
4.41 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. Andre Hirakawa
UCSD Undergraduate Research Assistant
3.6 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.

16. Kaela Alagos
UCSD Undergraduate Research Assistant
1.5 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.

17. Mariah Price
UCSD Undergraduate Research Assistant
2.7 person month
Ms. Price 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:
P50MD017344 - 8159 (PI: Boutelle) 9/24/21 - 6/30/26 2.4 calendar months
NIH/NIMHD Annual Direct Costs: **Caregivers as the Agent of Change for Childhood Obesity and Chronic Disease Risk Among Latino Families**
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 in No Cost Extension but not providing effort:
R01DK108686 (PI: Boutelle) 7/2016-6/2022 0 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) 8/2016-7/2022 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

Grants that ended in Year 3:
1R01DK103554 (PI: Boutelle) 4/1/15 - 3/31/21 0 calendar months
NIH/NIDDK Annual Direct Costs:
Treatment of Obesity Targeting Appetite and Cue Reactivity
The objective of this application is to evaluate a weight loss program based on improving sensitivity to appetitive cues and decreasing sensitivity to external food cues (called Regulation of Cues, or ROC). This study will compare ROC, ROC + Behavioral weight loss, Behavioral weight loss alone, and a control group on changes in BMI, body composition, and binge eating over the course of a 12-month treatment and at one-year follow-up in 280 overweight and obese individuals. Role: PI *The effort on this grant will be completed by the start date of the new grant so it is reflected as 0 calendar months.

2. Niloofar Afari

New grants:
HX003079-01A1 (PI: Pittman) 10/01/20-09/30/24 1.2 calendar months
VA HSR&D /yr (Total
Effectiveness and Implementation of eScreening in Post 9/11 Transition Programs
The objective of this project is to conduct hybrid type 2 stepped wedge randomized controlled trial to examine the effectiveness of a self-report screening technology, eScreening, in eight Post 9/11 Transition Care Management Programs while assessing the feasibility of a multicomponent implementation strategy. Role: Co-Investigator

IK2 CX002107 (PI: Gasperi) 10/01/20–9/30/25 1.2 calendar months
VA CSR&D (total) (donated)

Chronic Pain Conditions and Internalizing Psychopathology, A Genetic Epidemiology Investigation

The primary objective of this study is to derive chronic pain conditions and internalizing disorder phenotypes from electronic health records in the Million Veterans Program and to evaluate the genetic overlap between them using genome-wide association study methods. Secondary objectives are to explore the causal relationships among chronic pain conditions, internalizing disorders, and opioid use using quantitative genetic methodology. Role: Primary Mentor

1R01DK127491 (PI: Fortmann MPI) 12/1/20 –11/30/25 0 calendar months
NIH/NIDDK

ACT1VATE: Addressing Emotional Distress to Improve Outcomes among Diverse Adults with Type 1 Diabetes

The major goals of this project are: 1) To document the effectiveness of DSME + ACT1VATE versus DSME/S (UC) in improving HbA1c; 2) To compare the effectiveness of DSME + ACT1VATE versus DSME/S (UC) in improving diabetes self-management behaviors, DD, and health-related quality of life; and 3) To evaluate the cost-effectiveness of DSME + ACT1VATE versus DSME/S (UC). Role: Consultant

Other support that has not been reported previously:

VA Center of Excellence for Stress & Mental Health (PI: Lang) 10/1/06–ongoing 1.8 calendar months

Veterans Health Administration VA Center of Excellence for Stress and Mental Health at VA San Diego Healthcare System is a research, education, and clinical center focused on optimizing the well-being and functioning of veterans through integrated neurobiological and psychosocial science to develop, evaluate and disseminate treatment for trauma-related conditions. Dr. Afari is a member receiving support for leading projects on twin analyses of the relationship between PTSD and pain as well as for mentoring junior investigators. Role: Member

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

1R01DK106415 (PI: Afari) 6/01/16–5/31/22 (NCE) 3.6 calendar months
NIH/NIDDK

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.

Grants that ended in Year 3:

T29IP0379 (PI: Anthenelli) 4/01/2019–3/31/21 0.24 calendar months
Tobacco-Related Disease Research Program

Novel Pharmacotherapy Approaches in Smokers with Serious Mental Illness (UCSD)

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

3. David Strong

New grants:

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 (including indirect costs):

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.

P30CA023100 (PI: Lippman) 5/2019-4/2024 1.2 calendar months NIH/NCI Total Award Amount (including indirect costs):

Specialized cancer center core support grant

The main goals of this project are to: 1) elucidate the biology of cancer and catalyze trans-disciplinary team science across the science spectrum; 2) develop and test innovative preventive, diagnostic, and therapeutic approaches; 3) conduct cancer prevention and control research to reduce cancer disparities in vulnerable populations; 4) provide underrepresented minorities with access to cutting edge multi-disciplinary care; 5) provide training and education across the trainee continuum; and 6) develop and implement community-based cancer education and outreach programs. Role: Project Leader

Grants in No Cost Extension but not providing effort:

R01DK106157 (PI: Rhee) 8/2016-7/2022 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

Grants that ended in Year 3:

1R01DK103554 (PI: Boutelle) 4/1/15 - 3/31/21 0 calendar months NIH/NIDDK Annual: Total Costs Entire Period: Total Costs

Treatment of Obesity Targeting Appetite and Cue Reactivity

The objective of this application is to evaluate a weight loss program based on improving sensitivity to appetitive cues and decreasing sensitivity to external food cues (called Regulation of Cues, or ROC). This study will compare ROC, ROC + Behavioral weight loss, Behavioral weight loss alone, and a control group on changes in BMI, body composition, and binge eating over the course of a 12-month treatment and at one-year follow-up in 280 overweight and obese individuals. Role: Co-I

T29IP0584 (PI: Brouwer) 4/2019-3/2021
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 facilitarots 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.

CDPH-16-10109 (PI: Zhu) 1/2017-6/2021
California Department of Public Health (CDPH)
California Student Tobacco Survey
The main goal of this project is to conduct a population survey on tobacco use behaviors of middle school and high school students in California. Role: Investigator

T29IP0384 (PI: Mackey) 4/2019-3/2021
Tobacco-Related Disease Research Program
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

1R01CA234539 (PI: Pierce) 9/2018-8/2021
NIH/NIDDK
The role of ENDS use in changing rates of escalation and quitting of cigarette smoking in those under age 35 years in US population
This objective of this project explored the long-term role of ENDS in changing the escalation and quitting of cigarette smoking using the first four waves of the national population assessment of tobacco and health (PATH) longitudinal study. 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 21). We also attached Award Chart on page 19.

9. APPENDICES: None