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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Management and Outcomes of Binge Eating Disorder (BED)

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Scientific Information Submissions

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review of Management and Outcomes of Binge Eating Disorder, which is currently being conducted by AHRQ's Evidence-based Practice Center (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

DATES: Submission Deadline on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

Online submissions: <http://effectivehealthcare.AHRQ.gov/index.cfm/submit-scientific-information-packets/>. Please select the study for which you are submitting information from the list to upload your documents.

E-mail submissions: SIPS@epc-src.org.

Print submissions:

Mailing Address:

Portland VA Research Foundation
Scientific Resource Center
ATTN: Scientific Information Packet Coordinator PO Box 69539
Portland, OR 97239

Shipping Address (FedEx, UPS, etc.):

Portland VA Research Foundation
Scientific Resource Center
ATTN: Scientific Information Packet Coordinator
37105W U.S. Veterans Hospital Road
Mail Code: R&D 71
Portland, OR 97239

FOR FURTHER INFORMATION CONTACT:

Ryan McKenna, Telephone: 503-220-8262 ext. 58653 or Email: SIPS@epc-src.org.

SUPPLEMENTARY INFORMATION:

The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Center (EPC) Program to complete a review of the evidence for Management and Outcomes of Binge Eating Disorder.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on Management and Outcomes of Binge Eating Disorder, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at:
<http://effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1942>

This notice is to notify the public that the EPC Program would find the following information on Management and Outcome of Binge Eating Disorder helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.
- For completed studies that do not have results on ClinicalTrials.gov, please provide a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up/ withdrawn /analyzed, effectiveness/efficacy, and safety results.
- A list of ongoing studies that your organization has sponsored for this indication. In the list, please provide the ClinicalTrials.gov trial

number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

- Description of whether the above studies constitute ALL Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EPC Program. The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or can be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: <http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/>.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions. The entire research protocol, is available online at: <http://effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1942>

The Key Questions

KQ 1: What is the evidence for the effectiveness of treatments or combinations of treatments for binge eating disorder?

KQ 2: What is the evidence for harms associated with treatments for binge eating disorder?

KQ 3: Does the effectiveness of treatments for binge eating disorder differ by age, sex, race, ethnicity, initial body mass index, duration of illness, or coexisting conditions?

KQ 4: What is the course of illness of binge eating disorder?

KQ 5: Does the course of illness of binge eating disorder differ by age, sex, race, ethnicity, sexual orientation, body mass index, duration of illness, or coexisting conditions?

KQ 6: What is the evidence for the effectiveness of treatments or combinations of treatments for loss-of-control eating among bariatric surgery patients?

KQ 7: What is the evidence for harms associated with treatments for loss-of-control eating among bariatric surgery patients?

KQ 8: Does the effectiveness of treatments for loss-of-control eating among bariatric surgery patients differ by age, sex, race, ethnicity, initial body mass index, duration of illness, or coexisting conditions?

KQ 9: What is the course of illness of loss-of-control eating among bariatric surgery patients?

KQ 10: Does the course of illness of loss-of-control eating among bariatric surgery patients differ by age, sex, race, ethnicity, sexual orientation, initial body mass index, duration of illness, or coexisting conditions?

KQ 11: What is the evidence for the effectiveness of treatments or combinations of treatments for loss-of-control eating among children?

KQ 12: What is the evidence for harms associated with treatments for loss-of-control eating among children?

KQ 13: Does the effectiveness of treatments for loss-of-control eating among children differ by age, sex, race, ethnicity, initial body mass index, duration of illness, or coexisting conditions?

KQ 14: What is the course of illness of loss-of-control eating among children?

KQ 15: Does the course of illness of loss-of-control eating among children differ by age, sex, race, ethnicity, initial body mass index, duration of illness, or coexisting conditions?

PICOTS (Population(s), Intervention(s), Comparator(s), Outcome(s), Timing, Setting)

Population(s)

- Individuals meeting either DSM-IV or DSM-5 criteria for binge eating disorder (BED)
- Post-bariatric surgery patients meeting criteria for loss-of-control (LOC) eating after surgery/1/
- Children (6 years of age and older) meeting criteria for LOC eating/2/

Interventions

Applies only to KQs on effectiveness and harms of BED treatment in adults (KQs 1, 2, and 3), LOG treatment in bariatric patients (KQs 6, 7, and 8), and LOG treatment in children (KQs 11, 12, and 13).

- Pharmacological interventions
 - o Antidepressants, including: 1) selective serotonin reuptake inhibitors (SSRIs); 2) serotonin-norepinephrine reuptake inhibitors (SNRIs, excluding Sibutramine because it is unavailable in the United States); 3) norepinephrine reuptake inhibitors (NRIs); and 4) tricyclic antidepressants
 - o Anticonvulsants (antiepileptics)
 - o Weight loss drugs (orlistat)
 - o Appetite suppressants (excluding rimonabant because it is unavailable in the United States)
 - o Gamma-aminobutyric acid agonists
 - o Mixed gamma-aminobutyric acid agonist/glutamate antagonists
 - o Central nervous system stimulants

- Psychological or behavioral interventions
 - o Cognitive behavioral therapy (CBT)
 - o Interpersonal psychotherapy (IPT)
 - o Dialectical behavior therapy (DBT)
 - o Family-based therapy (for LOC eating in children and adolescents)
 - o Parent training (for LOC eating in children and adolescents)
 - o Behavioral weight loss interventions
 - o Virtual reality therapy
 - o Nutritional counseling or low-calorie diet (or both)
 - o Exercise
 - o Health education

- Complementary and alternative medicine (CAM) interventions
 - o Nutraceuticals and dietary supplements
 - o Acupuncture

- Combinations of pharmacotherapies; combinations of psychological interventions; combinations of CAM interventions; combinations of pharmacotherapy, psychological, behavioral, and/or CAM interventions

- Characteristics of interventions
 - o Pharmacotherapy and CAM: dosages, duration of treatment
 - o Psychological or behavioral: format (e.g., individual or group, therapist-led or self-help), frequency, duration of treatment

Comparators

Applies only to KQs on effectiveness and harms of BED treatment in adults (KQs 1, 2, and 3), LOC treatment in bariatric patients (KQs 6, 7, and 8), and LOC treatment in children (KQs 11, 12, and 13).

- Placebo or usual care
- Any active intervention or combination of active interventions from among those listed above

Outcomes

- Intermediate outcomes
 - Change in weight or body mass index (BMI) (or both)
 - Appetite-regulating peptide hormones
 - Blood lipids (cholesterol, triglycerides)
 - Blood glucose, hemoglobin A1c
 - Blood pressure
- Final health outcomes
 - Behavioral
 - Binge eating: frequency of binge episodes, frequency of binge days, binge abstinence
 - LOC eating: frequency of LOC eating episodes, LOC eating abstinence
 - Psychological
 - Shape and weight concerns, restraint, hunger, disinhibition
 - Depressive disorders and symptoms
 - Anxiety
 - Substance abuse
 - Physical health and functioning
 - BMI, weight status or stabilization
 - Hypertension
 - Type 2 diabetes, impaired glucose tolerance, insulin resistance
 - Dyslipidemia
 - Heart disease
 - Gastric reflux (gastroesophageal reflux disorder), gastroparesis, other gastrointestinal diagnoses or problems
 - Irritable bowel syndrome
 - Menstrual problems (female), hormonal problems (male or female)
 - Reproductive function
 - Social and occupational functioning
 - Work or school days lost
 - Marital or partner status
 - Quality of life: health-related quality of life or patient-reported outcomes not otherwise listed above
- Harms: Applies only to harms of treatment (KQs 2, 7, and 12)
 - Pharmacotherapy and CAM: sedation, dry mouth, headache, nausea, insomnia, diarrhea, fatigue, increased urinary frequency, sexual

dysfunction, abnormal dreams, sweating, palpitations, arrhythmia, cramping, diffuse pain, weight gain

- o Psychological or behavioral therapy: negative effects of disclosing symptoms during initial evaluation or therapy

- o Worsening of BED or LOC eating (or associated symptoms)

- Health care use and costs

- o Use of health care services: emergency room visits, hospitalizations (psychiatric hospitals, residential institutions, general hospitals), ambulatory physician visits (medical care, psychiatric care), ambulatory visits to other health care professionals (e.g., clinical psychologists), nutritional counseling

- o Costs of services: emergency room visits, hospitalizations (psychiatric hospitals, residential institutions, general hospitals), ambulatory physician visits (medical care, psychiatric care), ambulatory visits to other health care professionals, pharmacotherapies, and treatment costs for any harms

Timing

- Treatment studies: no minimum duration
- Course of illness studies: 1-year minimum followup

Settings

- Inpatient, including hospitals and residential treatment centers
- Outpatient, including schools and homes

/1/ Bariatric surgery patients may have had either BED or LOC eating diagnoses before surgery, but after surgery they are typically diagnosed only with LOC eating (i.e., loss-of-control eating behaviors without having consumed an unusually large amount of food).

/2/ Children, especially those who are preadolescent, tend to be diagnosed only with LOC eating, not BED, in part because parents or others may limit the quantity of food they are permitted to consume.

The relationship between the patient population, interventions, comparators, outcomes and timing of outcomes assessment (PICOTs) is depicted for each of the treatment KQs (Figure 1 in <http://effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1942#9028>) and each of the course of illness KQs (Figure 2 in

<http://effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1942#9028>).

Dated: OCT 06 2014

Richard Kronick, Ph.D.
AHRQ Director

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