



# Mental Health Assessment and Psychosocial Interventions for Bariatric Surgery

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## **PREFACE**

Quality Enhancement Research Initiative's (QUERI) Evidence-based Synthesis Program (ESP) was established to provide timely and accurate syntheses of targeted healthcare topics of particular importance to Veterans Affairs (VA) clinicians, managers and policymakers as they work to improve the health and healthcare of Veterans. The ESP disseminates these reports throughout the VA, and some evidence syntheses inform the clinical guidelines of large professional organizations.

QUERI provides funding for four ESP Centers and each Center has an active university affiliation. The ESP Centers generate evidence syntheses on important clinical practice topics, and these reports help:

- develop clinical policies informed by evidence;
- guide the implementation of effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- set the direction for future research to address gaps in clinical knowledge.

In 2009, the ESP Coordinating Center was created to expand the capacity of HSR&D Central Office and the four ESP sites by developing and maintaining program processes. In addition, the Center established a Steering Committee comprised of QUERI field-based investigators, VA Patient Care Services, Office of Quality and Performance, and Veterans Integrated Service Networks (VISN) Clinical Management Officers. The Steering Committee provides program oversight, guides strategic planning, coordinates dissemination activities, and develops collaborations with VA leadership to identify new ESP topics of importance to Veterans and the VA healthcare system.

Comments on this evidence report are welcome and can be sent to Nicole Floyd, ESP Coordinating Center Program Manager, at [Nicole.Floyd@va.gov](mailto:Nicole.Floyd@va.gov).

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## EVIDENCE REPORT

### INTRODUCTION

Obesity rates in the US have risen to near epidemic levels. After a period of relative stability from 1960 to 1980, the proportion of adults with a body mass index (BMI) above 30 increased steadily to over 35% by 2010.<sup>3,4</sup> Despite a plateauing of rates in recent years,<sup>5</sup> the prevalence and consequences of obesity remain significant enough that the American Medical Association officially declared it a disease in 2013.<sup>6</sup> Obesity has been linked to multiple negative health effects, including cardiovascular disease, Type 2 diabetes, hypertension, hyperlipidemia, and obstructive sleep apnea. Even after controlling for other risk factors, non-elderly individuals with a BMI of 30 to <35 have a 20% higher relative risk of death compared to their normal weight counterparts while those with a BMI  $\geq 35$  have more than an 80% higher risk, mostly due to the effects of cardiovascular disease.<sup>7,8</sup>

While caloric restriction, exercise, and behavioral modification remain mainstays for the treatment of overweight individuals (BMI 25 to <35), these strategies have not been shown to produce sustained weight loss in the severely obese (BMI  $\geq 35$ ). As a reflection that more intensive strategies may be required in these patients, the National Institutes of Health established guidelines for weight loss surgery in 1991 that included a BMI  $\geq 40$  or a BMI  $\geq 35$  in the presence of significant comorbidities.<sup>9</sup> Since that time, bariatric surgery has become increasingly popular for the treatment of obesity, and has been associated with greater and more sustained weight loss. Bariatric surgery has also increased short term resolution of medical comorbidities – including diabetes – when compared to non-surgical therapies.<sup>10-12</sup> However, concerns remain about the durability of improvements and the risks of surgery because outcomes beyond 5 years have not been published for US-based samples.

A variety of surgical procedures have been used to induce weight loss for severely obese patients. They result in weight loss via different mechanisms: mechanically restricting the size of the stomach, bypassing a portion of the intestines, or by a combination of these mechanisms. Additionally, there is evidence that these procedures generate alterations in gastric and neuropeptides that play a role in weight loss and early satiety.

Currently, the most common procedures performed are done laparoscopically, and they include gastric banding (adjustable gastric band), gastric bypass (Roux-en-Y gastric bypass) and gastric sleeve. The biliopancreatic diversion and vertical banded gastroplasty are performed infrequently and are primarily done by select surgeons and centers (specifics of these procedures will not be described in detail).

Gastric banding achieves weight loss by creating gastric restriction. The uppermost portion of the stomach is encircled by a band to create a gastric pouch with a capacity of 15 to 30 cc. The band consists of an inflatable doughnut-shaped balloon whose diameter can be adjusted by adding or removing saline via a reservoir port beneath the skin. The bands are adjustable allowing the size of the gastric outlet to be modified, depending on the rate of a patient's weight loss.

Gastric bypass achieves weight loss through a combination of gastric restriction and malabsorption. Reduction of the stomach to a small gastric pouch results in feelings of satiety following even small meals. This small pouch is connected to the lower segment of the small

intestine, bypassing the proximal small intestine. Thus, absorptive function is reduced. Possibly also aiding weight loss is the production of unpleasant gastrointestinal symptoms following ingestion of particular foods: symptoms include abdominal pain, cramping, and diarrhea.

Gastric sleeve is a more recently adopted procedure where the stomach is stapled into a tube. This procedure has been gaining interest as it is relatively simple to perform and offers a lower post-operative complication rate. It appears to have successful weight loss results and improvements in comorbidities, but longer term results, beyond 5 years, are not yet known.

Not all patients receive equal benefit from bariatric surgery. Some patients fail to lose adequate weight, lose but quickly regain weight, or have only marginal improvement in medical comorbidities. There is increasing interest in identifying bariatric candidates in whom surgery may be less effective, and in developing strategies to improve their post-operative outcomes.<sup>1</sup> Psychosocial factors are commonly cited as important predictors of post-operative outcomes.<sup>13,14</sup> Many bariatric surgery programs formally screen for mental health conditions during the pre-operative assessment in an attempt to select patients with the highest compliance and likelihood of successful weight loss, as well to identify patients at risk for worsening mental health or substance abuse after the surgery.<sup>15,16</sup> Others, including the Veterans Health Administration (VHA), do not require formal evaluation. Whether screening for mental health conditions in this population improves patient selection or post-operative outcomes remains unknown.

## METHODS

### TOPIC DEVELOPMENT

This project was nominated by Dr. Lisa Kearney, Senior Consultant for Technical Assistance, VA Central Office Mental Health Operations. Currently, the VHA does not have a policy requiring that all bariatric surgery candidates undergo a psychological evaluation prior to surgery. The Office of Patient Care Services and the Office of Clinical Operations are interested in reviewing the evidence for or against this practice to help determine if the VHA should implement mental health evaluations for bariatric surgery candidates prior to bariatric surgery. Initially, VA policy makers wanted to know if there was convincing evidence that routine specialized pre-operative screening for mental health conditions resulted in better patient outcomes, either in terms of patient selection for surgery or by identifying individuals who would benefit from a pre-operative intervention aimed at modifying mental health comorbidities. However, a preliminary literature search did not identify any studies that examined the impact of pre-operative mental health screening versus no screening on outcomes related to bariatric surgery. Therefore, with the input from a technical expert panel (TEP), this overarching goal was divided into 3 related questions for which a preliminary literature search indicated published data were likely to exist. Initial key questions were refined with input from a technical expert panel.

The final key questions are:

Key Question 1. What is the prevalence of mental health conditions among bariatric surgery candidates?

Key Question 2. What is the association between pre-operative mental health conditions and bariatric outcomes, including weight loss, quality of life, adherence to behavioral guidelines, risk of suicide, prevalence of mental health conditions, and peri-operative complications?

Key Question 3. Is there evidence to support any pre-operative intervention in patients with mental health disorders to improve post-operative bariatric outcomes, including weight loss? With the input from VA stakeholders and our technical experts, we further refined the term, “mental health conditions” to include:

1. The diagnosis of depression, anxiety, post-traumatic stress disorder, personality disorders, substance abuse disorders, or suicidality;
2. Eating disorders, primarily binge eating disorders.

Eating behaviors that are not classified as disorders, (eg, “grazing” and “cognitive restraint”), while important, were outside our scope of interest and were not included. We did not classify cigarette smoking as a substance use disorder.

“Candidates” was defined as persons seeking or being evaluated for possible bariatric surgery. We distinguish this population from a population of patients who all received bariatric surgery.

The PROSPERO registration number is CRD42014008675.

## **SEARCH STRATEGY**

We searched PubMed, MEDLINE on OVID, and PsycINFO using a broad set of search terms including “bariatric” or “obesity” or the names of the various surgical procedures and then terms for mental health conditions, maladaptive eating, binge eating, and other eating disorders. Because a member of our team had participated in an earlier systematic review on the related topic of pre-operative predictors of weight loss following bariatric surgery<sup>1</sup> and our review of that project’s search strategy and methods for identifying relevant articles gave us confidence their results were relevant to our needs, we used their search and results to cover the period from 1988 through 2010, and therefore ran our searches from October 2009 through August 2014. We then supplemented these 2 searches with a “related articles” search in PubMed between January 1990 and August 2014 to identify literature related to a key article by Malik and colleagues,<sup>2</sup> as well as a targeted search in the psychological literature database PsycINFO for articles related to bariatric surgery and mental health conditions published between January 2009 and August 2014 (see full search strategy details in Appendix A). Additional studies were recommended for inclusion by technical expert panel members and peer reviewers.

## **STUDY SELECTION**

After conducting an initial pilot screening of 200 titles in order to calibrate all 4 reviewers, all titles identified by the searches were independently reviewed by each of the 4 reviewers (AM, AD, MM, PS). Any title selected by at least one reviewer was included for abstract and full text review.

After eliminating obviously irrelevant titles, we assessed abstracts or full text articles for eligibility. To be included at this stage, an article had to address at least one key question, report findings from primary research or be a systematic review, and report data for patients with a BMI of 35 or greater (Appendix B). All articles were screened independently by 2 reviewers, and all inclusion conflicts were discussed with the larger group.

Within each key question, additional criteria were specified so that the review would focus on the highest quality, and most relevant studies. For Key Question 1, studies with data on prevalence were included if they met one of the following criteria: (1) random or consecutive sampling and over 200 patients or multiple study sites; (2) studies that did not use random or consecutive sampling and over 500 patients; (3) all studies of US Veterans; and (4) all clinical trials, whether randomized or non-randomized. Studies had to measure specific mental health conditions or eating disorders and had to do so with a recognized method (such as a validated instrument or a clinical evaluation which was sometimes, but not always, the Structured Clinical Interview for DSM-IV (SCID)). Studies had to report the prevalence of patients with the condition, rather than an average score of the overall population on a diagnostic scale. For example, we included studies stating, “the percent of persons with major depressive disorder was 15%,” but not studies reporting, “the mean score on the Beck Depression Inventory was 25.” In addition, we required pre-operative classifications of mental health conditions and eating disorders to be made pre-operatively; in other words, we excluded studies that asked patients to recall their pre-operative health status. For Key Question 2, we used the same criteria to restrict the sample to the better quality, more relevant samples, but also required studies to report post-operative assessments of at least one target outcome. For Key Question 3, the assessed

intervention had to occur pre-operatively, the outcomes had to be post-operative, and the target had to be related to eating disorders or mental health comorbidities.

## **DATA ABSTRACTION**

Data were extracted by 2 independent reviewers, and discrepancies were reconciled by the entire research team.

For Key Question 1 and Key Question 2, articles had data abstracted on the country of origin, whether findings were presented for US Veterans, sample analyzed, method of recruitment, details of the sample demographics, details of bariatric surgery, mental health diagnoses assessed, methods of assessment, and whether the assessments were kept confidential from the surgery team.<sup>17</sup> This latter item was added at the suggestion of the TEP, as there is evidence that reported prevalence is higher when subjects are told their response will be kept confidential from the surgical team. After identification of studies meeting all eligibility criteria, the appropriate prevalence or outcome data were highlighted by the clinician data abstractor and then given to the research team statistician for extraction of quantitative data.

For Key Question 3, articles discussing pre-operative interventions had data abstracted on the intervention setting, patient characteristics, description of the intervention, description of the care or treatments to which the intervention was compared, type of bariatric procedure patients underwent post-intervention, outcomes assessed, instruments used to assess the outcomes, timing of the outcome assessment, and the article findings.

## **QUALITY ASSESSMENT**

For Key Question 1 and Key Question 2, articles about prevalence and association were assessed for the representativeness of participants to some larger population.

For Key Question 3, articles addressing pre-operative interventions were assessed for quality using a modified Cochrane Risk of Bias tool to establish high, low, or unclear bias on 7 factors: outcome, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias.<sup>18</sup>

## **DATA SYNTHESIS**

We constructed evidence tables showing characteristics and results for all included studies, organized by key question. We analyzed studies to compare their characteristics, methods, and findings. We summarized findings for each key question and drew conclusions based on qualitative synthesis of the findings. For Key Question 1, we graphed the prevalence data from each study. For studies reporting more than one method for a particular mental health condition, the most relevant measure was selected by the study team psychiatrist. We also calculated the weighted median value, and compared these values between studies with different populations and designs to test the stability of the estimates.

## **RATING THE BODY OF EVIDENCE**

The evidence for Key Question 3 was assessed using the GRADE criteria, which uses the domains of study design limitations, inconsistency, indirectness, and imprecision in results.<sup>19</sup> The evidence for Key Questions 1 and 2 were also assessed using the same domains. The

GRADE Working Group classified the quality of evidence across outcomes according to the following criteria:

- High = Further research is very unlikely to change our confidence on the estimate of effect.
- Moderate = Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
- Low = Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
- Very Low = Any estimate of effect is very uncertain.

## **PEER REVIEW**

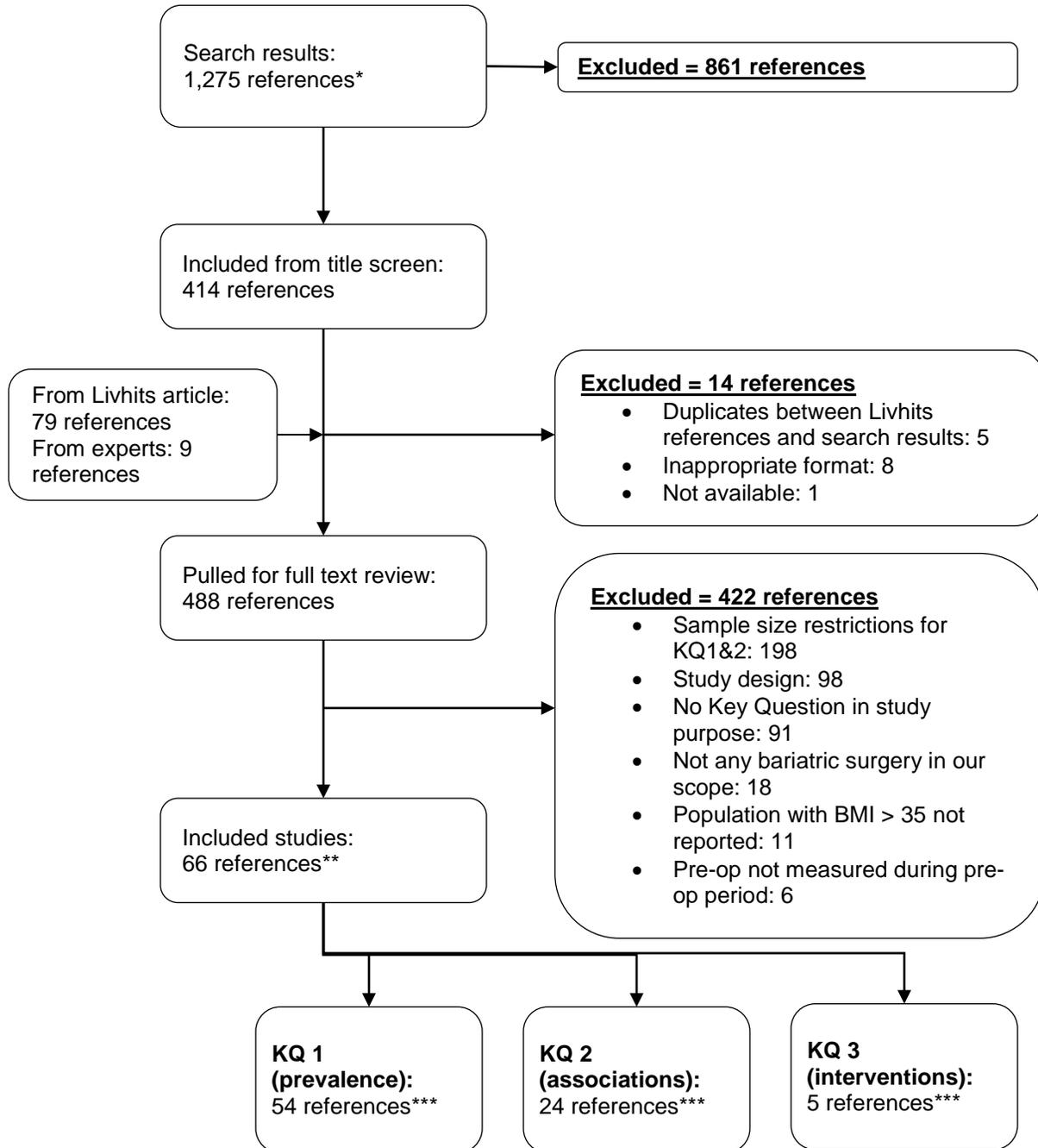
A draft version of this report was reviewed by 9 peer reviewers and 4 operational partners. Reviewer comments were addressed and our responses were incorporated into the final report. The complete set of comments and responses can be found in Appendix C.

## **RESULTS**

### **LITERATURE FLOW**

From the literature searches, we identified 1,275 reference citations. We selected 414 potential citations for inclusion, excluding 861 citations. We combined this list of 414 potential includes with the 79 references identified in the article by Livhits and colleagues and the 9 references identified by experts. When combined, 14 references were excluded as duplicates, leaving 488 references for full text review. Once the 488 full texts were reviewed, 422 were excluded from the report. The other 66 references were included, with 54 addressing Key Question 1, 24 addressing Key Question 2, and 5 addressing Key Question 3. Figure 1 details the review process and the number of references related to each of the key questions, as well as the counts for exclusion categories after the title screening had been completed.

**Figure 1. Literature Flow Chart**



\* New searches: 937 total after removed within-search duplicates and obviously non-relevant hits. Removed 7 inter-search duplicates for total of 930

\*\* Manuscript reference list includes additional references cited for background and methods plus websites relevant to key questions.

## Key Question 1: What is the prevalence of mental health conditions among bariatric surgery candidates?

We identified 240 articles reporting data on prevalence. From these, we selected the following articles as being the best quality, most informative, or most specific to VA.

- Studies with consecutive or random sampling of candidates for bariatric surgery or who had received surgery, with a sample size of at least 200 subjects;
- Studies with non-consecutive/non-random sampling of candidates for bariatric surgery or who had received surgery, as long as the sample size was greater than 500 or it was multisite;
- All studies specific to VA patients, regardless of sample size;
- Data from randomized controlled trials (RCTs) (which typically enroll highly selected populations, reducing generalizability, but typically assess patients in greater depth and with more rigor).

Using these criteria, we identified the following: 15 and 13 studies, respectively, that assessed consecutive or random samples of surgical candidates or patients receiving surgery ( $N > 200$  or multisite); 8 and 7 studies, respectively, that assessed non-consecutive/non-random samples of surgical candidates or patients receiving surgery ( $N > 500$  or multisite); 5 studies specific to VA, and 6 studies that were RCTs. Details of each included study are presented in Table 2. The assessed populations, not counting the VA sample, were relatively similar. In most studies, 67 to 85% of subjects were female, their mean age was mid-40 years of age, and the mean BMI was 45 to 50  $\text{kg}/\text{m}^2$ . The VA samples were predominantly men, but otherwise had similar demographics (mean BMI=42-52  $\text{kg}/\text{m}^2$ , slightly older mean age of 48-52 years of age).

Figure 2 presents the data for the prevalence of anxiety, depression, eating disorders, personality disorders, psychosis, PTSD, substance use disorders, and suicidality/suicidal ideation. In the figure, the different symbols represent the different kinds of studies listed above, and the size of the symbols is proportionate to its sample size.

We calculated the weighted median prevalence for the various conditions and disorders, which are as follows:

**Table 1. Mental Health Conditions in Bariatric Surgery Candidates and Patients**

<b>Mental Health Conditions</b>	<b>Weighted Median</b>
Anxiety	15%
Depression	25%
Any mood disorder	27%
Eating Disorders	16%
Personality Disorders	1%
Post-Traumatic Stress Disorder	1%
Psychosis	1%
Substance abuse disorders	7%
Suicidal ideation/suicidality	11%

\* Substance abuse disorders refers to alcohol and drug abuse or those merely described as substance abuse. Tobacco use was not included.

Some studies reported both “lifetime” and “current” prevalence, in which case we used the “current” prevalence data. If a study did not state it, we assumed presented data were “current” prevalence.

Some included studies were by the same authors and had similarly-described patient populations. It was not possible for us to determine whether or not these samples overlapped. So, in order to prevent “double counting,” we performed a sensitivity analysis that included only one value for each of the mental health conditions per group of related studies. This sensitivity analysis yielded median results little changed from the primary analysis.

Some mental health conditions varied greatly in their prevalence estimates. This variation was not consistently related to the sample characteristics. For example, the median prevalence of depression in the studies reporting consecutive or random sampling is 15% and 25% for candidates and patients undergoing surgery, respectively; the corresponding values for studies that used other methods to enroll patients reported estimates of 38% and 28%, respectively. The one exception to this conclusion is studies of Veterans, which reported the highest prevalence of all mental health diagnoses; in some cases these differences were quite marked. For example, the median prevalence of PTSD in Veteran samples was 24% compared to 1% overall and substance abuse was 24% compared to 2-7%. The sources of variation across samples are most likely attributable to the method used to make the diagnosis, geographic variations in the populations themselves, and chance (in particular, the Veteran samples were small relative to the other studies, with sample sizes between 25-102). So few studies reported that the mental health assessment was kept confidential that we were unable to do a sensitivity analysis on this as a source of variation. A prior study has reported that confidential assessments report a higher prevalence of mental health conditions.<sup>17</sup>

An additional assessed factor was quality of life (QOL). This was measured with either the Short Form-36 or the Impact of Weight on Quality of Life (IWQOL) instrument. One study using the GIQLI (gastrointestinal quality of life instrument) was not included here, as it is scored on a

different range and therefore not comparable to the rest of the included studies. Results are in Figure 3.

The weighted median QOL value was 52 (out of a score of 100 points), which is approximately the population average (SF-36 data for women aged 35-44, which is closest to this study population).

The highest outlier study for eating disorders came from a study of 25 bariatric surgery candidates identified from the MOVE! clinic (a weight loss clinic) at the VA San Diego Healthcare System.<sup>20</sup> The high outlier status may be due to particulars of this patient population or variability due to small sample size.

### **Summary of Findings**

Bariatric surgery candidates and those receiving surgery have depression, anxiety, and certain eating disorders (*eg*, binge eating ) at rates equal to or exceeding 15%. Other mental health disorders, such as psychoses, are less frequent. Published prevalence estimates vary, particularly for depression and binge eating disorder. The few assessments done in Veteran populations found higher proportions of comorbidities than are present in other populations, particularly PTSD.

### **Quality of Evidence for Key Question 1**

We judged the quality of evidence as moderate for the overall conclusion that mental health conditions and eating disorders are common in bariatric patients. The exact estimates we judge as low, due to the inconsistency noted, particularly for depression and eating disorders. All estimates for Veterans are judged low due to the small number of patients assessed (at most about 300 patients).

Table 2. Evidence Table of Studies of Prevalence of Mental Health Conditions in Bariatric Surgery Patients or Candidates

Author, Year Country	Sample (Candidates/All received surgery)	Method of Recruitment	Details of Sample	Details of Surgery	Mental Health Diagnoses Assessed	Methods of Assessment <i>Kept Confidential from Surgery Team</i>
Articles with Consecutive or Random Sampling of Candidates for Surgery (n=15)						
Allison, 2006 <sup>21</sup> USA	Candidates (% receiving surgery not stated)	Consecutive patients with extreme obesity seeking bariatric surgery at a university-based program; response rate=98%	N=210 82% female Mean BMI=50.4 Mean age=44.4	Not stated	Binge eating disorder Bulimia nervosa	QEWP-R Clinical interview <i>Not stated</i>
Castellini, 2013 <sup>22</sup> Italy	Candidates (% receiving surgery not stated)	Consecutive patients referring for the first time to the obesity surgery clinic; response rate=88%	N=394 73% female Mean BMI=44.6 Mean age=45	Not stated	Depression Binge eating Obsessive compulsive disorder Generalized anxiety disorder	SCID <i>Not stated</i>
Chen, 2012 <sup>23</sup> USA	Candidates (% received surgery not stated)	Consecutive patients enrolling in screening for bariatric surgery at the University of Chicago	N=334 76% female Mean BMI=49.2 Mean age=44	Not stated	Suicide Ideation	BDI-II <i>Not stated</i>
Chen, 2012 <sup>24</sup> USA	Candidates (% receiving surgery not stated)	Consecutive adult candidates for bariatric surgery at the University of Chicago; 2008-2010, response rate not stated	N=396 76% female Mean BMI=49 Mean age=44	Not stated	Suicide ideation	Suicidal behaviors questionnaire <i>Not stated</i>
Grothe, 2014 <sup>25</sup>	Candidates (% receiving surgery not stated)	Consecutive patients seeking bariatric surgery at a large academic medical center, 2009-2011; response rate not stated	N=935 75% female Mean BMI=46.9 Mean age=47	Not stated	Bipolar disorder	Mood Disorder Questionnaire Clinical interview <i>Not stated</i>
Hall, 2013 <sup>26</sup> USA	Candidates (% receiving surgery not stated)	Consecutive patients referred for psychological evaluation prior to RYGB at an urban academic medical center	N=505 84% female Mean BMI=50.7 Mean age=41.9	100% RYGB	Depression, personality disorders	Beck Depression Inventory II Personality Assessment Inventory: Depression Scale Semi-Structured Clinical

Author, Year Country	Sample (Candidates/All received surgery)	Method of Recruitment	Details of Sample	Details of Surgery	Mental Health Diagnoses Assessed	Methods of Assessment <i>Kept Confidential from Surgery Team</i>
						Interview <i>Not stated</i>
Hayden, 2014 <sup>27</sup>	Candidates (98% received surgery)	Consecutive patients meeting eligibility criteria for bariatric surgery at one institution, 2007-2009; response rate = 75%	N=204 82% female Mean BMI=42.7 Mean age=45	100% LAGB	Any Axis I disorder Any mood disorder Major depressive disorder Dysthymia Bipolar disorder Any anxiety disorder Panic disorder OCD PTSD Generalized anxiety disorder Schizophrenia Alcohol abuse Binge eating disorder	SCID <i>Not stated</i>
Hayden, 2012 <sup>28</sup> Australia	Candidates (% receiving surgery not stated)	Consecutive adult candidates for bariatric surgery at Monach University in Australia; 2007-2009; response rate=85%	N=201 82% female Mean BMI=43 Mean age=45	Not stated	Major depressive disorder Bipolar disorder	SCID <i>Not stated</i>
Kalarchian, 2007 <sup>29</sup> USA	Candidates (% receiving surgery not stated)	Consecutive candidates seeking bariatric surgery at a large urban medical center; dates not stated; response rate=29%	N=288 83% female Mean BMI=52.2 Mean age=46.2	Not stated	Any Axis I disorder Any Axis II disorder Major depressive disorder Bipolar Panic disorder OCD PTSD Generalized anxiety disorder	SCID SF-36 <i>Not stated</i>

Author, Year Country	Sample (Candidates/All received surgery)	Method of Recruitment	Details of Sample	Details of Surgery	Mental Health Diagnoses Assessed	Methods of Assessment <i>Kept Confidential from Surgery Team</i>
					Binge eating disorder Bulimia nervosa Anorexia Alcohol abuse Drug abuse HRQOL	
Lester, 2011 <sup>30</sup> Italy	Candidates (% receiving surgery not stated)	Consecutive patients seeking bariatric surgery referred for mental health evaluation	N=69 80% female Mean weight=116 kg Mean age=45	Not stated	Suicide Depression Not stated	MMPI-2 <i>Not Stated</i>
Marek, 2014 <sup>31</sup>	Candidates (% receiving surgery not stated)	Consecutive patients seeking bariatric surgery at one hospital, 2009-2012; response rate = 97%	N=1,283 72% female Mean BMI=49.2 Mean age=46	Not stated	Binge eating disorder	Clinical interview BES Chart review <i>Not stated</i>
Marek, 2013 <sup>32</sup> USA	Candidates (% received surgery not stated)	Consecutive patients seeking surgery at one site (Cleveland clinic); all administered pre-op evaluation, dates not stated)	N=982 67% female Mean BMI=49.2 Mean age=46	Not stated	Mental disorders, personality disorders, Maladaptive eating, substance abuse, sexual abuse Suicide/death ideation, anxiety, depression	Chart review, semi- structured interview <i>Not stated</i>
Mauri, 2008 <sup>33</sup> Italy	Candidates (% receiving surgery not stated)	Consecutive candidates for bariatric surgery presenting to the University of Pisa; 2001-2006; response rate not stated	N=282 80% female Mean BMI=43.5 Mean age=42	Not stated	Any Axis I disorder Any Axis II disorder Major depressive disorder Bipolar OCD PTSD Generalized anxiety disorder Binge eating disorder Bulimia nervosa HRQOL	SCID HAM-D Bulimic Investigatory Test, Edinburgh Q-LES-Q <i>Not stated</i>

Author, Year Country	Sample (Candidates/All received surgery)	Method of Recruitment	Details of Sample	Details of Surgery	Mental Health Diagnoses Assessed	Methods of Assessment <i>Kept Confidential from Surgery Team</i>
Wee, 2013 <sup>34</sup> USA	Candidates (% receiving surgery not stated)	Consecutive patients seeking weight loss identified via appointments (70% response rate) at 2 academic medical centers	N=574 73% female Mean BMI=61.2 Mean age=43	Not stated	Quality of Life	IWQOL SF-36 <i>Not Stated</i>
Windover, 2010 <sup>35</sup> USA	Candidates (43.6% received surgery)	Consecutive patients seeking surgery at Cleveland Clinic 2006- 2008	N=1,020 76.6% female Mean BMI=50.3 Mean age=46.4	66.5% RYGB 16.9% Adjustable banding 12.4% Sleeve	Suicide Attempts	Semi-structured Interview <i>Not stated</i>
Cremieux, 2010 <sup>36</sup> USA	All received surgery	All patients in a proprietary database of 5,000,000 Americans who had received bariatric surgery and had continuous insurance coverage	N=5,502 83% female Mean BMI not stated Mean age=44	73% RYGB Mix of other procedures	Depressive Disorders	Claims data <i>Not applicable</i>
Cunningham, 2012 <sup>37</sup> USA	All received surgery	Random sample of procedures done in Jan 2002-Nov 2004	N=350 80% female Mean BMI=47.2 Mean age=47	100% RYGB	Depression, generalized anxiety disorder, dysthymic disorder	Semi-structured interview, BDI II <i>Not stated</i>
Dixon, 2003 <sup>38</sup> Australia	All received surgery	Consecutive patients receiving bariatric surgery at a university program, 1999-2003; response rate not stated	N=487 85% female Mean BMI=44.1 Mean age=41.2	100% LAGB	Depression	BDI <i>Not stated</i>
Dixon, 2001 <sup>39</sup> Australia	All received surgery	Consecutive patients receiving bariatric surgery at a single institution, 1998-2001; response rate not stated	N=459 85% female Mean BMI=45.0 Mean age=41	100% LAGB	QOL	SF-36 <i>Not applicable</i>

Herpertz, 2006 <sup>40</sup> Germany	All received surgery	Consecutive patients at 6 German hospitals were approached day of admission (dates not stated)	N=153 67% female Mean BMI=51 Mean age=39	Not stated	Substance Abuse Disorder Mood Disorders Anxiety Disorders Eating Disorders	Composite International Diagnostic Interview Structured Interview for Anorexia and Bulimia Nervosa <i>Not stated</i>
Hood, 2012 <sup>41</sup> USA	All received surgery	Consecutive patients referred for RYGB at an urban medical center	N=530 84% female Mean BMI=50.7 Mean age=41.9	100% RYGB	Maladaptive eating	Binge Eating Scale <i>Not stated</i>
Legenbauer, 2011 <sup>42</sup> Germany	All received surgery	Consecutive patients receiving surgery in 6 German hospitals (99% of patients participated) (dates not stated)	N=151 67% female Mean BMI=51 Mean age=39	Mix of gastric banding and gastroplasty	Depressive Disorder Eating Disorders	Composite International Diagnostic Interview Structured Interview for Anorexia and Bulimia <i>Not stated</i>
Legenbauer, 2009 <sup>43</sup> Germany	All received surgery	Patients at 6 German hospitals were approached on the day of admission	N=151 68% female Mean BMI=51 Mean age=39	Gastric bypass	Any Mental Disorder Depressive Disorders Anxiety Disorders Binge Eating Behaviors	Composite International Diagnostic Interview Structured Interview for Anorexia and Bulimia Nervosa <i>Not stated</i>
Mitchell, 2014 <sup>44</sup>	All received surgery	Patients who received bariatric surgery as part of the LABS-2 study, 2006-2009; response rate=92%	N=2,266 79% female Median BMI=45.9 Median age=46	Various	Binge eating disorder Bulimia nervosa Quality of life	LABS-2 survey on eating disorders SF-36 IWQOL-Lite <i>Not stated</i>
Ostlund, 2013 <sup>45</sup> Sweden	All received surgery	Jan 1980 to Dec 2006; nationwide population based cohort	N=11,115 77% female Mean BMI=Not stated Mean age=40.1	37% RYGB 63% other	Depression, substance abuse, suicide attempt, alcohol abuse	ICD-9 or 10 codes for above from national databases <i>Not applicable</i>
Raebel, 2006 <sup>46</sup> USA	All received surgery	All patients receiving surgery in 10 sites sharing a clinical information system 2005-2009	N=11,719 81% female Mean BMI=44 Mean age=47	76% RYGB Mix of procedures	Depression, anxiety, substance abuse, bipolar disorder, PTSD	Medical records diagnosis <i>Not applicable</i>

Wolnerhanssen, 2008 <sup>47</sup> Switzerland	All received surgery	All patients with obesity treated with LAGB (probably at one Swiss hospital); 1996-2004; response rate not stated	N=380 78% female Median BMI=43.4 Median age=40	100% LAGB	Binge eating disorder	Clinical interview <i>Not stated</i>
Won, 2014 <sup>48</sup>	All received surgery	All patients undergoing bariatric surgery at a single institution, 2008-2011; response rate not stated	N=485 81% female Mean BMI=47.8 Mean age=46	100% laparoscopic RYGB	Any Axis I disorder Major depressive disorder Anxiety disorder Bipolar disorder	Clinical interview BDI-II Burns Anxiety Inventory Y-BOCS Weight and Lifestyle Inventory <i>Not stated</i>
Articles with Non-consecutive and Non-random Sampling of Candidates for Surgery (n=8)						
Adams, 2010 <sup>49</sup> USA	Candidates (50% received surgery)	Patients seeking bariatric surgery from 3 bariatric surgeons in Utah; non-bariatric seeking patients from a large database	N=835 84% female Mean BMI=47 Mean age=44	Gastric bypass	Quality of Life	IWQOL-Lite, SF-36 <i>Not stated</i>
Apovian, 2013 <sup>50</sup> USA	Candidates Assessment of Bariatric Surgery (ABS) study (100% received surgery)	Patients were “systematically” recruited at 2 academic medical centers in Boston (Response Rate=70%)	N=536 76% female Mean BMI=46.8 Mean age=44	55.4% RYGB 44.6% adjustable gastric banding	Quality of life	Impact of weight on quality of life (IWQOL)-Lite <i>Not stated (but yes in another ABS study)</i>
Caixas, 2013 <sup>51</sup> Spain (and compared to previously collected US data)	Candidates (% receiving surgery not stated)	June 2010 to Dec 2010 (Spain) recruited by hospital staff, non-obese Spanish subjects were recruited from hospital or university staff, acquaintances, or relatives with the same exclusion criteria as those of the patients. Non-obese control; patients attending an outpatient unit at 16 university hospitals in Spain, Duke database for North American subjects	N=400 Spanish Obese N=400 Spanish non-obese N=400 North American Obese N=400 North American non-obese For obese patients: 75% female Mean BMI=45.9 Mean age=43.1	Not stated	QOL, eating disorders, depression, anxiety, bipolar, schizophrenic disorder	Impact of weight on quality of life (IWQOL)-Lite, not stated for mental health condition <i>Not stated</i>

Corsica, 2012 <sup>52</sup> USA	Candidates (% receiving surgery not stated)	Patients seeking surgery at a major urban medical center	N=790 85% female Mean BMI=50 Mean age=42	Gastric bypass, adjustable gastric band (proportions not stated)	Depression, binge eating	Beck Depression Inventory Binge Eating Scale <i>Not stated</i>
Corsica, 2010 <sup>53</sup> USA	Candidates (% receiving surgery not stated)	Patients seeking surgery at a major urban medical center	N=546 85% female Mean BMI=50 Mean age=43	Gastric bypass, adjustable gastric band (proportions not stated)	Anxiety, depression, personality disorder, mania, schizophrenia, alcohol abuse, drug abuse, suicide ideation	Personality Assessment Inventory, BDI II <i>Not stated</i>
Kudsi, 2013 <sup>54</sup> USA	Candidates (>80% received surgery) Assessment of Bariatric Surgery (ABS) study	“Systematic” sample of patients seeking surgery at 2 academic medical centers in Boston (2008 – 2010), physicians gave permission for the research team to contact, response rate=75%	N=653 75% female Mean BMI =46.5 Mean age=44	Not stated	Alcohol abuse	AUDIT <i>Kept confidential from surgery team</i>
Lier, 2012 <sup>55</sup> Norway	Candidates (90% received surgery)	Patients referred for bariatric surgery from GPs in Norway. 99 subsequently participated in an RCT, 45 did not consent to participate in the RCT but are included in the prevalence data.	N=141 73% female Mean BMI=45.2 Mean age=42	100% RYGB	Axis II disorders, anxiety, depression, QOL, Axis I disorders	MINI, DSM IV Axis II, “questionnaires on anxiety, depression, and QOL” <i>Not stated</i>
Lin, 2013 <sup>56</sup> Taiwan	Candidates (54% received surgery)	Recruited from obesity surgery center, details not provided	N=841 69% female Mean BMI=35.7 Mean age=35.5	Not stated	depression, dysthymic disorder, general anxiety disorder, binge eating disorder, major depressive disorder, adjustment disorder, sleep disorder, psychotic disorder, bulimia nervosa, bipolar disorder, organic mental disorder, anxiety disorders; alcohol-related disorder, substance abuse, mood disorder, eating disorder, psychotic disorder	Taiwanese Depression Questionnaire, Chinese Health Questionnaire, Structured Clinical Interview for DSM IV <i>Not stated</i>

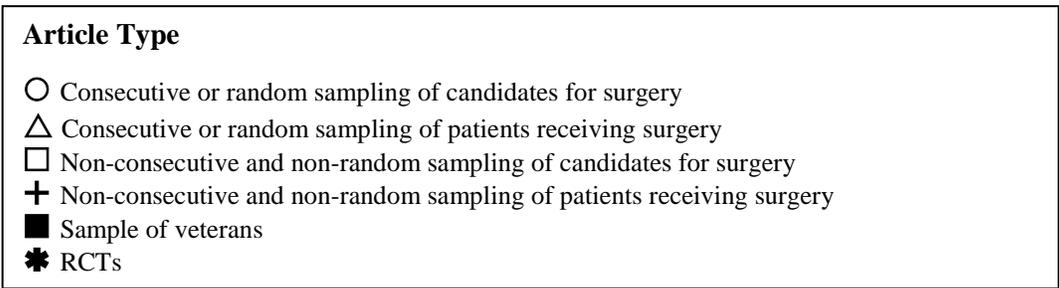
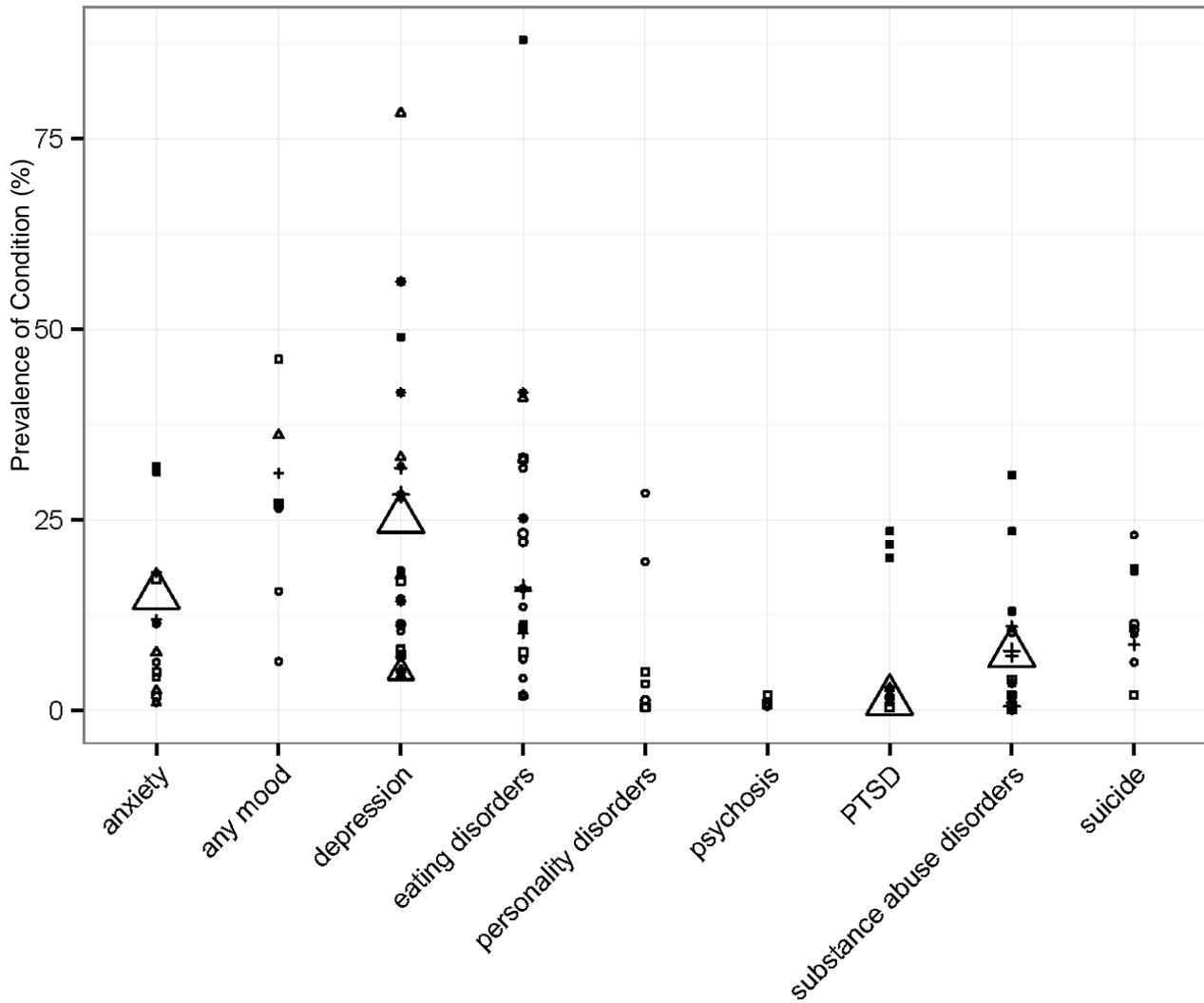
Articles with Non-consecutive and Non-random Sampling of Patients Receiving Surgery (n=7)						
Heinberg, 2012 <sup>57</sup> USA	All received surgery at the Cleveland Clinic (year not stated)	Patients who had surgery and completed 2 or more follow up visits (64% of total sample)	N=608 75% female Mean BMI=48.1 Mean age=Not stated	67% RYGB 17% Adjustable gastric banding 13% Sleeve	Binge eating, suicide history, substance abuse	Binge Eating Scale, MMPI-2-RF, Cleveland Clinic Behavioral Rating System, semi-structured psychiatric interviews <i>Not stated</i>
King, 2013 <sup>58</sup> USA	All received surgery	From the LABS-2 observational study, participants in LABS-2 who underwent surgery and had adequate data on an activity monitor Feb 2006-Feb 2009	N=850 79.2% female Mean BMI=45.8 Mean age=45	Not stated	QOL, depression, treatment for mental health recently, alcohol use disorder, anxiety impaired mental health functioning	SF-36 MD, BDI, Self-reported for treatment, psychiatric and emotional test survey, AUDIT <i>Not stated</i>
King, 2012 <sup>59</sup> USA	All received surgery	From the LABS-2 observational study, participants in LABS-2 who underwent surgery and completed AUDIT Feb 2006-Feb 2009	N=1945 78.8% female Mean BMI=45.8 Mean age=47	69.9% RYGB 25.2% Adjustable gastric banding 0.8% Biliopancreatic diversion 1.5% Banded gastric bypass 2.6% Sleeve	QOL, depression, alcohol abuse, maladaptive eating, past year treatment psychotic or emotional problem	SF-36, BDI, AUDIT <i>Not stated</i>
Mitchell, 2014 <sup>44</sup> USA	All received surgery	From the LABS-2 observational study, Feb 2008 - Feb 2009	N=2,266 79% female Median BMI=45.9 Median age=46	Not stated (but in other LABS-2 reports the proportion receiving RYGB was approximately 70%)	Eating disorders, QOL	Survey SF-36 <i>Not stated</i>
Mitchell, 2014 <sup>60</sup> USA	All received surgery	From the LABS-2 observational study, Feb 2008 - Feb 2009	N=2,146 78.5% female Median BMI=45.9 Median age=46	Not stated (but in other LABS-2 reports the proportion receiving RYGB was approximately 70%)	Depression	BDI <i>Not stated</i>

Mitchell, 2012 <sup>61</sup> USA	All received surgery	A sample of LABS-2 participants	N=199 83% female Median BMI=44.9 Median age=46		Major depressive disorder, dysthymia, any anxiety disorder, any eating disorder, post-traumatic stress disorder, any substance use disorder, binge eating disorder, QOL	BDI Eating Disorder Examination (EDE) Structured Clinical Interview SF-36 <i>Not stated</i>
Svensson, 2013 <sup>62</sup>	All received surgery	Patients participating in the surgical cohort portion of the Swedish Obese Subject (SOS) study, 1987-2001; response rate not stated	N=2,010 71% female Mean BMI=42.3 Mean age=47	68% VBG 19% gastric banding 13% RYGB	Self-reported alcohol problems	Self-reported alcohol consumption Answer to survey question: "Do you think you have alcohol problems?" <i>Not stated</i>
Articles with Samples of Veterans (n=5)						
Adams, 2012 <sup>63</sup> USA	All received surgery	All patients receiving bariatric surgery at the Jackson, MS VA 2003-2008 No recent substance abuse or serious mental health problems	N=61 33% female Mean BMI=45.5 Mean age=48	41% had bypass procedures 59% had banding procedures	Tobacco use Substance abuse	Medical records, psychologist evaluation <i>Not stated</i>
Ikossi, 2010 <sup>64</sup> USA	All received surgery	All patients undergoing laparoscopic RYGB at Palo Alto VA 2001-2007	N=102 20% female Mean BMI=48.5 Mean age=51	All received laparoscopic RYGB	PTSD	Medical record diagnosis
Rutledge, 2012 <sup>65</sup> USA	All received surgery	All patients receiving with loss surgery at the San Diego VA	N=55 31% female Mean BMI=44 Mean age=52 Patients with substance use, cognitive impairment, <i>etc</i>	82% received RYGB 18% received adjustable band	Use of antidepressants for moods, anxiety disorders, use of anxiolytics, history of substance abuse, history of PTSD, history of suicide attempt, history of bipolar disorder	Medical record, clinical psychologist interview <i>Not stated</i>
Rutledge, 2011 <sup>20</sup> USA	Candidates (% receiving surgery not stated)	Consecutive patients completing an intake class for MOVE at the San Diego VA and then advancing to surgery	N=25 16% female Mean BMI=42 Mean age=51	Not stated	Depression Anxiety Binge eating Substance abuse PTSD OCD Schizophrenia	23 item questionnaire <i>Not stated</i>

Rutledge, 2011 <sup>66</sup> USA	All received surgery	All patients completing weight loss surgery at the San Diego VA 1998-2007. Participants had to achieve a pre-op weight loss of 5%. Patients with substance abuse or psychiatric admissions in the prior 12 months or dementia were excluded.	N=60 28% female Mean BMI=45.1 Mean age=52	87% RYGB 13% adjustable gastric band	Depression Anxiety disorder Binge eating Substance abuse history Suicide attempts Percent using antidepressants Percent using anxiolytics	Medical record, clinical psychologist evaluation <i>Not stated</i>
Articles from RCTs (n=6)						
Arterburn, 2011 <sup>67</sup> USA	Candidates and persons meeting NIH criteria (not seeking surgery yet, % received N/A)	Patients enrolled in an RCT assessing a video-based decision aid (2008-2009)	N=152 73% female Mean BMI=47 Mean age=50	Mix of procedures	Depression warranting treatment	PHQ-9 <i>Not stated</i>
Kalarchian, 2013 <sup>68</sup> USA	Candidates (% received surgery not stated)	All patients who were at least 18 years of age and seeking bariatric surgery at a Bariatric Center of Excellence at a large, urban medical center were eligible. Dates not stated.	N=240 87% female Mean BMI=48 Mean age=45	Not stated	eating disorders, depression	BDI, EDE, EBI
Kalarchian, 2012 <sup>69</sup> USA	All received surgery	Patients 21 years old were eligible to participate if they had undergone bariatric surgery 3 years before study enrollment and had lost 50% excess weight from before surgery to study enrollment; recruited from flyers; randomized to intervention or not arms pts enrolled in an RCT to test a pre-surgery lifestyle intervention. Excluded: psych problems sufficiently severe to require immediate treatment (dates not stated)	N=36 88.9% female Mean BMI=43.2 Mean age=52.5	Surgery not stated	Binge eating, depression substance problems	Self-report substance problems, eating disorder examination, Beck Depression Inventory <i>Not stated</i>

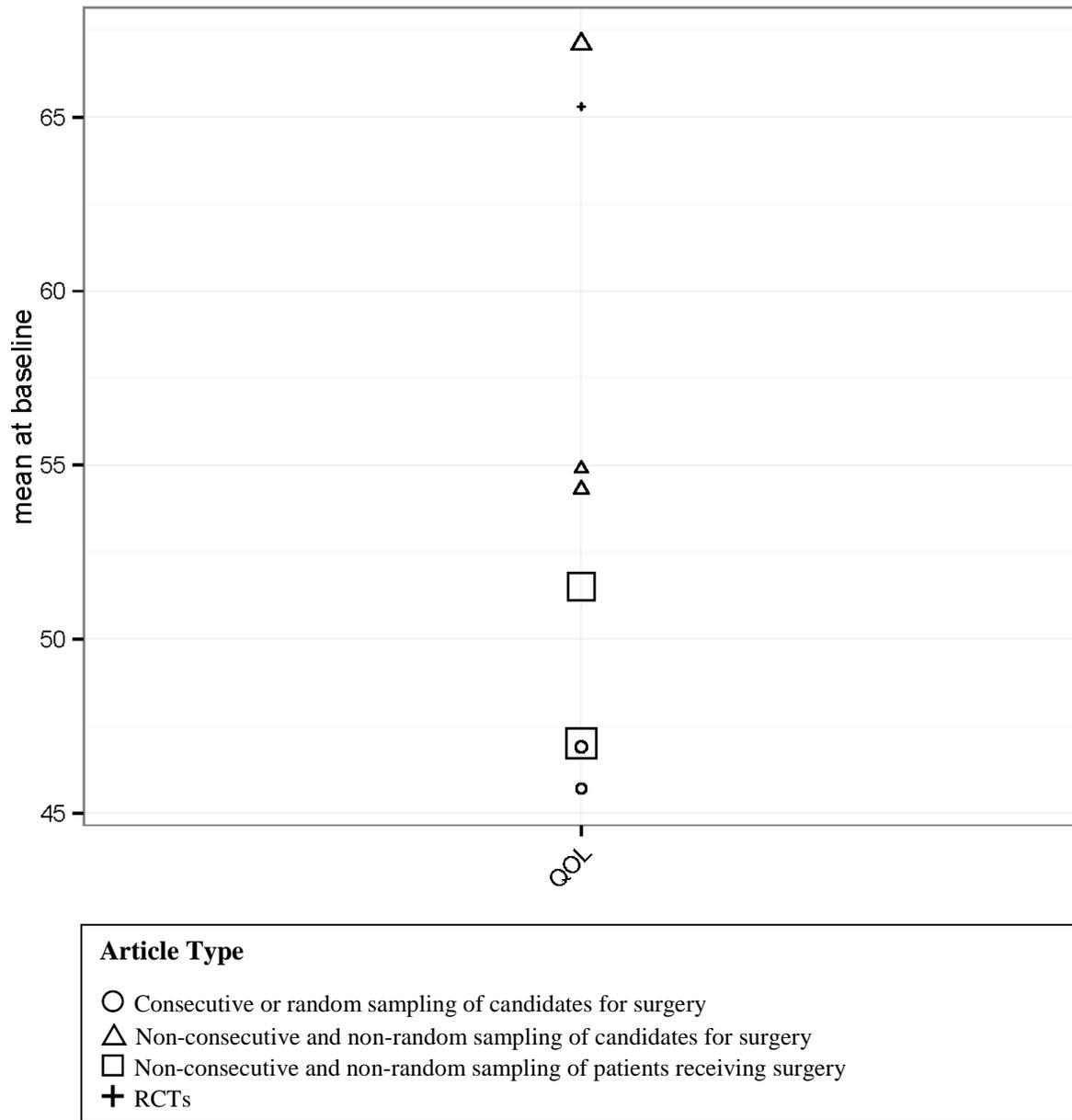
Nijamkin, 2013 <sup>70</sup> USA	All received surgery	Patients enrolled in an RCT assessing an intervention to improve depressive symptoms (dates not stated)	N=144 83% female Mean BMI=36 Mean age=44	All procedures performed by one surgeon 100% RYGB	Depressive symptoms	BDI-II <i>Not stated</i>
Peterli, 2013 <sup>71</sup> Switzerland	All received surgery	Participants in an RCT comparing gastric bypass to sleeve gastrectomy; 4 sites, recruitment not described (Jan 2007 to Nov 2011)	N=217 72% female Mean BMI=44 Mean age=42.5	50.7% received RYGB 49.3% received sleeve gastrectomy	Depression, QOL	Not stated for depression Gastrointestinal Quality of Life Index <i>Not stated</i>
Shah, 2011 <sup>72</sup> USA	All received surgery	Patients enrolled in an RCT to test a post-surgical exercise program Patients with major neuropsychiatric illness impeding competence or compliance were excluded	N=33 91% female Mean BMI=42 Mean age=50	Gastric bypass RYGB	Quality of Life	IWQOL-Lite SF-36 <i>Not stated</i>

Figure 2. Prevalence of Pre-operative Mental Health Conditions in Bariatric Surgery Candidates or Patients



(Note: size of symbol is proportional to the sample size)

Figure 3. Quality of Life Assessment in Bariatric Surgery Candidates or Patients



(Note: size of symbol is proportional to the sample size)

## Key Question 2: What is the association between pre-operative mental health conditions and bariatric outcomes, including weight loss, quality of life, adherence to behavioral guidelines, risk of suicide, prevalence of mental health conditions, and peri-operative complications?

We identified 24 studies reporting data on the association between pre-operative mental health conditions and post-operative outcomes.<sup>27,36,38,39,42,43,49,59,60,62-65,70-80</sup> Three articles specifically addressed outcomes in Veteran populations.<sup>63-65</sup> Details of each included study are presented in Table 3.

We present a synthesis of these data across 2 dimensions. First, we discuss the evidence by condition. Second, we discuss the collective evidence on the association of bariatric surgery and mental health outcomes and the association of mental health conditions and bariatric surgery outcomes.

### Evidence for associations by condition

In total, 11 articles addressed depression among bariatric surgery patients.<sup>27,36,38,42,43,60,65,70,71,73,78</sup> The method of assessing depression in each study is listed in Table 2. Seven focused on depression alone,<sup>36,38,60,70,71,73,78</sup> while 2 also evaluated anxiety,<sup>43,65</sup> one also evaluated eating disorders,<sup>42</sup> and one evaluated mood, anxiety, and eating disorders as well as schizophrenia and substance abuse.<sup>27</sup> Sample sizes ranged from 55 to 11,115, and 5 studies included multiple clinical sites.<sup>36,42,43,60,71</sup> The types of operations performed included RYGB alone<sup>70,78,79</sup>; gastric banding alone<sup>27,38,43,73</sup>; RYGB, banding, vertical banded gastroplasty, and “other”<sup>36</sup>; RYGB and sleeve gastrectomy<sup>71</sup>; RYGB, LAGB and other<sup>60</sup>; or not stated.<sup>42</sup>

Depression improved following bariatric surgery in all 8 studies measuring changes in mental health outcomes. Three studies examined trends in the rate of patients reporting depression over time. In the first study, 5% of patients undergoing a variety of surgical procedures were diagnosed with depression prior to surgery compared to 2.5% at 1-4 months and 2.8% at 3 years post-operatively.<sup>36</sup> In the second study, patients were divided into 2 groups after surgery: an intervention arm providing comprehensive behavioral and nutritional support, and standard care. In the comprehensive care group, 54.2% were depressed pre-operatively compared to 41.7% at 6 months and 14.9% at one year post-operatively. Rates of depression also decreased in the standard care group from 58.3% pre-operatively to 37.5% at 6 months and 31.8% at one year after surgery.<sup>70</sup> A third study of LAGB patients found decreased rates of any mood disorder, major depressive disorder, and bipolar disorder at 2 years post-operatively; the largest change was found in the rate of major depressive disorder, which decreased from 18.1% to 6.0%.<sup>27</sup>

Five studies examined trends in symptoms or treatment for depression: 3 studies compared Beck Depression Inventory (BDI) scores pre- and post-operatively,<sup>38,60,73</sup> one study tracked patient-reported symptoms of depression over time,<sup>71</sup> and the final study followed rates of antidepressant and psychotherapy use.<sup>65</sup> A study of LAGB patients found decreased BDI scores post-operatively among both a random sample of patients and a group of patients with elevated pre-operative depression scores (BDI>23).<sup>73</sup> Significant reductions were found in all BDI subscales for both groups, with the largest impact on negative self-attitudes. No formal comparison was made between changes in outcomes between the random and elevated-depression score groups. Another study of LAGB patients found that average BDI scores decreased from 17.7 pre-

operatively to 7.8 one year post-operatively; the trend stabilized, however, and started to regress with average scores of 8.0 at 2 years, 9.0 at 3 years and 9.6 at 4 years post-op.<sup>38</sup> A similar study of the Longitudinal Assessment of Bariatric Surgery (LABS) cohort also found decreased mean BDI scores from baseline (7.7) to 6 months (4.3) and one year post-op (4.1), but increasing scores thereafter: 4.7 at 2 years and 5.3 at 3 years.<sup>60</sup> In the study using self-reported symptoms of depression, 20% of sleeve gastrectomy patients and 11% of RYGB patients had diagnoses of depression at baseline. At one year after surgery, 93% of sleeve gastrectomy patients and 87% of RYGB patients reported improvement in their depression with 17% and 5%, respectively, reporting complete resolution of symptoms.<sup>60,71</sup> In a final study involving 55 Veterans undergoing bariatric surgery, the use of antidepressant medications and psychotherapy for depression decreased from 56% to 34% over the 5-year follow-up period.<sup>65</sup> This study also evaluated the impact of surgery on the treatment of anxiety, finding only non-significant increases in the rates of anxiolytic use and psychotherapy post-operatively. Changes in metabolic outcomes, including weight loss, were not associated with observed changes in the use of psychiatric therapies for their disorder.

Three studies evaluated post-operative weight loss in patients with depression, but did not report on changes in mental health outcomes. In the first study, patients with depression or anxiety at baseline experienced a 7.9 kg/m<sup>2</sup> decrease in their BMI on average at 4 years after surgery compared to 12.5 kg/m<sup>2</sup> in patients without these mental health comorbidities. Based on their analysis, pre-operative depression and anxiety explained 4% of the variance in weight loss among bariatric surgery patients.<sup>43</sup> In another study, patients with depression had no difference in weight loss at one year after bariatric surgery, but did have less sustained weight loss at 4 years compared to non-depressed patients.<sup>42</sup> This pattern was found for both patients with depression at the time of surgery as well as for patients with a history of depression at any time during their life, although the impact was larger among patients reporting active depression at the time of operation. Unfortunately, the study did not quantify differences in weight outcome between the 2 groups. A final study found no association between BDI scores and weight maintenance after RYGB, but did find that higher BDI scores pre-operatively (indicative of more severe depression) appeared to reduce the risk of significant weight regain at a mean follow-up of 28.1 months.<sup>78</sup> Each additional unit on the BDI scale was associated with a 6% reduction in the risk of experiencing significant weight regain, defined as  $\geq 15\%$  of total post-operative weight loss.

Four studies reported on alcohol or substance abuse disorders: 3 related to changes in these disorders after bariatric surgery and one regarding their impact on post-operative weight loss. The first study found no change in the proportion of patients reporting symptoms of alcohol abuse from baseline to one year after surgery (7.6 vs 7.3%,  $p=0.98$ ). Rates did increase, however, in the second post-operative year (7.6 vs 9.6%,  $p=0.01$ ), especially among young men undergoing RYGB. There were no differences, however, in the rate of either inpatient or outpatient treatment for substance abuse between pre-operative and post-operative assessments.<sup>59</sup> A second study also reporting on depression found a decrease in the rate of patients reporting alcohol abuse from 1% pre-operatively to 0% at 2 years post-operatively, but only included patients undergoing LAGB.<sup>27</sup> The largest study on the topic from the Swedish Obese Subjects (SOS) trial compared 2,010 surgical patients to 2,037 matched controls. In this study, bariatric surgery was associated with increased rates of alcohol abuse, medium-risk alcohol consumption, and self-reported alcohol problems, especially for patients undergoing RYGB. In line with previous studies, however, patients who underwent LAGB did not experience increased rates of

alcohol abuse when compared to non-surgical controls.<sup>62</sup> A final study evaluated the impact of alcohol and substance use disorders on weight loss among 66 Veterans undergoing bariatric surgery. Neither alcohol nor substance use was predictive of weight loss at 6 months or the rate of obesity at 12 months post-operatively; however, patients without these disorders lost more weight at 12 and 24 months and had lower rates of obesity at 24 months after their operation.<sup>63</sup>

Two studies specifically reported on suicide. The first used mortality data from nearly 17,000 patients undergoing bariatric surgery in Pennsylvania over a 10-year period, and compared post-operative suicide rates to rates for an age- and sex-matched US population. At 13.7 per 10,000 among men and 5.2 per 10,000 among women, both rates were significantly higher than standardized rates of 2.4 per 10,000 for men and 0.4 per 10,000 for women.<sup>74</sup> This study did not have the data to control for mental health comorbidities. The second involved a comparison of severely obese individuals undergoing RYGB with 2 control groups: individuals who sought but did not undergo bariatric surgery at the same hospital, and a population-based sample of severely obese adults.<sup>80</sup> Over the 6-year follow-up period, all 4 suicides and 2 of the 3 poisonings of undetermined intention occurred in the surgery sub-group. While the cumulative incidence of suicide was higher in the surgical group than in the combined control groups, the rate was not significantly different from either control group alone.

Three studies explored associations between eating disorders and bariatric surgery: one reporting the impact of eating disorders on weight loss, one reporting the impact of surgery on eating disorders, and one reporting on both. In a study that also reported on depression, history of an eating disorder had a small but significant effect on post-operative weight loss at 4 years, with those reporting a history of eating disorder losing *more* weight after bariatric surgery.<sup>42</sup> This study, however, did not quantify the difference between the 2 groups. In a second study also reporting on depression and substance abuse, 28 of 204 (14%) LAGB patients reported pre-operative binge eating disorder (BED) compared to only 7 (5%) after a 2-year follow-up period.<sup>27</sup> A final study found no differences in weight loss for BED compared to non-BED patients at 3 years after bariatric surgery.<sup>75</sup> One third of BED patients in this small sample (6 of 18) reported continued BED episodes following their operation.

Five studies examined changes in quality of life following bariatric surgery. One study showed a 26% increase in SF-36 physical component scores, and a 7% increase in mental component scores at 2 years after surgery.<sup>49</sup> Another study on quality of life using the SF-36 compared LAGB patients to community normal values (CN). Candidates' pre-operative mean scores were lower than CN values, with greater impairment in the physical component summary score (PCS) (36.8 vs 51.3,  $p=0.001$ ) than in the mental component summary score (MCS) (45.7 vs 48.8,  $p=0.001$ ). At one year after surgery, scores had improved in both domains, and were closer to CN benchmarks (PCS:  $52.4\pm 8.2$  and MCS:  $48.4\pm 7.7$ ); no subsequent reduction in quality of life was observed during the study's 4-year follow-up period.<sup>39</sup> A third study evaluating high volume exercise (HVE) in bariatric surgery patients utilized both IWQOL-L and SF-36 measures of quality of life.<sup>72</sup> IWQOL-L among patients receiving HVE increased from 61 at baseline to 74 at 6 weeks and 75 at 12 weeks post-op; patients in the control group had similar increases (from 67 to 83). The SF-36 physical component score also increased from 49 at baseline to 51 at 6 weeks and 53 at 12 weeks post-op in the control group; no sustained change was found among patients in the HVE group (52, 50, and 52 at baseline, 6 weeks, and 12 weeks, respectively). The mental component score, on the other hand, increased in the HVE group from 46 to 55 but did not

change among patients in the control group (49 at both baseline and 12 weeks). Changes in the HVE group could be due to a combination of bariatric surgery and the HVE intervention. A fourth study used linear analog scale assessment (LASA) to measure changes in quality of life among 148 patients undergoing RYGB. Mean LASA scores increased from baseline by 138% (3.4 to 8.1) after a follow-up of 4.0 years; only 4 patients (2.7%) experienced worsened quality of life after surgery.<sup>79</sup> Finally, in a study also reporting on changes in depression after bariatric surgery, quality of life was measured at baseline and one year post-operative using the GIQLI score. Based on this metric, quality of life increased from 99 to 128 on average by one year post-operative – a level that exceeds the majority of healthy individuals who score 121 points on average.<sup>71</sup>

We identified 2 studies each addressing PTSD and bipolar disorder. In the first study on PTSD, which also addressed a range of mental health conditions, 2.9% of patients undergoing LAGB were diagnosed with PTSD at baseline compared to only 1.3% at 2 years after surgery.<sup>27</sup> Unfortunately, the study did not report if this trend reached statistical significance. In the second study, 24 (24%) of 102 Veterans undergoing bariatric surgery at a single VA center were being treated for PTSD at the time of their operation.<sup>64</sup> There was no difference in the rates of short-term complications between the PTSD and non-PTSD groups, and only a non-significant difference in percent excess weight loss between the 2 groups at one year post-op (66 vs 72%, respectively;  $p=0.10$ ). PTSD symptoms appeared to wax and wane throughout the post-operative period without a definitive trend toward improvement or deterioration.

The same study reporting changes in the rate of PTSD found that 2.9% of patients undergoing LAGB had bipolar disorder during pre-operative evaluation compared to 2.7% of patients at 2 years post-operatively.<sup>27</sup> However, this trend did not reach statistical significance. A second matched-cohort study of almost 1,600 obese patients with bipolar disorder compared time to inpatient psychiatric hospitalization for obese patients undergoing and not undergoing bariatric surgery.<sup>76</sup> Approximately 9% of surgical patients were hospitalized during a mean follow-up period of 2.4 years compared to 10.6% of controls. After multivariate adjustment, there was no association between bariatric surgery and time to psychiatric hospitalization (HR 1.0, 95% CI 0.83-1.23), and no difference in risk-adjusted use of outpatient psychiatric services, including psychiatric, behavioral medicine, or substance abuse visits.

We found only one study addressing cognitive function following bariatric surgery among 50 patients in the LABS cohort.<sup>77</sup> Three cognitive domains were assessed at baseline as well as at 12, 24, and 36 months post-operatively: attention, executive function, and verbal memory. The study found sustained improvements in executive function throughout the follow-up period ( $p<0.001$ ), while memory improved from baseline to 12 months then stabilized from 12 to 36 months after surgery ( $p<0.001$ ). Observed trends in attention were more complex, with steady improvement from baseline to 24 months followed by dramatic decreases from 24 to 36 months, driven largely by the sub-group of patients who regained weight during the time period.

### **Association of Bariatric Surgery and Mental Health Outcomes**

Bariatric surgery is associated with reductions in both the rates and symptoms of a variety of mental health conditions, most notably depression. One study on LAGB patients, in particular, presented the widest evidence for improvement in mental health outcomes after surgery. Among 204 consecutive LAGB patients treated at a large US hospital, the diagnosis of any Axis I

disorder dropped from 40% to 20% by 2 years post-op with commensurate reductions in mood disorders (27% to 15%), anxiety disorders (15% to 4%), and eating disorders (12% to 5%;  $p < 0.001$  for mood and anxiety disorders,  $p < 0.01$  for eating disorders).<sup>27</sup> This study also reported the only evidence on changes in the prevalence of schizophrenia, finding no difference between patients reporting symptoms at baseline and at 2 years post-operatively.

All 8 of the studies that measured changes in depression found significant improvements. This includes a reduction in the number of patients reporting depression,<sup>27,36,70</sup> a reduction in the symptoms of depression,<sup>38,60,71,73</sup> and a reduction in medication or psychotherapy treatment for depression.<sup>65</sup> Interestingly, one study found no change in the rates of hospitalization for depression between baseline, one year, and 2 years post-operatively, but did find increased rates in the third year: 0.9% vs 1.7% ( $p = 0.03$ ).<sup>60</sup>

The evidence for an association between bariatric surgery and rates of alcohol abuse was mixed, and appeared to depend on the type of surgery being performed. Two studies found increased rates of alcohol consumption, alcohol abuse, and treatment for alcohol dependence after bariatric surgery, but only for patients undergoing RYGB as opposed to LAGB. Rates of alcohol consumption and abuse were lower than baseline in the first year following RYGB, but significantly increased over baseline in the second year.<sup>59</sup> Results from the SOS trial found similar increases in consumption and self-reported alcohol abuse among VBG patients, but did not report longitudinal data to determine year-to-year changes.<sup>62</sup> Neither study found a significant difference in alcohol consumption or abuse among LAGB patients, a result that was confirmed by a third study focusing only on patients having this procedure.<sup>27</sup>

Two studies tracked suicide after bariatric surgery, one finding elevated incidences compared to population averages and the other suggesting elevated cumulative incidence compared to matched non-surgical controls.<sup>74,80</sup> Findings of the latter study, however, did not reach statistical significance.

All 5 studies measuring quality of life showed improvements following bariatric surgery.<sup>39,49,71,72,79</sup> In studies using a scale with multiple domains, such as the PCS and MCS of the SF-36, there was improvement across all components with larger and more sustainable changes being seen in physical status than in mental status.<sup>39,49,72</sup> Quality of life continued to improve between baseline and one year post-operatively. However, the one study that followed patients beyond one year found a slight attenuation over time, but not to pre-operative levels.<sup>39</sup>

There was no clear evidence on post-operative changes in PTSD or bipolar disorder. One study suggested a decreased rate of PTSD following bariatric surgery, but did not provide statistical tests<sup>27</sup>; another found that symptoms fluctuated after surgery without a definite trend towards improvement or deterioration.<sup>64</sup> A study of LABG patients reported no change in the rate of patients reporting bipolar disorder,<sup>27</sup> while another found no association between bariatric surgery and time to psychiatric hospitalization or the risk-adjusted use of outpatient psychiatric services for patients with bipolar disorder.<sup>76</sup>

Minimal evidence exists regarding changes in cognitive function, and results appear to vary by domain: memory improved from baseline to 12 months then stabilized, attention increased from baseline to 24 months then decreased from 24 to 36 months, and executive functioning increased throughout the follow-up period.<sup>77</sup>

## **Association of Baseline Mental Health Conditions and Post-surgical Weight Change**

There was conflicting evidence regarding the impact of pre-operative mental health conditions on post-operative weight loss. The majority of studies found no association between the presence of any Axis I disorder—including depression—and weight outcomes. The only study looking at patients with any pre-operative Axis I disorder found no difference in percent excess weight lost at 2 years post-operatively.<sup>27</sup>

Minimal and contradictory evidence exists regarding pre-operative depression and post-operative weight loss. One study found less post-surgical weight loss in patients with a diagnosis of depression or anxiety.<sup>43</sup> Another found no difference in weight loss at one year for patients with depression, but less sustained weight loss at 4 years.<sup>42</sup> Another study found no association between BDI scores and weight loss on average, but did report a reduced risk of significant weight regain ( $\geq 15\%$  of total weight loss) in patients with higher pre-op BDI scores.<sup>78</sup>

The one study reporting on substance abuse found no difference in short-term weight loss; however, patients without a diagnosis of substance abuse had lost more weight at 12 and 24 months, and had lower rates of obesity at 24 months after their operation.<sup>63</sup>

Two studies provide mixed results on the effect of eating disorders on weight loss. One study found that those with an eating disorder lost more weight after surgery while the other found no difference.<sup>42,75</sup> The first study looked at patients with the diagnosis of an eating disorder at any point in the patient's lifetime and followed patients for 4 years; the second study looked only at patients diagnosed with an eating disorder at the time of surgery and followed patients for 3 years post-operatively.

In the one study on PTSD, there was no difference in percent excess weight loss at one year post-op between patients with and without the disorder.<sup>64</sup>

### **Summary of Findings**

There are conflicting data regarding the impact of mental health conditions on post-operative outcomes, including weight loss, mental health symptoms, quality of life, and suicide. The most consistent evidence suggests lower rates of depression, fewer symptoms of depression, and decreased usage of anti-depressant therapies after bariatric surgery. A causal role of bariatric surgery cannot be established with the existing studies. Aside from depression, only quality of life demonstrated consistent improvement across multiple studies, although the use of different scales and timelines complicates the evaluation. There is insufficient evidence to determine the relationship between pre-operative mental health conditions and post-operative weight loss outcomes.

### **Quality of Evidence for Key Question 2**

The quality of evidence is moderate that bariatric surgery is associated with lower rates and fewer symptoms of depression, compared to pre-operative status. The quality of evidence is low regarding the association between bariatric surgery and quality of life improvements following surgery. All other associations between mental health conditions and outcomes following bariatric surgery are judged very low-quality evidence.

Table 3. Evidence Table of Studies of Associations between Pre-Operative Mental Health Conditions and Bariatric Outcomes

Author, Year Country	Sample (Candidates/All received surgery)	Method of Recruitment	Details of Sample	Details of Surgery	Mental Health Diagnoses Assessed	Methods of Assessment <i>Kept Confidential from Surgery Team</i>
Articles with Consecutive or Random Sampling of Patients Receiving Surgery (n=12)						
Ahmed, 2013 <sup>76</sup> USA	All received surgery	All patients with diagnosis of bipolar disorder who underwent bariatric surgery between 2006-2009	N=144 89% female Mean BMI=42 Mean age=44 Follow-up rate: N/A	86% lap RYGB, 7% LAGB, 4% open RYGB, 4% gastric sleeve	Time to psychiatric hospitalization, outpatient visits for psychiatric or behavioral health	Administrative records <i>Not applicable</i>
Alosco, 2013 <sup>77</sup> USA	All received surgery	Consecutive patients enrolled in LABS study from 3 clinical sites	N=50 92% female Mean BMI=47 Mean age=44 Follow-up rate: 100%	98% RYGB, 2% gastric banding	Cognitive function	IntegNeuro test series <i>Not stated</i>
Batsis, 2009 <sup>79</sup> United States	All received surgery	Consecutive patients referred for bariatric surgery to a single institution who also lived in the county, 1990-2005; response rate=38.0%	N=148 73% female Mean BMI=47 Mean age=46	100% RYGB	QOL	LASA <i>Not applicable</i>
Cremieux, 2010 <sup>36</sup> USA	All received surgery	All patients in a proprietary database of 5,000,000 Americans who had received bariatric surgery and had continuous insurance coverage	N=5,502 83% female Mean BMI not stated Mean age=44 Follow-up rate: N/A	73% RYGB Mix of other procedures	Depressive Disorders	Claims data <i>Not applicable</i>
Dixon, 2003 <sup>38</sup> Australia	All received surgery	Consecutive patients receiving bariatric surgery at a university program, 1999-2003; response rate not stated	N=487 85% female Mean BMI=44.1 Mean age=41.2	100% LAGB	Depression	BDI <i>Not stated</i>
Dixon, 2001 <sup>39</sup> Australia	All received surgery	Consecutive patients receiving bariatric surgery at a single institution, 1998-2001; response rate not stated	N=459 85% female Mean BMI=45.0 Mean age=41	100% LAGB	QOL	SF-36 <i>Not applicable</i>

Author, Year Country	Sample (Candidates/All received surgery)	Method of Recruitment	Details of Sample	Details of Surgery	Mental Health Diagnoses Assessed	Methods of Assessment <i>Kept Confidential from Surgery Team</i>
Hayden, 2014 <sup>27</sup>	Candidates (98% received surgery)	Consecutive patients meeting eligibility criteria for bariatric surgery at one institution, 2007-2009; response rate = 75%	N=204 82% female Mean BMI=42.7 Mean age=45	100% LAGB	Any Axis I disorder Any mood disorder Major depressive disorder Dysthymia Bipolar disorder Any anxiety disorder Panic disorder OCD PTSD Generalized anxiety disorder Schizophrenia Alcohol abuse Binge eating disorder	SCID <i>Not stated</i>
Hayden, 2011 <sup>73</sup> Australia	All received surgery	Random sample of patients who had undergone lap band surgery at a single bariatric center	N=191 84% female Mean BMI=43 Mean age=42 Follow-up rate: Not stated	Lap band	Depression	BDI <i>Not stated</i>
Lapidoth, 2011 <sup>75</sup> Sweden	All received surgery	Consecutive patients receiving surgery at 4 Swedish bariatric clinics (96% agreed to participate)(dates not stated)	N=130 78% female Mean BMI=46 Mean age=41 Follow-up rate: 78%	76% gastric bypass, 14% gastric banding, 5% VBG, 4% BPD	BED Quality of life	EDO, EDE-Q, SF-36 <i>Not stated</i>
Legenbauer, 2011 <sup>42</sup> Germany	All received surgery	Consecutive patients receiving surgery in 6 German hospitals (99% of patients participated) (dates not stated)	N=151 67% female Mean BMI=51 Mean age=39 Follow-up rate: 64%- 80%	Mix of gastric banding and gastroplasty	Depressive Disorder Eating Disorders	Composite International Diagnostic Interview Structured Interview for Anorexia and Bulimia <i>Not stated</i>

Author, Year Country	Sample (Candidates/All received surgery)	Method of Recruitment	Details of Sample	Details of Surgery	Mental Health Diagnoses Assessed	Methods of Assessment <i>Kept Confidential from Surgery Team</i>
Odom, 2009 <sup>78</sup> USA	All received surgery	Consecutive patients undergoing surgery at one institution; response rate=18.1%	N=203 85% female Mean BMI=29.6 Mean age=51	RYGB	Depression	BDI <i>Not stated</i>
Tindle, 2010 <sup>74</sup> USA	All received surgery	All patients undergoing bariatric surgery between 1995-2004 in Pennsylvania Health Care Cost and Containment Council database	N=16,683 % female not stated Mean BMI= not stated Mean age= not stated Follow-up rate: N/A	Not stated	Suicide	Death certificates recorded by Pennsylvania State Department of Health <i>Not applicable</i>
Articles with Non-consecutive and Non-random Sampling of Patients Receiving Surgery (n=6)						
Adams, 2012 <sup>80</sup> USA	All received surgery	Patients receiving surgery from 3 bariatric surgeons in Utah, 2000-2011; response rate=92.6%	N=418 84% female Mean BMI=47.3 Mean age=43	All RYGB	Suicide	National Death Index <i>Not stated</i>
Adams, 2010 <sup>49</sup> USA	All received surgery	Patients seeking bariatric surgery from 3 bariatric surgeons in Utah; non- bariatric seeking patients from a large database	N=835 84% female Mean BMI=47 Mean age=44 Follow-up rate: 52%	Gastric bypass	Quality of Life	IWQOL-Lite, SF-36 <i>Not stated</i>
King, 2012 <sup>59</sup> USA	All received surgery	From the LABS-2 observational study, participants in LABS-2 who underwent surgery and completed AUDIT Feb 2006-Feb 2009	N=1945 78.8% female Mean BMI=45.8 Mean age=47 Follow-up rate: 86%	69.9% RYGB 25.2% Adjustable gastric banding 0.8% Biliopancreatic diversion 1.5% Banded gastric bypass 2.6% Sleeve	QOL, depression, alcohol abuse, maladaptive eating, past year treatment psychotic or emotional problem	SF-36, BDI, AUDIT <i>Not stated</i>

Author, Year Country	Sample (Candidates/All received surgery)	Method of Recruitment	Details of Sample	Details of Surgery	Mental Health Diagnoses Assessed	Methods of Assessment <i>Kept Confidential from Surgery Team</i>
Legenbauer, 2009 <sup>43</sup> Germany	All received surgery	Patients at 6 German hospitals were approached on the day of admission	N=151 68% female Mean BMI=51 Mean age=39 Follow-up rate: 64%-80%	Gastric bypass	Any Mental Disorder Depressive Disorders Anxiety Disorders Binge Eating Behaviors	Composite International Diagnostic Interview Structured Interview for Anorexia and Bulimia Nervosa <i>Not stated</i>
Mitchell, 2014 <sup>60</sup> USA	All received surgery	From the LABS-2 observational study, Feb 2008 - Feb 2009	N=2,146 78.5% female Median BMI=45.9 Median age=46	Not stated (but in other LABS-2 reports the proportion receiving RYGB was approximately 70%)	Depression	BDI <i>Not stated</i>
Svensson, 2013 <sup>62</sup>	All received surgery	Patients participating in the surgical cohort portion of the Swedish Obese Subject (SOS) study, 1987-2001; response rate not stated	N=2,010 71% female Mean BMI=42.3 Mean age=47	68% VBG 19% gastric banding 13% RYGB	Self-reported alcohol problems	Self-reported alcohol consumption Answer to survey question: "Do you think you have alcohol problems?" <i>Not stated</i>
Articles with Samples of Veterans (n=3)						
Adams, 2012 <sup>63</sup> USA	All received surgery	All patients receiving bariatric surgery at the Jackson, MS VA 2003-2008 No recent substance abuse or serious mental health problems	N=61 33% female Mean BMI=45.5 Mean age=48 Follow-up rate: N/A	41% had bypass procedures 59% had banding procedures	Tobacco use Substance abuse	Medical records, psychologist evaluation <i>Not stated</i>
Ikossi, 2010 <sup>64</sup> USA	All received surgery	All patients undergoing laparoscopic RYGB at Palo Alto VA 2001-2007	N=102 20% female Mean BMI=48.5 Mean age=51 Follow-up rate: 95%	All received laparoscopic RYGB	PTSD	Medical record diagnosis

Author, Year Country	Sample (Candidates/All received surgery)	Method of Recruitment	Details of Sample	Details of Surgery	Mental Health Diagnoses Assessed	Methods of Assessment <i>Kept Confidential from Surgery Team</i>
Rutledge, 2012 <sup>65</sup> USA	All received surgery	All patients receiving with loss surgery at the San Diego VA	N=55 31% female Mean BMI=44 Mean age=52 Patients with substance use, cognitive impairment, <i>etc</i> Follow-up rate: Not stated	82% received RYGB 18% received adjustable band	Use of antidepressants for moods, anxiety disorders, use of anxiolytics, history of substance abuse, history of PTSD, history of suicide attempt, history of bipolar disorder	Medical record, clinical psychologist interview <i>Not stated</i>
Articles from RCTs (n=3)						
Nijamkin, 2013 <sup>70</sup> USA	All received surgery	Patients enrolled in an RCT assessing an intervention to improve depressive symptoms (dates not stated)	N=144 83% female Mean BMI=36 Mean age=44 Follow-up rate: 92%	All procedures performed by one surgeon 100% RYGB	Depressive symptoms	BDI-II
Peterli, 2013 <sup>71</sup> Switzerland	All received surgery	Participants in an RCT comparing gastric bypass to sleeve gastrectomy; 4 sites, recruitment not described (Jan 2007 to Nov 2011)	N=217 72% female Mean BMI=44 Mean age=42.5 Follow-up rate: 32%- 100%	50.7% received RYGB 49.3% received sleeve gastrectomy	Depression, QOL	Not stated for depression Gastrointestinal Quality of Life Index <i>Not stated</i>
Shah, 2011 <sup>72</sup> USA	All received surgery	Patients enrolled in an RCT to test a post-surgical exercise program Patients with major neuropsychiatric illness impeding competence or compliance were excluded	N=33 91% female Mean BMI=42 Mean age=50 Follow-up rate: 100%	Gastric bypass RYGB	Quality of Life	IWQOL-Lite SF-36 <i>Not stated</i>

### Key Question 3: Is there evidence to support any pre-operative intervention to improve post-operative outcomes among patients with mental health conditions?

We identified no studies assessing the effect of a pre-operative intervention targeted at mental health conditions or eating disorders that assessed the impact on post-operative bariatric outcomes, specifically weight loss. We identified 5 studies of interventions aimed at improving pre-operative mental health disorders or eating disorders in bariatric surgery candidates. These studies measured changes in pre-operative status of these disorders. We describe these studies here as providing at least tangential evidence relevant to the study question.<sup>68,81-84</sup> Details of each included study are presented in Table 4.

All 5 studies included only a single institution (and 2 of these were performed at the same institution). Three were conducted in the United States and 2 were from Europe. The patient characteristics were similar across studies with a mean age ranging from 41 to 48 years of age, the percent female ranging from 60 to 88%, and the baseline BMI ranging between 45 to 49 kg/m<sup>2</sup>. The sample size varied from 10 to 243 patients. Overall the risk of bias for all 5 studies was high, in large part based on the inherent challenges with surgical studies, specifically the difficulty in blinding participants during the data collection phase. Also, adherence to the pre-operative interventions was low.

Kalarchian performed a behavioral lifestyle intervention for bariatric surgery candidates (N=121) and compared results to usual care (N=114), which included a physician-supervised diet.<sup>68</sup> Patients who decided not to pursue surgery were dropped from the study. The intervention occurred over 6 months; patients in both arms of the study underwent an insurance-company-mandated, physician-supervised pre-operative weight loss program. Usual care patients were expected to arrange for a physician-supervised weight loss program on their own. Patients were 83% white and 86% had education beyond high school.

The intervention focused on the health benefits of lifestyle change before and after bariatric surgery and on establishing realistic weight loss goals. The assessment of outcomes was only on bariatric surgery candidates. Patients were instructed to limit themselves to 1200 to 1400 calories per day, maintain a diet supportive of nutritional needs following surgery, and undertake at least 30 minutes of physical activity for 5 days weekly. A mix of individual (one hour), face-to-face (one hour), and phone (15-20 min) coaching was performed weekly over 6 months.

At 6 months, 187 participants (78%) were still candidates for surgery; included in the data analysis on this cohort were Beck Depression Inventory (BDI), Eating Disorder Examination (EDE) and Eating Behavior Inventory (EBI) scores. Lifestyle patients lost more weight than the usual care group (8.3 vs 3.3 kg,  $p < 0.0001$ ). Both groups experienced improvement in depression: BDI decreased from 15.2 to 11.8 in the lifestyle group and 14.0 to 11.0 in the usual care group.

For the score on the EBI, there was a significant group effect ( $p < 0.007$ ), a time effect ( $p < 0.0001$ ), as well as a group by time interaction ( $p < 0.0004$ ), indicating that lifestyle patients had larger improvements in eating behaviors than usual care patients. However, there was a significant effect for time only for EDE subjective bulimic episodes ( $p < 0.02$ ), objective bulimic episodes ( $p < 0.0001$ ), and BDI score ( $p < 0.0001$ ), suggesting that both groups improved over time.

The second intervention study assessing changes in pre-operative psychosocial behavior was a Spanish study performed by Abiles and colleagues.<sup>81</sup> The intervention used cognitive behavioral therapy (CBT) for bariatric surgery candidates and assessed differences between those with and without binge eating disorder (BED) at baseline. One hundred ten consecutive severely obese bariatric surgery candidates were enrolled in the CBT program, which consisted of 12 two-hour sessions over 3 months. Patients were categorized as having BED or not having BED at baseline. Outcomes assessed included mood (using the Abbreviated Scale of Anxiety and Depression [GHQ]), QOL (using the QLI-sp), and weight. These were measured before as well as at 3 months and 12 months after the intervention. A pre-post study design was used.

Patients with BED were more anxious and depressed, and had lower self-esteem and quality of life as compared to non-BED patients before the intervention ( $p < 0.05$ ). Following the CBT intervention, differences in self-esteem, depression, and eating disorders were reduced in the patients with BED.

Multivariate regression showed that CBT was effective at treating psychological comorbidity regardless of whether BED was present at baseline. At one year post-CBT, weight loss of greater than 10% of body weight was noted in 61% of patients, with no differences between patients with or without BED at baseline.

In the third study by Aston and colleagues,<sup>84</sup> patients seeking bariatric surgery with a history of substance abuse/dependence or at risk for substance use ( $n=86$ ) underwent a single-session 90-minute educational intervention about the health effects of alcohol/substances on bariatric surgery outcomes, alternative coping strategies, and providing treatment resources.

Patients completed a pre- and post-intervention questionnaire measuring knowledge of substance use health effects, the Alcohol Use Disorders Identification Test Consumption Items, and items on motivation for abstinence. Patients reported a significant increase in knowledge regarding the negative effects of substance abuse after surgery ( $\chi^2 = 42.3$ ;  $p < .001$ ). Patients also reported more healthy alternative coping strategies after the intervention ( $\chi^2 = 18.9$ ;  $p = .001$ ). More patients reported a lower intention of consuming alcohol after surgery ( $\chi^2 = 16.2$ ;  $p = .001$ ) and were more likely to report health reasons as motivation to abstain ( $\chi^2 = 102.9$ ;  $p < .001$ ).

The fourth study, also performed by Ashton, assessed the effectiveness of a brief 4-session group CBT intervention for binge eating in bariatric surgery candidates.<sup>82</sup> In this study, 90% of participants had more than a high school education and 68% of participants were white. Again, a pre-post design was used.

The 4-session CBT group was designed specifically for bariatric surgery patients. The group met weekly for 1 ½ hours over a 4-week period. The number of participants at each session ranged from 2 to 12. A licensed psychologist or supervised postdoctoral fellow ran each session. The intervention included self-monitoring, stimulus control, regulation of eating patterns, cognitive restructuring, body image processing, stress management and relaxation training, social skills/assertiveness training, and group support. Two hundred forty-three patients participated in all 4 CBT sessions. The main reasons for missing sessions included medical disorders, transportation, and work. Patients were assessed for binge eating disorder and binge eating episodes (using the structured clinical interview and binge eating syndrome (BES) questionnaire) before and after the 4-week intervention (pre-surgery).

The CBT intervention was associated with a decrease in binge eating episodes from 2.84 before the intervention to 1.18 after the intervention. The change in BES and BEEs did not vary based on characteristics such as race or gender ( $p>0.10$ ).

The last study by Wild and colleagues was conducted in a single university center in Germany.<sup>83</sup> Bariatric surgery candidates were given a thematic interventional group therapy of 12 sessions at 2-week intervals focusing on motivation and psychosocial state. The goal was to reduce depression in this population. Depression decreased following the treatment (12.8 to 8.6; 95% CI: 0.5, 7.8). Quality of life improved following the treatment (30.9 to 40.9; 95% CI: -13.3, -6.4). This study had a small sample size as only 10 of 16 patients completed the intervention, therefore the ability to reach conclusions are limited.

### **Summary of Findings**

There were no studies that assessed the impact of a pre-operative intervention addressing mental health conditions on post-operative outcomes, such as surgical weight loss or the prevalence of the mental health disorders. Five low-quality studies reported pre-operative improvements in targeted mental health behaviors, as well as pre-operative physician-supervised weight loss before surgery and substance abuse, for bariatric surgery candidates.

### **Quality of Evidence for Key Question 3**

There is no evidence specific to Key Question 3 and only low-quality evidence that interventions to change pre-operative psychosocial factors have clinically important effects on pre-operative status.

Table 4. Studies Presenting Pre-Operative Interventions Among Bariatric Surgery Candidates with Mental Health Conditions

Author, Year	Setting	Baseline Patient Characteristics	Intervention Description/ Comparators	Study Design	Outcomes Assessed (Instruments Used)/ Timing of Assessment	Findings	Risk of Bias Assessment
Kalarchian, 2013 <sup>68</sup>	large urban medical center, USA	Mean age: 45.2 Percent female: 86.7 Average BMI: 47.9 N=240	Behavioral lifestyle (on health benefits of decreasing calories and increasing physical activity) versus usual care (provided synopsis of same information) / pre-operative care as usual	RCT	Weight, Depression (BDI=Beck Depression Inventory score), Eating disorders (EDE=Eating Disorder Examination)/ 0 and 6 months	LIFESTYLE participants lost significantly more weight than those receiving USUAL CARE [8.3 +/- 7.8 kg vs 3.3 +/- 5.5 kg, F(1,183) = 23.6, P < 0.0001], with an effect size of 0.72 Lifestyle group- BDI- pre- 15.2(10.3), post- 11.8(8.8), Usual care group-pre-14.0(8.9), post- 11.0(8.7) there was a significant effect for time only for EDE subjective bulimic (P < 0.02), objective bulimic episodes (P < 0.0001), and BDI score (P < 0.0001), indicating that both groups improved over time.	Outcome: Low Allocation concealment: Unclear Blinding of participants and personnel: Unclear Blinding of outcome assessment: Unclear Incomplete outcome data: Low Selective reporting: Low Other bias: Low
Abiles, 2013 <sup>81</sup>	one hospital in Spain	Mean age: 41 Percent female: 70 Average BMI: 49 N=110	3 month CBT program/ with or without binge-eating disorder	Pre-post intervention	Binge eating disorder (EDE-Q), Mood (Abbreviated Scale of Anxiety and Depression (GHQ)), QOL (QLI-sp), Weight/ before and after 3 month intervention and 12 months	Multivariate analysis demonstrated that CBT was effective to treat psychological comorbidity (depression, QOL, anxiety, self-esteem) regardless of the presence/ absence of BED or degree of obesity (P<.001 for all). At one yr post-CBT, weight loss versus baseline (before CTT) was > 10% in 61%, with no intergroup differences.	Outcome: Low Allocation concealment: Unclear Blinding of participants and personnel: Unclear Blinding of outcome assessment: Unclear Incomplete outcome data: Low Selective reporting: Low Other bias: Low

Ashton, 2013 <sup>84</sup>	academic medical center, USA, one site	Mean age: 46 Percent female: 67 Average BMI: 48, N=87	90-minute psycho-education and discussion about effects of substances and addictions after surgery	Pre-post intervention	knowledge of health effects of substances, Alcohol Use Disorders Identification Test-Consumption Items (AUDIT-C)	increased knowledge of negative effects of substance abuse after surgery ( $X^2=42.3;P<.001$ ). Patients reported a lower intention of consuming alcohol after surgery ( $X^2=16.2;P<.001$ )	Outcome: Low Allocation concealment: High Blinding of participants and personnel: High Blinding of outcome assessment: High Incomplete outcome data: Low Selective reporting: Low Other bias: Low
Ashton, 2009 <sup>82</sup>	academic medical center, USA, one site	Mean age: 47 Percent female: 82 Average BMI: 34-129, median 49 N=243	brief 4-session cognitive behavioral group psychotherapy for binge eating/ pre-post design	Pre-post intervention	Binge eating disorder and binge eating episodes (structured clinical interview BES, questionnaire)/ after 4 week intervention (pre-surgery)	binge eating episodes decreased from 2.84 +/- 2.03 before intervention to 1.18 +/- 1.34 after intervention	Outcome: Low Allocation concealment: High Blinding of participants and personnel: High Blinding of outcome assessment: High Incomplete outcome data: Low Selective reporting: Low Other bias: Low
Wild 2011 <sup>83</sup>	Single, university center, Germany	Mean age: 48 Percent female: 70 Average BMI: 45.4 N=10	Thematic interventional group therapy 12 sessions at 2 week intervals focusing on motivation and psychosocial state. Goal to reduce depression	Pre-post intervention	QOL Anxiety Eating disorder (binge eating) Depression (SF-36, SF-12 PHQ-D)	Depression decreased pre to post treatment [12.8 (3.4) to 8.6 (5.8), difference CI (.5, 7.8]. QOL improved [30.9 (10) to 40.7 (10.7) difference CI (-13.3, -6.4)] (only 10/16 completed the study)	Outcome: Low Allocation concealment: Low Blinding of participants and personnel: High Blinding of outcome assessment: High Incomplete outcome data: Low Selective reporting: Low Other bias: High

## SUMMARY AND DISCUSSION

### SUMMARY OF EVIDENCE BY KEY QUESTION

#### Key Question 1

Bariatric surgery candidates and those receiving surgery have depression, anxiety, and certain eating disorders (eg, binge eating) at rates equal to or exceeding 15%. Other mental health disorders, such as psychoses, are less frequent. Published prevalence estimates vary, particularly for depression and binge eating disorder. The few assessments done in Veteran populations found higher proportions of comorbidities than are present in other populations, particularly PTSD.

#### Key Question 2

There are conflicting data regarding the impact of mental health conditions on post-operative outcomes, including weight loss, mental health symptoms, quality of life, and suicide. The most consistent evidence suggests lower rates of depression, fewer symptoms of depression, and decreased usage of anti-depressant therapies after bariatric surgery. A causal role of bariatric surgery cannot be established with the existing studies. Aside from depression, only quality of life demonstrated consistent improvement across multiple studies, although the use of different scales and timelines complicates the evaluation. There is insufficient evidence to determine the relationship between pre-operative mental health conditions and post-operative weight loss outcomes.

#### Key Question 3

There were no studies that assessed the impact of a pre-operative intervention addressing mental health conditions on post-operative outcomes, such as surgical weight loss or the prevalence of the mental health disorders. Five low-quality studies reported pre-operative improvements in targeted mental health behaviors, as well as pre-operative physician-supervised weight loss before surgery and substance abuse, for bariatric surgery candidates.

## LIMITATIONS

### Publication Bias

We were not able to do a formal test of publication bias since we did not perform a quantitative analyses. However, publication bias is always likely to exist for subjects such as this, where prevalence data and association data are presumably present on a majority of patients receiving the procedure.

### Study Quality

Most studies had limitations in their methods. These include an unclear method of enrolling participants, poor or unstated follow-up rate, and use of a pre-post design for studies of interventions. There are some notable exceptions, of course, such as the LABS-2 study, which probably provides the most rigorous evidence on variables included in that study, albeit in a selected sample. LABS-2 is a multi-site study with clear enrollment criteria, provides very detailed follow-up rate at multiple time points, and uses standardized measures to collect all data,

including comorbidities, quality of life, and mental health conditions, both pre-operatively and at regular time points following surgery.

### **Heterogeneity**

The estimates for prevalence of mental health conditions and eating disorders vary, and most of this variation is unexplained. Hence, heterogeneity is a concern and lowers the confidence in conclusions.

### **Applicability of Findings to the VA Population**

There are striking differences in the gender of patients assessed in VA compared to non-VA populations. From the limited VA studies that have been done, the prevalence of mental health conditions and eating disorders is higher than in non-VA populations. Therefore, generalizing results from the non-VA population to the VA population needs to be done with caution.

### **Other**

We limited the scope of our evaluation to particular mental health conditions. However, other factors, such as cognitive functioning, temperament, socioeconomic status, and personality traits may also play a role in patient safety and success with bariatric surgery.

Binge eating disorder has undergone change in how it is defined, not existing formally as a psychiatric disorder until DSM-5, which appeared in 2013/2014. If the diagnosis was made by a scale, that was listed. However, if the diagnosis was made by interview, it is not always clear what criteria were used.

Mental health conditions were defined by the authors of the original studies and it was not always clear what types of disorders were included under diagnostic terms such as anxiety, depression and others. We were only able to specify according to the information given.

## **RESEARCH GAPS/FUTURE RESEARCH**

In order to generate VA-relevant data, a more broadly-based data collection effort is needed among Veterans seeking bariatric surgery. This should include a sufficient number of sites to be representative of the diversity within the VA system, have clear eligibility criteria, use the same standardized instruments for classifying disorders, measure outcomes at regular intervals following surgery (*eg*, 3 months, 6 months, 12 months, 2 years, *etc*), and report the follow-up rate at each time point. For studies of associations, the addition of a control group would improve the ability to make causal inferences. The Swedish Obese Subjects study has shown that causal inferences are possible using non-randomized patients. Very careful attention to the selection of controls, as in the Swedish Obese Subjects study, is required. To assess the effectiveness of pre-operative interventions, randomized clinical trials are ideal.

One difficulty in comparing studies was the use of different measures, at separate sites, to diagnose mental health conditions. Future research should focus on determining the best methods of diagnosing these conditions and the VA should meet and decide which measures will be used across all VA sites.

More research into the severity or chronicity of mental health conditions is needed, as these were not usually reported but may contribute to the effect of mental health conditions on bariatric

outcomes. Specifically, more research is needed in both the VA and non-VA patients who may be seeking bariatric surgery. Long-term studies, beyond 2 years, on sustainability of the changes in response to interventions should be studied as well.

## **CONCLUSIONS**

Mental health conditions and eating disorders are seen in rates exceeding 15% in bariatric surgery candidates and patients, in particular depression, anxiety, and binge eating disorders. Moderate quality evidence supports an association between bariatric surgery and lower rates of depression post-operatively. There is inconsistent evidence about the association of other mental health conditions and eating disorders on subsequent post-operative outcomes. There are no studies assessing the effect of pre-operative interventions aimed at mental health conditions or eating disorders. There is insufficient evidence to recommend for or against routine specialized pre-operative mental health screening in bariatric surgery candidates in addition to the existing general evaluation by the surgical and/or medical bariatric team. More research is needed to determine the optimal screening process and helpful interventions to address mental health and eating disorders in bariatric surgery candidates. Likewise, research is needed to better define the optimal mental health evaluations needed for clearance for bariatric surgery.

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