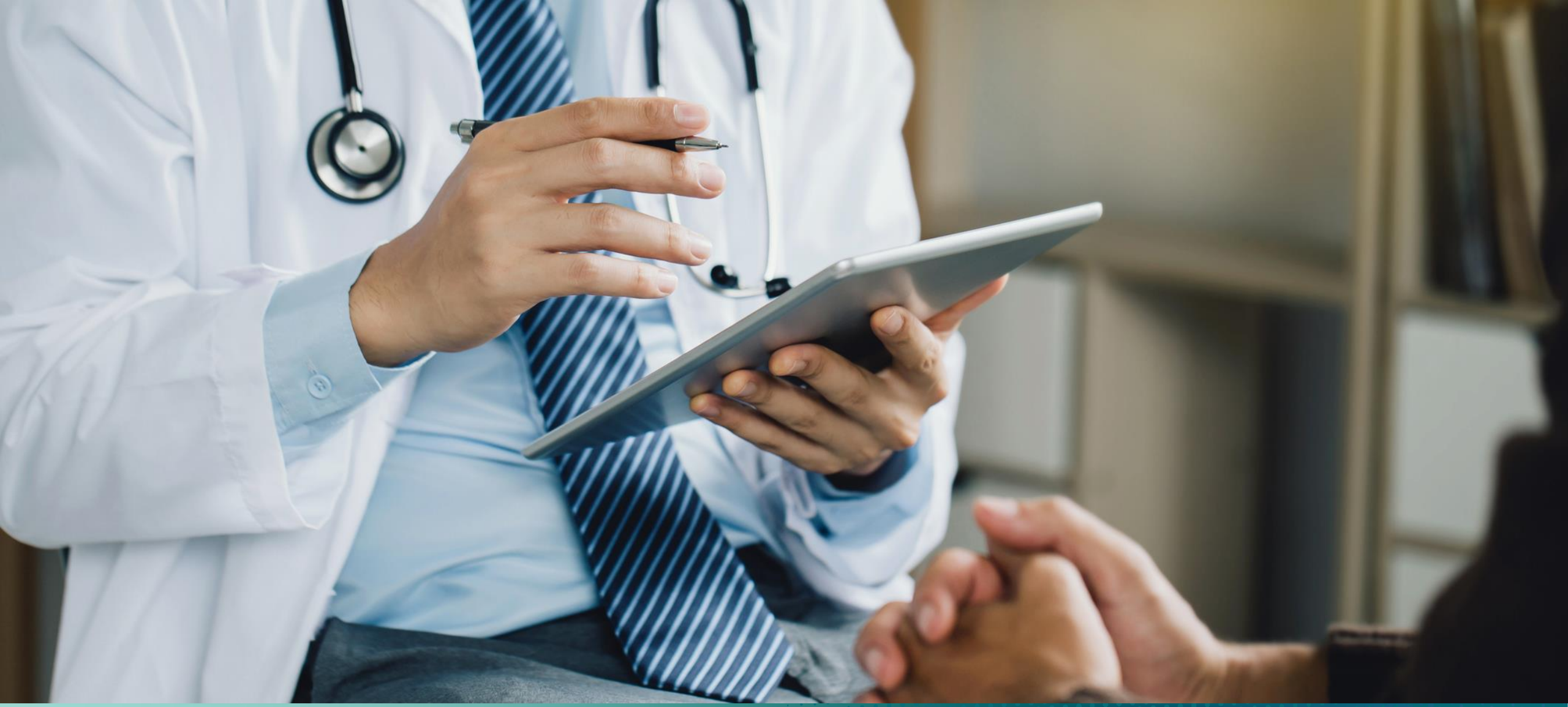

Optimizing Clinical Trial Design for Binge Eating Disorder:

Overcoming Challenges and Improving Outcomes

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Introduction

Binge Eating Disorder (BED) is the most prevalent eating disorder globally, characterized by recurring episodes of excessive food consumption paired with feelings of a lack of control.

This disorder, formally recognized in the DSM-5 in 2013 and codified in the ICD-11 under 6B82, is distinct from other eating disorders due to the absence of compensatory behaviors post-binge. BED poses significant challenges, including increased risks of obesity, metabolic syndromes, and mental health conditions such as depression and anxiety.

This whitepaper provides an in-depth exploration of BED's epidemiology, contributing factors, and advances in treatment. From the biological and psychological underpinnings of the disorder to the evolution of therapeutic approaches, the document highlights the need for integrated strategies to enhance patient outcomes. By examining emerging pharmacotherapies and innovative clinical practices, this paper aims to inform healthcare professionals and stakeholders about the latest developments and challenges in managing BED effectively.

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Overview of Binge Eating Disorder

Key Characteristics of BED

- **Recurrent Episodes:** Episodes typically occur at least once a week for three months.
- **Loss of Control:** Inability to stop eating or control the type and amount of food consumed.
- **Associated Emotional Distress:** Feelings of guilt, shame, or depression post-binge episodes.
- **Physical Health Risks:** Increased risk of obesity, type 2 diabetes, and cardiovascular diseases.

Historical Perspectives and Evolution of Understanding

BED was first formally recognized in the DSM-5 (Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition) in 2013. Initial research in the 20th century categorized it as a subset of obesity or bulimia, but further studies revealed distinct psychological and behavioral profiles. Increased awareness and research over the last few decades have led to its recognition as a standalone disorder, fostering better treatment strategies and reducing stigma.

Contributing Factors

1. **Biological Factors:** BED has been linked to dysregulation of hunger hormones like leptin and ghrelin and abnormalities in brain regions associated with reward processing, such as the hypothalamus and amygdala. Genetic predispositions, including variations in the dopamine and serotonin pathways, play a role. Research into these mechanisms has grown significantly since the early 2000s.
2. **Psychological Factors:** Individuals with BED often have co-occurring psychological conditions, such as depression, anxiety, or PTSD. Low self-esteem and negative body image can exacerbate binge behaviors. Cognitive-behavioral therapy (CBT) has been a pivotal treatment modality developed in the last two decades.
3. **Environmental Factors:** Socioeconomic factors, exposure to diet culture, and trauma, such as childhood abuse or neglect, are major contributors. The role of media and unrealistic beauty standards has been increasingly recognized since the early 2000s.

Insights on Binge Eating Disorder

Epidemiological Statistics and Trends

- **Prevalence:** In the United States, BED affects approximately 2.8% of the adult population, with higher rates among females.
- **Trend Analysis (2013–2023):** Prevalence rates have slightly increased due to improved diagnosis and awareness. Obesity trends and societal pressures have also contributed.
- **Projection (2023–2033):** Rates may continue to rise marginally with growing awareness, with a projected prevalence of 3-3.5% by 2033.

Advancements in Research

In recent years, research has emphasized neurobiological underpinnings, including reward pathways and impulse control mechanisms. Emerging therapies, such as GLP-1 receptor agonists (e.g., liraglutide), show promise in addressing BED and its comorbidities.

Market for BED Treatment

- **Market Value:** The global BED treatment market was valued at approximately $460 million in 2022, projected to grow to $750 million by 2030 due to increased diagnosis and novel pharmacological therapies.
- **Growth Drivers:** Rising awareness, new drug approvals, and a broader range of therapeutic options.

Key Drugs in the Market

Drug Name	Manufacturer	Market Share (%)	Earning Potential (USD million)
Vyvanse (lisdexamfetamine)	Takeda	45%	$207 million
Contrave	Currax	25%	$115 million
Topamax (topiramate)	Janssen Pharmaceuticals	15%	$69 million
GLP-1 agonists	Various	10%	$46 million
Off-label antidepressants	Various	5%	$23 million

ICD-11 Classification

ICD-11 Code for BED: 6B82

Diagnostic Criteria (According to ICD-11)

1. Recurrent episodes of binge eating (eating a larger amount of food than normal in a discrete time).
2. Sense of lack of control during episodes.
3. Binge eating episodes associated with at least three of the following:
   - Eating rapidly.
   - Eating until uncomfortably full.
   - Eating large amounts without hunger.
   - Eating alone due to embarrassment.
   - Feeling guilty or depressed post-episode.
   - Episodes occur at least once weekly over three months.
   - Significant distress or impairment in functioning.

Evolution Over Time

Initial iterations of ICD classified BED under atypical eating disorders. ICD-11's explicit recognition reflects a broader understanding of its unique psychological and physical health implications.

Impact on Clinical and Research Perspectives

The formal classification in ICD-11 has improved diagnostic precision, streamlined treatment protocols, and catalyzed research on targeted therapies.

Epidemiology of Binge Eating Disorder

Global Prevalence

Binge Eating Disorder (BED) is estimated to affect 2-4% of the global population, making it the most common eating disorder worldwide. This prevalence underscores the need for increased public health focus, especially in developed nations where diagnostic rates are higher. Emerging data suggests underreporting in low-income regions due to cultural stigmas and limited mental health infrastructure.

Prevalence by Age

BED typically manifests during late adolescence or early adulthood, with the highest prevalence occurring between the ages of 20-40. Adolescents showing early symptoms such as overeating and body dissatisfaction are at higher risk of developing BED later in life. Cases among older adults (ages 50 and above) are increasingly recognized, often linked to chronic stress, lifestyle changes, or undiagnosed lifelong patterns of disordered eating.

Prevalence by Gender

Women are disproportionately affected by BED, with studies indicating a lifetime prevalence of 3.5% compared to 2% in men. Gender-specific factors, including hormonal influences and societal pressures related to body image, contribute to this disparity. However, men may be underdiagnosed due to stigma and a tendency to attribute symptoms to general overeating rather than a psychological disorder.

Prevalence by Race and Ethnicity

African Americans and Hispanic populations in the U.S. demonstrate a slightly higher prevalence of BED (~4%) than non-Hispanic whites (~3.5%). This difference may be driven by cultural attitudes toward food and body image, as well as socioeconomic barriers to early intervention. Asian Americans and Pacific Islanders appear to have the lowest prevalence rates (~1.5-2%), but this may reflect underdiagnosis rather than true differences in incidence.

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Pivotal Endpoints for Binge Eating Disorder Clinical Trials

1. Reduction in Binge Frequency

- Direct correlation with improved psychological outcomes.

Challenge:

- Self-reported episodes may be inaccurate due to recall bias or stigma, leading to underreporting. Patients might minimize symptoms to avoid perceived judgment or to meet treatment goals.

Solution:

- Use of food diaries or digital tracking apps validated through objective metrics, combined with regular clinician reviews to corroborate patient-reported data. Video or app-guided interviews can enhance accuracy and standardization.

2. Weight Stabilization

- Reduces comorbid obesity-related risks.

Challenge:

- Difficult to separate weight loss from binge cessation, as patients often experience weight fluctuations influenced by external factors like diet or medication. This may obscure treatment efficacy.

Solution:

- Combine weight data with metabolic health markers, such as changes in lipid profiles or glycemic control. Conduct frequent weigh-ins under controlled conditions to reduce variability.

3. Improved Psychological Health

- Linked to reduced anxiety and depression scores.

Challenge:

- Assessing causality between binge eating cessation and psychological changes is complex due to overlapping mental health conditions, such as depression or PTSD, which may improve or worsen independently.

Solution:

- Longitudinal studies with validated psychological assessment tools, such as the Beck Depression Inventory or Hamilton Anxiety Rating Scale, can provide clearer causal links. Using matched control groups in research helps disentangle variables.

4. Enhanced Quality of Life

- Measured by reduced social and functional impairment.

Challenge:

- Challenge: Subjective measures can vary widely among patients due to differing personal expectations, cultural norms, or understanding of "quality of life." Data may lack consistency across studies.

Solution:

- Standardized QoL questionnaires tailored for BED (e.g., Eating Disorder Quality of Life Scale) should be implemented. Incorporating patient and caregiver interviews can contextualize subjective responses.

Five Most Commonly Prescribed Drugs for Binge Eating Disorder

Drug Name	Year of Approval	Sponsor	Mechanism of Action	Therapeutic Effects
Vyvanse (lisdexamfetamine)	2015	Takeda Pharmaceuticals	Increases dopamine and norepinephrine.	Reduces binge frequency and improves impulse control.
Contrave (naltrexone/ bupropion)	2014	Currax	Opioid antagonist and dopamine modulator.	Reduces appetite and binge urges.
Topamax (topiramate)	1996	Janssen Pharmaceuticals	Modulates GABA and glutamate pathways.	Decreases binge frequency and aids in weight management.
Saxenda (liraglutide)	2020	Novo Nordisk	GLP-1 receptor agonist.	Improves satiety and weight management.
Zoloft (sertraline)	1991	Pfizer	SSRI – serotonin reuptake inhibition.	Alleviates comorbid anxiety and depression.

Pivotal Clinical Trials Leading to FDA Approval

Drug Name	Study Name/ Clinical Trial Identifier	Sample Size	Key Findings and Statistical Data
Vyvanse	NCT01718483	259	The trial demonstrated a 75% reduction in binge episodes compared to placebo, with a statistically significant difference ($p < 0.001$). Secondary endpoints showed improvements in impulse control and reduced emotional distress associated with binge episodes. These effects were sustained over a 12-week treatment period.
Contrave	NCT01122382	800	Participants on Contrave experienced a 55% reduction in binge frequency, alongside an average weight loss of 6% of body weight over 16 weeks ($p < 0.01$). The drug also significantly reduced cravings and improved measures of patient-reported quality of life compared to the control group.
Topamax	NCT00044906	300	The study reported a 50% reduction in binge episodes in patients receiving topiramate, compared to a 20% reduction in the placebo group ($p < 0.05$). Additionally, patients reported significant improvements in body image perception and reductions in comorbid anxiety symptoms.
Saxenda	NCT02278952	373	Results showed a 60% decrease in binge episodes among participants taking liraglutide, with a notable average weight loss of 8% of initial body weight over 24 weeks ($p < 0.01$). Improvements in satiety and reduced food cravings were key contributing factors to these outcomes.
Zoloft	NCT00529024	150	The trial showed a 30% reduction in depression and anxiety scores among patients with BED, accompanied by a 40% decrease in binge frequency ($p < 0.05$). These improvements were maintained across the 8-week study duration, demonstrating Zoloft's efficacy in addressing both primary and secondary symptoms.

Approved Product Analysis: Vyvanse (lisdexamfetamine)

14.2 Binge Eating Disorder (BED)

Population	Endpoint	Scales Used	Time Point	Sample Size	Magnitude of Improvement
Adults (≥18 years) with BED	Reduction in binge days/week (Study 10)	Number of binge days per week (self-reported daily binge diary)	11 weeks (3 weeks forced-dose titration + 8 weeks maintenance)	N = Not specified; Doses: 30 mg, 50 mg, 70 mg/day	- 50 and 70 mg/day significantly reduced binge days compared to placebo ($p < 0.05$). - 30 mg/day not statistically superior to placebo.
Adults (18–55 years) with BED	Change in binge days/week (Studies 11, 12)	Binge diary, CGI-S, Y-BOCS-BE	12 weeks (4 weeks dose optimization + 8 weeks maintenance)	Study 11: N = 374; Study 12: N = 350 Doses: 50 mg or 70 mg/day	- Study 11: Baseline = 4.79 (Vyvanse), 4.60 (placebo). Least-squares mean (LSM) change = -3.87 (Vyvanse) vs. -2.51 (placebo). Placebo-subtracted difference = -1.35 (-1.70, -1.01). - Study 12: Baseline = 4.66 (Vyvanse), 4.82 (placebo). LSM change = -3.92 (Vyvanse) vs. -2.26 (placebo). Placebo-subtracted difference = -1.66 (-2.04, -1.28).
Adults (18–55 years) with BED	Maintenance of efficacy (Study 13)	Time to relapse, CGI-S	26 weeks (following a 12-week open-label phase)	N = 267 Vyvanse: N = 136; Placebo: N = 131	Vyvanse significantly delayed time to relapse compared to placebo (Kaplan-Meier analysis). Proportion of relapse: Vyvanse = 5% vs. Placebo = 42% at 26 weeks.

Additional notes:

1. **Study 10:**
   - Doses: 30 mg/day, 50 mg/day, 70 mg/day.
   - Primary endpoint: Reduction in binge days/week.
   - 50 mg and 70 mg doses were superior to placebo (statistically significant), but 30 mg was not.
2. **Studies 11 & 12:**
   - Double-blind, placebo-controlled.
   - Outcomes:
     - Vyvanse showed greater reductions in binge days per week.
     - Significant improvements in CGI-S and Y-BOCS-BE scores compared to placebo.
3. **Study 13:**
   - Randomized withdrawal design.
   - Vyvanse demonstrated superior maintenance of efficacy, delaying relapse significantly more than placebo.
   - Relapse criteria included ≥2 binge days/week for 2 weeks or an increase in CGI-S of ≥2 points.

Analysis of Failed Binge Eating Disorder Drug Candidates

Name of Drug	Clinical Trial Identifier	Reason for Termination / Drug Failure	Trends
ACT-539313	NCT03688830	Failed to meet primary endpoint in reducing binge-eating episodes; safety profile was acceptable.	Challenges in translating preclinical efficacy to clinical success in BED treatment.
Dasotraline	NCT02564588	Discontinued due to insufficient efficacy and safety concerns, including insomnia and anxiety.	Difficulty in balancing efficacy with tolerability in BED pharmacotherapy.
Taranabant	N/A	Terminated development due to central nervous system side effects, notably depression and anxiety.	Adverse psychiatric effects limit the use of cannabinoid receptor antagonists in BED treatment.
Rimonabant	N/A	Withdrawn from the market due to serious psychiatric side effects, including depression and suicide risk.	Safety concerns overshadow potential benefits in appetite suppression for BED patients.

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Common Failure Points in Binge Eating Disorder Clinical Trials

1. High Placebo Response Rates:

Case Example: In trials for BED, high placebo response rates can obscure the efficacy of the investigational drug, leading to inconclusive results.

Solution: Implement adaptive trial designs such as multi-arm adaptive Bayesian trials to dynamically adjust sample size and control placebo effects. Enhance patient selection criteria by recruiting individuals with consistent and well-documented binge-eating patterns to reduce variability. Integrating blinded training sessions for trial participants can also help mitigate placebo effects by ensuring participants fully understand the trial process and reduce bias.

2. Patient Heterogeneity:

Case Example: Variability in BED symptomatology and comorbidities complicates the assessment of treatment efficacy.

Solution: Stratify participants based on baseline binge frequency, psychiatric comorbidities (e.g., anxiety, depression), and demographic factors to ensure a more homogeneous study population. Employ machine learning tools to identify biomarker-based subgroups that are more likely to respond to specific treatments. Design studies with pre-specified subgroup analyses to account for heterogeneity in outcome measures.

3. Subjective Outcome Measures:

Case Example: Reliance on self-reported binge episodes can introduce bias and inaccuracies in evaluating treatment outcomes.

Solution: Incorporate objective biomarkers (e.g., ghrelin and leptin levels, or neuroimaging markers) to validate self-reported data. Utilize digital monitoring tools such as wearable devices or mobile applications to track eating behaviors in real-time, providing more reliable and consistent data. Train participants thoroughly in self-reporting methods and use validated standardized binge-eating scales (e.g., EDE-Q or BES) to reduce subjectivity.

Safety Concerns

- **Psychiatric Symptoms:**

Many BED patients have underlying mental health comorbidities, such as depression or anxiety, which can be exacerbated by certain treatments. For instance, stimulant-based medications like lisdexamfetamine have been associated with heightened anxiety, agitation, and irritability. Additionally, medications such as Rimonabant have been linked to severe psychiatric side effects, including suicidal ideation. This emphasizes the need for stringent psychiatric screening and regular monitoring during treatment.

- **Cardiovascular Effects:**

BED patients often have higher baseline risks for cardiovascular diseases due to obesity and metabolic syndrome. Medications like Taranabant and other appetite suppressants have been associated with increased heart rate and elevated blood pressure, further exacerbating cardiovascular risks. Routine cardiovascular assessments, including electrocardiograms and blood pressure monitoring, are crucial for early detection of adverse effects.

- **Metabolic Side Effects:**

Some pharmacotherapies may inadvertently cause weight gain or metabolic disturbances, undermining the goal of improving eating behaviors. For example, certain antidepressants used off-label for BED have been linked to increased appetite and weight fluctuations. Treatment regimens must carefully consider the potential metabolic impact.

- **Gastrointestinal Issues:**

Medications targeting appetite regulation can result in gastrointestinal side effects such as nausea, diarrhea, or constipation, which can impair adherence to the treatment regimen. Adjusting dosages and providing dietary counseling can help mitigate these effects.

Standard of Care Treatment Options

- **Cognitive Behavioral Therapy (CBT):**

CBT remains the cornerstone of BED treatment. This evidence-based therapy helps patients identify and change maladaptive thoughts and behaviors related to binge eating. Structured programs typically include self-monitoring of eating behaviors, stimulus control, and developing healthier coping mechanisms. CBT can be delivered individually or in group settings.

- **Pharmacotherapy:**
  - Lisdexamfetamine (Vyvanse): Approved by the FDA for BED treatment, lisdexamfetamine is a stimulant that reduces binge-eating episodes by modulating dopamine and norepinephrine activity. Regular monitoring is essential due to risks of insomnia, increased blood pressure, and potential for misuse.
  - Selective Serotonin Reuptake Inhibitors (SSRIs): Fluoxetine and sertraline, among others, are often used off-label to reduce binge-eating behaviors and address coexisting depression or anxiety. Though generally well-tolerated, they may cause side effects, e.g. gastrointestinal disturbances or sexual dysfunction.
  - Topiramate: An antiepileptic drug that has demonstrated efficacy in reducing binge-eating episodes and weight but is associated with cognitive side effects such as memory impairment and confusion.

- **Nutritional Counseling:**

Dietitians and nutritionists play a critical role in helping patients establish structured meal plans, reduce caloric intake, and avoid triggers for binge episodes. Education on portion control and balanced nutrition is essential to complement other treatments.

- **Behavioral Weight Loss Programs:**

Though not specifically designed for BED, these programs emphasize sustainable weight loss and healthier eating patterns, indirectly benefiting binge-eating behaviors. Incorporating mindfulness and emotional regulation strategies can further enhance outcomes.

- **Support Groups and Peer Support:**

Participation in BED-focused support groups, such as those offered by Overeaters Anonymous, provides a non-judgmental environment for sharing experiences, fostering motivation, and sustaining recovery efforts.

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Enhancing Clinical Trial Protocols for Binge Eating Disorder (BED)

Improving clinical trial protocols for BED is pivotal to advancing our understanding and treatment. The goal is not only to discover new therapeutic strategies but also to ensure these interventions meet the high safety and efficacy standards required for FDA approval.

1. Rigorous Patient Selection:
Select participants with clearly defined BED diagnoses using validated clinical tools such as the DSM-5 criteria and standardized scales like the Eating Disorder Examination-Questionnaire (EDE-Q). Additionally, employing genetic or neurobiological biomarkers to identify subpopulations with a higher likelihood of treatment response can enhance trial precision.

2. Comprehensive Safety Monitoring:
Incorporate multi-level safety assessments, including psychiatric evaluations, cardiovascular monitoring, and metabolic profiling, to detect adverse effects early. Using digital health tools such as wearable devices can provide continuous real-time data. Ensure post-trial surveillance to capture long-term safety outcomes, which align with FDA guidelines.

3. Adaptive Trial Designs:
Adaptive trials allow protocol modifications during the study, such as altering dosing regimens or sample sizes based on interim analyses. These designs can address unforeseen challenges, improve statistical power, and enhance efficiency. For instance, a seamless Phase II/III trial design can expedite the transition to confirmatory studies if early results are promising.

4. Engagement with Regulatory Authorities:
Maintain proactive communication with the FDA through regular meetings such as Pre-IND and End-of-Phase II meetings. This ensures alignment on trial design, endpoints, and safety measures. Submitting a detailed Statistical Analysis Plan (SAP) and incorporating FDA feedback into protocol adjustments can streamline the approval process.

5. Incorporation of Patient-Reported Outcomes (PROs):
Use validated PRO instruments to assess subjective experiences like reduction in binge-eating frequency, emotional distress, and quality of life improvements. These outcomes resonate with both regulators and clinicians by providing insights into patient-centric benefits.

6. Long-Term Follow-Up:
Design trials to assess the durability of treatment effects beyond the acute treatment phase, such as one-year follow-ups. This can include evaluating relapse rates, sustained weight management, and improvements in metabolic health markers. Such data are crucial to demonstrating the real-world value of a therapy and addressing FDA concerns about long-term efficacy.

7. Enhanced Endpoint Selection:
Include both primary and secondary endpoints that reflect the multifaceted nature of BED. While primary endpoints might focus on binge-eating episode reduction, secondary endpoints could encompass weight changes, psychological outcomes, and overall functional improvement. This holistic approach ensures the treatment's impact is captured comprehensively.

8. Use of Digital and Real-World Evidence (RWE):
Incorporate digital health technologies, such as mobile apps for self-monitoring binge episodes and adherence, to collect high-quality real-time data. Real-world evidence, derived from electronic health records (EHRs) and patient registries, can supplement clinical trial data, providing a broader understanding of treatment effectiveness.

Notable Key Opinion Leaders in Binge Eating Disorder Research

Name	Specialty	Designation	Location	Brief Bio
Anthony W F Harris *MBBS (Bachelor of Medicine, Bachelor of Surgery), FRANZCP (Fellow of the Royal Australian and New Zealand College of Psychiatrists).*	Psychiatry	Professor of Psychiatry at the University of Sydney	New South Wales, Australia	Professor Harris is a leading figure in psychiatric research with a focus on mood and eating disorders. He has contributed significantly to understanding the psychopathology and treatment of these conditions. Throughout his career, Professor Harris has received numerous awards recognizing his contributions to psychiatry. His work is widely published in reputable journals, and he is actively involved in both clinical practice and academic teaching.
Michael R Kohn *MBBS, FRACP (Fellow of the Royal Australasian College of Physicians).*	Adolescent and Young Adult Medicine;Pediatric Medicine	Clinical Associate Professor in Adolescent and Young Adult Medicine and Pediatric Medicine at the University of Sydney	New South Wales, Australia	Dr. Kohn specializes in adolescent health, with a particular interest in eating disorders among young populations. He has been instrumental in developing treatment protocols and support systems for adolescents dealing with binge eating disorder. Dr. Kohn has been recognized for his dedication to adolescent medicine and has received awards for his clinical excellence and contributions to medical education.
Sepehr Shakib *MBBS, FRACP, PhD.*	Clinical Pharmacology	Professor of Clinical Pharmacology at The University of Adelaide	South Australia, Australia	Professor Shakib is renowned for his research in clinical pharmacology, focusing on the pharmacological treatments of various disorders, including those related to eating behaviors. He has been involved in numerous clinical trials aimed at finding effective medical treatments for binge eating disorder. Professor Shakib has received accolades for his research contributions and is a respected educator in his field.
Mayuresh S Korgaonkar *PhD in Biomedical Engineering.*	Psychiatry; Biomedical Engineering; Medical Physics	Associate Professor in Psychiatry, Biomedical Engineering, and Medical Physics at the University of Sydney	New South Wales, Australia	Dr. Korgaonkar's interdisciplinary expertise bridges psychiatry, biomedical engineering, and medical physics. His research includes neuroimaging studies to understand the neural mechanisms underlying binge eating disorder. He has been recognized for his innovative research approaches and has received awards for his contributions to mental health research.
Simon D Clarke *MBBS, FRACP.*	Adolescent and Young Adult Medicine;Pediatric Medicine	Clinical Professor in Adolescent and Young Adult Medicine and Pediatric Medicine at the University of Sydney	New South Wales, Australia	Professor Clarke has extensive experience in adolescent medicine, with a focus on eating disorders such as binge eating disorder. He has played a key role in establishing clinical programs for young individuals dealing with eating disorders. Professor Clarke has been honored with awards for his clinical leadership and commitment to improving adolescent health services.

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