

RESEARCH UPDATE

Research Institute at Lindner Center of HOPE to Study Effect of Lisdexamfetamine on Prefrontal Brain Dysfunction in Binge Eating Disorder

In the beginning of 2015, the US Food and Drug Administration (FDA) approved Vyvanse® (lisdexamfetamine dimesylate) capsules as the first and only treatment for adults with moderate to severe BED. Now, the Research Institute at Lindner Center of HOPE is participating in a 12 week open label study of Lisdexamfetamine (LDX/ Vyvanse) in participants with binge eating disorder.

The goal is to compare the brain functioning as observed with fMRI in binge eaters who are taking Vyvanse® as compared to controls. Staff will examine the effects of LDX treatment on frontal lobe and striatal brain activation in BED patients undergoing 12 weeks of open-label treatment with LDX. The overall hypothesis is that patients with BED suffer from dysfunction of reward/emotional brain systems, especially in response to food cues, and that prefrontal and striatal brain regions that mediate affect and decision-making will normalize in response to food cues after 12 weeks of LDX treatment. Inclusion criteria include: subjects will meet the DSM-IV-TR criteria for a diagnosis of binge eating disorder (BED) for at least the last 6 months; will report at least 3 binge eating (BE) days per week for the 2 weeks prior to LDX initiation prospectively documented in take-home binge diaries and are women, through the ages of 18 and 55 years, inclusive. Of note, for this study overweight and obese women are also being recruited as healthy controls. Reimbursement for time and travel is provided.

Recruitment will begin in late August 2015

Open-label study to evaluate Phentermine/topiramate extended release (PHEN/TPM ER; Qsymia®) in ten subjects with overweight or obesity and DSM-V Binge eating disorder (BED)

The Research Institute at Lindner Center of HOPE is participating in a 12 weeks open label study of Qsymia in binge eating disorder. Qsymia is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of 30 kg/m² or greater (obese) or BMI of 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia. The hypothesis is that this medication will decrease urges to binge eat and help weight loss in BED patients. Inclusion criteria: male or female subject between 18-65 years of age meeting the Diagnostic and Statistical Manual of Mental Disorders 5th Edition (DSM 5) criteria for BED who are overweight or obese.

Recruitment will begin in September 2015

www.lindnercenterofhope.org

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The Source

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PSYCHIATRY AND PSYCHOLOGY NEWS FOR MENTAL HEALTH PROFESSIONALS

AUGUST 2015



Events

September 1

Grand Rounds: Dr. Stephen Billman presents on the topic of Insomnia at Noon, Lindner Center of HOPE Gymnasium/Conference Center

September 9

Christ Tuell, EDD, LPCC-S, LICDC, presents to faculty and staff at The Christ College of Nursing and Health Services on Suicide Awareness and Prevention



Intermittent Explosive Disorder: An Important but Under-Recognized Medical Disorder

**By Susan L. McElroy, MD, Lindner Center of HOPE, Chief Research Officer
University of Cincinnati College of Medicine, Professor of Psychiatry and Neuroscience**

Intermittent Explosive Disorder (IED) is a common and serious disorder that is often unrecognized and untreated. People with IED are periodically unable to restrain impulses that result in verbal and physical aggression. The aggressive behaviors are unplanned, out of proportion to provocation, and cause distress and psychosocial impairment, including interpersonal difficulties, divorce, school suspension, job loss, and financial and legal problems.

The violent behaviors of IED, often called explosive outbursts or rage attacks, are often preceded by aggressive or violent impulses, described as “the need to attack,” “the need to defend oneself,” “the need to strike out,” “seeing red,” or “an adrenaline rush.” These impulses are associated with tension, anger, increased physiological arousal, and increased energy. The explosive outbursts are brief, lasting 10 to 30 minutes, and usually followed by feelings of depression, remorse, guilt, and fatigue.

Once thought to be rare, we now know that IED is very common. Research has shown that the lifetime prevalence of IED in the general population is 1 to 7 percent. The average age of onset

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is 14 to 18 years among adults, and 13 among adolescents. IED is most common among males and younger people. Of note, people with IED often have other psychiatric disorders, like depression, bipolar disorder, alcohol or drug abuse, and anxiety.

The cause of IED is unknown but biological, psychological, and social factors are thought to be involved. Importantly, IED runs in families suggesting that genetic factors are involved. Research also suggests that abnormalities in serotonin function in the central nervous system play a role in IED.

IED is usually treated with medications and/or cognitive behavioral therapy (CBT). Medications that may be helpful include serotonin reuptake inhibitors (like fluoxetine), anti-epilepsy medications (like carbamazepine), or mood-stabilizers like lithium. When treating IED, it is crucial that other psychiatric conditions are identified and properly managed.

No medication, however, is approved by the United States Food and Drug Administration for the treatment of IED. Hence, Azevan Pharmaceuticals is sponsoring a study to see if a novel medication is efficacious for IED in adults. This medication affects vasopressin, a hormone in the brain thought to play an important role in regulating aggressive behavior. This medication has been shown to reduce aggressive behavior in animals. The Research Institute at the Lindner Center of HOPE will be participating in this study which is scheduled to begin in late August. The Research Institute will be recruiting volunteers with IED to participate at that time. If an individual has questions about the study and might be interested in participating, they can call (513) 536-0710 for further information.

Research Institute at Lindner Center of HOPE to Test Medication for Intermittent Explosive Disorder (IED) Treatment

Before the end of August Lindner Center of HOPE researchers anticipate recruiting for a new medication trial that could impact the treatment of Intermittent Explosive Disorder (IED). IED, characterized by an inability to resist aggressive urges and explosive outbursts, affects six percent of the general population with no designated medications currently available for treatment.

The exploratory Phase II study, expected to begin in mid to late August, has been designed to examine the efficacy, safety and tolerability profile of the novel V1a vasopressin antagonist (SRX246) against placebo, in adults meeting the DSM-5 (Diagnostic and Statistical Manual) criteria for IED. A large body of translational research indicates that blocking the vasopressin (V1a) receptor might be a plausible form of treatment. Studies have found that vasopressin (V1a) has an established role in signaling social and emotional behavior, including aggression.

DSM-5 criteria for IED defines it as recurrent behavioral outbursts representing a failure to control aggressive impulses as manifested by either:

- Verbal aggression or physical aggression toward property, animals or other individuals, occurring, on average, twice weekly for a period of three months. The physical aggression does not result in damage or destruction of property and does not result in physical injury to animals or other individuals.

- Three behavioral outbursts involving damage or destruction of property and/or physical assault with physical injury against animals or other individuals occurring within a 12-month period.

The behavior is distressing for the individual and is not premeditated and not due to another psychiatric illness.

"This disorder comes with lots of complications," according to Dr. Susan McElroy, Chief Research Officer, Lindner Center of HOPE. "Often we see individuals struggling with IED facing legal problems, social issues, marital difficulties, child abuse concerns, medical problems from injuries sustained during the physical outbursts, significant distress, severe psychosocial complications and even loss of employment."

"The potential for gaining control over IED with medication would be incredibly beneficial for those struggling."

The clinical trial is seeking to recruit males and females age 18 to 55 with moderate IED. Candidates with substance abuse disorders, compromised medical health or currently taking psychotropic medications will not be eligible to participate. Those meeting criteria should expect to participate in 8 weeks of treatment.

If interested in participating in the trial, contact (513) 536-0710.



IN THE NEWS

OCD Educational Event – Save the Date



On December 5, 2015, Lindner Center of HOPE will be offering a full day educational event for clinicians on "Advances in the Treatment of OCD and Comorbid Disorders." Topics covered will include an overview of the diagnosis and treatment of OCD, treatment of individuals with OCD and eating disorders, advances in pharmacological approaches and medical procedures for treating OCD, OCD and addiction treatment, diagnosing and treating Pediatric Autoimmune Neuropsychiatric Syndrome (PANS), and treatment of morbid and violent obsessions.

Presenters will include research and clinical faculty of the University of Cincinnati's Department of Psychiatry including **Dr. Susan McElroy**, who is internationally known for her research in bipolar disorder, eating disorders, OCD, obesity, and impulse control disorders. In addition, presenters will also consist of members of the Lindner Center of HOPE's OCD and Anxiety Disorder Treatment program, such as Charles Brady PhD and Jennifer Wells, LISW. Six CME hours for physicians, nurse practitioners, psychologists, and social workers and counselors will be offered. Please contact Pricila Gran at pricila.gran@lindnercenter.org or (513) 536-0318 for additional information.

More on the Web - lindnercenterofhope.org

> Library of Resources

This library offers resources that will enhance the understanding of mental illness, specific diagnoses, and treatment options.

> Treatment Teams

Lindner Center of HOPE has a diverse team offering patients and families expertise in diagnosis and treatment.

> Support Groups

Review the list of support groups available at the Center.

> For the Patient with Complex, Co-Morbid Needs

A short-term residential treatment center where clinicians are dedicated to bringing the latest treatment methods to optimize successful patient outcomes. Call (513) 536-0537 to learn more about Sibcy House.



Openings in DBT Groups

Lindner Center of HOPE has openings in their Dialectical Behavior Therapy groups, both afternoon and evening groups. To refer someone, please call Kelly at (513) 536-0634.