

about the MOOD & METABOLIC CLINIC
a division of the Mood Disorders Program at University Hospitals Case Medical Center

*“We are
committed to
changing the lives
of people and
families through
patient-centered
research.”*

*- Dr. David Kemp, Director,
Mood & Metabolic Clinic*



EMOTIONAL WELLNESS & HEALTHY LIVING

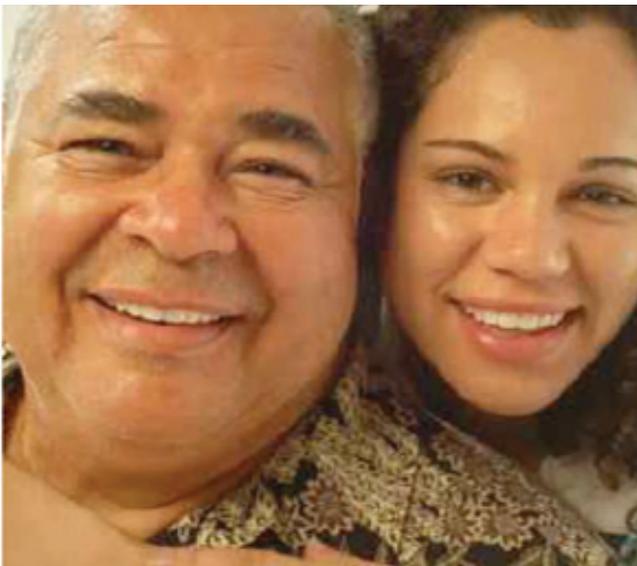
The Mood & Metabolic Clinic developed from the understanding that patients with mood disorders experience higher rates of metabolic-related health conditions than the general population. Tragically, patients with mood disorders experience a shortened lifespan, primarily due to elevated rates of heart disease and type-2 diabetes. On average, individuals with mood disorders will lose between 15-25 years of life and experience a reduced quality of life if these medical conditions are not successfully recognized and treated.

Our psychiatrists and psychologists provide a range of pharmacotherapy and cognitive-behavioral interventions to treat mood disorders that co-occur with obesity, diabetes, or metabolic syndrome. We also conduct patient-centered clinical trials that allow individuals and their families to receive state-of-the-art treatments under safe and meticulously monitored conditions.

WHAT ARE CLINICAL TRIALS?

A clinical trial is a medical research study involving volunteer participants. Clinical trials are a standard research practice and are done on all medications before they are approved by the Food and Drug Administration. Some trials evaluate the effects of new or existing medications. Some may study new forms of psychotherapy (talk therapy). Others may study a combination of therapies. Carefully conducted clinical trials are the safest and fastest way to find treatments that work and offer new ways to improve health.

All new research must be approved by a committee called an Institutional Review Board (IRB). It is the IRB's job to ensure that a clinical trial is ethical and that a volunteer's rights are protected.



CLINICAL TRIAL OPPORTUNITY

Pioglitazone for the treatment of depression and co-occurring metabolic syndrome.

Who can participate?

Men and women:

- Between 18 and 70 years old.
- Diagnosed with major depressive disorder or bipolar disorder.
- Free from heart failure.
- All participants will be screened for metabolic syndrome at the initial study visit. Metabolic syndrome includes such signs as abdominal obesity, high blood pressure, elevated cholesterol/triglyceride levels and increased blood sugar.

What do I need to know about this study?

David E. Kemp, MD, is conducting this research study at University Hospitals Case Medical Center and focuses on the treatment of symptoms of depression in participants who have metabolic syndrome, or are at risk for developing heart disease or type 2 diabetes. The goal of this research is to test whether depression can be treated with pioglitazone, an FDA approved medication that enhances the way the body uses blood sugar.

What should I know about participating in this study?

- Study participation may last from 20 to 24 weeks and will include weekly or semi-weekly visits with investigators.
- All participants will receive the same treatment.
- The study does not include the use of placebo (often called a sugar pill).
- In most cases, participants will not be required to stop their current psychiatric medications.

What are some possible benefits to participation?

- You may benefit from the new medication under study.
- Results from the study may help others in the future.

What are some possible drawbacks to participation?

- There is no guarantee that this medication will work to treat your depression.
- Participation in the trial may be burdensome and time consuming.
- There may be unknown risks associated with the study treatment.

For more information, please call 216.844.2869



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WHAT IS DEPRESSION AND BIPOLAR DISORDER?

Everyone occasionally feels blue or sad, but these feelings usually pass within a couple of days. When these feelings last for two weeks or more, it may be a sign of depression or bipolar disorder.

Symptoms of depression may include:

- Sadness • Change in appetite • Trouble sleeping • Difficulty concentrating • Loss of interest • Feelings of guilt/worthlessness • Feeling like life is not worth living • Loss of energy • Irritability

Symptoms of bipolar disorder may include:

- Mood swings • Racing thoughts • Restlessness • Distractibility • Impulsivity • Decreased need for sleep • Inflated self-esteem • Talkativeness

People suffering from depression or bipolar disorder can get better with treatment. Intensive research into the illness has resulted in the development of medications, psychotherapies, and other methods to treat people with these disabling disorders.

ARE YOU DEPRESSED?

If you are currently experiencing symptoms of depression or bipolar disorder, you may benefit from participation in an ongoing clinical research study. If you would like more information, please contact, David E. Kemp, MD at the Mood Disorders Research Program.