



Yale Program For Women's Reproductive Behavioral Health (WRBH)



Current Research Studies

❖ Paid Menstrual Cycle Research Study

What is PMDD?

Approximately 3 - 9% of women are diagnosed with **Premenstrual Dysphoric Disorder, or PMDD**, a condition that is more severe than premenstrual syndrome (PMS). Women who experience PMDD often experience emotional symptoms that are more moderate to severe than routine PMS. These emotional symptoms take place each month prior to the onset of menstruation. Some women may have symptoms which last anywhere from 10 days to 2 weeks, while others may find that their symptoms only interfere with daily activities for several days prior to menses. After several days of menstrual flow, women with PMDD feel as if they are back to "normal". Women with PMDD may experience some of the following symptoms:

- Feeling angry or irritable
- Feeling depressed or hopeless
- Feeling anxious, tense or on edge
- Feeling sad or tearful
- Being more sensitive to rejection
- Feeling overwhelmed or out of control
- Loss of interest or pleasure in routine activities & hobbies
- Decreased energy and motivation
- Difficulty sleeping or oversleeping

Women who experience more mild symptoms each month may benefit from simple changes in their lifestyle. Exercise may reduce stress and help to improve both mood and physical symptoms. In addition, healthy eating habits (like reducing consumption of caffeine and salty foods), along with vitamin supplements, may also help alleviate some symptoms of PMS. Women who suffer from more severe mood symptoms may require treatment. Treatment can alleviate the intense psychological turmoil and distress caused by these symptoms each month.

Although exercise, proper nutrition, calcium, and other supplements such as vitamin B6 may help alleviate some of the milder symptoms of PMS that occur, research studies have shown that these strategies do not consistently alleviate the types of symptoms that occur with PMDD. Some medications that affect hormone levels, such as gonadotropin releasing hormone agonists and serotonin reuptake inhibitors (SSRI's), have proven to be effective treatment

regimens for women who suffer from PMDD. Oral contraceptives have not been consistently helpful with the severe mood symptoms associated with PMDD, although they may help decrease cramping, breast tenderness, and heavy menstrual flow. The most effective treatments for PMDD are the medications known as SSRI's. Sixty percent of women have marked improvement with SSRI's such as sertraline (Zoloft®) or fluoxetine (Prozac®). WRBH is currently looking for women with PMDD to participate in a paid research study involving brain imaging & treatment with Prozac®.

Why participate in a research study for PMDD?

If you are one of the 3 – 9 % of women who experience significant mood symptoms prior to menses, participation in a research study provides you with the opportunity to receive a comprehensive, diagnostic evaluation of your symptoms and physical health. All participants undergo a rigorous two-month screening process to determine if they meet criteria for PMDD. Those who meet criteria for PMDD will receive a free comprehensive laboratory work up, as well as free treatment for their symptoms through participation in a research study. In addition, by being a research participant, you are contributing to the ever-growing body of research on women, hormones, and mood. Your participation will contribute to our knowledge of this area and help us to develop future treatments for this population of women.

What's involved if I decide to participate?

This study is approximately 6-8 months long. All women participate in a paid 2-month screening process during which we determine if you meet criteria for PMDD. The screening process involves completing daily mood ratings. Women who participate in this study complete the following:

- One intake visit (approximately 2 hrs long)
- Four 45-minute in-office appointments during the two-month screening process.
- Four brain imaging sessions using a technique called Magnetic Resonance Spectroscopy (MRS). MRS is a non-invasive procedure, which measures different neurochemicals in your brain. MRS is not harmful to your health, and does not involve any dyes or radiation. For this study we are interested in measuring gamma-aminobutyric (GABA) acid, a neurotransmitter that is affected by the hormonal changes that occur during the menstrual cycle. Participants undergo two MRS scans before treatment with medication, and two MRS scans after treatment with medication.
- Blood drawing at various visits to measure hormone levels at different phases of the menstrual cycle.
- Optional lumbar punctures.

Who is eligible to participate?

Menstruating women between the ages of 18 - 44, who experience a regular menstrual cycle each month and are not taking hormonal birth control, are invited to contact WRBH for further information. Participants must experience moderate to severe emotional symptoms before their periods each month. Participants will receive free medication treatment along with a

comprehensive evaluation of their symptoms through their participation in a paid research study.

Women will not be eligible for this study if they are taking birth control, are currently pregnant, are currently taking medication for the treatment of depression and anxiety, or are using drugs.

All participants can earn between \$665.00 - \$1680.00 for their participation.

All inquiries are confidential.

HIC #10098

**For more information, please contact 1-800-ASK-YALE
(press 2 for Yale Research Clinics, then press 1 for WRBH),
or call us locally at 203-764-9932.**

❖ **Cognitive Processing Therapy (CPT) Study for Pregnant Women with a Previous Pregnancy Loss or Complication**

What is the purpose of this study?

The purpose of this study is to assist women in reducing their anxieties, worries, and fears as a result of a previous pregnancy complication or loss through a type of therapy called Cognitive Processing Therapy (CPT). CPT is a form of psychotherapy in which a clinician will meet with you and provide you with tools that can be used to help you deal with your pregnancy, anxiety and worries. This treatment employs homework that is completed between sessions and involves writing things down in a journal in order to reinforce the tools that will be learned in each treatment session.

Who is eligible to participate?

Women between the ages of 18-49 who are currently between 8-30 weeks pregnant and have experienced a previous pregnancy loss or complication(s).

This study has 2 groups of subjects:

Group 1 (CPT Study)

If you have experienced a previous pregnancy loss or complication and are experiencing anxiety regarding your current pregnancy, you may qualify for our CPT Study. If you are eligible to take part in this study, you will be randomly assigned to one of two groups. The first group will undergo 6 weeks of CPT that involves one visit each week, while the second group will be assigned to a waitlist that will allow them to receive CPT after a waiting period of 6-7 weeks. Each CPT session will be videotaped. Women assigned to either group will also have the option of taking part in the startle study, which is explained below.

Group 2 (Startle Study)

If you have not experienced a previous pregnancy loss or complication, you may qualify for our Startle Study. However, if you have experienced a previous pregnancy loss or complication and did not experience emotional stress after the loss and are not worried about your current pregnancy, you may qualify for our Startle Study.

This study involves the investigation of the effects of a startle procedure on arousal and stress reactivity in pregnant women, which will be measured by examining urine samples for levels of cortisol, a hormone that is involved in the body's response to stress. If you choose to take part in this study, you will participate in a videotaped exercise similar to a hearing test. You will wear a set of headphones while sitting in a chair and will hear a series of noises of different volumes. While listening to these noises, your eye blinking, skin temperature and heart rate be monitored.

For both groups, women will not be eligible to participate if they are currently taking medication for the treatment of depression and anxiety, or are using drugs.

Study Compensation:

- In office interview = \$20
- Group 1 (participants enrolled in the CPT Study) = \$10 for each behavioral assessment; there is 1 assessments/week for 6 weeks for a total of \$60. Completing the in office interview and behavioral assessments = \$80.
- Group 2 (participants enrolled in the Startle Study) = \$50 for each startle session. If you complete all 3 startle sessions you will receive \$170.
- Both Groups: 2 week postpartum interview after delivery = \$10 gift card
- Both Groups: Infant assessment at 4 – 6 months postpartum = \$75 gift card

All inquiries are confidential.

HIC #0707002918

**For more information, please contact 1-800-ASK-YALE
(press 2 for Yale Research Clinics, then press 1 for WRBH),
or call us locally at 203-764-9935.**

❖ Oral Contraceptive & Brain Imaging Study

What is the purpose of this study?

The purpose of this study is to investigate the effect of oral contraceptive pills (OCPs or birth control pills) on cortical GABA concentrations as measured by proton magnetic resonance spectroscopy (1H-MRS) in non-depressed, healthy menstruating women. The OCPs being studied are Zovia 1/35E® or Necon® 1/35.

What's involved if I decide to participate?

This study is approximately 3 months long and involves the following visits:

- Fifteen minute phone screen to determine if you are eligible for an intake visit.
- One intake visit (approximately 1.5 hrs long) to determine your eligibility for the study. This visit involves a urine drug test and blood draw.
- Nightly completion of a short 3-minute questionnaire asking about any mood symptoms that you might experience during months 1 and 2 of the study.
- Two brain imaging sessions using a technique called Magnetic Resonance Spectroscopy (MRS). These two sessions occur on the same day, usually a Saturday. This testing day is approximately 7 hours long and involves having your blood drawn two times to measure hormone levels.

Who is eligible to participate?

Menstruating women between the ages of 18 - 45, who experience a regular menstrual cycle each month and are not taking medication including birth control pills, are invited to contact WRBH for further information. You must have had a gynecological exam, including a PAP smear, during the past year in order to participate.

Women will not be eligible for this study if they are currently pregnant or trying to get pregnant, are currently taking medication for the treatment of depression and anxiety, or are using drugs.

All participants can earn up to \$275.00 for their participation.

All inquiries are confidential.

HIC #0701002178

**For more information, please contact 1-800-ASK-YALE
(press 2 for Yale Research Clinics, then press 1 for WRBH),
or call us locally at 203-764-9932 or 203-764-9935.**

❖ Evaluation & Treatment of Postpartum Depression

What is Postpartum Depression (PPD)?

Pregnancy and childbirth can be welcomed, happy events in a woman's life. However, with any change comes a certain amount of stress. There are increasing demands upon a woman's body and time as she progresses through pregnancy and delivery, and begins to care for her new infant. Many women feel overwhelmed, anxious, and uncertain about how they will juggle home, work, and their relationships when the new baby arrives.

As many as 8 out of 10 new mom's experience what are called the "baby blues". The "baby blues" are considered to be a normal part of early motherhood and usually resolve within ten days after delivery. Although the "baby blues" are normal, some new mom's will experience more severe or prolonged symptoms of depression. These symptoms are more severe than the "baby blues" and occur in at least one out of ten women after delivery. Although it is not clear why women get depressed after delivery, many physicians believe that the rapid changes in hormones, which occur with pregnancy and delivery, may play a role. Below are some of the symptoms of PPD:

- Feeling sad, blue, or down in the dumps
- Loss of interest or pleasure in life, routine activities, and hobbies
- Loss of appetite
- Decreased energy and motivation
- Difficulty falling asleep or staying asleep, even when the baby is sleeping
- Sleeping more than usual
- Increased crying or tearfulness
- Feeling worthless, hopeless, or overly guilty
- Irritability and or anxiety
- Unexplained weight loss or weight gain

What types of treatments are available for PPD?

If you have or develop any of these symptoms, it is important to remember that this is not something you brought upon yourself, and it does not reflect a personal weakness or an inability to cope. Individual therapy, behavior therapy, support groups, and medications, if necessary, are available to help you begin to feel like yourself again.

Is treatment available for PPD at WRBH?

Yes, we offer free treatment with individual counseling and medication with our licensed Advanced Practice Registered Nurse (APRN) who has over ten years of experience working with women and their families who have experienced PPD. This free treatment is available

through participation in a paid research study and uses a medication called Zoloft®. Zoloft® is an FDA-approved medication for the treatment of major depression in men and women.

WRBH has also studied the use of medications like Zoloft® in pregnant and breastfeeding women, and provides consultations regarding the risks versus benefits of using a medication like Zoloft® to treat PPD. These consultations are conducted with our Psychiatry Residents who are clinically supervised by Dr. Epperson. Please see our website for more information about scheduling an appointment with a WRBH Psychiatry Resident.

What's involved if I decide to participate?

Women who participate in our PPD study undergo two brain imaging sessions using a technique called Magnetic Resonance Spectroscopy (MRS). MRS is a non-invasive procedure, which measures different neurochemicals in your brain. MRS is not harmful to your health, and does not involve any dyes or radiation. For this study we are interested in measuring gamma-aminobutyric (GABA) acid, a neurotransmitter that is affected by the hormonal changes that occur after childbirth. The first MRS session occurs before treatment with Zoloft® begins, and the second MRS session occurs six to eight weeks after treatment with Zoloft® has begun.

Who is eligible to participate?

Women who meet criteria for PPD after an initial evaluation with a member of WRBH may be eligible for participation if they are within the first 3 months postpartum.

Women will not be eligible for this study if they are taking birth control, are currently pregnant, are currently taking medication for the treatment of depression and anxiety, or are using drugs.

All participants can earn up to \$200.

All inquiries are confidential.

HIC #9958

**For more information, please contact 1-800-ASK-YALE
(press 2 for Yale Research Clinics, then press 1 for WRBH),
or call us locally at 203-764-7520.**

➤ **Brain Imaging Study of Cigarette Use in Smokers and Non-Smokers**

The differences in Male and Female Smokers

There are several note-worthy differences between males and females in regard to cigarette smoking behavior, however, the most shocking difference is that women seem to have a more difficult time quitting smoking than men. The purpose of this study is to examine the differences in gamma-aminobutyric (GABA) acid, a neurotransmitter that is affected by hormonal changes, in men and women smokers and non-smokers.

Why participate in a research study on cigarette use?

Data from this study will help us to better understand the role that sex differences may play in smokers who continue smoking and those who attempt to quit. Please note that while women will have the opportunity to quit smoking for a period of time during this study, that at this time this study is not designed as a “stop smoking” study for men.

What’s involved if I decide to participate?

This study is approximately 2 months long. Both men and women participate in 2 brain imaging sessions using a technique called Magnetic Resonance Spectroscopy (MRS). MRS is a non-invasive procedure, which measures different neurochemicals in your brain. MRS is not harmful to your health, and does not involve any dyes or radiation. MRS is very similar to MRI (or magnetic resonance spectroscopy). Please note that at this time we no longer need male non-smoking and smoking participants for this study.

- Women who are non-smokers who participate in this study complete the following:
 - One intake visit (approximately 1.5 hrs long) that includes blood work, urine pregnancy test, and urine drug screen.
 - Two MRS scans scheduled at specific times during the menstrual cycle (typically 3 – 3.5 weeks apart).
 - Blood drawing at each MRS session to measure hormone levels.
 - A drug and pregnancy test at each MRS session.

- Women who are smokers who participate in this study complete the following:
 - One intake visit (approximately 1.5 hrs long) that includes blood work, urine pregnancy test, and urine drug screen.
 - Two MRS scans scheduled at specific times during the menstrual cycle (typically 3 weeks apart).
 - Blood drawing at each MRS session to measure hormone levels.
 - A drug and pregnancy test at each MRS session.
 - Smoking women will have the option of stopping smoking after their 2nd MRS scan. These women will remain abstinent until they participate in a 3rd

scan approximately 6 to 10 days later. Please note that we will provide contingency management and support to help these women remain abstinent from smoking. There is financial incentive provided for each day that a woman continues to remain abstinent from smoking.

Who is eligible to participate?

Male smokers and female smokers and non-smokers between the ages of 18 - 50, who are physically healthy and not taking any medications, are invited to contact us for further information regarding study criteria. Women will not be eligible for this study if they are taking birth control or are currently pregnant. Potential participants who are using drugs will not be eligible for participation. Drug testing is conducted during this study.

All participants can earn \$400 for their participation.

Female smokers who opt to quit smoking for 6-10 days can earn up to an additional \$395.

Participants who come from the greater Hartford area or New London County receive additional compensation for their time and travel to the clinic on test days.

All inquiries are confidential.

HIC #11080

**For more information, please contact 1-800-ASK-YALE
(press 2 for Yale Research Clinics, then press 1 for WRBH),
or call us locally at 203-764-9932 or 203-764-9935.**

➤ **The MENSES Study: Menstruation & Seizure Susceptibility Study**

What is the purpose of this study?

The purpose of this study is two-fold: 1) We are hoping to sample a large number of women with epilepsy to see how many women experience mood changes, also known as premenstrual syndrome or PMS, prior to their periods; and 2) We hope to learn more about how menstrual cycle-related changes in hormones and/or changes in a brain chemical called gamma aminobutyric acid (GABA) may affect the frequency and/or timing of seizures in women with epilepsy.

What's involved if I decide to participate?

There are two parts to this study. At this time we are hoping to enroll up to 150 women into the **Screening Phase** (first part of the study). The **Brain Imaging Phase** (second part of the study) of the study is currently on hold.

After signing the study consent form and completing the intake appointment, you will enroll in the first part of the study called the **Screening Phase**. During the **Screening Phase** you complete a daily diary about your mood and seizures over the course of 2-3 months. This diary is completed once each evening at home. At the end of the 2-3 months, you mail your diary back to the clinic.

The second part of the study is called the **Brain Imaging Phase**. During the **Brain Imaging Phase** you will be asked to participate in a series of Magnetic Resonance Spectroscopy (MRS) scans over the course of the following month. MRS is a non-invasive procedure, which measures different neurochemicals in your brain. MRS is not harmful to your health, and does not involve any dyes or radiation. It is very similar to an MRI (or magnetic resonance imaging). The timing of the MRS scans will depend on the seizure frequency you reported during the previous two menstrual cycles. You will have a total of two MRS scans: 1) the first scan will occur 3 - 9 days after you get your period, and 2) the second scan will occur another time during that same menstrual cycle. Throughout this phase of the study, you will be asked to refrain from consuming alcohol for one week prior to each of the two testing days. You are expected to continue taking your medications for epilepsy as prescribed by your neurologist. Other medications which you are required to take must be cleared by the research staff before you can proceed to this phase of the study. On each scan day you will report to the Yale Program for Women's Reproductive Behavioral Health (100 York Street, New Haven) one hour prior to your MRS scan where you will be asked to complete questionnaires regarding your seizures, mood and behavior, as well as have 4 teaspoons of blood drawn for hormone measurements.

Who is eligible to participate?

Women between the ages of 18-45 who have focal epilepsy, are regularly menstruating, do not take more than 3 anti-seizure medications, do not use drugs, do not have a psychiatric disorder that requires immediate treatment, and do not drink more than 10 alcoholic beverages per week are invited to contact us for more information.

You will be invited to continue into the second phase of this study involving brain imaging if you meet criteria for the type of seizure pattern that we are interested in studying, and you are not using a hormonal form of birth control (such as oral contraceptive pill, birth control patch, birth control ring, and Depo-Provera®) and have not used this type of steroid birth control in the previous four months. In addition, in order to participate in the second phase of this study you must also not have any implanted metallic devices (such as pacemaker, orthodontic braces, shrapnel).

All participants earn \$50 for their participation and completion of the Screening Phase.

**Participants in the Brain Imaging Phase can earn up to \$200
for completing both MRS scans.**

All inquiries are confidential.

HIC #0704002598

**For more information, please contact 1-800-ASK-YALE
(press 2 for Yale Research Clinics, then press 1 for WRBH),
or call us locally at 203-764-9932.**

❖ Upcoming Studies at WRBH
(Check back regularly for more information on these upcoming studies)

No upcoming studies at this time.

Eligibility For All Research Studies:

All research studies and evaluations for possible participation in a research study at WRBH are at no cost to the client, and health insurance is not necessary. Financial compensation is provided for most studies. Certain criteria apply for research study participation. Only qualifying individuals will be eligible for research participation and treatment at WRBH.

For Further Information:

WRBH is open Monday through Friday 8:30 a.m. to 4:30 p.m. All appointments, with the exception of certain research study appointments, occur during these hours. **Studies, evaluations, and consultations are not conducted over the telephone.**

If you would like more information about a research study or to inquire about scheduling an appointment, please call **1-800-ASK-YALE** (press 2 for Yale Research Clinics and then press 1 for WRBH) or call the local telephone numbers listed with each study. Please state the study that you are calling about when leaving a message. Your call will be answered or returned by a member of the WRBH research staff within 24-hours, and you will be screened over the telephone to determine your eligibility.

WRBH is not an emergency service. While we make every effort to schedule research participants as quickly as possible, emergency services are not available through our Program at this time. Please note that if you are not a patient of this Program and you are experiencing an emergency that you should contact your own physician or go to the nearest emergency room to seek treatment. Thank you for your cooperation.

Directions to WRBH at Yale:

The Yale Program For Women's Reproductive Behavioral Health is located in the University Towers building in downtown New Haven at 100 York Street (at the intersection of York and George Streets). To reach our office, take Exit 1 off Interstate 91 or Exit 47 off Interstate 95 in New Haven (Route 34 exit). Follow the Route 34 connector to the end to Exit 3; follow Exit 3 onto North Frontage Road. At the first traffic light turn right onto York St (Walgreen's is on the corner). Go 2 blocks to the 2nd traffic light and turn left onto Crown St. Go one block, to the first traffic light, and turn left onto Park St. Go one block, to the first traffic light, and turn left onto George St. Our parking lot entrance is on your left off of George St., marked by a large maroon sign that says **University Towers Medical Center Resident & Visitor Parking (100 York St)**. We are located on the 2nd floor in Suite 2H. **Parking is free.**