RESEARCH ON SYMPTOM MONITORING AND PREVENTIVE COGNITIVE THERAPY FOR PERINATAL DEPRESSION

The Department of Psychiatry at the University of Texas Southwestern Medical Center is conducting research sponsored by the National Institute of Mental Health (NIMH) on perinatal depression, aiming to develop a treatment program for conceiving or pregnant women at risk for depressive relapse and recurrence. We are recruiting women with a history of depression who are planning to become pregnant or are pregnant. Eligible patients must have experienced at least one episode of Major Depressive Disorder (MDD) in their life, but must **not** be currently depressed.

Research has shown that about 7.5% of women have a new episode of MDD during pregnancy, and 6.5% have a new episode in the first 3 months after birth. The risk is likely even higher for women with a history of depression. Maternal depression is associated with maternal behaviors that put her fetus/infant at risk (e.g., smoking and substance abuse while pregnant, inadequate obstetrical care, not using car seats, and not using the back sleep position for infant). High prenatal life event stress in women is also significantly associated with compromised fetal neurobehavioral development, lower infant birth weight, and younger gestational age at birth.

Eligible patients in this research study will receive diagnostic evaluation and regular internet (or telephone)-based monitoring of their depressive symptoms. In addition, half of the patients will receive an innovative intervention called Preventive Cognitive Therapy (P-CT). This intervention is based on cognitive therapy, which is a well-validated treatment for depression and is designed to reduce the chance that depression will return. Patients will also receive education on preconception planning (when appropriate) and will undergo follow-up evaluations.

We intend for the internet (and telephone)-based delivery of our research components to be convenient for patients and clinicians. We are creating these tools and resources; therefore we will request feedback from the patients and their clinicians on how to improve.

Interested English-speaking female volunteers will be provided evaluations and interventions at no charge to the patient. Patients will be compensated for time spent completing evaluations. Eligible patients will have experienced at least one previous episode of Major Depressive Disorder, and will be either considering conception or are pregnant (see full inclusion/exclusion criteria below).

If you have a patient who may be eligible for the study, or if you would like additional information, please contact:

Psychosocial Research and Depression Clinic

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(214) 648-5351

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INCLUSION / EXCLUSION CRITERIA

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INCLUSION CRITERIA:

- 1. Females aged 18-45 years
- 2. Actively attempting conception (off birth control/sexually active) or pregnant
- 3. Has access to a computer or is willing to use clinic computer
- 4. At least one previous episode of nonpsychotic Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) diagnosis of Major Depressive Disorder (MDD), treated or untreated, of 4 weeks duration
- 5. Does not met criteria for current DSM-IV MDD and the 17-item Hamilton Rating Scale for Depression (HRSD₁₇) score is less than or equal to 12 at diagnostic evaluation and randomization
- 6. Medically healthy according to structured medical history
- 7. Able to provide informed consent
- 8. Has an obstetrician/gynecologist/or other health care provider

EXCLUSION CRITERIA:

- 1. Not attempting conception or not pregnant
- 2. History of DSM-IV Major Depressive Episode (MDE) with psychotic features
- 3. History of hospitalization for suicide attempt
- 4. DSM-IV diagnoses of bipolar 1 or 2 or any psychotic episode; substance abuse within last 6 months; eating disorder
- 5. No identified primary care, nurse midwife, or obstetrical physician to monitor pregnancy or patient refuses to sign release of information
- 6. HRSD₁₇ is greater than 12 or has DSM-IV MDE
- 7. Prescribing MD or obstetrician will not participate by documenting willingness to communicate with study personnel and/or withdraw antidepressant medications
- 8. Lacks English literacy