

# **Purpose of Study**

The purpose of this study to understand and reduce suicidal thoughts and behaviors in Veterans. We will test whether combining talk therapy (Brief Cognitive Behavioral Therapy, BCBT) with brain stimulation (Transcranial Magnetic Stimulation, TMS) reduces suicide in Veterans. We will also investigate if games, tests, and pictures of the brain (using fMRI; functional magnetic resonance imaging) differ in suicidal Veterans. Depending on the results of the initial interviews and assessments, you may choose to participate in all, or some, portions of this study described below.

## **Study Overview**

- **Baseline Visit:** You will answer questions to see if you are eligible for the study. If you are eligible, we will also ask you questions about how you are doing, drug and alcohol use, and suicidal thoughts and behaviors (This will take 2-3 hours, and may occur over 1-2 visits). If you are currently inpatient, we will complete the baseline visit on the inpatient unit, and may complete part of it in Building 32. If you are currently outpatient, we will complete the baseline visit in Building 32.
- If you participate in the brain imaging part of the study:
  - You will answer more questions, and complete computer tests and games, and have a picture of your brain taken in an fMRI scanner (This will take 2 hours).
- If you participate in the treatment part of the study:
  - You will have 15-minute brain stimulation sessions called TMS up to 5 times a week for 15 to 36 sessions.
    - You will have a 50/50 chance of having either active or sham (placebo) brain stimulation.
  - You will have 12 weekly 60-minute sessions of Brief Cognitive Behavior Therapy (BCBT)
- If you participate in both the MRI and treatment parts of the study:
  - You will come to one more fMRI appointment after you finish the treatment part of the study (This will take 2 hours).
- **Follow-up Visits:** You will answer questions *up to* 3 more times about how you are doing over the following 6-24 months at different times.
- You will be paid for your time and effort *up to* \$425 using electronic funds transfer (EFT) or gift cards.
- You will complete all parts of the study at the Providence VA.

#### **Study Visits**

- Baseline Visit (2-3 hours, and may occur over 1-2 visits)
- Brain imaging (fMRI) Visits (2 hours, if applicable)
- Treatment Visits (if applicable):
  - o TMS, 15-36 visits occurring up to 5 days per week over about 3-8 weeks (about 15 minutes each visit)
  - o BCBT, 12 weekly visits (about 60 minutes each visit)
  - Up to 3 Follow-Up Visits, 6, 12, and 24 months after BCBT ends or after your fMRI scan (1.5 hours each visit)



### **Therapy Descriptions**

*Transcranial Magnetic Stimulation (TMS, brain stimulation):* Transcranial Magnetic Stimulation is a non-invasive treatment that uses coiled wires to create a pulsating magnetic field. The pulses coming from the coil cause electrical changes in your brain that control and regulate mood.

*Brief Cognitive Behavioral Therapy (BCBT, talk therapy)*: Brief Cognitive Behavioral Therapy is a structured talk therapy. This therapy will include learning skills to help with regulating your emotions, creating plans for safety, problem solving, learning to be present, and understanding how one's thinking effects one's actions.

## **Questions**

If you have questions, you may contact the following:

- Study Coordinators:
  - o Treatment Study: Dr. Melanie Bozzay at 401-273-7100 x16244 (Room 111)
  - o Brain Imaging (fMRI) Study: Hannah Swearingen at 401-273-7100 x14449 (Room 143)
- Study Investigators:
  - o Dr. Jennifer Primack at 401-273-7100 x16295
  - o Dr. Noah S. Philip at 401-273-7100 x16235
  - o Dr. Jennifer Barredo at 401-273-7100 x16290
- Research Administration at (401) 273-7100 ext. 13066
- Providence VAMC Patient Advocate at (401) 273-7100 ext. 13093