

Announcement of BWP Bipolar Study

This study is being conducted by Barton W. Palmer, Ph.D. and his colleagues at the Veterans Medical Research Foundation (VMRF) and the University of California, San Diego (UCSD). We refer to this as the **BWP Bipolar Study**. This announcement comprises a four-page PDF file:

Page 1: This cover page

Page 2: The official UCSD-approved flyer

Two corrections to the flyer should be noted:

- The contact person is not Tia, as indicated, but Casey. The phone number is unchanged.
- Casey emphasizes: *“One thing I want to stress is that we require that all of our participants have a current and contactable doctor or therapist that we can contact if anything concerning may arise.”*

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Capacity to Consent to Research on Bipolar Disorder

This study is being conducted by Barton Palmer, Ph.D. and his colleagues at the Veterans Medical Research Foundation (VMRF) and the University of California, San Diego (UCSD).

Purpose:

We are trying to understand how thinking abilities and psychiatric symptoms impact a patient's ability to make informed decisions about participating in a research study, as well as how decision making abilities may change over periods of up to 26 weeks.

Who can participate?

This study will include two groups of people: (1) 172 people with Bipolar I or II disorder, and (2) 118 healthy comparison subjects (that is people, with a lifetime absence of any major neuropsychiatric disorder).

Exclusion/inclusion criteria:

The potential participants have to be at least 18 years old and be fluent in English. People who suffered from serious strokes or have a diagnosis of dementia or Parkinson's disease cannot participate in this study. Participants with Bipolar Disorder cannot have had alcohol or substance dependence during the two months preceding enrollment.

Study Visits:

Screening Visit: During this visit, we consent the potential participant, collect basic demographic information, and verify their diagnosis (or absence of one) by using the Structured Clinical Interview for the DSM-IV-TR (SCID). If they meet the criteria for Bipolar Disorder I or II, or are deemed to have no psychiatric disorders, they are asked to participate in the remainder of the study. This visit typically lasts 2 to 3 hours.

Baseline Visit: Involves clinical and symptoms ratings, neuropsychological testing, and measures meant to capture the participant's ability to consent to research. This visit typically lasts 2 to 3 hours.

Follow-Up Visits: Participants are assessed 3 additional times: 6 weeks, 12 weeks, and 26 weeks after the baseline visit. These follow-up visits involve the same assessments and last as long as the baseline visit.

Compensation:

Participants are compensated \$30 dollars per visit, including the screening visit (regardless of the outcome of the SCID). When they complete the 26-week visit, which is the final visit for the study, they are compensated \$50 instead of \$30.

Possible Risks:

There is the possibility of boredom, fatigue, or distress from completing the assessments. There is also the risk of loss of confidentiality but we have taken every possible step lower this risk. In addition, it is possible that the screening procedures will reveal a previously undetected psychiatric condition. In such an event, we will take appropriate actions to ensure the immediate safety of the participant or others and will provide appropriate referrals for any clinical follow-up.

Contact for referrals: Casey Loughran 858-535-5795 (or x5795)

Inclusion/Exclusion Rules for BWP Bipolar Study

Age

- **Enroll** if subject is 18 years or older

Diagnosis

- **Enroll** if subject has Bipolar I or II

Head injuries

- **Enroll** if the head injury occurred before the age of 7 and there are no learning disabilities caused by the injury.
- **Do not enroll** if the head injury occurred after the age of 7 and/or if the subject experienced loss of consciousness ≥ 20 minutes.

Strokes

- **Enroll** if mild (no hospitalization and/or paralysis) and did not occur within the past month.
- **Pending enrollment** if a mild stroke occurred within one month (call one month later to reschedule).
- **Do not enroll** if it was major (hospitalization and/or paralysis).

Seizures

- **Enroll** if mild seizure occurred after initial diagnosis of Bipolar Disorder, did not require anticonvulsants, and did not occur within the past month.
- **Pending enrollment** if a mild seizure occurred within one month (call one month later to reschedule).
- **Do not enroll** if seizure required anticonvulsants.

Alcohol/drug dependence

- **Enroll** if subject has not used alcohol or drugs for the past 2 months.
- **Do not enroll** if any use has occurred in the past 2 months

Alcohol/drug abuse

- **Enroll** if subject is sober at the time of visit
- **Postpone visit** if subject is intoxicated at time of the assessment

Learning disabilities

- **Enroll** if learning disability is not due to a head injury.

Hearing

- **Enroll** if subject can hear with hearing aide or can participate in the interview.
- **Do not enroll** if hearing loss hinders ability to complete the interview.

Vision

- **Enroll** if can see with glasses.
- **Do not enroll** if vision loss hinders ability to complete the interview.

→ Check to see if there are any other medical conditions that might hinder your ability to complete paper and pencil tasks.

→ All participants must have an available doctor in case circumstances necessitating clinical response arise

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