Title: Using Combined EEG and Non-invasive Brain Stimulation to Examine and Improve Reward Functioning in Opioid Use Disorder

NCT number: NCT04432493

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Neural Mechanisms of Goal-Directed Navigation in People Who Use Opioids

Electrophysiology and Neuromodulation Laboratory

Center for Molecular and Behavioral Neuroscience

Eligibility to Participate in a Research Study You are invited to participate in a research study that is being conducted by Dr. Travis Baker, who is an Assistant Professor at the Center for Molecular and Behavioral Neuroscience at Rutgers University. The purpose of this research is to understand the brain processes that allow us to perform complex cognitive tasks. We will investigate these mechanisms in human subjects who do or do not use opioids using behavioral and neuroimaging methods (transcranial magnetic brain stimulation and electroencephalography). These non-invasive brain imaging methods will increase our understanding of the relationship between brain activity, behavior during goal-directed navigation and the effect of opioids on these processes, which in turn will allow for improved medical and clinical innovations of neuroscience.

Participants: Approximately 150 subjects of 18 years or older will participate in the study. Subjects participate in 1 session, lasting from 1 to 2 hours.

Procedures: Participation in this study will involve the following: You will sit in front of a computer and complete a variety of cognitive tasks (e.g. navigate a virtual T-maze to find rewards). During this task, we will also conduct an EEG-TMS experiment, where we will place electrodes on your head and place a TMS stimulation coil near your scalp using a robotic arm to modulate your brain state. The electrodes will allow us to collect electroencephalography data (i.e., your brainwaves) while you perform the computerized tasks. You will also complete some questionnaires to gather information about you background, demographic information and personality. The session will last approximately 2 hours.

The TMS machine produces a strong magnetic field, so if you have metal implants and clips within your head they may be influenced by the magnetic field and shift in position. Thus, if you have such implants you must inform us and withdraw from the study. Metal earrings and necklaces also must be removed prior to the study. If you have shrapnel, surgical implants, or other pieces of metal in your body that cannot be removed, you may not be able to participate in studies involving the TMS machine. Further, because the risks to an unborn fetus are unknown, we will ask you to confirm that to the best of your knowledge you are not pregnant. Please ask the experimenter any questions that may arise while you answer each question.

Exclusions:

You cannot participate in this study if any of the following apply:

- you have a history of epilepsy or seizure
- you have any magnetic metal such as iron, nickel or cobalt implanted in or on your body or clothes
- including metal flakes or filings, surgical pins or plates, electrical devices such as a pace maker, jewelry, or metal ink tattoos.
- you are pregnant
- Use of psychoactive or vasoactive medications

This research is confidential. Confidential means that the research records will include some information about you and this information will be stored in such a manner that some linkage between your identity and the response in the research exists. Some of the information collected about you includes name, address, email, phone number, test-data and some sensitive questions about yourself (e.g., history of substance use and neurological conditions). Please note that we will keep this information confidential by limiting individual's access to the research data and keeping it in a secure location and identifying information will be maintained only in a password-protected database. All other data and records will contain only the ID number. Electronic data will be accessed via password-protected computers that are available only to the PI and co-PIs for this study.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or harm to self or others.

The research team and the Institutional Review Board at Rutgers University are the only parties that will be allowed to see the data, except as may be required by law. If a report of this study is published, or the results are presented at a professional conference, only group results will be stated. All study data will be kept for retained indefinitely to provide sufficient time for follow-up analysis and publication of de-identified data.

Risks and Discomforts:

The following risks and/or discomfort are possible:

- The TMS stimulation can generate a slight tingling feeling on the skin. This should never hurt; if it starts to bother you, let the experimenter know to stop the experiment. Adjustments will be made immediately in coil positioning and stimulation settings to reduce discomfort. In addition, stimulation may cause possible moderate headaches.
- An additional risk of TMS stimulation is seizures, which are though to be caused by a group of nerves that become hyper-synchronized. According to the 2008 Safety of TMS consensus group, the risk of seizures with repetitive TMS is VERY low. Out of 3000 studies published within the last 10 years, only 17 have resulted in seizures, 12 of which occurred following parameters that exceeded clinical safety guidelines. The current study is in accordance with these safety guidelines. Of the 4 studies that met the clinical safety guidelines, all participants suffered from additional neurological impairments. All seizures have stopped spontaneously with no long-term adverse effects. Importantly, no-one has ever developed a recurring seizure disorder (epilepsy) after a TMS-induces seizure.

You may receive no direct benefit from taking part in this study. It is however hoped that the information obtained will help our understanding of the function of the human brain. You will receive $25 for each hour of this session, plus an additional $25 for travel ($75 total). If the study has to be terminated for any reason, you will receive an amount of compensation in proportion to the duration of your participation (e.g. rounded off to the nearest hour).

Participation in this study is voluntary. You may choose not to participate, and you may withdraw at any time during the study procedures without any penalty to you. In addition, you may choose not to answer any questions with which you are not comfortable.

If you have any questions about the study or study procedures, you may contact the lead investigator of this project:

Contact
Travis Baker, PhD
Assistant Professor
Center for Molecular and Behavioral Neuroscience
197 University Avenue
Newark, NJ 07102
Rutgers University,
Newark USA

If you have any questions about your rights as a research subject, please contact an IRB Administrator at the Rutgers University, Arts and Sciences IRB:

Institutional Review Board
Rutgers University, the State University of New Jersey
Liberty Plaza / Suite 3200
335 George Street, 3rd Floor
New Brunswick, NJ 08901
Phone: 732-235-2866
Email: humansubjects@orsp.rutgers.edu

You will be given a copy of this consent form for your records.

Sign below if you agree to participate in this research study:

Subject (Print) _____

Subject Signature

_____ Date _____

Researcher's signature or Person Obtaining Consent

_____ Date _____