Study Protocol

TITLE: Brain stimulation study of human visually-guided navigation using repetitive transcranial magnetic stimulation (rTMS)

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EXTERNAL (NON-EMORY) COLLABORATORS

None

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REVISION HISTORY

Revision #	Version Date	Summary of Changes

Table of Contents

1. Study Summary

Project Title	Brain stimulation and visually-guided navigation
Project Design	In this project, participants will volunteer, based on recruitment efforts such as the Psychology student database. There is no random assignment. The number of subjects for each experiment was determined using a power analysis. The intervention is transcranial magnetic stimulation (TMS).
Primary Objective	Testing the causal role of OPA using repetitive TMS (rTMS)
Secondary Objective(s)	None
Research Intervention(s)/Interactions	TMS
Study Population	Typical adults (18 years or above)
Sample Size	38
Study Duration for individual participants	2 visits – 90 minutes each
Study Specific Abbreviations/ Definitions	rTMS – repetitive transcranial magnetic stimulation OPA – Occipital Place Area fMRI – functional magnetic resosnance imaging
Funding Source (if any)	**NIH 5-R01-EY029724 - 03**

2. Objectives

In this study, we are investigating the neural mechanisms *causally* involved in how people navigate through their immediately visible environment (e.g., walking around one's bedroom flawlessly and effortlessly, not bumping into the walls or furniture). To investigate whether particular neural mechanisms are *causally* involved in "visually-guided navigation", we use repetitive transcranial magnetic stimulation (rTMS) to temporarily disrupt the functioning of particular brain regions in healthy adults while we show them simple visual stimuli of places (e.g., bedrooms, kitchens, and living rooms) and ask them to perform simple computer tasks (e.g., imagine they are walking through the room, and respond via button press whether they can leave through a door on the left, center, or right wall, as indicated by a continuous path on the floor), or ask them to complete simple behavioral tasks (e.g., actually walk around a small room and search for hidden objects).

3. Background

Our ability to navigate through our immediately visible environment is crucial for our survival. However, the representations and computations underlying this remarkable ability are not well understood, and current computer vision algorithms (robots) still lag far behind human performance. One promising strategy for attempting to understand "visually-guided navigation" is to characterize the neural systems that accomplish it. Indeed, the results – albeit only from a handful of studies over the past five years – from functional magnetic resonance (fMRI) on adult humans have begun to elucidate the cortical regions involved in visually-guided navigation, with the central finding that there is at least one visual cortical region – called the occipital place area (OPA) (Dilks et al., 2013) – that may play a central role in our ability to navigate through currently visible places (e.g., walking around our bedroom flawlessly and effortlessly, not bumping into the walls or furniture our bedroom) (Persichetti & Dilks, 2018; Kamps et al., 2016; Kamps et al., 2018). However, given that fMRI is a correlational method, and we need to know if this functionally specific brain region is *causally* involved in visually-guided navigation. Understanding the causal involvement of this region will provide important clues about how humans navigate their world, and also perhaps someday be harnessed to help those individuals who devastatingly lose the ability to navigate, as a result of eye diseases, brain surgery, stroke, neurodegenerative diseases, or developmental disorders.

The use of rTMS to investigate the causal involvement of particular brain regions in particular human abilities (as proposed here for the causal involvement of OPA in visually-guided navigation, in particular) is not novel. Several studies (Pitcher et al, 2007; Pitcher et al., 2008; Pitcher et al., 2009; Sadeh et al., 2011; Pitcher et al., 2012; Solomon et al., 2013; Pitcher, 2014; Pitcher et al., 2014) have used it to investigate face recognition, two studies (Dilks et al., 2013; Ganaden et al., 2013) have used it to investigate scene recognition (i.e., our ability to recognize, not navigate through, a bedroom, for example), and yet two other studies (Rafique et al., 2015; Mullin et al., 2013) have used it to investigate object recognition. In all of these studies, the disruption of face, scene, or object recognition occurred between ~50 to 150 ms after a briefly flashed stimulus, and after that all processing returned to normal. This brief temporal window of disruption demonstrates that the effects of rTMS on visual cortex are very transient (see Bolognini & Ro, 2010 and Wassermann, 1998 for reviews), and no permanent disruption of function has ever been reported. After the experiment, participants will remain under supervision for about 15 minutes, verbally confirm they feel safe to leave (after the 15 minutes), and then will be escorted to the exit.

4. Study Endpoints

The general question for this research is to determine, using rTMS, the *causal* involvement of OPA in visually-guided navigation, using two tasks (a simple computer-based task and a simple behavioral task,

described above in the Abstract, and again just below). Given this question then, we propose to test the following two specific hypotheses:

Experiments involving the simple computer-based task (e.g., imagine you are walking through the room, and respond via button press whether they can leave through a door on the left, center, or right wall, as indicated by a continuous path on the floor)

i) If OPA is causally involved in visual scene navigation, then disruption of this region, using rTMS, will lead to a decrement in performance on the "visually-guided navigation task" (i.e., imagine you are walking through the room, and respond via button press whether they can leave through a door on the left, center, or right wall, as indicated by a continuous path on the floor), but not on the "scene categorization task" (i.e., imagine you are standing in the pictured room, and respond whether you are in a bedroom, kitchen, or living room) – the control *condition*.

Primary outcome measure: To determine baseline performance, we will also apply rTMS to a control site (i.e., the vertex – a bit of the brain at the very top of the head, not implicated in visually-guided navigation, and identified as the direct midpoint between the bridge of the nose and the inion, and between the participants' temples), and predict a decrement in performance on the visually-guided navigation task, only after rTMS is applied to OPA (but not vertex). There are no secondary outcome measures.

Experiments involving the simple behavioral task (i.e., actually walk around a small room and search for hidden objects).

ii) If OPA is causally involved in visually-guided navigation, then disruption of this region, using rTMS, will lead to a decrement in performance in navigating through the room to find a hidden object, but not in identifying what the object is (the control condition).

Primary outcome measure: As described just above, to determine baseline performance, we will also apply rTMS to the control vertex site, and predict a decrement in performance on the visually-guided navigation task, only after rTMS is applied to OPA (but not vertex). There are no secondary outcome measures.

5. Study Intervention/Investigational Agent

TMS, first successfully demonstrated in 1985 (Barker et al., 1985), is a very safe and noninvasive method for affecting brain function. It relies upon the properties of electromagnetic induction; a rapidly changing magnetic field is generated when a high-voltage current is passed through a coil. When this coil is held in close proximity to any electrically conducting medium (such as the brain), this time-varying magnetic field induces current in a direction opposite to the original current in the coil. As a result of this ion flow, action potentials are triggered in neurons that are within the induced current field, along with a subsequent period of deactivation, presumably through prolonged inhibitory postsynaptic potentials (i.e., making a postsynaptic neuron less likely to generate an action potential). Because normal ongoing brain activity is disrupted by this induced current, TMS provides a way for investigators to produce a transient and reversible period of brain disruption or "virtual lesion." Thus, unlike other experimental

techniques [e.g., fMRI, electroencephalography (EEG)/ event-related potentials (ERPs)], TMS can assess whether a given brain area is *necessary* for a given function, rather than simply correlated with it. Again, TMS has been used in many studies investigating those brain areas (identified with fMRI) to be causally involved in face, scene, and object processing (Pitcher et al, 2007; Pitcher et al., 2008; Pitcher et al., 2009; Sadeh et al., 2011; Pitcher et al., 2012; Solomon et al., 2013; Pitcher, 2014; Pitcher et al., 2014; Dilks et al., 2013; Ganaden et al., 2013; Rafique et al.., 2015; Mullin et al., 2013).

The TMS device is housed in the Facility for Education & Research in Neuroscience (FERN), Psychology and Interdisciplinary Studies Building, #795, Emory University, 36 Eagle Row, Suite 180, Atlanta, Georgia 30322.

6. Procedures Involved

Participation will require up to two visits each taking about one and a half hours. During the first visit, participants will be scanned (using fMRI). Before scanning, all participants will be asked to remove all jewelry and other metal-containing objects (including credit cards). They will then enter a large room where a powerful magnet is located. They will be asked to lie down on a narrow table and will be put in a small tunnel approximately 6 feet long and 2 feet in diameter. They will then be asked to lie as still as possible during the scan for approximately 90 minutes. During scanning, they will hear a loud banging noise as the MRI machine takes pictures of their brain. As a consequence, they will be given earplugs to make them more comfortable. While they lie in the scanner, a computer display will be placed at one end of the tunnel. They will be able to see the display through the back-projecting mirror in front of their face. Once scanning begins, they will then need to respond to things they see on the display screen, and for this they will be given a small box with buttons that will be placed under their hand when they are placed into the scanner. Specifically, they will be asked to view pictures of faces, places, objects, and abstract patterns. Such "localizer" stimuli enable us to identify (or localize) the brain region (i.e., OPA) in each individual using fMRI that will then be targeted with rTMS in the proposed study.

During the second visit (the rTMS visit), participants will be seated comfortably in a chair and asked to complete either a simple computer-based task (e.g., imagine you are walking through the room, and respond via button press whether they can leave through a door on the left, center, or right wall, as indicated by a continuous path on the floor), or a simple behavioral task that will require them to actually walk around in a small room and search for hidden objects. Either during, or just before, each of these tasks, participants will receive rTMS. In rTMS, we place a small plastic coil next to the participant's head. The position of the coil will be guided by the fMRI study described just above, which was conducted on that participant in the prior visit. The coil will be placed over the relevant brain region using the Brainsight TMS-MRI co-registration system for visualizing the coil position with respect to the participant's individual fMRI scan. The coil will then generate a magnetic pulse, and stimulation will occur. During stimulation, the participants may feel a gentle flick, and hear an audible click. The pulse is not usually painful, but it can cause a twitch of the hand or face muscles. Even though hearing loss is a rare

occurrence from rTMS, hearing protection (i.e., ear plugs) will be used during the TMS experiments.

Instead of having source records (i.e. surveys), we are only going to collect brain image data for the fMRI portion of the study and psychophysical data for the rTMS portion. No further data is collected after procedures are completed.

During the experiment, participants may withdraw at anytime. After the experiment, participants will remain under supervision for about 15 minutes, verbally confirm they feel safe to leave (after the 15 minutes), and then will be escorted to the exit. If participants do not feel safe to leave after the 15 minutes is up, they will be asked to stay until you do feel safe to leave. If further assistance is needed, Dr. Gregory Berns (M.D./Ph.D), the head of FERN, will be contacted to come to the testing room.

7. Data Specimen Banking

All participants will be given a non-identifying ID number. Hardcopy data will be kept in a locked filing cabinet in a secure office. Electronic data will be stored on a secure electronic hard drive. Electronic data will also be shared with Emory University and will be secured according to Emory IT policies.

8. Sharing of Results with Participants

The research material obtained will consist only of brain images (MRI and fMRI), and psychophysical data (rTMS) that will be used solely for research purposes. We will not make use of any existing specimens or records. The data and subject identity will remain confidential. All participants will be identified by codes known only to the members of my research team. All paper data will be secured in a locked filing cabinet in a secure office in the Psychology Building at Emory University. All electronic data will be password protected and stored on a computer in the Psychology Building at Emory University, according to Emory IT policies.

Furthermore, the study team will review the MRI scan. If there are any incidental findings or we discover that data from the scan suggest something that may be important clinically, we will share them with Dr. Gregory Berns, the head of FERN, who will determine its clinical relevance.

9. Study Timelines

Participation will require up to two visits. During the first visit, participants will be asked to lie as still as possible during the fMRI scan for approximately 90 minutes. During the second visit (the rTMS visit), participants will be seated comfortably in a chair and asked to complete either a simple computer-based task or a simple behavioral task that will require them to actually walk

around in a small room and search for hidden objects. This will also take approximately 90 minutes.

Study enrollment will begin shortly after IRB approval and continue until all participants' data are collected (38 adults). Based on our prior experience with collecting TMS data in typical adults, we estimate that we can successfully complete the two proposed studies within two to three years.

10. Inclusion and Exclusion Criteria

Inclusion:

i) Healthy adults aged 18 and up

ii) Normal or corrected-to-normal vision

Exclusion:

i) no metal in the body

ii) personal or first-degree family history of epileptic seizure

iii) a known brain injury

iv) claustrophobia

v) taking certain medications that may increase the risk of seizures (e.g., bupropion, varenicline, chlorpromazine, theophylline) or reduce the effects of rTMS, such as benzodiazapines

vi) Adults unable to consent, pregnant women, prisoners

11. Vulnerable Populations

This research does not involve any individuals who are in the vulnerable populations list.

12. Local Number of Participants

We plan to enroll about 38 healthy adult participants (19 for each of the two proposed experiments). The number of participants was determined using a power analysis, with an effect size of $\eta_p^2 = 0.14$ (estimated from previous similar studies), an alpha level of 0.05, and power at two levels: 90% and 80%. Thus in each of the two proposed studies, we will test 19 participants (90% power), but could lose 4 participants to attrition and still have 80% power. Note in prior TMS studies, a similar number of participants were tested.

We will recruit an equal number of men and women, and all efforts will be made to recruit minorities. No exclusion of women and minorities is necessary for this study. Census estimates from 2010 for Atlanta, Georgia, were 43.1% white, 50.1% African American, 0.2% American

Indian and Alaskan Native, 2.7% Asian, and <1% Native Hawaiian and other Pacific Islander; Hispanic or Latino were 5.3%. Using these census estimates, we will recruit minority participants to ensure that the subject sample represents the community. Recruitment of women and minorities will be assessed quarterly to ensure adequate representation. Participants will be recruited via the subject pool database maintained by the Emory University Psychology Department.

13. Recruitment Methods

Participants will be recruited via the subject pool database maintained by the Emory University Psychology Department. The database involves names and contact information of people who have agreed to participate in research for course credit (1 credit up to 60 minutes) or to be paid for their participation. However, the participants in this study will not receive credit, but rather will be paid $20/hour in cash for the rTMS portion. For the fMRI portion, the participants will be paid $25/hour. Additionally, participants may be recruited in the community and at Emory University by word of mouth. No flyers or printed advertisements will be used.

To ensure that the participant does not have any metal in his or her body, the study team administers a screening form (attached) to the participant both during recruitment and before going into the scanner. Furthermore, to minimize any possible risk of a seizure during testing, the participant will certify that neither she, nor parents, brothers or sisters, or children have ever suffered an epileptic seizure. The participant will also certify that she has never suffered a known brain injury, and that she is not taking certain medications that may increase the risk of seizures or reduce the effects of rTMS. To ensure that the participant does not have any of the above contraindications, the study team administers another screening form (attached) to the participant both during recruitment and before study participation.

14. Withdrawal of Participants

Some people become nervous or claustrophobic (anxious or afraid of closed spaces) in the fMRI scanner. If this happens to the participant, they may ask to be withdrawn immediately. They may also experience a sense of dizziness in the magnet. Such dizziness is due to the strong magnetic field, and if it disturbs them, they may ask to be withdrawn.

The most common risk and discomfort of rTMS expected in this study is mild discomfort or tingling due to twitching of muscles in the head or face. If, at any time, the participant feels uncomfortable due to such twitching, he or she may indicate so verbally, and we will stop the experiment. In the studies cited above between 5-15% of participants experience discomfort, and withdraw from the study.

The study team has the right to end the subject's participation in this study for any of the following reasons: If it would be dangerous for the participant to continue, if the participant does

not follow study procedures as directed by the study team, or if the sponsor decides to end the study.

The subject's participation is voluntary, and she has the right to refuse to be in this study. The participant can stop at anytime after giving her consent. The participant has the right to leave a study at any time without penalty. The participant may refuse to do any procedures the she does not feel comfortable with, or answer any questions that she does not wish to answer. If the participant choose to withdraw, she can request that her information not be used in the study.

15. Risk to Participants

With fMRI, the risks are minimal. For example, the MRI machine is loud (similar to riding in a loud train), and, as such, participants will be given earplugs to lessen the noise. Participants may experience some muscle discomfort while lying in the scanner. They may also become too hot or too cold, in which case they may ask for an adjustment of room temperature or a blanket. Some people become nervous or claustrophobic (anxious or afraid of closed spaces) in the scanner. If this happens to the participant, they may ask to be withdrawn immediately. They may also experience a sense of dizziness in the magnet. Such dizziness is due to the strong magnetic field, and if it disturbs them, they may ask to be withdrawn. Because the magnetic field will affect any metallic object, they should not participate if they have any type of metallic implant in their body, including pacemakers, aneurysm clips, shrapnel, metal fragments, orthopedic pins, screws, or plates, metallic IUD's, or piercings that you cannot remove. If potential participants have any of these items in their body, there is a risk that the magnetic field could cause them to move or heat up. It is important that they inform the study personnel if they have any implants. To ensure that the participant does not have any metal in his or her body, the study team administers a screening form (attached) to the participant both during recruitment and before going into the scanner.

This type of brain scan is not designed to detect problems of the brain. A radiologist will not be reading the scan. The study team will review the scan. If there are any incidental findings or we discover that data from the scan suggest something that may be important clinically, we will share them with Dr. Gregory Berns (M.D./Ph.D), who will determine its clinical relevance, and contact you with further information (e.g., to seek a health professional).

With rTMS, there are minimal risks involved with this procedure (Wasserman, 1998), although it may at times be unpleasant. The most common risk and discomfort of rTMS expected in this study is mild discomfort or tingling due to twitching of muscles in the head or face. If, at any time, the participant feels uncomfortable due to such twitching, he or she may indicate so verbally, and we will stop the experiment. In the studies cited above between 5-15% of participants experience discomfort, and withdraw from the study. The twitching immediately subsides after the TMS is no longer administered. Some people undergoing TMS (approximately 3%) also experience headaches, which are believed to be due to excessive muscle tension. In the case of a headache, the experiment will be immediately stopped. The headaches are not recurring

and subside following termination of the procedures. Also, approximately 1% of people undergoing TMS experience neck stiffness and neck pain. This stiffness and pain are believed to be due to the straight posture of the head and neck during the application of TMS. In the case of neck stiffness and/or pain, the experiment will be stopped. There are no reports of any such effects recurring.

Next, TMS produces a clicking noise when the current passes through the coil. This click can result in tinnitus and transient decreased hearing if no protection is used. To prevent this adverse effect all experimental participants will wear earplugs. Animal and human studies have demonstrated that earplugs can effectively prevent the risk of hearing disturbances or discomfort due to TMS. The ear protection devices reduce the intensity level of the click to approximately 80 dB.

Finally, risk of seizures in healthy participants is very low, but not zero. Loo et al. (2008) provide a particularly useful and comprehensive review of all reported seizures in healthy participants that have occurred during TMS. In the first one, a participant experienced a seizure during TMS (Tharayil et al., 2005). This participant was taking chlorpromazine, and had some family history of epilepsy (a brother experienced a childhood seizure). In the second incident, an event resembling a seizure was reported during TMS stimulation (Nowak et al, 2006). However, that case is disputed and may instead have been an incidence of fainting, not a seizure (Epstein, 2007). In any case, no long-term effects were found in follow-up neurological exams or EEG. Given that these are the only two cases of seizures or possible seizures that have been reported from the thousands of participants (probably tens of thousands of participants by now) who have experienced TMS, the risk of such events from the stimulation in the proposed study would seem to be very small. That said, to minimize any possible risk of a seizure during testing, the participant will certify that neither she, nor parents, brothers or sisters, or children have ever suffered an epileptic seizure. The participant will also certify that she has never suffered a known brain injury, and that she is not taking certain medications that may increase the risk of seizures or reduce the effects of rTMS. To ensure that the participant does not have any of the above contraindications, the study team administers a screening form (attached) to the participant both during recruitment and before study participation. If, in the rare event, the participants experience a seizure, Dr. Gregory Berns (M.D./Ph.D.) will be contacted immediately to come to the testing room, and Emory EMS (404-727-6111) will also be contacted immediately.

For the computer-based and behavioral tasks, the risks are minimal. The participant may become frustrated or tired. We will provide encouragement and rest-breaks as needed. During both tasks, a study assistant will be in the room with the participant the entire time.

16. Potential Benefits to Participants

There is no direct benefit to individual participants from taking part in this study.

17. Compensation to Participants

During the first visit (fMRI), participants will receive $25/hour to compensate for their time and effort. During the second visit (rTMS), the participants will receive $20/hour to compensate for their time and effort. If they do not finish the study, we will compensate them for the time they have completed.

18. Data Management and Confidentiality

All participants will be given a non-identifying ID number. Hardcopy data will be kept in a locked filing cabinet in a secure office. Electronic data will be stored on a secure electronic hard drive. Electronic data will also be shared with Emory University and will be secured according to Emory IT policies. Only study personnel who are involved in the project will be allowed access to these data, and are also responsible for receipt or transmission of these data. If a participant declines to participate in all portions of the study, the participant will not be assigned a study ID number and the study coordinators/data collects will refrain from collecting any data on the participant. If the participant agrees to participate in some portions of the study by not others, the participant will be assigned a study ID number and the study coordinators/data collectors will be instructed to collect data only on those aspects of the study to which the participant has agreed to participate. These procedures will help prevent unauthorized inclusion of the patient's data in the database.

19. Provisions to Monitor the Data to Ensure the Safety of Participants

All procedures in this research are minimal risk.

20. Provisions to Protect the Privacy Interest of Participants

Participants will only interact with at most two study personnel during their visits. No personal information, beyond the information from the screening forms discussed above (attached), will be asked.

21. Economic Burden to Participants

None.

22. Informed Consent

All participants will provide informed consent by reading and signing a consent form before any experiments begin. Informed consent will be sought and obtained from all participants at the Dilks Lab in the Psychology Department, by members of the research team, who have all

completed certified human subjects training. On the consent form, the risks, benefits and experimental procedures will be clearly explained. Any questions regarding the procedures will be answered fully. All subjects will be told that they are under no obligation to participate in the experiment and may freely withdraw at any time without consequence. All subjects will be given a copy of the consent form. Typical completion of the consent form process takes about 10 to 15 minutes.

While subjects are receiving money compensation for participating, the experiments proposed here are purely voluntary and subjects are able to withdraw at any point while still receiving compensation. Subjects will not be impaired in any way that would render them unable to understand consent and testing procedures, or unable to make mature, informed judgments. All subjects will also be able to respond by pushing a button or describing what is seen, thus successfully being able to complete the experimental tasks.

We will not include any non-English-speaking participants in this study for several reasons. First, we do not have a TMS screening form in languages other than English, which is crucial for selecting eligible participants in our study. Second, we do not have a consent form in languages other than English. Third, the tasks involved in the rTMS part of the study, although somewhat simple, can get a bit tricky if the participant does not speak English. Thus, we need participants who are able to fully understand the taks to properly conduct the experiment.

23. Setting

Data collection will occur at the Facility for Education & Research in Neuroscience (FERN), Psychology and Interdisciplinary Studies Building, #795, Emory University, 36 Eagle Row, Suite 180, Atlanta, Georgia 30322.

Participants will be recruited via the subject pool database maintained by the Emory University Psychology Department. The database involves names and contact information of people who have agreed to participate in research for course credit (1 credit up to 60 minutes) or to be paid for their participation. However, the participants in this study will not receive credit, but rather will be paid $20/hour in cash. Additionally, participants may be recruited in the community and at Emory University by word of mouth.

24. Resources Available

Again, participants will be recruited via the subject pool database maintained by the Emory University Psychology Department. This database contains hundreds of prospective participants, enabling the recruitment of about 38 partcipants highly feasible. Likewise, the Psychology Department at Emory University has all of the facilities necessary to conduct and complete the research, as described just below. Finally, all persons assiting with the research will be adequately trained by the PI on the protocol, research procedures, and their duties.

MRI and TMS: The Psychology Department has both its very own Siemens 3T magnetic resonance imaging (MRI) scanner, and TMS device, which are dedicated to research. In addition, we have a full-time director and technician for the center in which the scanner is housed, called the Facility for Education and Research in Neuroscience (FERN). Also in FERN is a mock scanner, which is especially important for training those participants who have never been in an MRI before.

Laboratory of the Principal Investigator: The Dilks Lab in the Psychology Department is comprised of approximately 1000 square feet, and includes office space that can accommodate up to 6 full-time staff members (research assistants/ graduate students/postdocs), two behavioral testing rooms (one with a SR Research EyeLink 1000 Plus Eye Tracker), and a conference room. The laboratory is also equipped with a high-speed 6-core MacPro for imaging analysis, 4 MacAir laptops, a dedicated laptop for fMRI data acquisition, and three desktop work stations. All computers provide access to behavioral and neuroimaging analysis software, including Matlab, SPM 8/12, AFNI, FSL, SPSS, R and Python. Finally, my lab currently consists of four outstanding graduate students, who all have the full competency to collect and analyze fMRI, psychophysical, and TMS data.

25. Multi-Site Research When Emory is the Lead Site

This is not a multi-site study.

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