University of California, San Diego
Consent to Act as a Research Subject

Assessing Neural Networks Using EEG- Phase 2 Study

Who is conducting the study, why you have been asked to participate, how you were selected, and what is the approximate number of participants in the study?
Dr. Singh and colleagues are conducting a research study to find out more about how electroencephalography (EEG) might improve the evaluation and treatment of patients with schizophrenia (SCZ) or schizoaffective disorder (SAD). Recording EEG involves placing small metal electrodes on the scalp and measuring electrical activity produced by the brain.

You have been asked to participate in this study, because you expressed interest in participating and may have SCZ/SAD. There will be approximately 100 participants in the study.

Why is this study being done?
The purpose of this study is to learn whether a person's EEG activity can predict if he or she will respond to specific forms of EEG neurofeedback. EEG neurofeedback is a treatment where a patient learns to control electrical activity generated by his or her brain. While some health plans consider EEG neurofeedback an effective treatment for psychiatric symptoms (and will reimburse neurofeedback treatments), in general, EEG neurofeedback is considered an alternative treatment, and there is inadequate information on its effectiveness in psychiatric disorders.

Where is the study being done?
The study is being done at UCSD, 9500 Gilman Drive, La Jolla CA 92093, in one of the following locations-
The Stein Building
The Holly Building

What will happen to you in this study and which procedures are standard of care and which are experimental?
If you agree to be in this study, the following will happen to you:

During your first visit, you will participate in a psychiatric interview. You will be asked to complete questionnaires about symptoms related to SCZ or SAD, anxiety and depression, memory tests, and EEG recording. This visit will last about 60 to 90 minutes. We will also ask for permission to speak with your psychiatrist at this visit to obtain a current medication list and to confirm diagnosis.

If you are eligible for the study, you will be asked to participate in 24 visits over 12 weeks, with 2 visits per week. You will be assigned by chance to a study group and your chance of being assigned to each group is 50%. Neither you nor the researcher(s) can choose the group to which you will be assigned. Depending on which group you are assigned to, you will undergo the following:

1. Neurofeedback: During the neurofeedback, small metal electrodes that detect your brain's electrical activity are placed on the surface of your scalp. Your brain's activity will be shown on a computer screen as a visual metaphor, such as an airplane flying. You will be asked to pay attention to the screen and make the plane fly as much as possible. Your EEG will be recorded during this time.

2. Placebo neurofeedback: You will use the same equipment as the active neurofeedback, but will view a pre-recorded neurofeedback session rather than receiving feedback based on your brain signals.

Visit duration at sessions 6 and 12 and two follow-up visits at 1 and 3 months after completing the final neurofeedback session, will be approximately 60-90 minutes long. All other visits will be 30-45 minutes long.

During longer visits, in addition to neurofeedback, your EEG will be recorded while you are resting with your eyes closed or open, or doing a memory test. You will also be asked to complete paper and pencil and computer tests that measure memory.

How much time will each study procedure take, what is your total time commitment, and how long will the study last?

As mentioned above, you will be asked to participate in a total of up to 27 sessions (one baseline visit, 24 neurofeedback sessions, and a two follow-up visits), over a 6-month period. Most sessions will be 30-45 minutes long and will occur twice weekly. Three sessions will be 60-90 minutes long.

What risks are associated with this study?
Participation in this study may involve some added risks or discomforts. These include the following:

1. Feeling tired or annoyed, which improves with rest.

2. Headaches that are mild, and improve after rest.

3. For some subjects, the volume of sounds played through earphones may be too loud. To avoid this, sounds will be presented at a volume usually tolerable to human ears. Volume will be changed based on your preference as needed.

4. Some of the questions asked may be uncomfortable; for example, 'Have you been feeling depressed in the past week?' However, be assured that all questions are ones routinely asked in doctor's offices.

5. Loss of confidentiality. Answers and responses during visits, which include medical and mental health information, will be written down. While this information will be de-identified and will be stored on password-protected computers that are themselves stored in locked facilities, it

is theoretically possible that this information may become public in the event of theft or error. That said, this possibility is extremely unlikely. The study investigators have conducted clinical research for over 10 years without ever experiencing such an event.

6. It is theoretically possible that this research may involve risks that are currently unknown. For example, it is possible that EEG neurofeedback may worsen symptoms in some patients, though studies have generally demonstrated positive effects of EEG neurofeedback on SAD or SCZ symptoms.

You will be assigned to a study group at random (by chance). Your assignment is based on chance rather than a medical decision made by the researchers. The study group you are assigned to might not be the group you would prefer to be in. Your assigned study group might also prove to be less effective or have more side effects than the other study groups(s), or other treatments available for your condition.

Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

What are the alternatives to participating in this study?
The alternative is to not participate in the study.

What benefits can be reasonably expected?
Direct benefits to the participant are not expected.

Can you choose to not participate or withdraw from the study without penalty or loss of benefits?
Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time without penalty or loss of benefits to which you are entitled.

If you decide that you no longer wish to continue in this study, you can tell any member of the study team at any time and you will then be requested to come in for about 15 minutes (optional) to complete questionnaires.

You will be told if any important new information is found during the course of this study that may affect your wanting to continue.

Can you be withdrawn from the study without your consent?
You may be withdrawn from the study for the following reasons: Dr. Singh and colleagues determine that the potential benefits of the study do not outweigh the potential risks of the study. You may also be withdrawn from the study if you do not follow the instructions given by the study personnel.

Will you be compensated for participating in this study?
If you complete the full study, you can expect to receive up to a total of $500.

You will receive compensation at each of the study weeks noted below or at an assessment visit on the weeks they are conducted.

Week 0 (Baseline Visit): $50, regardless of whether you are enrolled in the study
Week 3: $50
Week 6: 100
Week 9: $50
Week 12: $100
1-month follow-up visit: $75
3-month follow-up visit: $75

Are there any costs associated with participating in this study?
There may be time and travel expenses associated with participation in this study.

What if you are injured as a direct result of being in this study?
If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) for more information about this, to inquire about your rights as a research subject or to report research-related problems.

What about your confidentiality?
Research records will be kept confidential to the extent allowed by law. Research records may be reviewed by the UCSD Institutional Review Board.

Participation in this study may involve a loss of confidentiality, but information about you will be handled as confidentially as possible. The study investigators have conducted clinical research for over 10 years without ever experiencing such an event.

Your research records will be labeled with a code number. The list that matches your name with the code number will be kept in a locked file in the research team's office. Any research records that identify you will be kept only as paper records in locked storage or on password-protected computers.

Your personal information can only be accessed by authorized personnel including study investigators, regulatory personnel, or as needed during life-threatening emergencies in order to maintain your safety or those of others.

Any presentations or publications from this information will not identify you.

Under California law, we must report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder including physical, sexual, emotional, and financial abuse or neglect. If any investigator has or is given such information, he or she may be required to report such information to the appropriate authorities.

Who can you call if you have questions?
Dr. Singh and/or _____ have explained this study to you and answered your questions. If you have other questions or research-related problems, you may reach Dr. Singh at 858-922-4365.

You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) to inquire about your rights as a research subject or to report research-related problems.

Conflict of Interest

Dr. Fiza Singh (Principal Investigator), Dr. Eric Granholm (Co-investigator) and Dr. I-Wei Shu (Co-investigator) are co-founders of BioSignal Solutions, LLC, a company that may potentially benefit from the research results from this study. The terms of this arrangement have been reviewed by the University of California, San Diego in accordance with its conflict of interest policies.

Your Signature and Consent

You have received a copy of this consent document and a copy of the "Experimental Subject's Bill of Rights" to keep.

You agree to participate.

_____ _____

Subject's signature Date

_____ Initial here if we may contact you regarding future studies Dr. Singh is directly involved in as an Investigator.

_____ Initial here if we may contact you to follow-up on your progress since completing the study.