Principal Investigator: Michael Avissar MD, PhD
For emergency or questions call:
Michael Avissar, MD, PhD (215)880-4300

Version date: 08/22/22

Consent Summary

An open-label extension trial of individualized repetitive transcranial magnetic stimulation in patients with auditory verbal hallucinations who completed protocol #8116

Overview

This page is a summary of the study that you are asked to participate in. The goal of this research is to look at the effect of low frequency Repetitive Transcranial Magnetic Stimulation (rTMS) on some of the symptoms of schizophrenia, specifically auditory verbal hallucinations. This outline is not meant to replace the consent form, which begins on the next page. The consent form contains detailed information about the study and about the risks that you will need to consider before making your decision.

Voluntary

You do not have to participate if you do not want to. Also, you may stop participating at any time.

Alternative Treatments/Alternatives to Participation

Your participation in this study is entirely voluntary, and you do not need to participate in this study to receive treatment for your symptoms. There are many treatments that may help your symptoms, depending on your individual history. Treatment with medications and therapy can help manage the condition. Your psychiatrist may try different drugs, different doses or combinations over time to achieve the desired result. Psychotherapy may help you learn to cope with stress and manage your illness, and identify early warning signs of relapse. Your doctor can provide you with further information about these treatment options.

Procedures

This study uses Repetitive Transcranial Magnetic Stimulation (rTMS), which induces electrical currents in the brain. The rTMS needs to be given every weekday for 2 weeks (one 20 minute session of rTMS per day). You will also undergo medical and safety screening, post treatment clinical assessments, and post treatment EEG session.

Risks and Inconveniences

- rTMS: this is a procedure that is used to create weak electrical currents in the brain. The main risk is the possibility of having a seizure. There are also other risks such as headaches and hearing problems. Please review these carefully in the full consent form.
- Screening and assessments: distress can be experienced from answering emotionally difficult screening questions and discussion about your psychiatric problems.
- EEG: you may experience scalp itching/irritation due to the recording procedures.
- COVID-19: the study includes in-person procedures and going out in public and travelling involves some risks of infection with COVID-19.

Benefits

This research study is not meant to benefit you directly, although some benefit is possible.

Questions

You may contact the study doctor, Michael Avissar, MD, PhD at 646-801-7792 with any questions.

NEW YORK STATE PSYCHIATRIC INSTITUTE
Informed Consent to Participate in a Research Study

The purpose of this consent form is to provide you with information you need to consider before you decide whether to participate in this research study.

STUDY TITLE: An open-label extension trial of individualized repetitive transcranial magnetic stimulation in patients with auditory verbal hallucinations who completed protocol #8116

PRINCIPAL INVESTIGATOR: Michael Avissar MD, PhD
AFFILIATION OF PRINCIPAL INVESTIGATOR: Columbia University/NYSPI

PURPOSE OF STUDY

The Repetitive Transcranial Magnetic Stimulation (rTMS) is a type of brain stimulation that uses a magnet to change activity in the brain. rTMS uses magnetic pulses to induce an electrical current in the brain to alter brain activity and function in specific areas. For example, stimulating the part of the brain controlling movement will cause parts of your foot or leg to twitch. TMS is proposed as a novel treatment for people with schizophrenia. We want to see if low frequency rTMS can lessen some of the symptoms of schizophrenia, specifically auditory verbal hallucinations (hearing voices). Auditory verbal hallucinations describe the experience of hearing voices that are not really there. You are being asked to participate in the present extension study because of your recent completion of the pilot rTMS study (the protocol #8116) and because under that protocol you showed little to no reduction of auditory verbal hallucination severity after the rTMS intervention. We are investigating whether targeting a different area of your brain involved in hallucinations than that used in protocol #8116 will work more effectively. TMS is not a proven treatment. We do not know if it works, but we are studying its use in schizophrenia to see if it can be used to treat these symptoms in the future.

During an rTMS session, an electromagnetic coil is placed against your scalp on the right side of the head. In contrast to the previous study that you just completed (protocol #8116), we will be targeting a different brain area also thought to be involved in the production of auditory hallucinations. A recent study has suggested that this form of treatment, applied over the area of the brain that can receive various types of sensory input such as auditory inputs, can lead to fewer or less intense auditory hallucinations. However, TMS is not approved by the Food and Drug Administration (FDA) in the treatment of schizophrenia and is not a proven treatment for auditory hallucinations.

You will be expected to stay on the same doses of medications and/or continue other treatment during this study. However, if your symptoms worsen during the study you will be removed from the study, and your psychiatrist will be notified so that your medications can be adjusted as needed. The medications that you are already taking will be continued throughout the study. You do not have to participate in this research to receive treatment for your illness.

Suicide Risk Management Plan (SRMP)
After enrollment, a weekly measure of suicide will be administered. If you are thought to be at risk of suicide, the study PI will further screen you and determine whether there's need for immediate referral. If you have your own

mental health provider, we will give preference to contacting him/her. If he/she is unable to see you within a certain time frame for various reasons or if you do not have your own mental health provider, we will develop a referral list or refer you directly to an available mental health provider depending on the assessed level of risk. In an urgent and emergent high-risk crisis situation, the study PI will request that you go to the emergency room and the study PI will talk to the responsible emergency room physician and provide all pertinent information. If you are not able to get to an emergency room on your own, the study doctor may call upon community resources such as 911. In the event you are in a high acute risk situation, we may contact your emergency contact without notifying you.

VOLUNTARY

You have the right to receive a clear explanation of this study. Your participation in this research study is voluntary. If you decide not to participate, or if you later decide to stop participating, you will not lose any benefits to which you are otherwise entitled. A decision not to participate will not affect your treatment at NYSPI or Columbia University Irving Medical Center. You do not have to participate in this research to receive treatment for your illness. You can stop this study at any time.

ALTERNATIVES TO PARTICIPATION

Your participation in this study is entirely voluntary and you do not need to participate in this study to receive treatment for your symptoms. There are many treatments that may help your symptoms, depending on your individual history. Changing your dose of medication, adding new medications, or undergoing psychotherapy is other treatment options. Your doctor can provide you with further information about these treatment options.

STUDY PROCEDURES

This study will take place at the New York State Psychiatric Institute (NYSPI). There will be several sessions involved in this study, and these will occur on different days. The total participation period in this study is 4 weeks. In the first week, you will be evaluated to see if you are eligible to complete the study procedures, which will include a medical and safety screening. A more detailed description of this procedure is provided later in this form. During the second and third week, the rTMS treatment session will be administered for 20 minutes per day. The first day will also include a 20-minute procedure to determine the correct dose or intensity of TMS for you. You will receive once-daily rTMS over a period of 2 weeks (from Monday to Friday, weekends off). On the fourth week, you will undergo clinical assessments and brain wave recordings (EEG). MRI is not included in the current study since we will use your existing MRI scan that was used when you participated in protocol #8116.

Evaluation/Screening
If you are interested in participating in this study, you will undergo a complete medical and safety evaluation. This will take about 2 hours and will determine whether you qualify for the study. A physician will interview you and perform a physical examination. Female participants will have a urine pregnancy test at the screening. The results of evaluation will be used to determine if you are eligible for the study and will be retained as study

records regardless of your eligibility. You will be eligible for the study if the evaluation shows that you are not pregnant, and you are physically healthy and psychiatrically stable.

Clinical Assessments
You will be asked to take part in a session with a clinical rater once during this study: after you complete all TMS treatment sessions. The rater will ask you questions about your symptoms, mood, and quality of life. The ratings session will take about 2 hours.

TMS treatment
TMS is given using a magnetic stimulator, which is a device that generates a magnetic field. By rapidly turning the magnetic field on and off in a coil held next to your head, a small amount of electric current is briefly generated in the brain. You will be asked to remove any metal or magnetized objects (such as keys, jewelry, hair pins and credit cards) before starting the TMS procedure. The TMS stimulator produces a clicking noise which is about as loud as a siren, but it only lasts for a brief moment like someone snapping their fingers.

Earplugs will be worn throughout the session to protect your hearing from the clicking noise made by the stimulator. You may also experience a tapping sensation under the coil on your scalp. On the first day only, you will undergo a 20-min procedure with TMS to determine your motor threshold, which is the lowest intensity that a TMS pulse needs to stimulate the part of your brain that controls hand and finger muscles. For the treatment sessions, your face and scalp landmarks will then be matched against the MRI of your head and brain to identify the scalp areas to use for stimulation. You will have a stylus placed against the tip and bridge of your nose and both ears to establish your skull landmarks using an infrared camera. You will receive once-daily rTMS sessions over a period of 2 weeks (from Monday to Friday, weekends off), and therefore accrue a total of 10 rTMS stimulation sessions. The rTMS parameters that will be used are a stimulation frequency of 1 Hz (1 pulse per second) for 20 minutes per treatment session.

You may stop the procedure at any time. Trained staff will be with you at all times.

EEG
You will participate in one session of electroencephalography (EEG, or brainwave recording), which will take place the week after treatment. In EEG, we use a special cap with (nonstimulating) electrodes to record electrical activity at the surface of your head, reflecting underlying brain activity. This cap is placed on your head with special gel, to record brain activity while you listen to sounds and perform simple tasks. The process of setting up the cap takes about an hour and will mess up your hair. Though we have a special sink and shampoo for removing the EEG gel after the session, we recommend that you wash your hair again when you get home. The EEG session will last about 3.5 hours (including cap setup).

RISKS AND INCONVENIENCES

COVID-19
There is an ongoing risk for exposure to the respiratory disease caused by the SARS-CoV-2 virus. The disease is named Coronavirus Disease 2019 (COVID-19). Going out in public and traveling involves some risk of infection with COVID-19. There is risk of COVID-19 infection during in-office visits and during travel for

research purposes. Some of the visits may be conducted remotely using the telephone or video teleconferencing to minimize COVID-19 risks related to travel. We respect your privacy and would conduct these remote procedures when you are able to be present in a private space. COVID-related risks can be reduced by taking recommended precautions. These include always wearing a mask, staying at least 6 feet away from others and practicing hand hygiene in public and while traveling. If you do not feel comfortable traveling to the medical center for an appointment, for example if the subway or bus you would normally take is crowded, you can reschedule, or we may be able to arrange alternative transportation (if it is the case that alternative transportation, such as Uber or Lyft, can be offered.) We have also minimized the in-office assessments to lessen this risk. We will keep you informed about current public health recommendations, such as federal and local government guidelines and directives. The Food and Drug Administration's (FDA) guidance for conducting clinical trials during the COVID-19 pandemic can be found here: https://www.fda.gov/media/136238/download.

Screening

Screening can be associated with minor psychological distress (answering emotionally difficult screening questions). Study personnel are trained at monitoring your comfort and providing reassurance in the advent of psychological discomforts.

Transcranial Magnetic Stimulation (TMS)

The most serious known risk of TMS is the production of a convulsion (seizure). Persons with epilepsy or a family history of epilepsy cannot participate in this study. Using low frequency rTMS like the procedures put forth in this study, the risk in inducing a seizure is very low. But, should this occur, facilities that handle these emergencies are available. If you have a seizure, you may require hospital admission and follow-up neurological evaluation. Having had a seizure may adversely affect your medical insurability, your future employment, and your ability to drive. It is not known whether having had one seizure will make a person more prone to having future seizures.

The most commonly reported side effect of TMS is a "muscle-tension" type headache. If a headache occurs, it usually starts during or immediately after the TMS and lasts from minutes to hours after TMS. The headache usually goes away with standard over-the-counter pain medications. Neck pain may also occur, and it is usually managed easily with standard pain medications. You may also experience some discomfort on your head where the stimulator is held. This is due to contraction of scalp muscles. The clicking noise produced during the stimulation may temporarily affect hearing, which should return to normal once the session is ended. You will wear earplugs to reduce your exposure to the clicking noise during each TMS session and your hearing will be tested before and after the full treatment protocol. Studies in which hearing protection was used reported no permanent change in hearing after TMS. The TMS session will be stopped if the earplugs come loose. TMS can produce currents in skin electrodes (and jewelry, glasses, and watches) and implants that can heat them. Likewise, wires, electronic devices, and brain implants can have a voltage induced by a magnetic pulse. While TMS has been safely done with individuals with these devices, to err on the side of caution, we will not recruit you for this study if you have any implants whatsoever and as mentioned, you must remove all jewelry, glasses and watches during study procedures.

The effects of TMS on cognition are relatively low and no evidence has indicated longer lasting side effects of TMS on cognition. In addition, psychiatric adverse events induced by rTMS were transient and relatively minor in severity, occurring at a rate between 1 and 5%. Although cases of rTMS induced psychiatric changes have been reported, it is still unknown if such side effects occur at a higher rate than during the natural course of each disease state. TMS can also induce a short lasting increase in heart rate and blood pressure, and can briefly alter

cerebral hemodynamics, which is of import in individuals with medical illnesses such as acute stroke. Therefore, you will be screened for medical illness and also have vital signs obtained.

In general, the efficacy of TMS on schizophrenia patients has not been established, though rTMS has been proposed as a promising treatment for people with schizophrenia, especially those who experience auditory hallucinations. The effect on pregnancy and the unborn fetus are unknown, so pregnant women are excluded from the study. Women of childbearing potential must use a medically acceptable birth control method during the study. If you are a woman, you will be asked to take a pregnancy urine test before exposure to magnetic stimulation. You will be excluded from the study if the test indicates you may be pregnant.

TMS may involve other risks that are not known at the present time. The long-term effects of TMS are not known.

EEG
There is the rare instance of scalp itching/irritation due to the recording procedures. Additionally, you will sit in an enclosed room for the EEG recordings, which can cause mild anxiety for some people. We will be monitoring you throughout the session and you will be able to get our attention should anything arise.

Clinical Assessments
Answering questions about symptoms can cause emotional distress. If you become anxious or upset during the assessments, you can ask for a break or tell the person performing the assessment that you are uncomfortable, and they will move on to another question.

Summary of key safety recommendations

- You should refrain from using alcohol, drugs or other non-prescribed medications the evening before the study.
- You should tell us about any past or present medical problems, including high blood pressure or seizures, and about use of medication, drugs and alcohol.
- You should tell us about any metallic implants in your body.

BENEFITS

Participation in this study may have no direct benefit to you. However, in the course of this research your symptoms may improve. The purpose of this study is to conduct research that may improve treatment for patients in the future.

RESULTS OF YOUR ASSESSMENTS

The results of most of the clinical assessments conducted in this study will not be shared with you, as we do not expect them to be relevant to your health or regular psychiatric treatment. If the study doctors feel that their overall assessment of your symptoms is relevant to your health or regular treatment, they may share this assessment with you or a doctor of your choosing.

CONFIDENTIALITY

Your right to privacy and the confidentiality of your participation in this project, should you choose to participate, will be safeguarded, and if research papers are written you will not be mentioned by name. Research records, like other medical and clinical records, will be kept confidential to the extent permitted by law. Any information obtained during this study and identified with you will remain confidential and will only be available to the research staff at the New York State Psychiatric Institute, institutional personnel, or to federal and New York State regulatory personnel. The FDA may have access to your study records. Your name and other personal identifying information will be stored in an electronically secure database at the New York State Psychiatric Institute. All information will be stored in locked files and will not have your name or any other identifying information associated with it. Once deidentified, information collected for this study may be used for future research studies or distributed to another investigator for future research studies without identifiers. Biospecimens collected for pregnancy and drug screening will be immediately discarded and will not be used for commercial profit.

This research is covered by a Certificate of Confidentiality issued by the National Institute of Mental Health. With this Certificate, the researchers cannot be forced to release any research data in which you are identified, even under a court order or subpoena, without your written consent. The Certificate does not prevent the researchers from reporting suspected or known neglect or sexual or physical abuse of a child, or threatened violence to self or others. Such information will be reported to the appropriate authorities.

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, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Records will be available to research staff, and Federal, State, and Institutional regulatory personnel (who may review records as part of the routine audits).

STUDY COMPENSATION

You will be compensated as follows:

- Pre-treatment session (medical and safety screening): $30
- Treatment day: $100
- Post-treatment session (clinical assessment and EEG tasks): $100

You will undergo 1 pre-treatment session, 1 post-treatment session and 10 treatment days.

Total compensation for all sessions is $1130.

If you do not finish the study, you will be paid for the part of the study that you did complete.

Reasonable transportation costs (such as subway/bus fare) will be reimbursed at $10 for public transportation, or up to $50 (with receipts) for driving expenses. If neither public transit nor driving is feasible, we will arrange

and cover the full cost of transportation.

We are required by law to report these payments to the IRS. Therefore, your Social Security Number and amount earned will be reported, and you will receive the appropriate IRS form at the end of the year in which you were paid. It is possible that your income from this study may affect your eligibility for Medicaid and other city, state and federal support services and benefits. No information about which study you participated in will be provided to the IRS.

IN CASE OF INJURY

Federal regulations require that research participants be informed about our institution's policy with regard to compensation and payment for treatment of research-related injuries. If you believe that you have sustained an injury as a result of participating in a research study, you may contact the Principal Investigator, Dr. Michael Avissar at 646-774-5431 so that you can review the matter and identify the medical resources that may be available to you.

In case of injury, New York State Psychiatric Institute (NYSPI) will provide short term emergency medical treatment, which has been determined to be necessary by NYSPI's doctors, and which is within the capability of NYSPI to provide. In addition, we will provide assistance in arranging follow up care in such cases.

NYSPI and the Research Foundation for Mental Hygiene do not provide compensation or payment for treatment of research related injuries. However, you should be aware that you do not give up your legal right to seek such compensation through the court by participating in this research.

Please be aware that:

- NYSPI and Columbia University New York Presbyterian Hospital will furnish the emergency medical care determined to be necessary by the medical staff of the hospital or the facility.
- You will be responsible for the cost of such care, either personally or through your medical insurance or other form of medical coverage.
- No monetary compensation for wages lost as a result of injury will be paid to you by the NYSPI/Columbia University New York Presbyterian Hospital.

By signing this consent form, you are not waiving any of your legal rights to seek compensation through the courts.

You will be notified of significant new findings that may relate to your willingness to continue to participate in this study.

QUESTIONS

The researchers will answer, to the best of their ability, any questions that you may have, now or in the future, about the study procedures or about your response to them. You can contact Dr. Michael Avissar, the Principal Investigator, at 646-774-5431. If you have any questions about the rights of research participants or if you have any complaints, you may call the NYSPI-IRB Main Office at (646) 774-7155 during office hours.

You will be given a copy of this consent form to keep.

Principal Investigator: Michael Avissar MD, PhD
For emergency or questions call:
Michael Avissar, MD, PhD (215)880-4300

Version date: 08/22/22

STATEMENT OF CONSENT

My participation is voluntary, and I can withdraw from the study at any time without prejudice. I have read the above and agree to participate in this research study. Signing this form does not waive any of my legal rights.

Check one of the following:

☐ I may be contacted for follow-up for this study or recruitment for future studies. By checking this box, I understand that my identifying information may be shared within and outside of the division of Experimental Therapeutics at NYSPI/ Schizophrenia Research Program at NKI for purposes of contacting me for future studies.

☐ I do not wish to be contacted for follow-up for this study or recruitment for future studies. By checking this box, I have requested not to be contacted for future studies and I do not want my information to be shared within or outside of the department for any purposes.

Signature of participant _____

Printed name of participant _____

Date _____

I have discussed the proposed research with this individual and, in my opinion, they understand the benefits, risks and alternatives (including non-participation) and are capable of freely consenting to participate in this research.

Signature of investigator obtaining consent _____

Printed name of investigator obtaining consent _____

Date _____

Principal Investigator: Michael Avissar MD, PhD
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Consent Summary

An open-label extension trial of individualized repetitive transcranial magnetic stimulation in patients with auditory verbal hallucinations who completed protocol #8116

Overview

This page is a summary of the study that you are asked to participate in. The goal of this research is to look at the effect of low frequency Repetitive Transcranial Magnetic Stimulation (rTMS) on some of the symptoms of schizophrenia, specifically auditory verbal hallucinations. This outline is not meant to replace the consent form, which begins on the next page. The consent form contains detailed information about the study and about the risks that you will need to consider before making your decision.

Voluntary

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Procedures

This study uses Repetitive Transcranial Magnetic Stimulation (rTMS), which induces electrical currents in the brain. The rTMS needs to be given every weekday for 2 weeks (one 20 minute session of rTMS per day). You will undergo medical and safety screening, post treatment clinical assessments, and post treatment EEG session.

Risks and Inconveniences

- rTMS: this is a procedure that is used to create weak electrical currents in the brain. The main risk is the possibility of having a seizure. There are also other risks such as headaches and hearing problems. Please review these carefully in the full consent form.
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STUDY TITLE: An open-label extension trial of individualized repetitive transcranial magnetic stimulation in patients with auditory verbal hallucinations who completed protocol #8116

PRINCIPAL INVESTIGATOR: Michael Avissar MD, PhD
AFFILIATION OF PRINCIPAL INVESTIGATOR: Columbia University/NYSPI

PURPOSE OF STUDY

The Repetitive Transcranial Magnetic Stimulation (rTMS) is a type of brain stimulation that uses a magnet to change activity in the brain. rTMS uses magnetic pulses to induce an electrical current in the brain to alter brain activity and function in specific areas. For example, stimulating the part of the brain controlling movement will cause parts of your foot or leg to twitch. TMS is proposed as a novel treatment for people with schizophrenia. We want to see if low frequency rTMS can lessen some of the symptoms of schizophrenia, specifically auditory verbal hallucinations (hearing voices). Auditory verbal hallucinations describe the experience of hearing voices that are not really there. You are being asked to participate in the present extension study because of your recent completion of the pilot rTMS study (protocol #8116) and because under that protocol you showed a slight to moderate reduction of auditory verbal hallucination severity after rTMS treatment sessions. We are investigating whether extending that treatment will result in further reductions in hallucinations. TMS is not a proven treatment. We do not know if it works, but we are studying its use in schizophrenia to see if it can be used to treat these symptoms in the future.

As in the previous study that you just completed (protocol #8116), an electromagnetic coil is placed against your scalp on the left side of the head during an rTMS session, and we will continue to target the same brain area suggested to be involved in the production of auditory hallucinations. Other studies have suggested that this form of treatment, applied over areas of the brain that are involved in auditory processing (listening to and responding to sounds), can lead to fewer or less intense auditory hallucinations. However, TMS is not approved by the Food and Drug Administration (FDA) in the treatment of schizophrenia and is not a proven treatment for auditory hallucinations.

You will be expected to stay on the same doses of medications and/or continue other treatment during this study. However, if your symptoms worsen during the study you will be removed from the study, and your psychiatrist will be notified so that your medications can be adjusted as needed. The medications that you are already taking will be continued throughout the study. You do not have to participate in this research to receive treatment for your illness.

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COVID-19
There is an ongoing risk for exposure to the respiratory disease caused by the SARS-CoV-2 virus. The disease is named Coronavirus Disease 2019 (COVID-19). Going out in public and traveling involves some risk of infection with COVID-19. There is risk of COVID-19 infection during in-office visits and during travel for research purposes. Some of the visits may be conducted remotely using the telephone or video teleconferencing to minimize COVID-19 risks related to travel. We respect your privacy and would conduct these remote

procedures when you are able to be present in a private space. COVID-related risks can be reduced by taking recommended precautions. These include always wearing a mask, staying at least 6 feet away from others and practicing hand hygiene in public and while traveling. If you do not feel comfortable traveling to the medical center for an appointment, for example if the subway or bus you would normally take is crowded, you can reschedule, or we may be able to arrange alternative transportation (if it is the case that alternative transportation, such as Uber or Lyft, can be offered.) We have also minimized the in-office assessments to lessen this risk. We will keep you informed about current public health recommendations, such as federal and local government guidelines and directives. The Food and Drug Administration's (FDA) guidance for conducting clinical trials during the COVID-19 pandemic can be found here: https://www.fda.gov/media/136238/download.

Screening

Screening can be associated with minor psychological distress (answering emotionally difficult screening questions). Study personnel are trained at monitoring your comfort and providing reassurance in the advent of psychological discomforts.

Transcranial Magnetic Stimulation (TMS)

The most serious known risk of TMS is the production of a convulsion (seizure). Persons with epilepsy or a family history of epilepsy cannot participate in this study. Using low frequency rTMS like the procedures put forth in this study, the risk in inducing a seizure is very low. But, should this occur, facilities that handle these emergencies are available. If you have a seizure, you may require hospital admission and follow-up neurological evaluation. Having had a seizure may adversely affect your medical insurability, your future employment, and your ability to drive. It is not known whether having had one seizure will make a person more prone to having future seizures.

The most commonly reported side effect of TMS is a "muscle-tension" type headache. If a headache occurs, it usually starts during or immediately after the TMS and lasts from minutes to hours after TMS. The headache usually goes away with standard over-the-counter pain medications. Neck pain may also occur, and it is usually managed easily with standard pain medications. You may also experience some discomfort on your head where the stimulator is held. This is due to contraction of scalp muscles. The clicking noise produced during the stimulation may temporarily affect hearing, which should return to normal once the session is ended. You will wear earplugs to reduce your exposure to the clicking noise during each TMS session and your hearing will be tested before and after the full treatment protocol. Studies in which hearing protection was used reported no permanent change in hearing after TMS. The TMS session will be stopped if the earplugs come loose. TMS can produce currents in skin electrodes (and jewelry, glasses, and watches) and implants that can heat them. Likewise, wires, electronic devices, and brain implants can have a voltage induced by a magnetic pulse. While TMS has been safely done with individuals with these devices, to err on the side of caution, we will not recruit you for this study if you have any implants whatsoever and as mentioned, you must remove all jewelry, glasses and watches during study procedures.

The effects of TMS on cognition are relatively low and no evidence has indicated longer lasting side effects of TMS on cognition. In addition, psychiatric adverse events induced by rTMS were transient and relatively minor in severity, occurring at a rate between 1 and 5%. Although cases of rTMS induced psychiatric changes have been reported, it is still unknown if such side effects occur at a higher rate than during the natural course of each disease state. TMS can also induce a short lasting increase in heart rate and blood pressure, and can briefly alter cerebral hemodynamics, which is of import in individuals with medical illnesses such as acute stroke. Therefore, you will be screened for medical illness and also have vital signs obtained.

In general, the efficacy of TMS on schizophrenia patients has not been established, though rTMS has been proposed as a promising treatment for people with schizophrenia, especially those who experience auditory hallucinations. The effect on pregnancy and the unborn fetus are unknown, so pregnant women are excluded from the study. Women of childbearing potential must use a medically acceptable birth control method during the study. If you are a woman, you will be asked to take a pregnancy urine test before exposure to magnetic stimulation. You will be excluded from the study if the test indicates you may be pregnant.

TMS may involve other risks that are not known at the present time. The long-term effects of TMS are not known.

EEG

There is the rare instance of scalp itching/irritation due to the recording procedures. Additionally, you will sit in an enclosed room for the EEG recordings, which can cause mild anxiety for some people. We will be monitoring you throughout the session and you will be able to get our attention should anything arise.

Clinical Assessments

Answering questions about symptoms can cause emotional distress. If you become anxious or upset during the assessments, you can ask for a break or tell the person performing the assessment that you are uncomfortable, and they will move on to another question.

Summary of key safety recommendations

- You should refrain from using alcohol, drugs or other non-prescribed medications the evening before the study.
- You should tell us about any past or present medical problems, including high blood pressure or seizures, and about use of medication, drugs and alcohol.
- You should tell us about any metallic implants in your body.

BENEFITS

Participation in this study may have no direct benefit to you. However, in the course of this research your symptoms may improve. The purpose of this study is to conduct research that may improve treatment for patients in the future.

RESULTS OF YOUR ASSESSMENTS

The results of most of the clinical assessments conducted in this study will not be shared with you, as we do not expect them to be relevant to your health or regular psychiatric treatment. If the study doctors feel that their overall assessment of your symptoms is relevant to your health or regular treatment, they may share this assessment with you or a doctor of your choosing.

CONFIDENTIALITY

Your right to privacy and the confidentiality of your participation in this project, should you choose to participate, will be safeguarded, and if research papers are written you will not be mentioned by name. Research records, like other medical and clinical records, will be kept confidential to the extent permitted by law. Any information obtained during this study and identified with you will remain confidential and will only be available to the research staff at the New York State Psychiatric Institute, institutional personnel, or to federal and New York State regulatory personnel. The FDA may have access to your study records. Your name and other personal identifying information will be stored in an electronically secure database at the New York State Psychiatric Institute. All information will be stored in locked files and will not have your name or any other identifying information associated with it. Once deidentified, information collected for this study may be used for future research studies or distributed to another investigator for future research studies without identifiers. Biospecimens collected for pregnancy and drug screening will be immediately discarded and will not be used for commercial profit.

This research is covered by a Certificate of Confidentiality issued by the National Institute of Mental Health. With this Certificate, the researchers cannot be forced to release any research data in which you are identified, even under a court order or subpoena, without your written consent. The Certificate does not prevent the researchers from reporting suspected or known neglect or sexual or physical abuse of a child, or threatened violence to self or others. Such information will be reported to the appropriate authorities.

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, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Records will be available to research staff, and Federal, State, and Institutional regulatory personnel (who may review records as part of the routine audits).

STUDY COMPENSATION

You will be compensated as follows:

- Pre-treatment session (medical and safety screening): $30
- Treatment day: $100
- Post-treatment session (clinical assessment and EEG): $100

You will undergo 1 pre-treatment session, 1 post-treatment session and 10 treatment days.

Total compensation for all sessions is $1130.

If you do not finish the study, you will be paid for the part of the study that you did complete.

Reasonable transportation costs (such as subway/bus fare) will be reimbursed at $10 for public transportation, or up to $50 (with receipts) for driving expenses. If neither public transit nor driving is feasible, we will arrange and cover the full cost of transportation.

We are required by law to report these payments to the IRS. Therefore, your Social Security Number and amount earned will be reported, and you will receive the appropriate IRS form at the end of the year in which you were paid. It is possible that your income from this study may affect your eligibility for Medicaid and other city, state and federal support services and benefits. No information about which study you participated in will be provided to the IRS.

IN CASE OF INJURY

Federal regulations require that research participants be informed about our institution's policy with regard to compensation and payment for treatment of research-related injuries. If you believe that you have sustained an injury as a result of participating in a research study, you may contact the Principal Investigator, Dr. Michael Avissar at 646-774-5431 so that you can review the matter and identify the medical resources that may be available to you.

In case of injury, New York State Psychiatric Institute (NYSPI) will provide short term emergency medical treatment, which has been determined to be necessary by NYSPI's doctors, and which is within the capability of NYSPI to provide. In addition, we will provide assistance in arranging follow up care in such cases.

NYSPI and the Research Foundation for Mental Hygiene do not provide compensation or payment for treatment of research related injuries. However, you should be aware that you do not give up your legal right to seek such compensation through the court by participating in this research.

Please be aware that:

- NYSPI and Columbia University New York Presbyterian Hospital will furnish the emergency medical care determined to be necessary by the medical staff of the hospital or the facility.
- You will be responsible for the cost of such care, either personally or through your medical insurance or other form of medical coverage.
- No monetary compensation for wages lost as a result of injury will be paid to you by the NYSPI/Columbia University New York Presbyterian Hospital.

By signing this consent form, you are not waiving any of your legal rights to seek compensation through the courts.

You will be notified of significant new findings that may relate to your willingness to continue to participate in this study.

QUESTIONS

The researchers will answer, to the best of their ability, any questions that you may have, now or in the future, about the study procedures or about your response to them. You can contact Dr. Michael Avissar, the Principal Investigator, at 646-774-5431. If you have any questions about the rights of research participants or if you have any complaints, you may call the NYSPI-IRB Main Office at (646) 774-7155 during office hours.

You will be given a copy of this consent form to keep.

Principal Investigator: Michael Avissar MD, PhD
For emergency or questions call:
Michael Avissar, MD, PhD (215)880-4300

Version date: 08/22/22

STATEMENT OF CONSENT

My participation is voluntary, and I can withdraw from the study at any time without prejudice. I have read the above and agree to participate in this research study. Signing this form does not waive any of my legal rights.

Check one of the following:

☐ I may be contacted for follow-up for this study or recruitment for future studies. By checking this box, I understand that my identifying information may be shared within and outside of the division of Experimental Therapeutics at NYSPI/ Schizophrenia Research Program at NKI for purposes of contacting me for future studies.

☐ I do not wish to be contacted for follow-up for this study or recruitment for future studies. By checking this box, I have requested not to be contacted for future studies and I do not want my information to be shared within or outside of the department for any purposes.

Signature of participant _____

Printed name of participant _____

Date _____

I have discussed the proposed research with this individual and, in my opinion, they understand the benefits, risks and alternatives (including non-participation) and are capable of freely consenting to participate in this research.

Signature of investigator obtaining consent _____

Printed name of investigator obtaining consent _____

Date _____

Principal Investigator: Michael Avissar MD, PhD
For emergency or questions call:
Michael Avissar, MD, PhD (215)880-4300

Version date: 08/22/22

Consent Summary

An open-label extension trial of individualized repetitive transcranial magnetic stimulation in patients with auditory verbal hallucinations who completed protocol #8116

Overview
This page is a summary of the study that you are asked to participate in. The goal of this study is to track how long the reduction in hallucinations lasts after the TMS treatment you received during your participation in study #8116. This outline is not meant to replace the consent form, which begins on the next page. The consent form contains detailed information about the study and about the risks that you will need to consider before making your decision.

Voluntary
You do not have to participate if you do not want to. Also, you may stop participating at any time.

Alternatives to Participation
This is not a treatment study, and your participation will not affect any treatments you may be taking or planning to take. There are multiple options to participate in research through New York State Psychiatric Institute (NYSPI) and you are free to participate in one or more of these other studies rather than this one.

Procedures
The total participation period is 2 months. You will undergo medical and safety screening at week 1, and follow-up assessment sessions will be given at week 1, week 2, week 4, and week 8.

Risks and Inconveniences
- Screening and assessments: distress can be experienced from answering emotionally difficult screening questions and discussion about your psychiatric problems.
- COVID-19: Some study procedures may be conducted in-person. Going out in public and travelling involves some risks of infection with COVID-19.

Benefits
This research study is not meant to benefit you directly, although some benefit is possible.

Questions
You may contact the study doctor, Michael Avissar, MD, PhD at 646-801-7792 with any questions.

NEW YORK STATE PSYCHIATRIC INSTITUTE
Informed Consent to Participate in a Research Study

The purpose of this consent form is to provide you with information you need to consider before you decide whether to participate in this research study.

STUDY TITLE: An open-label extension trial of individualized repetitive transcranial magnetic stimulation in patients with auditory verbal hallucinations who completed protocol #8116

PRINCIPAL INVESTIGATOR: Michael Avissar MD, PhD
AFFILIATION OF PRINCIPAL INVESTIGATOR: Columbia University/NYSPI

PURPOSE OF STUDY

Auditory verbal hallucinations (AVH), or "hearing voices", are a common symptom of schizophrenia. You are being asked to participate in the present project because of your recent completion of the pilot rTMS study (protocol #8116) and because under that protocol you experienced a large improvement or reduction of AVH severity following 10 days of rTMS treatment sessions. The purpose of this study is to evaluate how long that reduction lasts.

VOLUNTARY

You have the right to receive a clear explanation of this study. Your participation in this research study is voluntary. If you decide not to participate, or if you later decide to stop participating, you will not lose any benefits to which you are otherwise entitled. A decision not to participate or to withdraw your participation will not affect any current or future treatment you may receive from the New York State Psychiatric Institute or Columbia University Irving Medical Center. You can stop this study at any time. We will use the information we collect about you for research purposes only.

STUDY PROCEDURES

This study will take place at the New York State Psychiatric Institute (NYSPI). Screening and assessments may be conducted remotely through telephone. There will be several sessions involved in this study, and these will occur on different days. The total participation period in this study is 2 months. In the beginning, you will undergo a brief screening session to see if you are eligible to complete the study procedures. You will then partake in clinical assessment sessions on the first, the second, the fourth and the eighth week.

Screening
If you are interested in participating in this study, you will undergo a 30 minutes screening session. This will determine if you are eligible for the study and will be retained as study records regardless of your eligibility. You will be eligible for the study if the evaluation shows that you are medically and psychiatrically stable.

Clinical Assessments
You will undergo four psychological assessment sessions over a period of two months. Each will take about 2 hours. The rater will ask you questions about your symptoms, mood, and quality of life. You may stop the procedure at any time. Trained staff will be with you at all times.

Suicide Risk Management Plan (SRMP)
After enrollment, a weekly measure of suicide will be administered. If you are thought to be at risk of suicide, the study PI will further screen you and determine whether there's need for immediate referral. If you have your own mental health provider, we will give preference to contacting him/her. If he/she is unable to see you within a certain time frame for various reasons or if you do not have your own mental health provider, we will develop a referral list or refer you directly to an available mental health provider depending on the assessed level of risk. In an urgent and emergent high-risk crisis situation, the study PI will request that you go to the emergency room and the study PI will talk to the responsible emergency room physician and provide all pertinent information. If you are not able to get to an emergency room on your own, the study doctor may call upon community resources such as 911. In the event you are in a high acute risk situation, we may contact your emergency contact without notifying you.

RISKS AND INCONVENIENCES

COVID-19
There is an ongoing risk for exposure to the respiratory disease caused by the SARS-CoV-2 virus. The disease is named Coronavirus Disease 2019 (COVID-19). Going out in public and traveling involves some risk of infection with COVID-19. There is risk of COVID-19 infection during in-office visits and during travel for research purposes. Some of the visits may be conducted remotely using the telephone or video teleconferencing to minimize COVID-19 risks related to travel. We respect your privacy and would conduct these remote procedures when you are able to be present in a private space. COVID-related risks can be reduced by taking recommended precautions. These include always wearing a mask, staying at least 6 feet away from others and practicing hand hygiene in public and while traveling. If you do not feel comfortable traveling to the medical center for an appointment, for example if the subway or bus you would normally take is crowded, you can reschedule, or we may be able to arrange alternative transportation (if it is the case that alternative transportation, such as Uber or Lyft, can be offered.) We have also minimized the in-office assessments to lessen this risk. We will keep you informed about current public health recommendations, such as federal and local government guidelines and directives. The Food and Drug Administration's (FDA) guidance for conducting clinical trials during the COVID-19 pandemic can be found here: https://www.fda.gov/media/136238/download.

Screening
Screening can be associated with minor psychological distress (i.e., answering emotionally difficult screening questions). Study personnel are trained at monitoring your comfort and providing reassurance in the advent of psychological discomforts.

Clinical Assessments

Answering questions about symptoms can cause emotional distress. If you become anxious or upset during the assessments, you can ask for a break or tell the person performing the assessment that you are uncomfortable, and they will move on to another question. You are not required to disclose anything that you are not comfortable with disclosing.

BENEFITS

Although you may not receive direct benefit from your participation, others may ultimately benefit from the knowledge obtained from this research.

RESULTS OF YOUR ASSESSMENTS

The results of most of the clinical assessments conducted in this study will not be shared with you, as we do not expect them to be relevant to your health or regular psychiatric treatment. If the study doctors feel that their overall assessment of your symptoms is relevant to your health or regular treatment, they may share this assessment with you or a doctor of your choosing.

CONFIDENTIALITY

Your right to privacy and the confidentiality of your participation in this project, should you choose to participate, will be safeguarded, and if research papers are written you will not be mentioned by name. Research records, like other medical and clinical records, will be kept confidential to the extent permitted by law. Any information obtained during this study and identified with you will remain confidential and will only be available to the research staff at the New York State Psychiatric Institute, institutional personnel, or to federal and New York State regulatory personnel. The FDA may have access to your study records. Your name and other personal identifying information will be stored in an electronically secure database at the New York State Psychiatric Institute. All information will be stored in locked files and will not have your name or any other identifying information associated with it. Once deidentified, information collected for this study may be used for future research studies or distributed to another investigator for future research studies without identifiers. Biospecimens collected for pregnancy and drug screening will be immediately discarded and will not be used for commercial profit.

This research is covered by a Certificate of Confidentiality issued by the National Institute of Mental Health. With this Certificate, the researchers cannot be forced to release any research data in which you are identified, even under a court order or subpoena, without your written consent. The Certificate does not prevent the researchers from reporting suspected or known neglect or sexual or physical abuse of a child, or threatened violence to self or others. Such information will be reported to the appropriate authorities.

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, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Records will be available to research staff, and Federal, State, and Institutional regulatory personnel (who may review records as part of the routine audits).

STUDY COMPENSATION

You will be compensated as follows:

- Screening session: $25
- Clinical assessment session: $60

You will undergo 1 screening session and 4 clinical assessment sessions.

Total compensation for all sessions is $265.

If you do not finish the study, you will be paid for the part of the study that you did complete.

Reasonable transportation costs (such as subway/bus fare) will be reimbursed at $10 for public transportation, or up to $50 (with receipts) for driving expenses. If neither public transit nor driving is feasible, we will arrange and cover the full cost of transportation.

We are required by law to report these payments to the IRS. Therefore, your Social Security Number and amount earned will be reported, and you will receive the appropriate IRS form at the end of the year in which you were paid. It is possible that your income from this study may affect your eligibility for Medicaid and other city, state and federal support services and benefits. No information about which study you participated in will be provided to the IRS.

IN CASE OF INJURY

Federal regulations require that research participants be informed about our institution's policy with regard to compensation and payment for treatment of research-related injuries. If you believe that you have sustained an injury as a result of participating in a research study, you may contact the Principal Investigator, Dr. Michael Avissar at 646-774-5431 so that you can review the matter and identify the medical resources that may be available to you.

In case of injury, New York State Psychiatric Institute (NYSPI) will provide short term emergency medical treatment, which has been determined to be necessary by NYSPI's doctors, and which is within the capability of NYSPI to provide. In addition, we will provide assistance in arranging follow up care in such cases.

NYSPI and the Research Foundation for Mental Hygiene do not provide compensation or payment for treatment of research related injuries. However, you should be aware that you do not give up your legal right to seek such compensation through the court by participating in this research.

Please be aware that:

- NYSPI and Columbia University New York Presbyterian Hospital will furnish the emergency medical

care determined to be necessary by the medical staff of the hospital or the facility.

- You will be responsible for the cost of such care, either personally or through your medical insurance or other form of medical coverage.
- No monetary compensation for wages lost as a result of injury will be paid to you by the NYSPI/Columbia University New York Presbyterian Hospital.

By signing this consent form, you are not waiving any of your legal rights to seek compensation through the courts.

You will be notified of significant new findings that may relate to your willingness to continue to participate in this study.

QUESTIONS

The researchers will answer, to the best of their ability, any questions that you may have, now or in the future, about the study procedures or about your response to them. You can contact Dr. Michael Avissar, the Principal Investigator, at 646-774-5431. If you have any questions about the rights of research participants or if you have any complaints, you may call the NYSPI-IRB Main Office at (646) 774-7155 during office hours.

You will be given a copy of this consent form to keep.

Principal Investigator: Michael Avissar MD, PhD
For emergency or questions call:
Michael Avissar, MD, PhD (215)880-4300

Version date: 08/22/22

STATEMENT OF CONSENT

My participation is voluntary, and I can withdraw from the study at any time without prejudice. I have read the above and agree to participate in this research study. Signing this form does not waive any of my legal rights.

Check one of the following:

☐ I may be contacted for follow-up for this study or recruitment for future studies. By checking this box, I understand that my identifying information may be shared within and outside of the division of Experimental Therapeutics at NYSPI/ Schizophrenia Research Program at NKI for purposes of contacting me for future studies.

☐ I do not wish to be contacted for follow-up for this study or recruitment for future studies. By checking this box, I have requested not to be contacted for future studies and I do not want my information to be shared within or outside of the department for any purposes.

Signature of participant _____

Printed name of participant _____

Date _____

I have discussed the proposed research with this individual and, in my opinion, they understand the benefits, risks and alternatives (including non-participation) and are capable of freely consenting to participate in this research.

Signature of investigator obtaining consent _____

Printed name of investigator obtaining consent _____

Date _____