Evaluating the Efficacy of Combined Cognitive Processing Therapy and Stellate Ganglion Blocks for PTSD

NCT06570213

Protocol ID 23091404

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RUSH

Consent/Authorization for Participation in a Research Study

Project Summary	
Protocol Title	Evaluating the Efficacy of Combined Cognitive Processing Therapy and Stellate Ganglion Blocks for PTSD: A Randomized Controlled Trial
Site Principal Investigator	Philip Held, PhD
Department	Department of Psychiatry and Behavioral Sciences
Site Address and Contact Information	325 S. Paulina St, Suite 200 Chicago, IL 60612 312-942-1423
Sponsor(s)	Department of Defense

Name of Participant: _____

Key Information:

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

This consent (permission) form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected.

The **purpose** of this study is to understand if we can improve the treatment for posttraumatic stress disorder (PTSD). We are looking into whether the combination of Stellate Ganglion Block (SGB) treatment and Cognitive Processing Therapy (CPT) can reduce symptoms of PTSD. CPT is a trauma-focused talk therapy that can help you identify and challenge unhelpful trauma-

related beliefs about yourself, others, and the world. It is known to be a highly effective talk therapy for PTSD. SGB treatment is a procedure involving an injection of local anesthetic into a bundle of nerves located in the neck that is part of the sympathetic nervous system, which controls our body's response to stressful situations and blocks pain.

In this study, you will be randomly assigned (assigned by chance, like the flip of a coin) using a computer algorithm to receive either two active SGB injections or two placebo (saline) injections. A placebo is a non-active substance that does not have any actual effect on PTSD symptoms, and it will be used to help us measure the effect of the SGB procedure.

Following this random assignment, you will then be randomized again to either receive 1-week of CPT or 1-week of daily symptom monitoring. Daily monitoring is when you check in with a member of the study team about how you are feeling and review daily symptom scores from your surveys. The purpose of randomly assigning you to these groups is to determine if the treatment is effective by comparing treatment groups.

If you agree to participate in this study, your participation may last up to seven and a half (7.5) months. The baseline visit may be done in one to two (1-2) sessions based on your scheduling availability and will be done virtually via a telehealth platform called Microsoft Teams.

If you are deemed to be eligible for this study, you will be asked to:
(1) Participate in either two (2) 50-minute CPT sessions per day within 5 days (10 sessions total) OR five (5) sessions of Daily Monitoring (1 session per day over 5 days). You will be randomly assigned to only one of these groups.

(2) Have two (2) SGB injection visits (about 30 minutes per visit), one before starting CPT or daily symptom monitoring, and one after. You will be randomly assigned to receive an active SGB injection OR a placebo (saline) injection.

(3) Wear a sensor device (a Fitbit) that collects heart rate variability information for up to 6 months. We will mail the sensor device to you after the virtual baseline assessment visit, but before you start treatment. You will be asked to wear the device on your wrist from the baseline assessment visit to the 6-month follow-up assessment visit (approximately 6 months).

(4) Complete study-related assessments. During assessment visits, you will be asked to complete interviews and self-report surveys that ask about demographic information, mental health symptoms, and trauma-related thoughts. For a detailed description of study procedures, please see the "*What are the activities you will be doing if you participate in this study?*" section of this consent form.

There are **risks** to you for participating in this study. There is a risk of feeling temporarily distressed during CPT treatment. CPT is a commonly used treatment for PTSD that is well-

supported by research and is recommended as a first-choice treatment in guidelines published by the Veterans Administration and the Department of Defense. Research has shown CPT to be both effective and safe. Any increased distress tends to decrease over the course of treatment. All sessions will take place during regular business hours and clinical staff will be available to assist in the case of distress or a crisis. We will also obtain the contact information of a trusted individual who resides no more than a 20-minute drive from you, if available. Should you experience increased distress during any of the visits, we will first contact your trusted individual to complete a wellness check before we reach out to 911/emergency services for a formal wellness check. If you experience an emergency or a life-threatening medical situation during a telephone/video assessment or treatment session, call 911 or go to your nearest emergency room immediately.

Although unlikely, there is also a risk of loss of confidentiality if your medical information or identity is obtained by someone other than the investigators. To prevent this risk, all study staff will work very hard to make sure that all data is stored securely so that only members of the study staff will have access to data that could identify you. No data that could identify you will ever be revealed to any outside parties without your consent. Your identity will not be revealed in any report, publication, or at scientific meetings.

SGB treatment has been shown to be effective and safe. Following the procedure, you may feel a warmth or tingling sensation in your arm or face. The injection site may be painful and may become bruised. Some people experience the feeling of a lump in their throat or experience voice hoarseness. For a detailed list of risks, you should know about, please see the "*What are the risks and discomforts of participating in this study?*" section of this consent form.

You may **benefit** from taking part in this study. Researchers have demonstrated that CPT is effective at reducing symptoms of PTSD. Researchers believe that SGB may reduce PTSD symptoms as well. You have the option to not participate in this study and may discontinue at any time. Your only other option to participating in this study is to not participate.

Detailed Information: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

Why are you being invited to participate in this study?

You are being asked to participate in this study because you are at least 18 years of age and have experienced a traumatic event in your lifetime.

How many participants will take part in this study?

Approximately 180 participants will be enrolled in this study at Rush University Medical Center.

What are the activities you will be doing if you participate in this study?

Intake Assessments

After you have provided your consent and you receive a copy of this informed consent form, you will be asked to meet with a qualified member of the study team for an intake assessment during which you will be asked about several mental health symptoms. This visit will occur via Microsoft Teams, a telephone/video platform. The virtual baseline assessment session will be recorded so it can be reviewed by the assessor and principal investigator (PI) to help determine your eligibility (if you can join the study). You will also be asked to complete surveys either before or after you complete the virtual baseline assessment. The baseline assessment may be completed in 1-2 virtual visits based on your scheduling availability.

You will be told if you are eligible or not by a member of the study staff. If you are eligible, you will be sent a wearable sensor device (a Fitbit) to wear on your wrist to measure your heart rate variability. Heart rate variability is a measure of the variation in time it takes for your heart to beat, and may be a sign of your overall heart health. We will send the device to you through the mail. You will be asked to wear the Fitbit for the entire duration of being in the study.

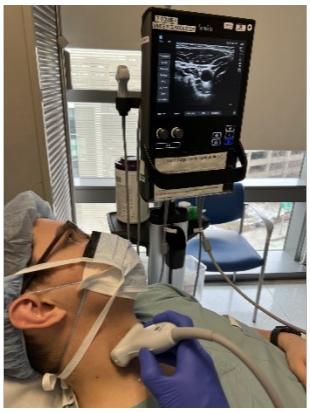
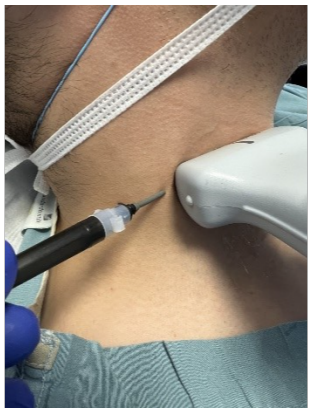
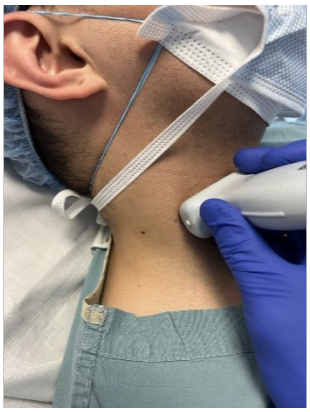
To be eligible to participate in this study, you must have a personal smartphone that you can use for the duration of the study.

SGB or Placebo Injection Visits

You will then be asked to complete two separate visits to the Rush Pain Clinic to receive an SGB injection or a placebo saline injection. Each visit will last approximately 30 minutes. You will be asked to schedule a second visit two (2) weeks after your first injection.

You will be informed about which SGB or placebo condition you were assigned to following the completion of your 6-month follow-up assessment. If you are either ineligible or eligible but are no longer interested in participating in the present study, we will provide you with appropriate referrals to other resources at Rush University Medical Center or in the community, as needed.

During your visit to the Rush Pain Center to receive your injections, a medical assistant will attach an electrocardiogram (ECG, a test that measures the electrical activity of the heart), non-invasive blood pressure, oxygen saturation, and respiratory monitors. You will then be allowed to adapt to the room for 10 minutes. You will be moved to a supine position (i.e., lying down) and an IV catheter will be placed into a vein in your arm. A nasal cannula (a tube that delivers oxygen directly to your nostrils) will be placed in your nose and deliver oxygen.The anesthesiologists will discuss the procedure with you. An ultrasound system will be used to view the anatomy of your neck and needle position.

The images above show the procedure and the injection site area.

For the SGB procedure, your neck will be sterilized and numbed using a local anesthetic medication (lidocaine). An ultrasound device will also be placed on your neck to help with visualization. If you are assigned to the active SGB group, you will then be injected with 7ml (about 1.5 teaspoons) of 0.5% bupivacaine (an anesthetic medication used for the SGB procedure) at the side of your neck. If you are assigned to the placebo injection group, the same procedure will occur, but you will be injected with saline at the side of your neck. These injections will be administered by a study doctor, who works at the Rush Pain Clinic and is trained to conduct the SGB procedure.
After the procedure is complete, you will not be able to drive or operate heavy machinery for at least 24 hours. Therefore, you will need to arrange transportation by someone else following the procedure.

You will be asked to have two injections approximately two weeks apart. A member of the study team will help you schedule these appointments and will make every effort to work with your schedule.

If you are either ineligible or eligible but are no longer interested in participating in this study, we will provide you with appropriate referrals to other resources at Rush University Medical Center or in the community, as needed.

Cognitive Processing Therapy or Daily Monitoring Sessions
After your first injection, study staff will randomly assign you using a computer algorithm to either receive daily CPT sessions (2 sessions a day for 5 days, Monday- Friday) or daily symptom monitoring sessions (1 session a day for 5 days, Monday-Friday). Each CPT session will last approximately an hour, and each daily symptom monitoring session will last approximately 15 to 30 minutes.

CPT is a talk therapy that can help you identify and challenge unhelpful trauma-related beliefs about yourself, others, and the world. Doing so will help you develop more balanced views and

behave in more adaptive ways that can be helpful in your recovery. You will participate in 10 1-hour-long sessions, which will occur twice per day for 5 consecutive days.

Daily monitoring is when you check in with a member of the study team about how you are feeling and review daily symptom scores from your surveys. These sessions will last approximately 15 to 30 minutes and take place once a day for 5 consecutive days.

All sessions will be video- and audio-taped.

Follow Up Assessments
You will be asked to complete several virtual follow-up visits following treatment where a member of the study team will complete assessments with you about your symptoms and mood. These follow-ups will take place 1 week after treatment completion (your second SGB or placebo (saline) injection), 1 month after treatment completion, 3 months after treatment completion, and 6 months after treatment completion. At these time points, you will also be asked to complete surveys about your symptoms which will be sent to you via email. At your 6-month follow-up, you will be asked to return the Fitbit device to the research team. You will be provided a pre-paid shipping label in order to do so.

What are the risks and discomforts of participating in this study?
There are risks to you for participating in this study. One potential risk is that you may experience some distress when sharing personal information during the interviews and CPT if you receive that treatment. Any distress from CPT is expected to reduce over time.

During the SGB or placebo (saline) treatment, you may feel a warmth or tingling sensation in your arm or face following the injection. The injection site may be painful and may become bruised. When the bupivacaine anesthetic begins to affect the nerve bundle, you may feel a lump in your throat or experience voice hoarseness (scratchy or raspy voice). Subjects who experience hoarseness will be advised not to eat or drink for six hours after the block. Subjects may also develop nasal congestion, especially on the side of the injection, or may even develop a headache. Side effects should disappear within 4 to 6 hours. Horner's syndrome revealed by a decreased pupil size, a drooping eyelid, and decreased sweating on the side of the face on which the block was placed may occur. Prior studies suggest that Horner's syndrome will occur in approximately 70% of subjects and will resolve within 4 to 6 hours of the block.

You will be instructed not to drive and/or operate heavy machinery for 24 hours after the procedure.

Side effects, risks, and/or discomforts from the Bupivacaine (anesthetic) injection as part of the SGB treatment may include:
Common side effects (>10%):

- Hypotension (low blood pressure)

- Bradycardia (slow heart rate)
- Nausea
- Vomiting
- Back pain
- Horner's syndrome (decreased pupil size, a drooping eyelid, and decreased sweating on the side of your face on which the block was placed) that resolves within a few hours

Less common side effects (1 to 10%):

- Chest pain
- Hypertension (high blood pressure)
- Tachycardia (fast heart rate)
- Headache
- Pain
- Paresthesia (abnormal sensation such as tingling, numbness, prickling, burning, chilling)
- Dizziness
- Chills
- Hypoesthesia (numbness)
- Anxiety
- Pruritus (itching)
- Hypokalemia (low potassium)
- Oliguria (low urine output)
- Urinary retention (bladder not emptying completely)
- Urinary tract infection
- Anemia (low levels of healthy blood cells)
- Muscle cramps
- Dyspnea (shortness of breath)
- Rhinitis (stuffy nose)
- Fever

Rare side effects (<1%):

- Agitation (irritation)
- Amnesia (memory loss)
- Angioedema (swelling under the skin)
- Asthenia (weakness)
- Atrial fibrillation (irregular heartbeat)
- Auditory disturbance (having trouble hearing sounds or understanding words)
- Blepharoptosis (droopy eye)
- Bronchospasm (difficulty breathing)

- Cardiac arrhythmia (irregular heartbeat)
- Change in vision
- Coma
- Confusion
- Cough
- Deep vein thrombosis (blood clot in deep vein)
- Drowsiness
- Dyskinesia (involuntary muscle movements)
- Electrocardiogram (ECG) abnormality
- Emotional lability (rapid changes in mood)
- Extrasystoles (extra, abnormal heartbeats)
- Fecal incontinence (inability to control bowel movements)
- Hallucination
- Hypersensitivity reaction (allergic reaction)
- Hypokinesia (slowed or reduced muscle movement)
- Hypomagnesemia (low level of serum magnesium)
- Hypothermia (low body temperature)
- Hypotonia (decreased muscle tone)
- Insomnia (having trouble sleeping)
- Jaundice (yellow tint to skin and eyes)
- Malaise (general discomfort)
- Myalgia (muscle pain)
- Myocardial infarction (heart attack)
- Nervousness
- Neuropathy (nerve numbness or weakness)
- Nightmares
- Orthostatic hypotension (form of low blood pressure)
- Pain at injection site
- Paresis (partial paralysis)
- Phlebitis (inflammation of veins)
- Pulmonary embolism (blood clot in lung)
- Seizure
- Skin rash
- ST segment changes on ECG (change in waves measured on ECG)
- Stupor (state of near unconsciousness)
- Syncope (fainting/temporary loss of consciousness)
- Tenesmus (continuous feeling of needing to evacuate bowel)
- Tinnitus (ringing in ears)

- Tremor (involuntary shaking)
- Urinary incontinence (involuntary leakage of urine)
- Urticaria (hives)
- Vertigo (dizziness)

Side effects, risks, and/or discomforts from the lidocaine injection as part of the SGB treatment may include:

- Allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue
- Breathing problems
- Changes in vision
- Chest pain
- Feeling faint or lightheaded, falls
- Headache
- Seizures
- Slow, irregular heartbeat
- Trembling or shaking
- Unusually weak or tired
- Anxiety or nervousness
- Backache
- Feelings of cold, heat, or numb
- Irritation at site where injected
- Nausea
- Vomiting

While SGB treatment is a safe procedure, there may be pregnancy/fetal risks for women of childbearing age/potential. Therefore, if this applies, you may be asked to discuss the procedure with a doctor that is a member of the research team (i.e., a study doctor) to ensure that the procedure will be safe regarding your specific risks.

There is a risk of loss of confidentiality. To minimize this risk, all participants will be assigned a participant study number that will be used to identify them. Only study team members will have access to the study data. There may be other risks that may happen that we cannot predict.

What if there is new information that may affect your decision to participate in this study?
During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

Can you leave or be removed from this study?
You have the right to leave the study at any time without penalty. For your safety, however, you should consider the study doctor's advice about how to leave this study. If you leave this study before the final study visit, the study doctor may ask you to complete the final steps. You can ask that your study-related information be removed from the study at any time. However, it may not be possible to withdraw or delete your information in cases when it has already been shared with other researchers. The removal of any study-related data does not include any information that may be stored on the secure Rush network server. Upon leaving the study, you will be given appropriate referrals to Rush University Medical Center or other community resources as needed.

If you become actively suicidal with intent, the study clinician will refer you to a higher level of care (i.e., psychiatric, medical, or emergency services). You will no longer be able to continue in this course of CPT, but may be able to enroll at a later time after reaching stability per eligibility requirements.

The researchers have the right to stop your participation in this study without your consent if:
(1) they believe it is in your best interests;
(2) you do not follow the instructions; or
(3) the study is canceled for any reason.

What about the confidentiality of your medical information?
This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold (keep back) or refuse your treatment, payment, enrollment, or eligibility for benefits if you do not sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. Philip Held, his study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information (the personal information we collect about you) that identifies you for the study described in this document.

During the study, Dr. Held and his study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. Some of this information will come from your medical record. The health information that Rush may use or disclose for this research includes:

- Name
- Dates related to study visits and length of study participation
- Email address
- Telephone number
- Medical Record Number or Health Plan beneficiary number, if applicable
- Responses to self-report assessments
- Audio and video recordings of sessions and copies of session materials

Dr. Held and the study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. The people who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- De-identified video recordings will be sent to approved external collaborators for analysis
- Monitoring agencies such as the Department of Defense
- The University of Illinois-Chicago

While you participate in the study you will have access to your medical record but Dr. Held is not required to release study information to you that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. The results of study tests/procedures performed as part of this study may become part of your medical record. Any study information in your medical record will be kept indefinitely. Your identity will not be revealed in any report, publication, or at scientific meetings. If you agree to be video recorded, all study visits will be recorded. If you consent to this in the checkbox below, video recordings will be shared with our collaborators for the purpose of data analysis. All audio and video recordings collected for research will be uploaded to the secure Rush University Medical Center server within one business day and will be deleted from the recording device immediately upon upload. Transcriptions of interview recordings will be stored on the secure server as well and will only be accessed by members of the study staff. Electronic copies of CPT worksheets will be stored in a secure folder and will be accessed only by you and members of the study staff. After your final visit, the worksheets stored in this folder will be deleted and copies will be uploaded to the secure Rush University Medical Center server. You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed below.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Held at 325 S. Paulina St, Suite 200. If the authorization is revoked, you will no longer be allowed to participate in the study, and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety (the entire time) of this research study. It will expire when the study is completed or withdrawn if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. All information and data collected in the study will be stored on the RUMC secure server or

in a secure, locked cabinet in the Department of Psychiatry. Only members of the study staff will have access to identifiable data. No identifiable data will ever be disclosed to outside parties. De-identified data may be reported in aggregate (with other participants' data) for internal clinical use, publications, or other presentations. In order to conduct the study, the study investigators will use and may share personal health information. This includes information already in your medical record, as well as information created or collected during the study. Any data shared will have all identifying information removed and will be assigned a unique study code. When identifying data cannot be removed (as in the case with audio and video files), they will be provided with a unique study code and stored in a separate and secure network location.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. This research study can be found by searching for the following Clinical Trial Registry Number (NCT#): NCT06570213.

Certificate of Confidentiality

To help us protect you and the information we will be collecting from you, this study has obtained a Certificate of Confidentiality by the U.S. government. This Certificate means that researchers cannot be forced, even by courts or the police, to disclose any information about you.

The Certificate does not stop you from disclosing, or agreeing in writing to allow researchers to disclose information about you. For example, if you would like an employer or insurer to know something about you that is documented in this study, you can write and sign a statement telling the researchers it is okay to give your employer or insurance company information.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research participants;
(4) for the purpose of auditing or program evaluation by the government or funding agency

A Certificate of Confidentiality does not prevent you from voluntarily releasing information

about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. Please contact the investigator for more information on how to provide this consent.

If you disclose actual or suspected abuse, neglect, or exploitation of a child, or disabled or elderly adult, the researcher or any member of the study staff must, and will, report this to Child Protective Services (such as the Department of Family and Human Services), Adult Protective Services, and/or the nearest law enforcement agency.

What are the costs to participate in this study?

Neither you nor your insurance will be billed for any equipment or services provided as a part of this studyThese expenses will be paid for with grant money from the study's sponsor, the Department of Defense. However, you will be responsible for your phone/internet service provider's standard charges as they apply to any study-related phone calls or video sessions. . Participating in this study may cost you additional money if you do not have an unlimited data/call plan. You are also responsible for the cost of transportation to and from the SGB/placebo saline injection visits, including the cost of parking.

Will you be paid for your participation in this study?

You will be paid up to $330 for completing all of the study-related assessments. Participants will be paid via an electronic gift card once they have completed all assessments for each time point. If you do not finish this study, you will be paid for the study visits you have completed. Payment for completion of surveys and assessments is based on a study team member checking to make sure survey responses are accurate.

In compliance with federal regulations, service members and federal civilian employees cannot be compensated for completing study procedures while on active duty.

Compensation is detailed in the table below.

Baseline	1-Week Follow-Up	1-Month Follow-Up	3-month Follow-Up	6-month Follow-Up
$40	$40	$50	$100	$100
				Total: $330

What if you are injured as a result of your participation in this study?

If you get ill or injured from being in the study, Rush University Medical Center will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Held at telephone number 312-942-1423.

You should let any healthcare provider who treats you know that you are in this study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact your study doctor.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover the costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries that may incur as a result of participation in this study.
By signing this form, you are not giving up any legal rights to seek compensation for injury

What other information should you know about?

Investigator Dual-Role

If your doctor is also the person responsible for this study, please note that he is interested in both your clinical care and the conduct of this study. You have the right to discuss this study with another person who is not part of the research team before making your decision whether or not to be in the study.

Who can you contact for more information about this study?

Questions are encouraged. If you have further questions about this study, you may call Dr. Philip Held at 312-942-1423 or email him at Philip_Held@rush.edu.

Who can you contact if you have concerns about your rights as a study participant?

Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?

Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits, or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Philip Held in writing at the address on the first page. Dr. Philip Held may still use your information that was collected before your written notice.

SIGNATURE BY THE PARTICIPANT:

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent/authorization form. You will be given a signed copy of this document.

Name of Participant _____

Signature of Participant _____

Date of Signature _____

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Name of Individual Obtaining Consent: _____

Signature of Individual Obtaining Consent _____

Date of Signature _____