# STUDY INFORMED CONSENT

## Written Exposure Therapy to Improve Lives after Stress Exposure (WISE)

**NCT number** NCT05390775
**Document Date** 01/17/2020

**University of North Carolina at Chapel Hill**
**Consent to Participate in a Research Study**
**Adult Participants**

**Consent Form Version Date:** 1/17/2020
**IRB Study #** 21-3008
**Title of Study**: WISE Trial: Written Exposure Therapy to Improve Lives after Stress Exposure
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**Funding Source and/or Sponsor:** Department of Veteran Affairs

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## Concise Summary

The purpose of this research study is to test a particular therapy in decreasing negative symptoms after motor vehicle collision. If you choose to participate you will be asked to attend five weekly telehealth writing therapy sessions via Zoom, which will last about one hour each. You will also be asked to complete four hour-long online surveys. Your participation will last three months. Potential risks involved in participation in this research study include emotional distress while you complete questionnaires and treatment sessions, and risk of release of your personal information. You may not receive any direct benefit from participating in this research study.

## What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

## What is the purpose of this study?

The purpose of this research study is to test a particular therapy in decreasing negative symptoms after motor vehicle collision. You are being asked to be in the study because you received

services in the emergency room after experiencing a motor vehicle collision and meet study eligibility criteria.

**Are there any reasons you should not be in this study?**

You should not be in this study if you are a prisoner, are pregnant or breastfeeding, are deaf or blind, or do not speak and read English fluently. You should not participate in this study if the traumatic event that brought you to the hospital resulted in admission to the hospital. You should also not participate in the study if the traumatic event that brought you to the hospital was the result of you trying to hurt yourself/injure yourself on purpose, or you have had a change in any psychiatric medications (including dose) in the last month, or if you are currently receiving exposure based psychiatric treatment. If you are experiencing ongoing domestic violence or abuse, you should not participate in the study and should tell one of the hospital care providers and/or call 1−800−799−7233. In addition, to be eligible for the study you must be 18 years of age or older and have a smart phone (cell phone with internet access) that you do not share with multiple people, must have had the same smartphone number for more than a year, and must not have lost smartphone service in the past year because you were unable to pay your bill. You must be willing to complete five weekly therapy sessions via videoconference. You must also have an email account that you check regularly that can be used to reach you, be willing and able to receive text and email messages related to the study, and have a mailing address where you can receive mail.

**How many people will take part in this study?**

Approximately 50 people at multiple institutions will take part in this study.

**How long will your part in this study last?**

Your participation in the WISE Study will last for about three months. You will be asked to attend five weekly therapy sessions via videoconference, which will each take one hour at most. You will be asked to complete occasional comprehensive surveys which are expected to take about 45-60 minutes to complete.

**What will happen if you take part in the study?**

Study participation would include the following:

*Intervention:* You will be randomized (like the flip of a coin) into one of two study arms. One is the experimental condition (the treatment we are testing) and the other is a control condition (for comparison to the experimental condition). Both arms involve five weekly writing therapy sessions. You will be asked to complete these five weekly writing therapy sessions during your participation in the study. The sessions will be conducted on your computer/smartphone via videoconference. Each session will take about an hour at most, and you will be asked to write for 30 minutes based on your therapist's instructions. Therapy sessions will be recorded.

*Surveys:* You will complete an assessment today or before your first treatment session that will consist of questions about you, how you are feeling, and your current and past health. You will complete the second part either by interview or by answering questions yourself on a computer or tablet. After your initial study assessment, we will also ask you to complete follow-up assessments in around four weeks, eight weeks, and three months. You can complete these

questions at a time that is convenient for you, and you can either complete them by telephone interview or by web-based survey. Each follow-up assessment will take approximately 45-60 minutes. These assessments will include questions about your past and current health, how you have been feeling, and any treatment that you received. During any of the assessments, you may refuse to answer any questions.

*Study Reminders:* You will receive reminders by email, text, phone, and/or mail when it is time to complete the various assessments in the study. Most phone calls and contacts will be made by a member of the WISE Study coordinating team. The study coordinating team is based at the University of North Carolina, in Chapel Hill, NC. The information that you provide to us today (name, phone number, email address, mailing address, and two personal contacts) is available to the WISE Study coordinating team through our highly secure study server. Since they will also be responsible for ensuring that you are paid for study activities, we will ask you to provide your social security number (SSN) and sign a document for them. If we are having difficulty reaching you, a member of the study team may also contact you through social media (for example, Facebook or LinkedIn). You may also receive a birthday and New Year's Day communication from the study team to wish you well.

*Hospital medical care records:* We will record basic information from the hospital medical care records about your past and current health, the reason for your emergency department or hospital visit, x-rays and tests performed in the emergency department or hospital, and any medications that you received.

**Unencrypted Communication Statement**:
The study team would like to message you by text messaging, however you may say "no" to receiving these messages and still participate in this study. If you say "yes", messages may contain personal information about you and may be sent or received by the study team's personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team. This information may include information such as reminders and notifications to contact the study team.

If you wish to stop receiving unprotected communication from the study team or have lost access to your device, please notify the study team using the study contact information on the first page of this consent form. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving unprotected communication, you will no longer receive un-encrypted (un-protected) messages specific to this study.

_____ Yes, I consent to the study team utilizing the following cell phone number to send communication: _____

_____ No, I do not consent to receive un-protected communication from the study team.

**What are the possible benefits from being in this study?**
Research is designed to benefit society by gaining new knowledge. There is little chance you will benefit from being in this research study.

**What are the possible risks or discomforts involved from being in this study?**

*Surveys and assessments:* You may face some sensitive questions during the interviews. These questions may cause you to experience some unpleasant or stressful feelings. However, we have taken measures to try and make this process as comfortable for you as possible.

*Study data confidentiality:* The greatest risk to you is the release of your study data information. Many steps have been taken to prevent this. These steps include: (1) All personnel involved in the study complete training in the protection of study participant's information, (2) All personnel sign a pledge of confidentiality, (3) The research team has obtained a Certificate of Confidentiality from the federal government to help ensure the complete anonymity of all of your records, (4) Survey forms, biological sample tubes, and survey data use your participant ID number only (or in the case of biological samples, a separate sample ID number) rather than personally identifying information such as your name, (5) Only approved WISE Study personnel will have access to your personally identifying information, and they will only be able to use this information to conduct the study (for example, to call you to schedule a follow-up appointment), (6) Web servers storing study data will be stored behind firewalls, and only known and approved users will have access. (7) Study data will be protected by multiple layers of computer and human security (128-bit encryption). (8) Your personally identifying information and study data will be kept in different computer files, and generally on different servers, providing an additional layer of protection. (9) The key to the code that connects your name to your study information will be destroyed at the conclusion of the study, at the latest by September 2025. At that point, all of your study information will be de-identified. De-identified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. (10) Study data containing personally identifiable information will be kept at the WISE Study Data Coordinating Center at the University of North Carolina (UNC). De-identified study data will be stored and analyzed by approved WISE Study investigators and collaborators. (11) Overall, the chance that any study information would be given to someone else is very small.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

**If you choose not to be in the study, what other treatment options do you have?**

You do not have to be in this research study in order to receive treatment.

**What if we learn about new findings or information during the study?**

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

**How will information about you be protected?**

Records of your participation in this study will be kept in locked file cabinets in locked research offices at the WISE Study Data Coordinating Center at the University of North Carolina (UNC) and, as described above, on servers with multiple layers of protection at the University of North Carolina. No study participants will ever be identified in any report or publication about this study. De-identified data may be used for future research without additional consent. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very

unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

**What is a Certificate of Confidentiality?**

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you 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.

You will be asked to sign a separate form ("HIPAA Authorization") to allow researchers to review your medical records.

**What will happen if you are injured by this research?**

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do. By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

**What if you want to stop before your part in the study is complete?**
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

**Will you receive anything for being in this study?**
You can receiving up to $250 for taking part in this study (see table below). Any payment provided for participation in this study may be subject to applicable tax withholding obligations

| Activity | Payment |
|---|---|
| Screening in Emergency department | $10 |
| Pre-Treatment Survey | $60 |
| Week 4 Survey | $60 |
| Week 8 Survey | $60 |
| Month 3 Survey | $60 |

Your name, address, and U.S. tax payer identification number (SSN or ITIN) are required to process payments and/or to report taxable income to the IRS. You must complete a W-9 (for U.S. persons) or W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents (for non-resident aliens) in order to receive payment for participation.

U.S. person participants must complete Form W-9 in order to receive payment for participation. If payment by UNC equals or exceeds $600 per calendar year for U.S. persons, UNC will report the amount to the Internal Revenue Service on Form 1099. Nonresident alien participants must complete Form W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents in order to receive payment for participation. Payments to nonresident alien participants may be subject to tax withholding and are generally reported to the Internal Revenue Service on Form 1042-S. This information will not be linked to any of the study data and will only be used for payment purposes.

If you do not provide your SSN or ITIN, or complete the appropriate documentation noted above, we cannot issue you a payment for participation. However, you may still choose to participate in this study.

**Will it cost you anything to be in this study?**
It will not cost you anything to be in this study.

**Who is sponsoring this study?**
This research is funded by the Department of Veteran Affairs. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

**What if you have questions about this study?**
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**What if you have questions about your rights as a research participant?**
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

**Participant's Agreement**:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____
Signature of Research Participant

_____
Date

_____
Printed Name of Research Participant

_____
Signature of Research Team Member Obtaining Consent

_____
Date

_____
Printed Name of Research Team Member Obtaining Consent

_____
Signature of Witness if applicable; e.g. literacy issues, visually impaired, physically unable to sign, witness/interpreter for non-English speaking participants using the short form)

_____
Date

_____
Printed Name of Witness