SUBJECT NAME		**SSN: N/A**
TITLE OF STUDY	**Evaluation of Web-Based CBT for Women Veterans with PTSD**	
PRINCIPAL INVESTIGATOR	**Keren Lehavot, PhD**	

LAY TITLE: Full RCT Study

Researchers:

Keren Lehavot, PhD, Principal Investigator, Psychologist (206) 277-1511
Tracy Simpson, PhD, Co-Investigator, Psychologist (206) 277-3337

24-hour emergency contact:

- **During business hours (8:00 a.m. − 4:30 p.m.),** please call the Study Office at (206) 277-4328 or Keren Lehavot at (206) 277-1511.
- **After business hours (nights and weekends),** please call (206) 762-1010 and ask the operator to page the on-call psychiatrist.

You are being invited to participate in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study. Please read this form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide whether you want to be in the study. You are free to discuss this with friends or family. This process is called "informed consent." We will give you a copy of this form to keep for your records.

1. Purpose of research study and how long it will last: The purpose of this study is to test the effectiveness of a web-based (Internet) Posttraumatic Stress Disorder (PTSD) treatment for women Veterans compared to a phone monitoring-only condition. The web-based treatment is called DESTRESS−WV, which stands for **DE**livery of **S**elf-**TR**aining and **E**ducation for **S**tressful **S**ituations−**W**omen **V**eteran version. It is an online intervention based on cognitive behavioral therapy (CBT). The goal of CBT therapy is to help people recognize and address their thoughts and their behaviors in positive ways with the aim of influencing their feelings and their ability to function as well as possible in their lives.

In order to determine if the study is right for you and whether you are a good fit for the study, if you decide to enroll in the study you would first participate in an eligibility screening interview. This would take place over the phone and would take up to two and a half hours. The interview includes questions about your mental health, previous trauma experience, and substance use. If you are

eligible based on this screening, you would be randomly assigned to one of the two study conditions.

If you are assigned to the DESTRESS−WV intervention condition, you will receive this intervention plus weekly phone monitoring from a study coach for 8 weeks. During these 8 weeks, you will be asked to log on to the web-based (internet) treatment twice a week, complete the online activities, and complete homework assignments. If you are assigned to the phone monitoring-only condition, you will receive weekly calls from a study coach for 8 weeks to check in with you to see how you're doing.

Another part of the study involves completing online surveys. This is a way for us to track your symptoms and see how they change over time. We would ask you to complete four online surveys while you're in the study: before you begin participating in either condition, after you finish the 8-week treatment or monitoring phase, and also 3 and 6 months after you finish the treatment/monitoring phase. Each online survey would take about 60-90 minutes to complete and will include questions regarding your PTSD symptoms, depression, and quality of life.

You have been asked to participate in this study because you are a woman Veteran 18 years of age or older, are likely to have Posttraumatic Stress Disorder, have not been in specialty mental health care for the past 2 months, and you have routine access to a computer and the Internet. We expect approximately 100 participants to participate in this study. The length of time you would be involved in the study is about 9 months, with the majority of activity occurring within the first 8 weeks of either the treatment or the monitoring condition.

This study is sponsored by Clinical Science Research & Development, which is part of the Veterans Health Administration.

Whether or not you take part in this study is completely up to you, and you can decide at any time to end your involvement.

2. Description of the study including procedures to be used: If you decide to participate in this study and sign this consent form, we will then invite you to participate in a screening interview to determine if this study is a good fit for you. If you are eligible, you would participate in the study procedures outlined in the table and text below.

Overview of Study Timing and Activities:

Study Week	Study Activity
Week 1	• Provide informed consent • Complete two brief questionnaires • Complete eligibility screening interview
Week 2	If eligible, complete baseline survey online Following Baseline Survey: • Assigned randomly to study condition (i.e., like flipping a coin) • Phone call from study coach
Weeks 3−10	• Weekly phone calls with study coach for 8 weeks
Week 11	• Complete first follow-up survey online
Week 23	• Complete second follow-up survey online
Week 35	• Complete third and final follow-up survey online • Debriefing (overview of study goals)

Informed Consent and Questionnaires. We will first ask you fill out several forms and mail them back to us. These include the informed consent document, HIPAA form, and two brief questionnaires. The questionnaires ask demographic questions about your background as well as about various stressful events that sometimes happen to people. Some of the stressful events that you will be asked about include physical assault, sexual assault, and combat.

Once we have reviewed the consent forms with you by phone, we would ask you to mail the signed forms back to us should you decide to participate, along with the completed questionnaires. Once we receive the forms, we will schedule a time for the screening interview.

Screening Interview. You will be evaluated by study staff to determine if the study is right for you and whether you are a good fit for the study. This screening appointment will take place over the phone and will take up to two and a half hours. You will have the option of breaking up the call into shorter segments. The interview will include questions about your mental health, previous trauma experience, and substance use. Examples of some of the most sensitive questions you will be asked to answer are:

- "Has there ever been a time when your life was in danger or you were seriously injured or harmed?"
- "What about experiencing some type of sexual violence?"

You are free to not answer any question that you do not want to answer.

If this study is not a good match for you, we will provide you with a list of resources of websites and organizations that serve women Veterans and that focus on a variety of health concerns.

Baseline and Follow-up Surveys. If the study is found to be a good fit for you, we will ask you to complete an initial (baseline) survey online. The online survey is a set of questionnaires and will take approximately 60-90 minutes to complete. You will also be asked to complete three follow-up surveys online. These will take place at the end of the 8-week treatment/monitoring phase, and again at 3 and 6 months following the end of treatment/monitoring. These follow-up surveys will also take approximately 60-90 minutes to complete.

These surveys will involve questions about PTSD symptoms, depressive symptoms, and quality of life. The first follow-up survey will also ask about your opinions and feedback regarding the intervention you were assigned to.

If you are found to be eligible for the study, you will also be sent a form which you will fill out along with the study coach during the first call. The form is a Safety Plan, which will provide guidance as to what you can do and whom you can contact if you are feeling particularly overwhelmed or distressed.

Assignment to Study Condition. Once you are in the study, you will be randomly assigned (similar to a flip of a coin) to one of two groups, either DESTRESS−WV or phone monitoring only. Your chances of being assigned to either group are equal. Regardless of which study condition you are assigned to, a study coach will call you every week for 8 weeks.

If you are assigned to phone monitoring only:

- A study coach will call you once a week for 8 weeks for approximately 10-15 minutes. The coach will assess your PTSD symptoms and safety.

If you are assigned to DESTRESS−WV:

Study Coach

- A study coach will call you once a week for 8 weeks for approximately 10-15 minutes. She will explain how to use the website that you will need to log onto twice per week during the 8-week treatment program. During the calls, she will address your progress in the program.

DESTRESS-WV Sessions

- You will be asked to log on to the website twice per week. However, you may log on to the website anytime and as many times as you wish. From the website, you will be able to find information about specific homework assignments and review educational materials.

  You will spend about 30−60 minutes each time you log on to the website. On two occasions, you will be asked to write about current stressors, demands, or hassles. Additionally, on two occasions you will be asked to write about a traumatic experience. You will be guided in using various coping skills taught in the program during this writing process.

DESTRESS-WV Homework

- Homework is assigned for each session (e.g., for each time you log into the website), and you would be required to complete the homework before you could move on to the next session. The homework assignments will require both time and effort. They will include stress management skills that you will be asked to practice and apply in your daily life.

DESTRESS-WV Security Basics

- The web page has been developed so that only you will be able to log onto the web page using a personalized username and password. You can log in as often as you want; however, you will have to enter your username and password each time. The log-in page will not reveal any information about the study.

- You will be given a study identification number during your initial phone call with the study coach that you will use for all communications done on the web (internet). This will help protect your identity and information. Also, only authorized study personnel (trainers, evaluators, and investigators) will be allowed to access your web-based data (internet). We suggest you access the website only in private/secure physical surroundings (such as at home rather than at the library or at work). This will help to reduce the risk of accidental breaches of security by onlookers, family members, coworkers, and supervisors.

  At the end of the data collection period for each participant, all the research information that was stored on the web server will be transferred to a non-web-based storage VA computer for evaluation. The records will not be used for any other research study or any other purposes.

The screening interview and phone calls with the study coach will be audio-recorded. We recognize that confidentiality of your information and securing your data on the website is critical. Please refer to Section 7 for steps we will take to protect your confidentiality and web-stored data.

After Study Treatment. The treatment/phone monitoring phase of the study is designed to last 8 weeks but may take up to 12 weeks. At the end of this time, you may feel that this was enough to meet your needs or you may feel that you need more treatment. If you feel that you need more treatment, you are welcome to pursue that either at the VA or in the community. We will give you a list of resources at the end of the treatment phase of the study as well as at the very end of study. However, the study cannot provide treatment beyond the treatment phase.

Maintaining Contact with Participants. Because the study takes place over 9 months' time, it will be important for us to be able to keep in good contact with you. If the study is a good fit for you, we will need to know how to get in touch with you if your phone is disconnected or if we are having trouble reaching you for some other reason. We will ask you for the name and contact information of at least one person who is likely to know where you are if we can't reach you. We will also ask you to update your contact information while you are involved in the study. If we are concerned about your whereabouts and safety, we may also access your Electronic Medical Record for additional information.

3. Description of any procedures that may result in discomfort or inconvenience: You may experience discomfort when answering questions that are sensitive for you, but you always have the option of not answering any question that you do not wish to answer. For example, during the screening evaluation, you will be asked to describe stressful events you experienced, and this may be upsetting to you. Also, with any mental health treatment for PTSD, you may experience a temporary increase in the severity of PTSD symptoms during certain portions of the treatment program. This may be especially true if you have tried very hard to avoid thinking about painful things from the past. Please tell the study coach if this is happening so she can work with you to lessen this possibility and help you get through it if it does occur.

If an emergency situation arises, you should not wait for a reply from the study coach. Instead, you should proceed immediately to your nearest emergency room, call 911, or call the Veterans Crisis Hotline at 1-800-273-8255 (TALK), and press 1.

If you are randomized to the DESTRESS-WV condition, you will also be asked to complete treatment homework assignments and to log on to the website twice per week during the 8-week treatment program. This may be an inconvenience for you. If you have never accessed the Internet before and/or if you don't know how to use a computer, you may experience some frustration with learning the study procedures.

Your participation in the study is completely voluntary and you may choose to not answer any question that you wish or discontinue your participation in the study at any time.

4. Potential risks of the study: There is a possible risk of loss of confidentiality (people not involved in the research study finding out personal information about you). Although we will make every effort to keep your information confidential, no system for protecting your confidentiality can be completely secure. It is still possible that someone could find out you were in this study and could find out information about you.

We will audio-record the screening interview and the phone calls with the study coach. These calls will be audio-recorded to make sure that study personnel are saying things that are consistent with study goals. Please note that your voice is technically identifiable according to patient privacy rules, so we will do everything possible to protect your voice identity. This recording may be transcribed (written down word for word) so that approved study staff members will be able to review your responses as part of the data collected for the study.

Additionally, recordings may be reviewed by approved study staff during data analysis to make sure that the transcript accurately captured what was said and how it was said. You will have the right to review and mark for erasure any portions of the audio-recording.

The use of the website to store personal information is not without risks. It is important that you use the website in private so that people around you can't access your information. This will help reduce the risk of accidental breaches of security by onlookers, family members, co-workers, and supervisors.

When you visit a website on the computer, things called "cookies" are usually left behind. Cookies are little bits of information that can be used to trace back to your user ID or email address. When you sign in on the study website, there might be a chance that cookies could be left behind and that could possibly lead back to you at your computer address. There are two ways that we will try to keep this from happening:

- The web designers have used something called a "session variable" concept to remove cookies from your browser as an additional way to protect your confidentiality. A session variable is used so a website can recognize your log in and give you access to certain sections of the website. Any time you log onto the study website, a unique session variable will be randomly generated. This session variable will expire and be automatically removed from your computer when you log out from the site.

- The other way to help protect your privacy is for you to use a computer that no one else uses at a time that you will not be interrupted. In addition, to be extra careful, we recommend that after each time you are on the study website, you delete the study site files and history from your browser. The study coach will explain to you how to do this during the initial phone call.

You will be asked not to leave your computer unattended while logged on to the website. If, for whatever reason, you get called away, it is important that you remember to close the session and not leave it open for others to see. If you have to use a public computer, like at a library or clinic, be sure to allot enough time to complete the session. Do not leave the computer unattended while you are logged into the website, and remember to delete the cookies and history from your browser at the end for extra security. If, for whatever reason, someone without permission views your responses, please notify the study coach.

If you suspect that someone has logged on with your username and password, please notify the study coach immediately, so that she can assign you a new username and password.

For details on the steps we will take to secure your privacy and confidentiality, please refer to Section 7.

The particular treatments or procedures in this study may involve risks that are currently unforeseeable. We will contact you as soon as possible if new findings occur during this research that may pose a risk to you.

5. Potential benefits of study: There may be no direct benefit to you from participating in this research. However, you may benefit by learning more about yourself by being in the study. If you are in the DESTRESS condition, you may benefit from the treatment that you are provided and skills that you learn. The phone monitoring condition may help you because you get a chance to track your PTSD symptoms over time. No benefit, however, can be guaranteed.

The findings from this study may benefit society by finding out if DESTRESS−WV is a good treatment option for women Veterans with PTSD.

6. Other treatment available: If you choose not to participate in this study, you could receive other treatments for your PTSD either at the VA or in the community. We will provide you with a list of information and resources if you wish.

7. Use of research results / Confidentiality: The information obtained about you will be held confidential. However, for purposes of this study, the following list of people or groups may know that you are in this study. They will have access to your records, which may include your medical records:

- Research team members at the VA
- Programming staff at Novus Origo, which programs and hosts DESTRESS-WV
- Clinical Science Research & Development (CSR&D) under the Veterans Health Administration
- Federal agencies including, but not limited to, the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), the VA Office of the Inspector General (OIG), and the Government Accounting Office (GAO)
- The VA committees that oversee research, including the Institutional Review Board that oversees the safety and ethics of VA studies
- Transcriptionists sanctioned by the VA Puget Sound IRB and Information Security Officer
- VA staff responsible for subject payments will be provided with your full name, address, and social security number in order to authorize payment for your participation in this study

The purpose of this access is to review and administer the study and make sure that it meets all legal, compliance, and administrative requirements. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy.

Identifying information about you (such as your name, mailing address, phone number, social security number) will be kept separately from other data. A link between identifying information and other information you provide as part of the study will be kept in a separate, secure location. Your information will be identified using a Study Identification (ID) Number randomly generated for research purposes. Your name will not be connected to your data. Your Study ID will be saved in a database along with study data, and your personal information will be stored in a separate file so that none of your answers will be stored with your identifying information. Only you and the researchers will know the Study ID. If you are assigned to the DESTRESS-WV condition, your Study ID will be used as your username to access the website, and you will also be assigned a unique password in order to access the website.

All of your study data, meaning the information that you provide the researchers in the screening interview, online surveys, in coaching calls, and on the website, will be saved at VA Puget Sound Health Care System using transmission and storage procedures that meet VA standards for information security.

Your name and contact information will be accessible only to approved research staff for the purposes of contacting you to complete the study and paying you for your participation. Please note that we will keep a list of names and completion status of all who participated in our research study.

This is so that we can be sure that you have no problems in receiving payment for participating in our study.

Once this study is completed, we will not use the study code linking you to your data for any additional research. The code linking you to your data will be held in a secure database until the VA receives authorization to destroy them in accordance with federal records regulations. It may be several years before the code linking you to your data is actually destroyed. All coded data will be stored on secured computers or in file cabinets in locked offices. These coded data will be kept indefinitely.

Online Surveys. You will be using the website Survey Monkey to complete online surveys for this study (https://www.surveymonkey.com/). Survey Monkey is not a VA system and is not managed by the VA. It is a commercial site. We have purchased the Gold license package from Survey Monkey and this includes a level of data security and privacy that meets the VA standards. You will not be asked to provide your name in these online surveys; instead, your data will only be linked to your unique Study Identification Number, not to your name. Nonetheless, when going to the site for the first time, we recommend that you take the time to review the site and read the privacy policy of the site. Be sure you feel comfortable using and answering questions on the site.

Research staff will log into the administrator side of our surveys in Survey Monkey to extract the data that has been entered by our subjects. That extract will be collected via a secure internet connection and then saved to the secure VA network.

Audio-recordings. Audio-recordings will be stored either in a locked filing cabinet in a locked office of study personnel or in a password-protected computer file within the VA network. Only approved research staff will have access to them. The recording will be labeled with a study code and will not be marked with your name or other identifying information. Recordings may be transcribed into a secure, password-protected folder on the VA network. Recordings that have not yet been uploaded into the password-protected VA network folder will be stored in a locked file cabinet in an office that will be locked when unoccupied. Current VA regulations require us to keep recordings indefinitely. As stated in Section 4, you will have the right to review and mark for deletion any portions of the audio-recording.

DESTRESS-WV Website. All web-based activities for the DESTRESS-WV condition will be completed through a website designed for the study using a secure server that provides encryption protection that meets VA standards to protect your confidentiality. The website is hosted and maintained by the commercial, web-based company Novus Origo. Researchers will need to have a special password to access your data. Only authorized study personnel will have this access to your data. We recognize that several homework assignments may involve personal information that is of a highly sensitive nature. Such information will be protected by encryption technology that meets VA information security standards. In the event that these security measures are compromised, we will notify you immediately and conduct a full investigation.

Certificate of Confidentiality. To help us protect your privacy, we have a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

Exceptions: A Certificate of Confidentiality does not prevent researchers from disclosing certain information about you for legal or ethical reasons. A Certificate of Confidentiality will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. Also, 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, we cannot use the Certificate to withhold that information.

The Certificate cannot be used to resist a demand for information from personnel of the United States government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

There may be publications about this study in the future. In these publications, we may use de-identified quotations from the individual interviews to illustrate specific points, but we will not include identifying information. No personal information will be given in a publication without your approval in writing.

Your study information will be used only for research purposes and will not be sold. Information gained from this research may be used commercially for the development of new ways to diagnose or treat diseases. However, neither you nor your family will gain financially from discoveries made using the information that you provide.

8. Special circumstances: The VA requires some Veterans to pay co-payments for medical care and services. You will still have to pay these co-payments as long as they are not related to this research study.

The total amount of money you can receive **for completing all study surveys** is:

- $25 − for the baseline online survey
- $30 − for the post-treatment online survey
- $30 – for the 3-month online follow-up survey
- $30 – for the 6-month online follow-up survey
- $35 – bonus for completing all surveys

for a total possible amount of $150 for completing all study surveys.

You will receive payment for completing each of the four surveys, as well as a bonus fifth check if you complete all of them on time. Payment may be made in the form of a check, which will be mailed to you within 8 weeks after completing each survey, or electronic fund transfer to your bank account, which will be processed within 2 weeks of completing the survey.

You may receive an Internal Revenue Service (IRS) Form 1099. If so, your social security number will be used for this purpose.

9. Withdrawal from the study: You do not have to take part in this study. If you are in this study, you can withdraw at any time. You will not be penalized for your decision to not participate or withdraw nor will you lose your VA or other benefits if you decide to do so.

If circumstances occur in which your study participation must be terminated, this may be done without your consent. If the research staff finds that continuing with the study is not in your best interest medically or psychologically, we may end your study participation early.

If you decide to withdraw, or if you are terminated from the study, a person from the study team may need to follow-up with you to discuss the necessary steps that you may need to take to end your participation in the study.

10. Questions or concerns related to the study: The study researchers (listed below) *must* be contacted immediately if:

- You think you may have been harmed or injured as a direct result of this research; and/or
- You have any questions regarding your medical care issues.

During business hours (8:00 a.m. − 4:30 p.m.)	Call Keren Lehavot, PhD at (206) 277-1511.
After business hours (nights and weekends)	Call (206) 762-1010 and ask the operator to page the on-call psychiatrist.

You may contact the Institutional Review Board (IRB) – VA Office at (206) 277-1715 if you:

- Would like to speak with a neutral party who is not involved with this study;
- Have questions, concerns, or complaints about the research;
- Would like to verify the validity of the study; or
- Have questions about your rights as a research subject.

An IRB is an independent body made up of medical, scientific, and non-scientific members, whose job it is to ensure the protection of the rights, safety, and well-being of human subjects involved in research.

11. Research-related injury: Medical treatment will be provided, if necessary, by the VA if you are injured by being in this study. You will not be charged for this treatment. Veterans who are injured because of being in this study may receive payment under Title 38, United States Code, Section 1151. Veterans or non-Veterans who are injured may receive payment under the Federal Tort Claims Act.

You do not waive any legal rights by signing this consent form.

12. Research subject's rights: I have read or have had read to me all of the above. The study has been explained to me, including a description of what the study is about and how and why it is being done. All of my questions have been answered. I have been told of the risks and/or discomforts, possible benefits of the study, and other choices of treatment available to me. My rights as a research subject have been explained to me and I voluntarily consent to participate in this study. I will receive a copy of this consent form.

I agree to participate in this research study as you have explained it in this document.

_____ _____

Subject Signature **Date**

_____

Print Name of Subject

N/A

_____ _____

Signature of Person Obtaining Consent **Date**

_____

Print Name of Person Obtaining Consent