APPROVED
AS MODIFIED
Aug 04, 2015
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CONSENT FORM

TITLE:	A Policy Relevant US Trauma Care System Pragmatic Trial for PTSD and Comorbidity (Trauma Survivors Outcomes and Support [TSOS 6]) Protocol
PROTOCOL NO.:	None WIRB® Protocol #20150987 49188
SPONSOR:	University of Washington
INVESTIGATOR:	Douglas Zatzick, MD 325 Ninth Ave Box 359911 Seattle, Washington 98104 United States
STUDY-RELATED PHONE NUMBER(S):	Douglas Zatzick, MD 206-744-9176 206-708-3576 (24 hours)
STUDY COORDINATOR(S):	Jeff Love, BA 206-744-9176
STUDY 1-800 NUMBER:	1-888-517-6311

Researchers' statement

We are asking you to be 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 or not. Please read the 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 if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

After traumatic injury such as the one you have experienced, some people may have difficulties returning to the routine of their everyday activities and may experience physical and emotional pain. The purpose of this study is to determine if recognizing and helping with physical and emotional post-injury concerns and preferences will enhance treatment. We also want to try to prevent recurrent, unnecessary hospital and emergency department utilization.

STUDY PROCEDURES

Screening & Evaluation

All study procedures are designed to work around your needs and be as flexible as possible in order to best fit into your recovery. If you decide to participate, the study staff will ask you questions regarding emotional symptoms such as, "Since your injury, how bothered have you been by repeated, disturbing dreams of the event in which you were injured?" We anticipate these questions will take about 15-20 minutes to answer. These questions will help us decide if the study is right for you. If at the end of these questions it is found this study is not a good fit for you, you will be paid $20 for your time today but will have no additional involvement in the study.

If at the end of these questions it is found that the study is a good fit for you, you will be enrolled into the study and asked additional questions about your post-injury concerns, physical and emotional symptoms, functioning, and health services utilization. Questions include, "Of everything that has happened to you since you were injured, what concerns you the most?", "Have you engaged in illegal activities in order to obtain drugs?" and "In the past month, how often have you been bothered by any of the following problems: thoughts that you would be better off dead or of hurting yourself in some way?" These additional questions may take approximately another 30-45 minutes. You will be paid $20 for your time today.

New Care Management Intervention vs. Usual Care

This study is being conducted at several hospitals. Half of the participants who enroll in this study will receive a new care management intervention aimed at improving their physical and emotional well-being, and the other half who enroll will receive the standard care offered at the hospital. If you decide to participate in this study, you will be informed which group you are assigned to and what type of care you will receive.

If you enroll in the study and are assigned to receive the "new care management intervention", as a study participant you will:

- Have your nurse notified of distress you may be experiencing.
- Work with study staff who will try to visit you sometime during your current hospital/emergency department stay to check in about how things are going for you and again ask about and address any physical or emotional concerns you may have after your injury. If necessary, the study staff will work with other hospital services (e.g., hospital pain service, psychiatry consultation service) to deal with any immediate issues that may come up while you are in the hospital.
- Have continuous communication with the study staff up to six months after your injury hospitalization. This communication will target any issues you and/or your study care manager are concerned with after your injury. This communication may occur over the phone, by email, text, or in-person depending on your preferences.
- Be linked to primary care and community providers that you may or may not have seen before the injury. Likewise, after you are discharged from the hospital, the study care manager will work with you and your health care providers to smooth the transition between hospital and community care; this may include making sure you get the appropriate medication prescriptions after your injury. Your study care manager team may assist your trauma center and community health care providers to find the most appropriate medications for your physical and emotional needs; at times your study team might be available to provide medications for your emotional needs if this is something required in your care plan.

If you enroll in the study and are assigned to receive the "usual care", as a study participant you will:

- Receive enhanced usual care provided during and after a traumatic injury, which includes having your nurse notified of distress you may be experiencing.

Follow-Up

You will be contacted by the study team over the telephone, through electronic communications (e.g., email, text), or other possible means (e.g., letter in the mail) to complete a 3-month, 6-month, and 12-month follow-up assessment. This follow-up interview will take about 45-60 minutes and you will be paid for your time. You will complete the follow-up interview over the phone or by another preferred method (e.g., faxed interview, hardcopy mailed to your residence, through the internet). A sample question from the follow-up interview includes, "In the last month, how often did you have a drink containing alcohol?" You have the right to refuse any question or stop any of the assessments at any point in time. If we cannot reach you through your email address or any of the phone numbers you provide, we may try to send you the interview through the mail or email.

Information from your Medical Record and Other Sources

If you agree to participate in this study, the study team will access your hospital chart for further information about your current injury, as well as any other medical records created throughout the duration of the study. Information from these medical records will help us better understand the medical care you receive and to optimize your care as part of the "new care management intervention" condition. We will ask you to sign a HIPAA form allowing us to access your medical records.

Contact

After a trauma, people sometimes relocate temporarily in order to receive better care. We realize that patients occasionally change where they live, yet, it is very important to us that these follow-up interviews take place. Therefore, in addition to contacting you with the information you provide during your initial interview, we will utilize several approaches to try and stay in touch with you across the study window. We have listed these approaches below, beginning with preferred methods and continuing through least preferred methods.

- Contacting other people in your life. We will ask you for phone numbers/addresses of at least two contact sources (for example friends or relatives). In the event that you are no longer at your residence, the alternative follow-up numbers you list will be another way of contacting you. We may often ask you to update your contact list, so that we can stay in touch with you.
- Looking at hospital records. In the case that we are unable to reach you after repeatedly trying to contact you through the information you have provided, we may look at hospital records where you were initially admitted and see if there is updated contact information.
- Conduct a public records search. We may also conduct a public records search to find new contact information. Examples of public records searches we may conduct include the Yellow Pages, or using a Google search to find additional contact information. We will only search for records or information that is open to the public.
- Contact through a social media page. If we find a social media page (e.g., Myspace, Facebook, Google+, etc.), we may attempt to contact you on these sites via private message. We will only send you this message if we are able to match at least three identifiers with information you have already provided us, including: first name, last name

and middle initial, date of birth, address, hometown, phone number or photo identification. This information will be sent to your inbox and will not be viewable to the public. No information identifying the study or its purpose will be included in this message.

- Sending you a hard-copy of the interview in the mail, email or other means (e.g., FAX). If we cannot reach you through any of the phone numbers you provide, we may send the interview to you through the mail, by email or by other means such as FAX. The interview form will not include your name or any identifying information. You should complete the interview in a confidential space where no one else can have access or see the interview. We will remind you of this again if we send you the interview.

RISKS, STRESS, OR DISCOMFORT

One risk to you from participating in this study is that private health information about you will be recorded by our study team. We must protect the privacy of health information about you. Health information includes all information about you that is collected during this study. This includes interview responses, medical records and other data that our study team collects. We may use or share your health information for research only if you let us.

Breach of confidentiality is a risk to being in the study if it happens that your information is taken by, given to, or seen by someone who should not be able to look at it or have it. We take all necessary precautions to prevent this, as described in the "Other Information" section below.

Other risks include feeling upset by some of the questions we ask, and being inconvenienced due to the time involved. The research associate or the study investigators will always be available during the study to discuss with you any distress you are experiencing. There is also a risk that you may find the interviews inconvenient. All efforts will be made to make the interviews as easy and short as possible. Our study staff is available in the evenings and on the weekends to complete the telephone interviews if that works best for your schedule.

There is also a risk that hospital staff or a patient roommate may overhear the interview. All efforts will be made to make the interviews as private as possible including: attempting to make sure that you are alone in the room when conducting the interview, stopping the interview while someone is in the room, moving the interview to a private family room, or attempting to secure confidentiality by closing your door, pulling the dividing curtain, and speaking in a low voice.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If the hospital in which you are consenting is currently providing the "new care management intervention," this "new care management intervention" will be offered to you free of charge. You can still continue with study treatment even if you decide to stop doing research interviews. If the hospital in which you are consenting is currently providing care as usual you are still entitled to all the routine medical care you would normally receive.

BENEFITS OF THE STUDY

If you are in the "new care management intervention" group, the study may help you with immediate post-injury needs and concerns, as well as possible reductions in symptomatic distress and functional disability. Regardless of whether you are receiving the "new care management intervention" or "usual care" the information we gain from this research may help us provide better support to people who come into the hospital with injuries similar to yours in the future.

Also, people who come to the hospital after you may benefit from our better understanding of your experience. It is possible that you may not receive any individual benefit from participation in this study.

SOURCE OF FUNDING

The study team and the University of Washington are receiving financial support from the National Institutes of Health to complete this research.

OTHER INFORMATION

The study team would like you to be aware that the costs for some aspects of your study participation may not be paid for by the study, but instead may become your responsibility. For example, if you are part of the group that is receiving the new intervention and medications are recommended as part of your treatment, you may be responsible for payment of these medications. If you have health insurance these costs might be covered by your plan, either in part or full. You will be responsible for confirming your prescription benefits. The study team will not cover prescription costs.

We will remove your name (and any other information that could identify you) from your health information and replace your name with a study ID number. Therefore, no one will know the information is yours. If the results of this research are published, we will not identify you at all. The data that are collected from you and stored in a digital format (e.g., your answers to questions were entered directly into a computer) will be filed on an encrypted secure server that is password protected, and data collected from you in a hard format (e.g., on paper) will be stored in a locked drawer and only the investigators with a key will have access to this drawer. Results of the interviews are confidential and will not be entered into your medical chart. The things that you tell us will be kept as private as possible and will not be shared in identifiable form with anybody outside the research study team. Study data linked to you will be kept until 06/30/2021, for research purposes. After that time any link between you and the data will be broken.

We may use or share your health information for research only if you let us. We may use health information about you as part of the study. We may also share your health information with certain people and groups. These may include the sponsor of the study, the National Institutes of Health, and its representatives, government agencies (including the US Food and Drug Administration), institutional review boards, and others who watch over the safety, effectiveness, and conduct of the research, and other researchers when a review board approves the sharing of the health information and others. Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm. We will do everything we can to keep others from learning about your participation in the research.

If during the interview process we find out that your injury occurred as part of an attempt to harm yourself, we will complete the interview today, but not continue with the telephone follow-up calls after you leave the hospital. To make sure you get the care you need, we will also contact your care team here in the hospital to tell them that the injury occurred as a result of you harming yourself. Also, if we discover at any time over the course of the study that you are so emotionally upset that you are at risk for harming yourself, we may need to break confidentiality to get you the care that you need.

Please keep in mind that regardless of whether you complete the interview on paper or electronically, the study staff may not review your interview responses instantaneously and therefore would not be able to immediately respond if you reveal any emotional distress or thoughts of self-harm.

We will do everything we can to keep others from learning about your participation in the research. This protection does not extend to circumstances involving sexual or physical abuse of a child or elderly person, or any threat of harm or violence (including physical or sexual abuse) to you, your family, or others.

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.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

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.

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.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of abuse or neglect of a child or elderly person.

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. You may skip any questions you don't wish to answer. You will receive up to a total of $135 for your participation if you complete all study related assessments. You will receive $20 after completing the interview today, $30 for completing the 3-month, $35 for completing the 6-month, and $50 for completing the 12-month follow-up interview. If, after completing this initial interview today we find that the study is not a good fit for you, you will still be paid $20 for your time today; however, we will not call you to ask any further questions. There are no anticipated costs of being part of the study beyond the usual after care that is routine following an injury.

Printed name of study staff obtaining consent	Signature	Date

Hospital Site

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions, concerns, or complaints later about the research, or feel I have been harmed by the research, I can contact the investigator listed on Page 1. If I have questions about my rights as a research subject or if I have questions, concerns, or complaints about the research, I may contact Western Institutional Review Board® (WIRB®) at 1019 39th Avenue SE Suite 120, Puyallup, Washington 98374-2115; Telephone: 1-800-562-4789 or 360-252-2500; or E-mail: Help@wirb.com. WIRB is a group of people who perform independent review of research. WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, I may contact WIRB if the research staff cannot be reached or if I wish to talk to someone other than the research staff. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Printed name of subject	Signature of subject	Date

Copies to: Researcher
Subject