Project Name:

Analysis of Influencing Factors for Post-Traumatic Stress Disorder (PTSD) in Emergency Trauma Patients

Sponsoring Institution: The First Affiliated Hospital of Air Force Medical University

Principal Investigator: Wei Zhao

Study Period: September 1, 2025 - June 30, 2027

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Dear Patient:

You are invited to participate in a research study titled "Analysis of Influencing Factors for Post-Traumatic Stress Disorder (PTSD) in Emergency Trauma Patients," led by Principal Investigator Wei Zhao. This study will be conducted in strict compliance with the Helsinki Declaration and relevant national laws and regulations of China.

Before deciding whether to participate in this clinical research, please carefully read the following content. It will help you fully understand the purpose of the study, research procedures and duration, potential benefits, risks, and discomfort associated with participation. You may discuss this with your relatives or friends and consult the research doctor, who will explain any questions you may have about the study to assist you in making a final decision.

I、 Research Background

Post-Traumatic Stress Disorder (PTSD) is a common and serious mental disorder following exposure to traumatic events. As a key initial treatment site for trauma patients, the emergency department has a significantly higher incidence of PTSD among its patients compared to the general population. PTSD not only severely impairs patients' mental health but also leads to long-term functional disabilities, increased comorbidity risks, and heavier medical burdens. Existing studies have shown that the occurrence of PTSD involves multiple types of factors, including neurocognitive, psychosocial, physiological, and trauma-related factors. However, current studies mostly focus on a single dimension, lacking a systematic exploration of the interaction of multiple factors and the special emergency environment. In the future, it is necessary to integrate multi-dimensional factors to provide a theoretical basis for the development of risk assessment tools and the implementation of early interventions, ultimately improving patients' long-term prognosis.

II、 Research Objectives

To determine the incidence of PTSD within 6 months in emergency trauma patients;

To identify factors associated with the development of PTSD;

To explore the interaction pathways among these factors and reveal the mediating or moderating roles of relevant factors in the occurrence of PTSD.

III、 Research Design

This is a professional medical study on post-traumatic stress responses, aiming to understand the physical and mental recovery process and related influencing factors of trauma patients like you after experiencing accidental injuries.

If you agree to participate, we will invite you to cooperate in completing the following: Within 24 hours of your injury, we will collect information about your basic situation, injury experience, physical indicators, and psychosocial status through questionnaires and examinations; We will contact you again for follow-up assessments at 1 month, 3 months, and 6 months after the injury to monitor your recovery progress.

IV、 Inclusion and Exclusion Criteria

Inclusion Criteria:

1. Aged 18-65 years (inclusive of boundary values);
2. Experienced a life-threatening major traumatic event, confirmed by clinical diagnosis;
3. Able to communicate normally with medical staff;
4. Fully informed about the study and voluntarily sign the informed consent form.

Exclusion Criteria:

1. Past history of mental illness or current use of psychotropic drugs;
2. Past cognitive impairment (e.g., dementia, Alzheimer's disease);
3. Terminal illness (e.g., advanced malignant tumors, end-stage organ failure, advanced neurological diseases, or any other disease with an expected survival period of less than 6 months as judged by the attending physician);
4. Unable to cooperate with follow-up.

V、Research Procedures

(I) Focus and Information Collection Methods

1. Initial Assessment: We will gather your basic information, details of the injury, and medical records, collect one blood sample, and perform a cranial magnetic resonance imaging (MRI) scan (based on your willingness) to evaluate the physical impact of the trauma.
2. Three Follow-up Assessments: We will contact you again at 1 month, 3 months, and 6 months after the injury. Assessments will be conducted through outpatient

interviews, telephone calls, or electronic questionnaires, using professional psychological scales to evaluate your emotions, stress levels, and social support during this period. A repeat cranial MRI scan may be performed (based on your willingness) to re-evaluate the physical impact of the trauma.

(II) Purpose of Data Analysis

All information you provide will be strictly confidential and used exclusively for this scientific research. By analyzing data from many participants like you, we aim to:

Identify factors potentially associated with the development of PTSD;

Gain a deeper understanding of how these factors interact with each other.

(III) Significance of the Study

This study aims to systematically reveal the complex pathways influencing psychological rehabilitation, helping us identify patients who require focused attention earlier and develop more precise and effective psychological support and intervention programs for them. Your participation and sharing are crucial, as they will provide valuable evidence for this medical research aimed at helping others. Thank you for taking the time to read and consider participating in this study.

VI、 Risks and Discomfort

(I) Potential Risks and Discomfort

We are committed to minimizing risks to you. The following are potential risks and discomfort associated with participating in this study:

1. Venous Blood Collection: Venous blood will be collected after your injury. The procedure will be performed by professional nurses, identical to routine laboratory blood draws. It may cause temporary needle stick pain, local bruising, or, in rare cases, mild infection.

2. Psychological Discomfort: The core of this study is to understand psychological responses after traumatic events. During follow-up, we will ask you to recall the traumatic experience and complete questionnaires about emotions, stress, and thoughts. Answering these questions may temporarily make you feel upset, sad, anxious, or remind you of unpleasant experiences—this is common in such studies. Our researchers are trained to communicate with you in a gentle and respectful manner.

(II) Risk Mitigation Measures

To address the above risks, we will take the following measures:

1. Professional Operations: All medical procedures will be performed by experienced medical staff using disposable sterile supplies to minimize physical risks;

2. Psychological Support: If you experience significant discomfort or emotional distress during the assessment, you may request to pause or withdraw from the study at any time. We will provide you with free referral information for professional psychological counseling resources.

Important Note: You have the right to withdraw from the study at any time and for any reason without affecting any medical services or legal rights you are entitled to at the hospital.

VII. Potential Benefits of Participation

We hope this study will bring value to you personally and to future trauma patients. The potential benefits of your participation include:

1. Systematic Attention and Assessment: During the study, you will receive regular, systematic follow-up and care from the research team. We will assess your psychological status at key time points after trauma (1, 3, and 6 months) using scientific scales.

2. Early Identification and Referral Opportunities: If follow-up assessments reveal significant psychological distress or if you meet the screening criteria for PTSD, our researchers will proactively inform you and provide recommendations for further diagnosis and consultation at the hospital's Department of Psychiatry or relevant professional institutions.

3. Enhanced Understanding of Personal Recovery: By participating in the study and communicating with researchers, you can gain a deeper understanding of common psychological and physiological responses after trauma, helping to reduce confusion or fear of unknown symptoms.

VIII. Study Costs

After you sign the informed consent form, the following services provided during the study will be free of charge to you, covered by the sponsor:

Scale assessments;

Cranial magnetic resonance imaging (MRI).

IX. Compensation and Remuneration

If you suffer an injury related to this study, you will receive free treatment at Xijing Hospital and compensation/remuneration in accordance with relevant Chinese laws.

X. Confidentiality of Personal Information

Information collected in this study will be kept confidential at the hospital. To protect your identity, all information about you in research documents will be labeled with a standardized identification number instead of your name. In all aggregated participant data, any information that could identify you will be removed to ensure that the data cannot be linked to a specific participant.

The Ethics Committee and regulatory authorities may directly access your original medical records to verify clinical trial procedures and/or data, within the scope permitted by applicable laws and regulations and without violating your privacy (the sponsor is not allowed to access such records). By signing this informed consent form, you or your legal representative authorize such access. Within the scope permitted by applicable laws and/or regulations, records identifying you will remain confidential and will not be disclosed. Results of this study may be published in medical journals, shared for scientific purposes, or used by the sponsor for product research or improvement; however, your identity and personal information will never be disclosed.

XI. Withdrawal from the Study

During the study, the research doctor will prioritize your best interests. If it is determined that you are no longer suitable to continue participating (including disease recurrence, intolerable toxic reactions, serious adverse events, etc.), or if the sponsor/Ethics Committee/national regulatory authorities require the study to stop, the research doctor will proactively explain the reasons and terminate your participation.

Your participation in this study is entirely voluntary. You have the right to refuse participation or withdraw at any time without penalty or loss of benefits, and your subsequent treatment will not be affected. If you wish to withdraw from the study, please notify your research doctor promptly. For your safety, the doctor will conduct a comprehensive examination and provide necessary care. If the researcher obtains information that may affect your continued participation, you or your guardian will be notified promptly.

XII. Contact Person and Contact Information

You may inquire about study-related information and progress at any time. If there are new safety-related information regarding the study, we will notify you promptly. If you have any questions about the study, experience any discomfort or injury during participation, or have concerns about participant rights, please contact:

Researcher: Yang Li

Telephone Number: 18098193316

XIII. Contact Information of the Ethics Committee

If you have any questions or claims regarding your rights and health related to participation in this study, please contact the Ethics Committee of Xijing Hospital:

Telephone Number: 029-84771794

Subject's Informed Consent Signature Page

I have carefully read the above Informed Consent Form and understand the purpose of the study, as well as the potential benefits and risks of participation. The researcher has clearly explained all medical terminology used above. I have had the opportunity to ask questions, and all questions have been answered in an understandable manner. I may choose not to participate in this study or withdraw at any time by notifying the responsible doctor, and my medical treatment and rights will not be affected. If I require other treatments, fail to comply with the study plan, suffer an injury related to the study, or for any other reason, the responsible doctor may terminate my participation.

I have read the above Informed Consent Form, received a copy, and my physician has provided a detailed explanation. I voluntarily agree to participate in this clinical trial.

Subject's full name (in block letters): _____

Subject's Telephone Number: _____

Subject's Signature: _____

Date:_____(Year/Month/Day)

(Note: If the subject lacks capacity for civil conduct, the guardian must sign; if the subject has limited capacity for civil conduct, both the subject and the guardian must sign.)

Guardian's full name (in block letters):_____

Relationship with Subject:_____

Guardian's Signature:_____

Guardian's Telephone Number:_____

Date:_____(Year/Month/Day)

Witness's Signature (if applicable): _____

Date: _____ (Year/Month/Day)

(If the subject or their guardian is illiterate, a impartial witness is required to sign. The witness shall read the Informed Consent Form and other written materials and witness the informed consent process.)

I confirm that I have fully explained the relevant content of this clinical trial to the patient, including potential benefits and risks, and answered all questions raised by the patient.

Researcher's Signature (in block letters):_____

Date: _____ (Year/Month/Day)

Researcher's Telephone Number: _____

Date: _____ (Year/Month/Day)