YALE UNIVERSITY
YALE UNIVERSITY SCHOOL OF MEDICINE
YALE-NEW HAVEN HOSPITAL

Verbal Consent for Participation in a Research Study

Title: Early Detection and Treatment to Reduce Events with Agitation Tool (ED-TREAT) Tool Development

Principal Investigator:
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Introduction

You are being asked to join a research study. The following information will explain the purpose of the study, what you will be asked to do, and the potential risks and benefits. You should ask questions before deciding whether you wish to participate, or at any time during the course of the study. You will be asked to provide verbal consent to participate at the end of this process.

Purpose

The purpose of this study is to develop and refine the Early Detection and Treatment to Reduce Events with Agitation Tool (ED-TREAT) by engaging patients in the process. ED-TREAT will be a clinical decision support tool in the electronic health record to help clinicians at the point of initial encounter in preventing agitation and aggressive behavior during a visit to the emergency department. We wish to receive input from patients directly for development and refinement of ED-TREAT during initial design of ED-TREAT.

You are being asked to participate because you work as a peer support worker and/or have been physically restrained as a patient in the emergency department (ED).

Procedures

As part of this study, we will ask you to participate in a 60 to 90-minute online or in-person focus group where we will discuss your experience with agitation events, how a decision tool to detect agitation can impact/improve management of agitation, and what design for a clinical decision tool would best help prevention of agitation and/or your experience in the ED.

Possible Risks

There are minimal risks to you for participation in this study. To protect your anonymity you will be assigned a study number and subsequently will be identified only through this number. Only research investigators will have access to the data. Electronic data will be maintained in password-protected files or on a password-protected online serve that only the PI and research assistant may access. All data will be maintained securely for three years after the conclusion of the study, at which time it will be permanently destroyed.

We are counting the numbers of participants, but assure you that your answers will be anonymized before they are analyzed by the research team. Your contributions will be secured and protected throughout the study and will remain confidential to everyone including the research team.

Voluntary Participation

Participation in this study is completely voluntary. Your email response will count as verbal consent to participate. However, you are free to decline to participate, to end participation at any time for any reason, or to refuse to answer any individual question at any time. You may withdraw from the study at any time without negative consequences. Your responses and decision to participate or withdraw from participation will not affect your relationship with Yale School of Medicine, Yale-New Haven Health, or any affiliated locations of employment or healthcare delivery. You will only be asked to participate for one phase of the study and will not be required or asked again to join another phase of the study.

Questions

If you have any further questions about this study or the focus group questions, you may contact the investigator, Dr. Ambrose Wong, MD, MSEd, at (203) 737-2489 or at ambrose.wong@yale.edu. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.