Title: Virtual cOaching in making Informed Choices on Elder Mistreatment Self-Disclosure (VOICES)

ClinicalTrials.gov ID: NCT03834870

Last Approval Date: 7/28/2020

Document: Informed Consent Form

COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
200 FR. 4 (2016-2)

YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL: SAINT RAPHAEL CAMPUS

Study Title: **V**irtual c**O**aching in making **I**nformed **C**hoices on **E**lder Mistreatment **S**elf-Disclosure (VOICES)

Principal Investigator: Fuad Abujarad, PhD
Department of Emergency Medicine
Yale University School of Medicine
464 Congress Ave, Suite 260
New Haven, CT 06519
(203) 737-5088

Funding Source: National Institutes of Health

Invitation to Participate and Description of Project

You are invited to take part in a research study. Your participation is voluntary. You can quit the study at any time. Your medical care will not change in any way if you say no.

Why is this study being done?

The purpose of this study is to find out who is at greatest risk of mistreatment..

You are being asked to take part in a research study because you are 60 years or older.

The mistreatment of older adults is a serious and widespread public health problem. Mistreatment includes many types, such as; emotional abuse, physical abuse, and sexual abuse; financial abuse; abandonment; and neglect.

What is involved in this study?

What happens if I say yes, I want to be in the study?
If you agree, you will be asked to participate during your visit at the St. Raphael Emergency Department today.

How long will the study take?
The study will take about 30 minutes of your time and will be completed today. Participation will not make your stay longer in the ED.

How many patients are expected to take part in the study?

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About 800 patients will be included in this study.

What are the procedures of the study?
First, we will obtain informed consent, then ask you to complete a demographics survey to learn more about you. Next, we will ask you to use the iPad to test a new tool that screens for mistreatment. Then we will ask you to complete a survey about your participation.

What are my risks if I take part in the study?
There are no medical interventions in this study, and direct medical risks are very small.

Identifying possible mistreatment can increase your risk of physical and emotional harm, or neglect. We will take all measures needed to lessen these risks. We are required to report any suspicion of mistreatment to your nurse.

The hospital, protective services for the elderly program, law enforcement, and the courts have systems in place to help keep you safe. If you feel that you are in urgent danger, your nurse and care team will create a safety plan until a more permanent solution can be found. This plan could include staying at the hospital or a safe home, or a court protective order. If you wish to disclose mistreatment, the Research Assistant will stay with you until a member of your care team comes in.

It is important to know that recognizing mistreatment may lead to harm from the caregiver or loss of the caregiver. In some cases, the caregiver may be arrested. Identification of mistreatment may also lead to you being discharged to a long-term care or skilled nursing facility.

Answering personal and sensitive questions can make us feel anxious and uncomfortable. You may be distressed while, or after using the tool. If there are any questions that you do not want to answer, or that make you upset, you can skip to the next question.

The Research Assistant will give you a brochure on resources that can offer help with mistreatment. These items can be kept with study staff until you leave the hospital if you do not want anyone else to see them.

There is a risk that the privacy of your personal information can be compromised. To lower this risk, you will be labeled by only a study number. All study-related information will be stored securely and only people who are part of the study can view it. All electronically stored data will be encrypted, and password protected.

Other Risks
As with all research, this study may involve risks that are currently unknown.

What are my benefits if I take part in the study?
Taking part in this study can give you a better understanding of what mistreatment is. Having a better idea of what mistreatment is can increase your emotional and physical health, your safety, and quality of life. Being in the study may also help us improve the safety of others in the future.

Will I be paid for my time?
Yes, we will give you:
- $20 gift card

If you participate fully in the study and complete the survey.

What happens if I say: NO, I do not want to be in the study?
You can stop being in the study at any time.
You will not be penalized.
The care you get from your doctor will not change.
No one will treat you differently.

What are my alternatives?
Your alternative is to not take part in the study.

What should I do if I want to be in the study?
You sign on the iPad. We will give you a signed copy of the informed consent to keep. By signing on the iPad, you are saying:

- You agree to participate in the study.

Do I have to participate?
No, you do not have to participate in this study if you do not want to.

Confidentiality and Privacy
Researchers are required by law to protect the privacy of your information. All health-related information that we gather about you for this research study will be kept in a locked cabinet or secure database and will remain confidential. When the results of future research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent is obtained.

The health-related information that we gather about you in this study is personal. Your information is also known as protected health information (PHI). All reasonable efforts will be made to protect the confidentiality of your PHI. Even with these protections, there is a possibility that information about you could be used or released in a way that it will no longer be protected.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure; if you have consented to the disclosure, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The protection offered by the Certificate of Confidentiality does not stop us from voluntarily reporting information about suspected or known sexual, physical, or other abuse of an older adult, or threats of violence to self or others. If any member of the research team is given such information, he or she will make a report to the appropriate authorities.

What Information Will You Collect About Me in this Study?

Your PHI is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to the Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- The entire research record and any medical records held by Yale New Haven Hospital.
- Information obtained during this research about any referrals made to EPS.

How will you use and share my information?

We will use your information for the study described in this consent form.
We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Officials from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the group that looks over, approves, and monitors research on human participants), who are responsible for making sure research follows all rules. These individuals are required to keep all information private.
- Service and Health care providers who give services to you in connection with this study.
- Connecticut Protective Services for the Elderly.
- The PI, Dr. Fuad Abujarad
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team

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Why must I sign this document?

By signing this form, you will allow researchers to use and share your information described above for this research study. This is to make sure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?

The permission to use and share your health information collected during your time taking part in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to *Fuad Abujarad, PhD. 464 Congress Ave, Suite 264-J* at the Yale University, New Haven, CT 06520.

If you withdraw, you will not be able to stay in this study. The care you get from your doctor outside this study will not change. No new health information from you will be taken after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to ensure the integrity of the study and/or study oversight.

Voluntary Participation and Withdrawal

This study will last the duration you are in the emergency department. This study may also be stopped, or your participation ended at any time by your physician, or study principal investigator without your consent.

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Participating in this study is voluntary. You are free to choose not to take part in this study. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits). You do not give up any of your legal rights by signing this form.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits. Your decision will not affect your future relationship with the Yale School of Medicine or Yale-New Haven Hospital.

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Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also means that I have been given a copy of this consent form.

By signing this form, I give permission to the researchers to use [and give out] information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

Name of Subject: _____

Signature:_____

Date: _____

_____ _____
Signature of Principal Investigator Date

or

_____ _____
Signature of Person Obtaining Consent Date

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at (203) 432-5919.

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Fuad Abujarad (203) 737-5088. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have about this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.

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