Feasibility of Elder Mistreatment VOICES Screening Tool for Older Adults with Cognitive Impairment

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Synopsis

Primary Objective The primary objective of this study is to conduct a study with eighty (N=80) participants in order to evaluate the feasibility of implementing the new and enhanced VOICES tool (HIC#: 2000023799) for older adults with cognitive impairment (CI) into the emergency Department (ED).
Secondary Objective (if applicable)
Study Duration Eight months.
Study Design This is a feasibility study of tablet-based screening tool to identify suspicion of elder mistreatment for older adults with cognitive impairment.
Number of Study Sites 1: Yale-New Haven Hospital Emergency Department at the Saint Raphael's Campus (YNHH-ED-SRC)
Study Population Older adults (age 60+) seen at the SRC ED.
Number of Participants 80
Primary Outcome Variables Acceptability, Demand, Implementation, and Practicality
Secondary and Exploratory Outcome Variables (if applicable) N/A

Abbreviations

Abbreviation	Explanation
CI	Cognitive Impairment
EM	Elder Mistreatment
YNHH	Yale-New Haven Hospital
SRC ED	Saint Raphael's Campus Emergency Department
ED	Emergency Department
EPS	Elder Protective Services
RA	Research assistant

Glossary of Terms

Glossary	Explanation

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1 Introduction

1.1 Introductory Statement

This document is a protocol for a human research study. The purpose of this protocol is to ensure that this study is to be conducted according to ICH GCP guidelines, and according to CFR 21 Part 812, other applicable government regulations, and Institutional research policies and procedures.

2 Background

2.1.1 Device Preclinical Experience

The VOICES tool has been developed and tested with more than 1000 patients at Yale Emergency Department (IRB Protocol ID:2000023799 and Submission ID:CR00008317).

2.1.2 Device Clinical Experience

In a prior clinical study at Yale Emergency Department (IRB Protocol ID:2000023799 and Submission ID:CR00008317), we developed an innovative digital health tool that runs on tablets called **VOICES** that screens, educates, and motivates older adults to make an informed decision about self-reporting of elder mistreatment. VOICES is a digital health intervention to screen and identify suspicion of elder mistreatment when there are no recognized signs and symptoms of abuse. The **VOICES** tool is currently being evaluated with older adults ***in emergency department settings***. 1000 subjects have used the VOICES tool so far without any issues. Study participants have demonstrated signs of feasibility, acceptance, demand, and full completion of the tool for those who consented to participate. There is an opportunity to expand **VOICES** to more vulnerable older adult populations, such as older adults with cognitive impairment.

2.2 Background/Prevalence of Research Topic

Elder mistreatment (EM) is a major public health problem with estimated prevalence in the United State ranges from 27.9% to 62.3% for emotional abuse and 3.5%–23.1% for physical abuse among older adults with cognitive impairment (CI). EM consists of physical, emotional, sexual and financial abuse as well as neglect committed by a person in a position of trust to the older adult. It causes serious adverse outcomes for its victims including injury, increased service utilization, mental distress and the risk of mortality. A major barrier in overcoming EM is the inability to accurately identify EM victims. It is estimated that only 1 in 24 cases become known to authorities.

Adults with CI are at even greater risk of elder mistreatment compared to those without. This is problematic as they are not likely to report that they are being mistreated, despite some of them having a general understanding of what constitutes EM. There are several perceived barriers to self-disclosure (informing others about the EM experiences) that limit help-seeking behaviors, including fear of nursing home placement, of losing autonomy or a caregiver, and of getting an abusive family member in legal trouble. As a result, reporting of EM remains low and providers often miss the opportunity to identify EM at point-of-care.

In our parent project, we used Digital Health frameworks to develop the Virtual cOaching in making Informed Choices on Elder Mistreatment Self-Disclosure (VOICES) tool. This is a new and innovative digital health tool that screens, educates, and motivates older adults to make an informed decision about self-identification (recognizing that they themselves are victims) and self-disclosure of elder mistreatment.

3 Rationale/Significance

3.1 Problem Statement

Is the VOICES tool, currently developed for older adults without cognitive impairment, **feasible** for older adults with cognitive impairment?

3.2 Purpose of Study/Potential Impact

Our aim is to assess the feasibility (N= 80) of the VOICES screening tool among older adults with cognitive impairment. If VOICES is feasible for identifying suspicion of EM with older adults with cognitive impairment, then we will be able to connect more victims of EM to necessary services and potentially prevent a multitude of poor EM outcomes.

3.2.1 Potential Risks

There are no medical interventions in this study, and direct medical risks are minimal. However, identification of potential EM without adequate safeguards could increase the risk of physical harm, emotional harm, risk of neglect, and financial loss to the victim. In addition, EM identification can potentially lead to adverse events including:

- retaliation of a family member or caregiver,
- an older adult may lose the caregiver or be abandoned by a caregiver, and a family member or paid caregiver may be arrested / incarcerated,
- discharge of a patient to a long-term care or skilled nursing facility, which they may not be able to afford,
- distress/anxiety during and/or after using the VOICES tool is a potential risk given the complex emotions typically associated with this phenomenon.
- there is a risk of compromised security of personal information.

Many of these adverse events would likely occur as a result of the mandatory report to Connecticut Protective Services for the Elderly (PSE) that the attending clinician would make with help of the care team (attending, clinician, nurses, and social worker). However, during this study the care team is expected to discover information that will require them to make a report to PSE even if the patient does not want them to do so.

Minimizing Risks:

Risks will be minimized through appropriate participant exclusions and close medical supervision throughout the protocol. We will inform all participants that there is a chance that they may experience adverse events due to the identification of EM by participating in the study and that their participation is voluntary. We will also remind participants that they can discontinue participation at any time.

In Summary: VOICES' goal is to help identify cases of EM when there are no recognized signs and symptoms of mistreatment. The subsequent procedures for the EM identification are important but are similar to the case when a provider identify suspicion of EM during normal clinical care:

- all patients who screen positive with the VOICES tool will be reviewed and assessed by the attending to evaluate if the tool's suspicion of mistreatment will either be confirmed (necessitating a report to authorities) or rejected (no report necessary).
- while the research team recognizes that the EM identified through the VOICES tool may lead to adverse events for patients associated with EM identification, we anticipate that the attending clinician response will minimize the possible adverse events due to the EM identification.
- We will train all RAs to detect common signs of distress and anxiety. If any are even suspected of being observed, the attending clinician at SRC ED will be

contacted immediately for consultation and next steps, which could include counseling, referrals, or a psychiatric evaluation.

- If the older adult screens positive on the VOICES for EM or the older adult wants to self-disclose EM, the RA will notify the attending physician at the SRC ED if there is suspicion of EM. Also, if the tool fails to identify EM but the patient would like to disclose EM, the RA will notify the attending clinician. The RA will stay with the participant until the attending clinician arrives and implements existing protocols for handling EM identification.
- The attending clinician and care team can address each patient's concerns around reporting, immediate safety concerns, and any concerns for retaliation or abandonment. If the assessment indicates suspicion of abuse, and the case gets reported to PSE, usually PSE will arrive within 12 hours to take care of the case. While waiting for PSE, the health care team members will discuss safety issues with the patient. If the older adult feels s/he is in immediate danger or does not feel safe going home, the care team will create a safe disposition plan that can include safety admission to the hospital until PSE can implement a more permanent solution.
- We will protect against psychological distress by informing all participants that there is a chance that they may experience some negative emotions while completing the surveys, after completing survey, or when they leave the hospital, but that they do not have to answer questions that they find distressing. We will also remind participants that they can discontinue participation at any time. We will also provide all older adults that we approach with the brochure on resources for aging well that also include free referral line. These options will be discussed with participants during initial recruitment.
- Although privacy and confidentiality will be preserved to the utmost extent possible, participants will be informed that, should EM be identified, the RA will report this to the attending at the SRC ED. For example, if in the course of research procedures, a participant reveals elder abuse to the RA, the RA will discuss with the participant his/her responsibility to report the abuse to the attending. The attending will coordinate with the care team to do an EM assessment and if they find suspicion of abuse, they will intervene to ensure patient safety. Also, if the participant divulges suicidality, the RA must report this to the attending and notify the PI.
- We will follow standard hospital operating procedures to guard against the possibility of study coercion, loss of confidentiality, psychological distress, and escalation of abuse, acknowledging that awareness or suspicion of reporting may anger the abuser but can also empower the patients and ultimately, make them safer.
- Our intent is to conduct a VOICES study session **without the presence** of the caregiver. From our experience, family members usually volunteer to leave the room, when they usually do so.

- We will ask the caregivers to leave the room before engaging the older adults in using the VOICES tool and after the consent. If the older adult wants the caregiver to remain, we will respect their wishes, but that patient will be excluded from the study and no study information will be presented.
- If a participant reveals depression, the research assistant will provide a referral to a mental health agency accessible to the subject. If a participant reveals severe depression or suicidality, or requests immediate psychiatric care for any reason, the RA will alert the patient's clinician to initiate an immediate psychiatric evaluation.
- Since the VOICES tool is a web-based application in nature, **no information** will be stored on the tablet. If the tablet gets lost or stolen, the patient's data will not be compromised. All iPads contain encryption software, per University Policy 5100.

3.2.2 Potential Benefits

Although there are risks to the subjects, the benefits outweigh the risks. EM can have profound medical consequences for victims, significantly increasing their risk for mortality, exacerbations of chronic illnesses, and depression. EM is very seldom identified, and low rates of identification and reporting have likely led to much of the associated morbidity and mortality. Therefore, by increasing identification of this morbid and mortal phenomenon, the VOICES tool may offer significant benefits to patients. A potential benefit for the participants is that they will gain better self-awareness, enhance and support self-disclosure, and improve reporting of EM at the point-of-care setting, which may result in, better emotional and physical health, increased safety, and quality of care

4 Study Objectives

4.1 Hypothesis

The hypothesis of this study is: the VOICES tool, developed for older adults without cognitive impairment, applicable and feasible for older adults with cognitive impairment?

- To what extent is VOICES satisfying to end-users?
- To what extent is VOICES likely to be used?
- To what extent can VOICES be delivered to participants in the ED with cognitive impairment?
- To what extent can VOICES be carried out with older adults with cognitive impairment without outside intervention?

4.2 Primary Objective

The primary aim and objective of this study is to determine whether VOICES tool is feasibility for identifying suspicion of elder mistreatment among older adults with cognitive impairment.

4.3 Secondary Objectives (if applicable)

N/A.

5 Study Design

5.1 General Design Description

Overview and Rationale: We will conduct a study with eighty (N=80) participants to evaluate the feasibility of implementing VOICES for older adults with cognitive impairment. *The objective of this study is to evaluate markers of feasibility rather than to determine the efficacy of VOICES*.

Settings: Participants for the feasibility study will be recruited from the large and diverse patient population of Yale-New Haven Hospital Emergency Department at the Saint Raphael's Campus(YNHH-ED-SRC). This is the same ED where we conducted the parent project.

Sample Size Justification: The sample size was determined based on the practical considerations of time and availability of subjects and the precision by which the targeted feasibility parameters will be estimated. For dichotomous outcomes (e.g. demand, implementation) a sample size of (N=80) will be a sufficient size to estimate a 95% confidence interval around a proportion with a width of no greater than 0.228. For continuous outcomes (e.g. acceptability, time to completion) a sample size of 80 produces a two-sided 95% confidence interval with a distance from the mean to the limits that is equal to 22% of the measure's standard deviation.

Recruitment: In the YNHH-ED-SRC setting we will seek to enroll eligible older adults with CI. This ED sees approximately 550 persons age 60 or older each week. To meet our recruitment goal of N=80, over the 4-month study period we will need to enroll approximately 5 participants each week. As such, we are confident we can meet our sample size. We will develop a rotating schedule for the RA that varies shifts by time to get a representative ED sample. For details on eligibility please see the (Protection of Human Subjects) section.

5.1.1 Study Date Range and Duration

The expected length of the study is 8 months, enrollment will be for 4 months and there is no follow-up.

5.1.2 Number of Study Sites

This study will be performed at one study site, the Yale-New Haven Hospital Emergency Department at the Saint Raphael's Campus(YNHH-ED-SRC).

5.2 Outcome Variables

5.2.1 Primary Outcome Variables

The primary outcome variables include the areas of **acceptability**, **demand**, **implementation**, and **practicality** of the VOICES tool.

- **Acceptability:** To what extent is VOICES satisfying to end-users?
- **Demand:** To what extent is VOICES likely to be used?
- **Implementation:** To what extent can VOICES be delivered to participants with cognitive impairment in the ED?
- **Practicality:** To what extent can VOICES be carried out with older adults with cognitive impairment without outside intervention?

5.2.2 Secondary and Exploratory Outcome Variables (if applicable)

N/A

5.3 Study Population

Participants aged 60 and older seen at YNHH-SRC-ED.

5.3.1 Number of Participants

The number participants to be recruited is 80 participants.

5.3.2 Eligibility Criteria/Vulnerable Populations

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Provision of signed and dated informed consent form
2. Stated willingness to comply with all study procedures and availability for the duration of the study
3. Age 60 or above
4. MoCA score between 14-25
5. Not in police custody
6. Non-full trauma track upon arrival
7. Able to consent and communicate in English
8. Agrees and able to use the iPad

An individual who meets any of the following criteria will be excluded from participation in this study:

1. Subjects who live in nursing homes or other long-term care settings
2. At the discretion of the clinician, patient will be excluded if they cannot safely undergo the studies required for participation
3. Subject refusal to participate
4. Subjects with clear signs of elder mistreatment
5. Severe hearing and vision impairment
6. Presenting with acute intoxication
7. Presenting with active psychotic symptoms
8. Presenting with COVID-19 diagnosis and/or severe COVID-19 symptoms

6 Methods

6.1 Treatment – Device

6.1.1 Intended Use for Device (provide the following information for each device being investigated in the study)

The VOICES tool goal includes:

1) Educate older adults on Elder Abuse and the type of help available for victims.

2) Screen for elder abuse to detect suspicion of elder abuse.

3) Motivate older adults (with suspicion of elder abuse) to self-identify and self-disclose abuse.

The ultimate goal of VOICES to identify older adults with high suspicion of being victims of abuse and encourage them to seek help.

The goal of our current study is to identify markers of feasibility and not to test the efficacy of VOICES. However, during the feasibility testing if the tool identifies a suspicion of abuse, then the RA will contact the attending clinician to coordinate with the care team at the ED to conduct an *Elder Abuse Assessment* to confirm or reject the findings from VOICES.

In practice, VOICES will identify "suspicion of elder abuse", if:

1) An older adult screened positive

2) An older adult indicated that they want to report abuse to their provider

A subject will be considered positive for suspicion of abuse if:

If the subject answers "Yes" to questions 2-4 of the 5-question mistreatment screener (Elder Abuse Suspicion Index, EASI-sa), AND/OR answers "Yes" to "Do you feel you have been mistreated in the last 12 months?"

Suspected Mistreatment Protocol

The VOICES tool only determines whether there is a *suspicion* of abuse, leaving the confirmation of legitimate abuse to the existing protocols in place at the ED. If the RA sees that the tool has identified *suspicion* of abuse, the RA will contact the attending to coordinate with the care team to perform a formal elder mistreatment assessment to confirm or reject the suspicion.

6.1.2 Device Administration and Schedule

The VOICES tool will be provided on an iPad to the eligible participant and self-administrated by the participant. The research assistant will provide technical assistance if necessary, but otherwise the participant is expected to go through the tool independently, guided by the tool's virtual coach.

We will assess the patient ability to consent by checking if the patient can:

- articulate a choice regarding study participation
- understand its purpose
- comprehend that participation does not constitute medical treatment

If the patient has the capacity to consent, then he/she will complete the consent process on their own.

If patient does not have the capacity to consent, he/she will be excluded from the study.

We will normalize the study approach to the patient and caregiver as much as possible to mitigate potential risk of the caregiver being the eligible participant's abuser. We will include in our introduction of the study that we are asking all individuals over 60 that meet the requirements in the ED to participate in the study, and that the patient has not specifically been flagged for mistreatment of any kind. We will initially open the topic by describing our study as inquiring about "safety at home", and follow-up with more detail if the caregiver or subject are interested.

On average, we anticipate the time needed to complete the consent may range from 15-20 minutes. The patient will be given as much time as needed to consider their participation in the study. The consent process will be completed without the presence of the caregiver.

If the caregiver did not leave the room, or if the patient wanted them to be present, then the patient will not be eligible for the study and cannot participate.

6.1.3 Method of Assignment/Randomization (if applicable)

N/A

6.1.4 Device Calibration

N/A

6.1.5 Storage Conditions

All tablets will be secured in a locked cabinet when not in use.

6.1.6 Concomitant therapy

NA

6.1.7 Restrictions

N/A

6.2 Assessments

6.2.1 Efficacy

Questionnaires to be administered:

- Demographics questionnaire
- Post-Use Survey questionnaire

Demographics will be used to confirm the recruitment of a diverse population, as well as identify any patterns in outcomes with certain populations. The post-use survey will be used to determine some measures in practicality (perceived time to complete tool), implementation (success of execution), and acceptability (5-point Likert scale response questions).

6.2.2 Safety

All data will be entered into databases that are protected with appropriate passwords and routine backups of all data will be carried out. All data collected on the subjects will be coded with numbers to maintain confidentiality. Access to the files will be restricted to the investigators and study personnel on this protocol. Clinical data will be stored with specific patient identifiers, (de-identification of samples), and maintained in a locked file, separate from any other clinical records with limited access, to assure patient confidentiality. Results will be assembled with confidential clinical research records, but will be unidentifiable without

these files, to assure confidentiality. The only data that will be used in this study is the information directly obtained from the subjects.

6.2.3 Adverse Events Definition and Reporting

An adverse event that must be reported to the IRB because it is one of the following:

1. Serious or life-threatening; AND

2. Unanticipated (unexpected) OR anticipated but occurring with a greater frequency than expected; AND

3. Possibly, probably or definitely related to the intervention.

This section describes the procedures and timelines for adverse events (AE) and serious adverse events (SAE), collection and reporting.

- No SAEs are expected from the direct use of VOICES tool on the iPad, but when SAEs occur as result of EM identification and disclosure that are related to the VOICES tool, they will be reported to the NIA Program Officer, Yale IRB, and to the research team within **48 hours** of study's knowledge of the SAE.
- AEs will be reported per Yale IRB policies. They will also be reported to the NIA Program Officer and the study's team at frequency requested by NIA. At minimum, included in semi-annual reports.
- In the unlikely event that such events occur, Reportable Events (which are events that are serious or life-threatening and unanticipated and possibly related)or Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs) that may require a temporary or permanent interruption of study activities will be reported immediately to the NIA Program Officer, Yale IRB, and to the research team, followed by a written report within 5 calendar days of the Principal Investigator becoming aware of the event to the IRB and any appropriate funding and regulatory agencies.
- The PI will apprise fellow investigators and study personnel of all UPIRSOs and adverse events that occur during the conduct of this research project through regular study meetings and via email as they are reviewed by the PI.
- All deaths will be reported within 24 hours of study's knowledge of death.
- The report of death will be submitted to NIA Program Officer, Yale IRB, and to the research team.
- Since the VOICES tool is a web-based application in nature, no information will be stored on the tablet. Data will be stored on Yale's secure servers. If the tablet becomes lost or stolen, the patient's data will not be compromised. All iPads contain encryption software, per University Policy 5100.

6.2.4 Pharmacokinetics (if applicable)

N/A

6.2.5 Biomarkers (if applicable)

N/A

6.3 Study Procedures

6.3.1 Study Schedule

Only one visit and no follow-up. The study will be carried out in one session, during the duration of the participant's visit in the ED. There will be no follow-up with the participant, and the expected time to perform the study is around 45-60 minutes, including consent and post-use survey. Consent is estimated to take between 15-20 minutes on average, and the

post-survey is estimated to take between 5-7 minutes on average. If a follow-up evaluation is necessary due to *suspicion* of mistreatment, the evaluation may take an additional 60 minutes performed by the care team.

6.3.2 Informed Consent

We will pay special attention to the ethical issues and the unique challenges of EM research as well as to consenting and enrolling older persons with cognitive impairments in our study. The consent process informs a volunteer about the study and fully explains the purpose of the research, that this is a research study, that participation is voluntary, and that the participant has the right to stop at any time. Our consent includes all of the eight basic elements of informed consent as articulated by 45 CFR §46.116,21 CFR §50 and Yale IRB Policy 200 Informed Consent for Human Research) and the additional elements of informed consent. Before agreeing to participate in VOICES, potential subjects will be made aware of and understand the risks of participation. They are the following:

- A statement that the study involves research. This includes:
  - An explanation of the purposes of the research, stressing that this is not an intervention
  - The expected duration of the subject's participation
  - A description of the procedures to be followed
  - A description of any foreseeable risks or discomforts to the subject.
  - A description of any expected benefits to the subject or to others
  - When applicable, a disclosure of appropriate alternative offered
  - A statement explaining how confidentiality of data will be managed
  - An explanation of the risk of injury
  - List of whom to contact with questions about the research, research subjects' rights, or in the event of a research-related injury to the subject, that include: Principal Investigator's contact information and IRB Administrator's contact information
- A statement that:
  - Participation is voluntary
  - Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled
  - The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- In addition to the eight required elements of informed consent, additional elements are added to the consent. They include:
  - A statement that VOICES may involve risks to the subject which are currently unforeseeable;
  - Anticipated circumstances in which the subject's participation may be terminated by the PI;
  - Any additional costs to the subject that may result from participation in the research;
  - The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

- The approximate number of subjects involved in the study;
- An explanation of what will be done with the participant information, in the presenting case as well as long-term.

We designed a detailed process on how to evaluate capacity and obtain informed consent from older adult with cognitive impairments.

First: We will use the Montreal Cognitive Assessment (MoCA) to evaluate the severity of CI at the time of enrolment.[72] From our pilot at the Adler Center, we found MoCA scores between 14 and 25 will mainly correspond to MCI or mild dementia. This was also confirmed by our preliminary findings when we piloted VOICES at a dementia clinic (N=30) where we found that VOICES use is feasible to patients with $14 \leq \text{MoCA} \leq 25$. Subjects who score out side this range will be excluded.

Second: During our digital informed consent process, we will use the criteria from "Evaluation to Sign Consent" to determine if the potential participant is capable of providing consent and by asking the questions (below). This approach is derived from the Evaluation to Sign Consent [DeRenzo EG, et al. J Health Care Law Polic 1998;1:66-87]. Factors to be considered include the ability to articulate a choice regarding study participation, understand the study's purpose, and comprehend that participation does not constitute medical treatment. In addition, the digital informed consent process will introduce "teach-back" questions throughout the duration of the consent process to gauge the participant's understanding to the content of the consent process.

Understand Its Purpose: What is the study about?

Q: "Why are we asking you to take part in this study?

Articulate a Choice Regarding Study Participation : Can you stop the study at any time?

Q: "True or False: If you do not want to participate, can you stop at any time?"

Comprehend That Participation Does Not Constitute Medical Treatment

Q: "True or False: This study will not interfere with your medical treatment at the center."

The RA will have access to the subject's responses and the RA will not enroll the subject if capacity to consent is not gained from the subject.

Third: Members of the study team who are responsible for participant recruitment and consent will be highly trained in obtaining informed consent and evaluating the capacity of the participants to understand the purpose, risks, benefits, confidentiality, and privacy associated with study is vital for valid informed consent. At the end of the consent process, the RA will review the subject's understanding of the study by asking the following questions:

- What are you being asked to do?
- What questions is this study trying to answer?
- What are the potential risks and benefits of participating in this study?
- Can you withdraw from the study, and what should you do if you decide to withdraw?

- Do you understand that participation in this study is voluntary and is not part of your medical treatment?

Individuals consenting will be given as much time as they need to comprehend the informed consent content.

6.3.3 Screening

The anticipated process for the screening and data collection is described below and is expected to take 45-60 minutes. The RA will be stationed in the ED and will work with designated nurses to identify potential participants.

We will have the RA perform the MoCA during the screening process to determine eligibility. No pre-existing or previously documented scores will be used to assess eligibility to maintain consistency with screening. The MoCA test on average can be conducted within 10 minutes. All team members will be certified and trained to perform the MoCA.

A MoCA score between 14-25 is associated with Mild cognitive impairment and Mild dementia. Our pilot study findings show that patients with 14-25 MoCA score can safely use the VOICES intervention to completion.

We are requesting a HIPPA waiver for recruitment purposes only. The RA will review the EPIC screen and will then check the demographics for patients 60 years or older. The care team will help the RA approach the patients to ask additional screening questions. We don't have resources and staffing to approach every patient and ascertain eligibility. Using Epic is more efficient for the RAs. The RA will track and document each EHR that the RA accesses using the VOICES tool screening log.

6.3.4 Enrollment

The research assistants will enroll subjects in the study, after they have consented and meet all eligibility criteria.

6.3.5 On Study Visits

There will be only one study visit necessary, which will be approximately a 45–60-minute session including:

- Introduction of study by research assistant
- Consent
- VOICES Tool self-administered by the eligible subject
- Post-use survey
- Incentive and resources to be given at end of study
- If the patient is eligible and would like to participate in the study, the RA will conduct the consent process in a private room used by the patient. Participants must be able to consent and communicate in English. For all patients participating in this study, the consent will be requested from the patient. Participants must be able and agree to use a tablet computer.
- Important considerations

- At the end of the consent process, the RA will review the subject's understanding of the study by asking the following question:
    - What are you being asked to do?
    - What questions is this study trying to answer?
    - What are the potential risks and benefits of participating in this study?
    - Can you withdraw from the study, and what should you do if you decide to withdraw?
    - Do you understand that participation in this study is voluntary and is not part of your medical treatment?

- The caregiver will be asked to step out of the room and go wait in the waiting room. The patient will undergo the study procedures on their own without the presence of the caregiver. If the caregiver did not leave the room, or if the patient wanted them to be present then the patient will not be eligible for the study and cannot participate.
- Participants will be given a description of the study and that they are testing the feasibility of VOICES and that the evaluation is not a measure of their individual performance but measure of the tool performance.
- The RA will collect the participant demographics to gather background information on the participants.
- Participants will be asked to go through the VOICES tool to completion. The RA will be monitoring the use of VOICES and documenting issues of interest that are observed.
- The RA will collect the post study survey from participants after using VOICES.
- Each participant will be given $75 Bank of America debit card as compensation for their time and participation.
- If a participant screens positive or wants to self-report EM, the RA will notify the attending physician.
- The RA will stay with the older adult until the social worker arrives.

6.3.6 End of Study and Follow-up

Participants will be given a $75 incentive upon completion of the post-use survey, as well as a brochure on resources from the CT Protective Services for the Elderly.

6.3.7 Removal of subjects

Since this study is a one-time study, if a participant decides to withdraw, the participant's withdrawal will be documented in the study record and the study will not continue from the point of their withdrawal. Also, participant will be told that they can quit the study at any time.

6.4 Statistical Method

6.4.1 Statistical Design

The purpose of this objective is to understand important areas of feasibility, including acceptability, demand, implementation, and practicality (Table 1). Data for the completion of this objective comes from the following sources: (1) Participant demographic data obtained on pre-survey, (2) participant responses given to questions during VOICES (EM screener, self-identification, self-disclosure), (3) participant responses on participant satisfaction given

to questions on post-survey, and (4) observations made by the RA on enrollment, VOICES administration, and data collection for each participant.

6.4.2 Sample Size Considerations

Sample Size Justification: The sample size was determined based on the practical considerations of time and availability of subjects and the precision by which the targeted feasibility parameters will be estimated. For dichotomous outcomes (e.g. demand, implementation) a sample size of (N=80) will be a sufficient size to estimate a 95% confidence interval around a proportion with a width of no greater than 0.228. For continuous outcomes (e.g. acceptability, time to completion) a sample size of 80 produces a two-sided 95% confidence interval with a distance from the mean to the limits that is equal to 22% of the measure's standard deviation.

6.4.3 Planned Analysis

6.4.3.1 Primary Analyses

Data analysis will be performed using SAS v9.4 (SAS Institute, Cary, NC). Analysis of feasibility will be primarily descriptive. Numeric summaries including frequencies for categorical outcomes and means, medians, standard deviations and interquartile ranges for continuous outcomes will be presented. Graphical summaries will be used to describe distributions of outcomes and relations with baseline characteristics. 95% confidence intervals for means and proportions will be estimated to describe uncertainty from sampling variation for feasibility outcomes.

6.4.3.2 Secondary Objectives Analyses

N/A

6.4.3.3 Safety

N/A

6.4.3.4 Analysis of Subject Characteristics

N/A

6.4.3.5 Interim Analysis (if applicable)

N/A

6.4.3.6 Health economic evaluation

N/A

6.4.3.7 Other

N/A

6.4.4 Subsets and Covariates

N/A

6.4.5 Handling of Missing Data

N/A

7 Trial Administration

7.1 Ethical Considerations: Informed Consent/Assent and HIPAA Authorization

We pay special attention to the ethical issues and the unique challenges of EM research and to consenting and enrolling older adults with cognitive impairment in our study. We designed a detailed process on how to evaluate capacity, and obtain informed consent form older adults. Evaluating the capacity of the participants to understand the purpose, risks, benefits, confidentiality, and privacy associated with the study is vital for valid informed consent. We will use standardized criteria to determine if the potential participant is capable of providing consent and by asking 2 questions: “What is the study about?” and “Can you stop the study at any time?”. This approach is derived from the Evaluation to Sign Consent.
Members of the study team who are responsible for participant recruitment and consent will be highly trained in obtaining informed consent. Additionally, we will employ evidence-based practices from the geriatrics to correctly address these challenges. Evaluating the capacity of the participants to understand the purpose, risks, benefits, confidentiality, and privacy associated with study is vital for valid informed consent. Participants must be able to consent and communicate in English. Patients who lack the ability to provide informed consent will be excluded from the study.

We are requesting a HIPPA waiver for recruitment purposes only. The RA will review the ED Track Board in EPIC and will then check the demographic and chief complaint for patient 60 years or older. They will then approach the patients identified as EMR screening eligible to ask additional screening questions. We don’t have resources and staffing to approach every ED patient and ascertain eligibility. Using Epic is more efficient for the RAs.

The RA will track and document each EHR that the RA accesses using the VOICES tool screening log.

1. What protected health information (medical information along with the HIPAA identifiers) about subjects will be collected and used for the research? Medical records will be reviewed to collect the following variables: MRN, DOB, Able to communicate in English, Living in community dwelling, any severe hearing/vision impairment, and Abbreviated Mental Test 4 (AMT-4) score (which asks the patient to report their age, date of birth, current location, and year).
2. How will the research data be collected, recorded and stored? We will have access-restricted files on each subject. Data of the study will be entered into a secure database. In this study, the following materials will be collected from human subjects: questionnaire, study subject’s study ID, and signature. All paper documents will be maintained in a locked file, separate from other clinical records to assure confidentiality. All electronically stored data will be encrypted and password-protected. Only the primary investigator, co-investigators, study coordinator and programmers will have access to subjects’ data. All datasets will be de-identified and only known to study investigators involved in consent and data acquisition. All information relating to participating subjects will be deidentified.
3. How will the digital data be stored? On secure database server.
4. What methods and procedures will be used to safeguard the confidentiality and security of the identifiable study data and the storage media indicated above during and after

the subject's participation in the study?

The VOICES system will be designed to ensure compliance with good research practice regarding the management of research data containing Protected Health Information (PHI). VOICES will adopt comprehensive security strategies that will assure the confidentiality and privacy of the patient and clinical information. Only authorized users will have access to patient PHI, which will help assuage concerns participants may have regarding the privacy and security of their data. The guidelines contained in the Common Framework give a detailed specification of technical architecture, privacy safeguards, and several approaches to health information exchange. We will utilize this framework to protect patient privacy and keep PHI under strict local control. We will continuously evaluate our security practices in order to quickly identify any new vulnerabilities that could compromise VOICES integrity and privacy. We will utilize the Yale Information Technology Services (ITS) existing privacy and security practices and technology, and incorporate Yale ITS-consistent policies into VOICES development and implementation. In addition to tier separation and firewall protection, the three-tiered architecture maintains VOICES security, confidentiality, and privacy. VOICES will maintain data security with appropriate encryption, system controls and audit trails. *Paper surveys will be stored in a locked area. All electronic data will be de-identified and stored in secure database.*

5. What will be done with the data when the research is completed? Are there plans to destroy the identifiable data? If yes, describe how, by whom and when identifiers will be destroyed. If no, describe how the data and/or identifiers will be secured.

   Data will be stored in safe secure server.

6. If appropriate, has a Certificate of Confidentiality been obtained? *YES*

7.2 Institutional Review Board (IRB) Review

The protocol will be submitted to the IRB for review and approval. Approval of the protocol must be obtained before initiating any research activity. Any change to the protocol or study team will require an approved IRB amendment before implementation. The IRB will determine whether informed consent and HIPAA authorization are required.

The IRB will conduct continuing review at intervals appropriate to the degree of risk, but not less than once per year.

A study closure report will be submitted to the IRB after all research activities have been completed.

Other study events (e.g. data breaches, protocol deviations) will be submitted per Yale IRB's policies.

7.3 Subject Confidentiality

Subject confidentiality is held in strict trust by the research team. Subject medical record review will be limited to the just the elements needed to complete the study. Only authorized HIPAA and GCP trained study team members will be allowed to extract research data from medical records and enter it into VOICES database. No direct subject identifiers will be entered into VOICES data analysis database.

Each subject will be assigned a unique study number. A master list linking the unique study number to the human subject will be maintained in a secure database file.

7.4 Deviations/Unanticipated Problems

If the study team becomes aware of an anticipated problem (e.g. data breach, protocol deviation), the event will be reported to the IRB by e-mail.

7.5 Data Collection

Data of the study will be entered into a secure database on a secure server. In this study, the following materials will be collected from human subjects: questionnaire, study subject's study ID, and signature. All paper documents will be maintained in a locked file, separate from other clinical records to assure confidentiality. All electronically stored data will be encrypted and password-protected. Only the primary investigator, co-investigators, study coordinator and programmers will have access to subjects' data. All datasets will be de-identified and only known to study investigators involved in consent and data acquisition. All information relating to participating subjects will be deidentified.

7.6 Data Quality Assurance

The VOICES system will be designed to ensure compliance with good research practice regarding the management of research data containing Protected Health Information (PHI). VOICES will adopt comprehensive security strategies that will assure the confidentiality and privacy of the patient and clinical information. Only authorized users will have access to patient PHI, which will help assuage concerns participants may have regarding the privacy and security of their data. The guidelines contained in the Common Framework give a detailed specification of technical architecture, privacy safeguards, and several approaches to health information exchange. We will utilize this framework to protect patient privacy and keep PHI under strict local control. We will continuously evaluate our security practices in order to quickly identify any new vulnerabilities that could compromise VOICES integrity and privacy. We will utilize the Yale Information Technology Services (ITS) existing privacy and security practices and technology, and incorporate Yale ITS-consistent policies into VOICES development and implementation. In addition to tier separation and firewall protection, the three-tiered architecture maintains VOICES security, confidentiality, and privacy. VOICES will maintain data security with appropriate encryption, system controls and audit trails.

7.7 Study Records

Documents that will be considered study records for this study are consent forms, demographics and post-use surveys.

7.8 Access to Source

All documents will be collected electronically for the purpose of this study. All electronically stored data will be encrypted and password-protected. Only the primary investigator, co-investigators, study coordinator and programmers will have access to subjects' data. All datasets will be de-identified and only known to study investigators involved in consent and data acquisition.

7.9 Data or Specimen Storage/Security

Data will be collected and stored digitally and maintained on a securely encrypted database server with password protection.

7.10 Retention of Records

Data will be retained based on Yale IRB policy.

7.11 Study Monitoring

The Principal Investigator (PI) will be responsible for ensuring participants' safety on a daily basis.

7.12 Data Safety Monitoring Plan

The DSMP will be monitored by the study team. The Principal Investigator (PI) will be responsible for ensuring participants' safety on a daily basis. To ensure that we are identifying both the adverse events that we might anticipate as well as those that we might not, the PI will review each case where either: (1) a report was made to PSE or (2) a patient was admitted to the hospital for safety to assess for any potential adverse events. The Data and Safety Monitoring Team (DSMT) will consist of Drs. Abujarad, Hwang, and Marottoli; this team will monitor participant safety, evaluate the progress of the study, and review procedures for maintaining the confidentiality of data, the quality of data collection, management, and analyses. They will monitor the study for reports of any adverse or unexpected events. Study participants will be advised to contact the study team to report any adverse events or concerns. VOICES will only be administrated for the intervention group, and there will be no control groups. The PI and the investigative team will monitor data and safety at the monthly study team meetings.
The following will be reviewed:

- Cumulative accrual
- Enrollment of subjects who meet the study eligibility criteria only
- Recruitment is proceeding as planned
- The informed consent process is conducted appropriately; informed consent is obtained
- Evaluate the progress of the trial, including periodic assessments of data quality and timeliness, recruitment, accrual and retention, participant risk versus benefit, and other factors that can affect study outcome
- Consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the trial
- Review study performance, make recommendations, and assist in the resolution of problems reported by the PI
- Evaluate data completeness and quality and as specified in the protocol

Prior to proceeding with any study procedures:

- Review the research protocol, informed consent documents and plans for data safety and monitoring
- Protect the safety of the study participants
- Ensure the confidentiality of the study data and the results of monitoring
- Review procedures for the privacy and confidentiality of subjects
- Review cumulative attrition and attrition by gender and race/ethnicity
- Review dropouts and ensure reason for withdrawal from the study are documented

The principal investigator will be responsible for monitoring the data, assuring protocol compliance, and conducting the safety reviews. During the review process the principal investigator will evaluate whether the study should continue unchanged, require modification/amendment, or close enrollment. The principal investigator and the

Institutional Review Board (IRB) and the NIA have the authority to stop or suspend the study or require modifications.

7.13 Study Modification

For any study modifications, we will update this study protocol. Then we will submit the updated protocol to Yale IRB for approval. Once approved the changes can be implemented in the study.

7.14 Study Discontinuation

N/A

7.15 Study Completion

The study will be completed by March 30th 2022. The PI will notify Yale IRB of the study completion.

7.16 Conflict of Interest Policy

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the trial. The study leadership in conjunction with the appropriate conflict of interest review committee has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

All investigators will follow the applicable conflict of interest policies.

7.17 Funding Source

The study is funded by the National Institute on Aging award number 3R01AG060084-04S1.

7.18 Publication Plan

At the completion of this study and the feasibility study for older adults with cognitive impairment, we expect to enhance the VOICES tool and create all related and necessary user guides. We anticipate that if feasible, VOICES will inform development of national Elder Mistreatment (EM)intervention and screening guidelines on a generalizable scale that will broaden the base for EM identification and intervention while closing health disparity gaps and respecting the autonomy of older adults. Yale University is committed to open and timely dissemination of research outcomes and is aware of and agrees to abide by the principles for sharing research resources.

As a Clinical and Translational Science Awards (CTSA) site, Yale will share the study results with other CTSA institutions and academic or healthcare institutions that would find them useful. In addition, the research team will seek to broadly disseminate through publication in peer-reviewed journals and presentations at national meetings to share and demonstrate the findings and the lessons learned from this project. We will seek to present at conferences such as the Gerontological Society of America annual meeting, the American Geriatrics Society annual meeting and the National Association of Adult Protective Services annual

meeting. We will share the de-identified research data and results developed from this study so that other institutions can benefit from the improvements to current elder abuse and neglect interventions. With additional funding, our future plan is to disseminate the findings and further enhance VOICES to accommodate its use as a tool in the clinical setting at Yale New Haven Hospital, making it a standard of care and rollout within the Yale New Haven Hospital system.

In accordance with the National Institutes of Health (NIH) policy to promote broad and responsible dissemination of information from NIH-funded clinical trials, we registered the VOICES trial on ClinicalTrials.gov (https://clinicaltrials.gov/ct2/show/NCT03834870). In addition, we will submit the VOICES trial results information to ClinicalTrials.gov. The results information will be submitted to ClinicalTrials.gov as outlined in the policy and according to the specific timelines stated in the policy (i.e. not later than 21 calendar days after the enrollment of the first participant).

The informed consent documents for the VOICES trial will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov and the trial number.

Yale has an internal policy and mechanism in place to ensure that clinical trials registration and results reporting occur incompliance with the NIH policy requirements. Since 2012, the Yale ClinicalTrials.gov (CTgov) team has been housed at the Yale Center for Analytical Sciences (YCAS). Through direct support from the Yale Center for Clinical Investigations (YCCI), the team assists researchers in all facets of using the ClinicalTrials.gov database. In addition, the Yale CTgov team provides guidance to Yale University with respect to clinical research study registration and results reporting as it pertains to regulatory compliance. For more information on the Yale ClinicalTrials.gov (CTgov) please visit their website at: (https://publichealth.yale.edu/ycas/clinical_trials_gov/).

8 Appendices

Appendix #	Title	Section	Topic

9 List of Tables

9.1.1.1 Table 1. Planned Data Analyses and Interpretation

Concept	Question	Outcomes of Interest
Acceptability	To what extent is VOICES satisfying to end-users?	Participant satisfaction measured using post-use satisfaction survey with a 5-point Likert response set.
Demand	To what extent is VOICES likely to be used?	Size of target population of older adults in the YIMA measured by the number of subjects who were approached compared to the number of subjects enrolled.
Implementation	To what extent can VOICES be delivered to participants with CI in the ED?	Degree of execution measured by % of potential participants approached who consent to participate in the feasibility study Success of execution measured by # of participants who used the tool to completion and reasons for not completing it as reported on post-survey
Practicality	To what extent can VOICES be carried out with older adults with CI without outside intervention?	Efficiency of implementation measured by the average time (1) to consent & orient participants to the tool and (2) needed to complete VOICES documented by the RA; and (3) patients perceived time of VOICES as measured on post-survey Factors affecting implementation measured by the number and source of interruptions during participation documented by the RA; The number of participants who want their caregiver/family member present during study as documented by the RA Positive/Negative effects of VOICES measured by participants' perceptions of safety concerns vs. benefits and the degree of engagement as reported on post-survey