# The Feasibility of the VOICES Digital Health Tool for Elder Mistreatment Screening in the Primary Care Setting

# STATISTICAL ANALYSIS PLAN

## 5/16/2023

**Principal Investigator:** Fuad Abujarad, PhD
Associate Professor of Emergency Medicine | Yale School of Medicine
464 Congress Ave, Suite 264-J
New Haven, CT 06519

**ClinicalTrials.gov identifier: NCT05224843**

**The SAP was prepared by the trial statisticians:**
Brent Vander Wyk, PhD
300 George St, Suite 715J
New Haven, CT 06519

**Version: 1.0**

**Sponsor:** *Research reported in this publication was supported by the National Institute on Aging of the National Institutes of Health Claude D. Pepper Older Americans Independence Center at Yale under Award Number 2P30AG021342-16. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health*.

**STUDY SUMMARY (revised 5/16/2023)**

| | |
|---|---|
| Title | The Feasibility of the VOICES Digital Health Tool for Elder Mistreatment Screening in the Primary Care Setting |
| Study Design | The design is a single arm trial to develop the digital intervention and conduct a feasibility study across five important areas including: acceptability, demand, implementation, practicality, and limited efficacy. |
| Study Duration | 7 months |
| Trial Sites | Yale Internal Medicine Associates (YIMA). |
| Objective | The primary objective of this study is to perform a feasibility evaluation of the VOICES screening tool among 80 older adults in primary care settings. |
| Number of Subjects | Over the course of this project, we recruited 80 participants. |
| Main Inclusion Criteria | **Inclusion Criteria:**<br>1. Age 60 or above<br>2. Living in Community Dwelling<br>3. Able to consent and communicate in English<br>4. Has no risk of COVID-19<br>5. Agrees and able to use the iPad<br>6. Stated willingness to comply with all study procedures and availability for the duration<br>of the study<br>7. Provision of signed informed consent, or assent if LAR provides consent |
| Intervention | Our intervention is innovative because it utilizes best practices, and innovations in the design and development of digital health to create the one of its kind VOICES EM Intervention. As an easy-to-use, user-friendly EA intervention that runs on tablets with the information and messages displayed on the screen and spoken through headphones for privacy. VOICES delivers content specifically designed to target three factors (attitudes, subjective norms, perception of control) while providing accurate education on EM and APS response and dispelling myths and stereotypes surrounding victimization. VOICES will address perceptions of control making it easy to self-report and ask for help. Another innovative feature of VOICES is the ability to deliver health information through the use of digital tools, multimedia, and digitally guided interviews to older adults to increase awareness of EM. |
| Duration of Intervention | One session 8.8 minutes on average |
| Primary Outcome | The primary outcomes are participation and usage. Participation will be determined by the number of patients enrolled in VOICES. Usage will be determined by the number of patients enrolled in the study that complete the VOICES tool. |
| Primary Analysis | Primary outcomes will be tabulated as counts and frequencies. |

| | |
|---|---|
| Other Pre-Specified Outcome Measures | 1. Acceptability<br>2. Demand<br>3. Practicality<br>4. Efficacy of the Brief Negotiation Interview<br>5. Efficacy of Self-Identification on Self-Disclosure<br>6. Accuracy |

## 1. BACKGROUND

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. 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. 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. 1,002 older adults 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 the use of the VOICES tool to a more vulnerable older adult populations, such as older adults in primary care settings.

## 2. AIMS

The primary objective of this study is to determine whether the VOICES tool is feasible for identifying suspicion of elder mistreatment among older adults in primary care settings.

## 3. STUDY DESIGN

The design is a single arm trial to conduct a feasibility study across five important areas including: acceptability, demand, implementation, practicality, and limited efficacy. The primary outcomes are participation and usage. Participation will be determined by the number of patients enrolled in VOICES. Usage will be determined by the number of

patients enrolled in the study that complete the VOICES tool. Over the course of this project, we recruited 80 subjects over 7 months.

## 4. OUTCOMES

The primary and Other Pre-Specified Outcome Measures are summarized in Table 1.

**Table 1. Primary and Other Pre-Specified Outcome Measures**

| Domain | Measure (P,O) | Source and Frequency |
|---|---|---|
| Implementation | Participation. Participation will be determined by the ratio of participants who are successfully enrolled to the total number of eligible patients. (P) | Study enrollment records |
| | Usage. Usage will be determined by the number of consented participants enrolled in the study who used VOICES to completion (P) | VOICES tool completion records |
| Acceptability | Participant satisfaction measured using post-use satisfaction survey with two 5-point Likert response set scales, developed by the research team (O) | Self-report, once per participant |
| Demand | Measured by the % of the patients who self-identified with elder mistreatment and the % who receive the Brief Negotiation Interview (BNI) portion of VOICES. | Measured by VOICES tool, once per participant |
| Practicality | Average time to consent & orient participants to the tool (O) | RA measurement, once per participant |
| | Average time needed to complete VOICES (O) | RA measurement, once per participant |
| | Average time patients perceived time of VOICES | Self-report, once per participant |
| Efficacy of the Brief Negotiation Interview | Measured as % participants that change their self-identification response after completing the educational component (O) | Measured by VOICES tool, once per participant |
| Efficacy of Self-Identification on Self-Disclosure | Measured as % of patients who disclose among those who self-identified (O) | Measured by VOICES tool, once per participant |
| Accuracy | Measured as percent of classified EM cases that were positive based on social worker assessment, and those referred to Adult Protective Services (APS). (O) | Measured by the outcome of the social worker assessment and by the outcome APS evaluation. |

EM: Elder Mistreatment; BNI: Brief Negotiation Interview; APS: Adult Protective Services

### 4.1 Primary Outcome

Implementation in Terms of Participation. Participation will be determined by the ratio of participants who are successfully enrolled to the total number of eligible patients.

Implementation in Terms of Usage. Usage will be determined by the number of consented participants enrolled in the study who used VOICES to completion.

## 4.2 Other Pre-Specified Outcomes

Acceptability: Participant satisfaction will be measured along multiple dimensions using post-use satisfaction survey with two 5-point Likert response set scales, developed by the research team. Scale 1: Likert scale 1-5, where 1= Very Dissatisfied, and 5= Very Satisfied Scale 2: Likert scale 1-5, where 1= Strongly Disagree, and 5= Strongly Agree

Demand: Demand will be assessed through examining how likely will VOICES be used by patients. To do this, the size of target population of EM victims in the ED will be measured by the % of the patients who self-identified with elder mistreatment and the % who receive the Brief Negotiation Interview (BNI) portion of VOICES.

Practicality: Practicality will be assessed by observing the ease of VOICES use by patients. To do this, a series of steps will be watched to determine the 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 Research Assistant; and (3) patients perceived time of VOICES as measured on post-survey. Each of these will be reported as part of the overall outcome.

Efficacy of the Brief Negotiation Interview: We will look at how many patients changed their readiness to identify and readiness to disclose after completing the Brief Negotiation Interview (BNI).

Efficacy of Self-Identification on Self-Disclosure: We will explore whether self-identification impacts likelihood of self-disclosure. Effect-size estimation measured by change in the % of patients who disclose among those who self-identified.

Accuracy: To understand the accuracy of the VOICES tool, a preliminary evaluation of the accuracy of VOICES as a screening tool in correctly classifying EM cases that were positive based on social worker assessment, and those referred to Adult Protective Services (APS). The percent correct classification will be reported.

# 5. RANDOMIZATION

Randomization is not applicable with the single arm design.

# 6. SAMPLE SIZE

## 6.1 Sample Size Determination for the Primary Outcome

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.

# 7 ANALYTIC PLAN

## 7.1 Analysis of Primary Outcome:

Implementation in Terms of Participation. Participation will be determined by the ratio of participants who are successfully enrolled to the total number of eligible patients. The numerator, denominator, frequencies and 95% confidence intervals will be reported.

Implementation in Terms of Usage. Usage will be determined by the number of consented participants enrolled in the study who used VOICES to completion. The numerator, denominator, frequencies and 95% confidence intervals will be reported.

## 7.2 Analysis of Other Pre-Specified Outcomes

Acceptability: Participant satisfaction will be measured along multiple dimensions using post-use satisfaction survey with two 5-point Likert response set scales, developed by the research team. Scale 1: Likert scale 1-5, where 1= Very Dissatisfied, and 5= Very Satisfied Scale 2: Likert scale 1-5, where 1= Strongly Disagree, and 5= Strongly Agree. The means and standard deviations will be reported.

Demand: Demand will be assessed through examining how likely will VOICES be used by patients. To do this, the size of target population of EM victims in the ED will be measured by the % of the patients who self-identified with elder mistreatment and the % who receive the Brief Negotiation Interview (BNI) portion of VOICES. Counts of participants will be reported.

Practicality: Practicality will be assessed by observing the ease of VOICES use by patients. To do this, a series of steps will be watched to determine the 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 Research Assistant; and (3) patients perceived time of VOICES as measured on post-survey. Each of these will be reported as part of the overall outcome. The means and standard deviations will be reported.

Efficacy of the Brief Negotiation Interview: We will look at how many patients changed their readiness to identify and readiness to disclose after completing the Brief Negotiation Interview (BNI). Counts of participants will be reported.

Efficacy of Self-Identification on Self-Disclosure: We will explore whether self-identification impacts likelihood of self-disclosure. Counts of participants who change willingness to disclose among those that self-identify will be reported.

Accuracy: To understand the accuracy of the VOICES tool, a preliminary evaluation of the accuracy of VOICES as a screening tool in correctly classifying EM cases that were positive based on social worker assessment, and those referred to Adult Protective Services (APS). The percent correct classification will be reported.