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

STATISTICAL ANALYSIS PLAN

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STUDY SUMMARY (revised 3/1/2023)

Title	Virtual cOaching in making Informed Choices on Elder Mistreatment Self-Disclosure (VOICES)
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	16 months
Trial Sites	Yale-New Haven Hospital Emergency Department on the Saint Raphael's Campus (YNHH-ED-SRC).
Objective	The purpose of this study is to evaluate the feasibility of using VOICES Elder Mistreatment (EM) intervention in the emergency department to detect cases of EM.
Number of Subjects	Over the course of this project, we recruited 1002 participants.
Main Inclusion Criteria	**Inclusion Criteria:** (1) Age 60 years or older; (2) non-full trauma track upon arrival; (3) Alert and oriented to person, place and time; (4) AMT4=4; (5) Able to consent and communicate in English; and (6) Agrees and able to use the iPad; (7) Not in police custody
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 2. Demand 3. Practicality 4. Efficacy of the Educational Material 5. Efficacy of the Brief Negotiation Interview 6. Efficacy of Self-Identification on Self-Disclosure 7. Accuracy

1. BACKGROUND

Elder mistreatment (EM) is a major public health problem with prevalence estimate ranges from 7.6% to 12.7% among older adults. EM causes serious adverse outcomes for its victims including injury, increased service utilization, mental distress and increased 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. This is problematic as older adults are not likely to report that they are being mistreated. To improve the screening for EM and promote self-disclosure we will study the Feasibility of **V**irtual c**O**aching in making **I**nformed **C**hoices on **E**lder Mistreatment **S**elf-Disclosure (**VOICES**). The overarching aim of this project is to evaluate the feasibility of using VOICES Elder Mistreatment (EM) Intervention that runs on tablets and used by older adults to detect EM in emergency department (ED) settings. VOICES will be utilizing virtual coaching, interactive multimedia libraries (e.g., graphics, video clips, animations, etc.), techniques form electronic screening for intimate partner violence, and brief motivational interviewing designed to enhance identifying EM among older adults. This project includes developing new *screening framework*, as well as a study to examine the feasibility of this complex interventions in real-world settings.

2. AIMS

Aim 1. Feasibility Study: To conduct a feasibility study (N= 1002) examining the use of VOICES in a busy ED.

Aim 2. Exploratory Aim: To perform a preliminary evaluation of the accuracy of VOICES as a screening tool in correctly classifying EM cases that were referred to Adult Protective Services (APS).

3. 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. 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 1,002 subjects over 16 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	Study enrollment records

	number of eligible patients. (P)	
	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 Educational Material	Measured as % of participants that change their self-identification response after completing the educational component (O)	Measured by VOICES tool, 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 Educational Material: To understand the efficacy of VOICES in this pilot, we will look at how many participants changed their self-identification response after completing the educational component.

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

Given that VOICES is a new tool, we did not have the needed information to estimate a power analysis or judge an approach sample size to calculate a meaningful sensitivity analysis when planning for the study. However, based on the initial analysis of the relevant population and our sample size, we estimate VOICES will detect EM in 40 to 70 older adults. We will report the 95% confidence intervals with our finding of sensitivity.

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 Educational Material: To understand the efficacy of VOICES in this pilot, we will look at how many participants changed their self-identification response after completing the educational component. Counts of participants 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.