

**Family Safety Net: Developing an Upstream Suicide Prevention Approach to
Encourage Safe Firearm Storage in Rural and Remote**

NCT05657119

March 14, 2023

STATEMENT OF COMPLIANCE

(1) [The trial will be carried out in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).

National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.]

INVESTIGATOR'S SIGNATURE

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines.

Principal Investigator or Clinical Site Investigator:

Signed:



Date: 02.28.23

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1 PROTOCOL SUMMARY

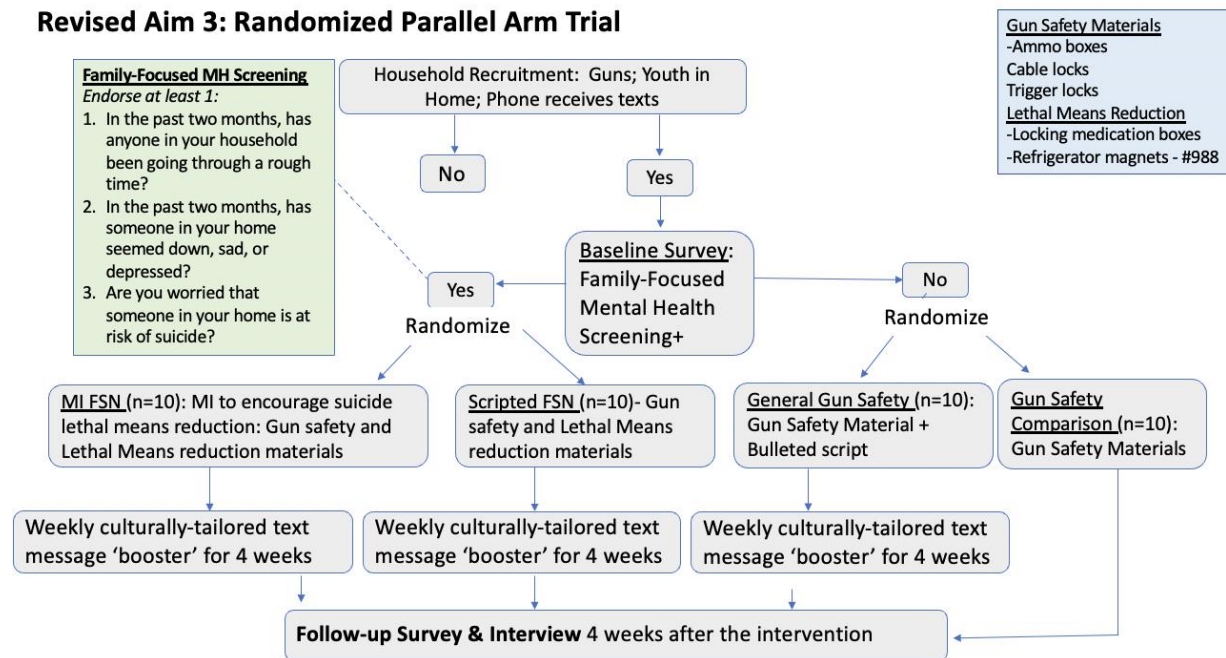
1.1 SYNOPSIS

Title:	Family Safety Net: Developing an upstream suicide prevention approach to encourage safe firearm storage in rural and remote Alaskan homes
Grant Number:	<i>R61MH125757-01</i>
Study Description:	<p>The pilot randomized control trial (n=70, 35/group) will assess feasibility, acceptability, and fidelity of the Family Safety Net (FSN) intervention, as well as examine preliminary efficacy at increasing safe storage practices and expected mechanisms of change based on our theoretical model. The primary outcomes are feasibility and acceptability of the intervention, with data collection also aimed at indications of efficacy. Efficacy signals will be assessed by outcomes related to firearm storage practices within households with adolescents. Firearm storage measures include whether household firearms are locked, unloaded with inaccessible ammunition. The harm reduction approach encourages persons within a firearm-owning population to reduce risk of firearm injuries and fatalities simply by decreasing youth access to guns within their homes.</p>
Objectives[*]:	<p>Conduct a pilot randomized control trial (n=70, 35/group) to assess feasibility, acceptability, and fidelity of the Family Safety Net (FSN) intervention, as well as examine preliminary efficacy at increasing safe storage practices and expected mechanisms of change based on our theoretical model.</p>
Endpoints[*]:	<p>Primary outcomes focus on intervention feasibility, acceptability, and fidelity. Although underpowered, we will examine preliminary efficacy by examining changes in targeted mechanisms and outcomes from baseline to follow-up between groups: current household gun storage (# and type of firearm; locked/unlocked, loaded/unloaded and location of ammo for each), and behaviors to increase mental wellness support and access to mental health resources</p>

Study Population:	Our prospective randomized controlled study design (n=70, 35/group) will recruit mainly Alaska Native adults who live in remote and rural Alaskan communities, who have a firearm in their primary household and live with someone who may be at increased suicide risk.
Phase[*] or Stage:	This is a pilot study to assess feasibility and acceptability.
Description of Sites/Facilities Enrolling Participants:	The sessions for all participants will occur in a community building in up to two of the 11 villages served by Maniilaq Association. There will be no sites outside of the United States.
Description of Study Intervention/Experimental Manipulation:	<p>Participants will be screened into either a suicide-prevention lethal means reduction arm (Family Safety Net - FSN) or a general gun safety arm, based on their survey responses. From there, participants are randomized into one of two groups, making four groups total.</p> <p>The FSN arm will be randomized into a motivational interviewing (MI) group (1) or a bulleted script group (2). The FSN MI group will participate in a 15-20-minute MI session focused on encouraging suicide lethal means and will take home gun safety and lethal means reduction materials, followed up with 4 weeks of tailored text messages. The scripted FSN group will participate in a 10-15-minute scripted session focused on gun safety and lethal means reduction and will take home gun safety and lethal means reduction materials, followed up with 4 weeks of tailored text messages.</p> <p>The general gun safety arm will be randomized into a gun safety intervention (3) and a gun safety comparison group (4). The general gun safety intervention group will participate in a 10-minute scripted conversation about safe gun storage practices, go home with safe gun storage materials, and 4 weeks of tailored text messages. The general firearm safety comparison group will receive safe gun storage materials for their home.</p>
Study Duration[*] :	2 months
Participant Duration:	Less than 90 minutes.

1.2 SCHEMA

Revised Aim 3: Randomized Parallel Arm Trial



1.3 SCHEDULE OF ACTIVITIES

TASKS/Milestones:

- FSN MI intervention (n=10) v. FSN bulleted script intervention (n=10) – 03/23
- General firearm safety intervention (n=10) v. supplies-only comparison (n=10) – 03/23
- Tailored text messages to both FSN groups and general firearm safety intervention group – 03/23-04/23
- Follow-up surveys and semi-structured interviews – 04/23

2 INTRODUCTION

2.1 STUDY OVERVIEW

This protocol is for the Aim 3 of the three aims of the Family Safety Net (FSN) study, HUM00225431, related to HUM00214780, HUM00192299 and HUM00185075. The key elements and cultural issues identified in Aim 1 shaped the development of the FSN intervention which was focused tested in Aim 2. Aim 3 will integrate what was learned from Aims 1 and 2 into a pilot randomized control trial (n=70, 35/group).

AIM 3: Implement the Family Safety Net (FSN) intervention as a pilot randomized control trial. Aim 3 has been shaped by the survey and interview data from Aim 1 as well as the feedback from the satisfaction interviews and feasibility of the focus testing in Aim 2. Aim 3 of the FSN includes a baseline survey, a brief session (dependent on group assignment), take-home home safety supplies, a follow up survey, and a follow up semi-structured

interview. Participants will be screened into either a suicide-prevention lethal means reduction arm (Family Safety Net - FSN) or a general gun safety arm, based on their survey responses. From there, participants are randomized into one of two groups, making four groups total.

The FSN arm will be randomized into a motivational interviewing (MI) group (1) or a bulleted script group (2). The FSN MI group will participate in a 15-20-minute MI session focused on encouraging suicide lethal means and will take home gun safety and lethal means reduction materials, followed up with 4 weeks of tailored text messages. The scripted FSN group will participate in a 10-15-minute scripted session focused on gun safety and lethal means reduction and will take home gun safety and lethal means reduction materials, followed up with 4 weeks of tailored text messages.

The general gun safety arm will be randomized into a gun safety intervention (3) and a gun safety comparison group (4). The general gun safety intervention group will participate in a 10-minute scripted conversation about safe gun storage practices, go home with safe gun storage materials, and 4 weeks of tailored text messages. The general firearm safety comparison group will receive safe gun storage materials for their home.

The primary outcomes are feasibility and acceptability of the intervention, with data collection also aimed at indications of efficacy. Efficacy signals will be assessed by outcomes related to firearm storage practices within households and health promotion activities. Firearm storage measures include whether household firearms are locked, unloaded, and with inaccessible ammunition. The harm reduction approach encourages persons within a firearm-owning population to reduce risk of firearm injuries and fatalities simply by decreasing youth access to guns within their homes.

2.2 RISK/BENEFIT ASSESSMENT

2.2.1 KNOWN POTENTIAL RISKS

The lethal means reduction interventions have very minimal risks in the short, intermediate, or long-term. It is possible that talking about potential reasons for locking, unloading and keeping ammo apart from firearms in one's home could bring up memories of past experiences, but the risk is no more than would occur in daily life.

2.2.2 KNOWN POTENTIAL BENEFITS

Benefits are improving participants' home safety and tools and resources to do so, and to provide interpersonal support to the people they live with.

2.2.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

The benefits to participants outweigh the potential very minimal risks.

3 OBJECTIVES AND ENDPOINTS

3.1.1.1 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS	PUTATIVE MECHANISMS OF ACTION
Primary			
Feasibility Acceptability	The <u>feasibility of the intervention</u> will be tested by assessing the % of people are eligible and agree (# agree/# eligible). For feasibility, we will consider level of attrition over the 4-week booster period, and ability to collect follow-up data (target: 85% or 60 people). To assess <u>participant satisfaction</u> : <u>Acceptability</u> (both cultural appropriateness and acceptability) will include items focused on the MI session, materials (trigger, cable locks and ammo boxes).	We consider 75% of participants 'agree' or 'strongly agree' with satisfaction statements to be acceptable.	NA
Secondary			
Efficacy of firearm storage Efficacy of mental wellness support	Our surveys will assess household firearm storage behaviors. For measuring household		Our hypothesized mechanisms leading to this outcome include perceived threat: the severity of

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS	PUTATIVE MECHANISMS OF ACTION
	<p>firearm storage, we will assess the frequency of different firearm storage behaviors. The four firearm storage outcomes include whether: (1) all household firearms were stored in a locked place or using a locking device; (2) all household firearms were stored unloaded; and (3) all household ammunition was stored in a locked place.</p> <p>Mental wellness behaviors include small acts of kindness and making mental health resources available.</p>		<p>firearm risk and susceptibility to that risk; perceived benefits to safely storing firearms: perceived barriers or issues hindering safe firearm storage within one's household: Self-efficacy related to one's ability to ensure safe firearm storage practices consistently.</p>
Tertiary/Exploratory			
NA.			

3.1.2 AIM 3 STUDY DESIGN

3.1.2.1 INCLUSION/EXCLUSION CRITERIA

- Inclusion:
 - Adults (over 18) who:

- Have lived in the region for 5+ years,
 - Read and Understand English,
 - Live in a household with at least one gun,
 - Have young people (under 29) who spend time in their home, and
 - Have a phone that can receive texts.
- Exclusion:
 - Someone who has a household member who has already participated in the FSN

3.1.2.2 SEQUENCE OF PARTICIPANT ACTIVITIES

Aim 3 randomized control trial (n=70) involves:

- (1) Recruitment: The research team and community steering committee members will deliver paper recruitment flyers to individuals in the community ahead of arriving. These will be distributed by the community partner agency, Maniilaq. Additionally, announcements will be made ahead of arrival on the radio to let the community know the research team is coming.
- (2) Respondent Driven Sampling Coupons:
 - One way participants can enter the study is to simply come into the space (after hearing about the program on the radio or from a flyer) and see if they qualify. If they do, they are given a coupon right then with a unique participant ID.
 - The other way to enter the study is through Respondent Driven Sampling (RDS), where participants receive a coupon from another participant, as none of the recruitment criteria for the study is stigmatized (young person who spends time in the home, have one or more firearms, lives in the region, has a cell phone that gets texts). Each participant who completes the session leaves with two RDS coupons each worth \$10 to give out to other community members that would qualify. These two coupons are linked to their participant ID. If either of the people they recruit and give a coupon to come in and participate in the study, the initial person gets \$10 for each coupon (up to two or total of \$20).
 - Either way that a person enters the study, they have a unique ID from their own coupon, and they leave with two RDS coupons each worth \$10 to give to community members. Participants can only get the additional incentive if their recruit participates in the study.
- (3) Qualifying for Study: Participants will be asked verbally if they qualify for the study, which will additionally be confirmed in the first few questions on the baseline survey, before they are consented. Participants qualify for the study if they:
 - Are 18 or older
 - Live in a home with firearms
 - Live in a home where young people (under 29) spend time
 - Are from the region
 - Are the only person from their household to participate in the study
 - Have a cell phone that gets text messages
- (4) Consent: If the participant qualifies and agrees to participate, they will be brought to a private room by the research staff. Research staff will walk through the screening criteria in the survey with the participant and go through the consent form on the iPad or on paper and answer the participant's questions. If they agree to participate, they will mark their consent, for both their participation and separately to have their session recorded, and additionally be offered a paper copy of the consent form to take home.

- (5) Baseline Survey: Once consented, participants will be asked to complete a 10-15-minute baseline survey on the iPad. The survey will be done independently or with the help of the researcher if troubled by reading comprehension or navigating the iPad technology.
- (6) Home Safety Session: Participants will be screened into either the lethal-means reduction focused FSN program or the general firearm safety program based on their survey responses. If a respondent answers “yes” to one of the following questions, they are in the lethal-means reductio FSN arm of the program:
- In the past two months, has anyone in your household been going through a rough time?
 - In the past two months, has someone in your home seemed down, sad, or depressed?
 - Are you worried that someone in your home is at risk of suicide?

They are then randomly assigned into one of two groups using a grouped randomization table:

a. The lethal means reduction MI FSN group (n=10) will:

- Participate in a short 20-minute motivational interviewing (MI) session that includes: (1) introduction to the session and setting the agenda; (2) discussing the person’s goals and strengths related to keeping loved ones safe through safe firearm and medication storage (e.g. making one’s home safer to protect the youth or other family living there) and supporting wellness (i.e. mental health promotion); (3) offering normative feedback about safe firearm storage practices within the community; (4) talk about the benefits of safer firearm and medication storage practices (e.g. enhancing youth safety or avoiding youth harm); (5) action planning to increase self-efficacy to overcome barriers and move toward reducing access to firearms and medications by locking and unloading all household guns and medications; and (6) summarizing key content of the session to re-enforce benefits, goals and values and support self-efficacy to facilitate safe firearm and medication storage practices and wellness support at home.
- Pick out safe storage devices to take home (e.g. trigger locks, cable locks, ammo boxes, medicine boxes, mental health crisis resources, local safety resources etc.)
- Be told about the next steps of the study, including text messages and follow up survey and interview in about 4 weeks.
- Receive 4-weeks of text messages tailored by their survey responses (1x to 4x weekly depending on baseline survey responses). They may opt out at any time.

b. The lethal means reduction bulleted script FSN group (n=10) will:

- Participate in a 15-minute conversation about lethal means reduction in their home, emphasizing that 10-minutes can save a life – the conversation includes discussing locations and storage of firearms, ammo, medications, and location of mental health crisis resources.
- Pick out safe storage devices to take home (e.g. trigger locks, cable locks, ammo boxes, medicine boxes, mental health crisis resources, local safety resources etc.)
- Be told about the next steps of the study, including text messages and follow up survey and interview in about 4 weeks.

- iv. Receive 4-weeks of text messages tailored by their survey responses (1x to 4x weekly depending on baseline survey responses). They may opt out at any time.
- c. The general firearm safety intervention group (n=10) will:
 - i. Participate in a 10-minute conversation about safe firearm storage in their home including discussing locations and storage of firearms and ammo.
 - ii. Pick out safe storage devices to take home (e.g. trigger locks, cable locks, ammo boxes, local safety resources etc.)
 - iii. Be told about the next steps of the study, including text messages and follow up survey and interview in about 4 weeks.
 - iv. Receive 4-weeks of text messages tailored by their survey responses (1x to 4x weekly depending on baseline survey responses). They may opt out at any time.
- d. The general firearm safety comparison group (n=10) will:
 - i. Pick out safe storage devices to take home (e.g. trigger locks, cable locks, ammo boxes, local safety resources etc.)
 - ii. Be told about the next steps of the study, including follow up survey and interview in about 4 weeks.

(7) Compensation: All participants will be compensated for their time taking the baseline survey \$20 in cash, regardless of group assignment.

- a. Participants will receive two RDS coupons at the end of their session each worth \$10 to give to people in the community who they think would qualify and like to participate.
- b. The participants are instructed to check back in at the end of the day or later in the week to verify if either of the people they gave coupons to came in and participated. If either of the people they gave coupons to participated in the study, the participant receives an additional \$10 for each of the people they recruited (total of 2 or \$20).

(8) Follow-Up Survey: One month after the initial session, a link will be sent to participants via text/email to complete a 10–15-minute (depending on skip logic) follow-up survey. The follow-up survey consists of items related to firearm storage, and facilitating factors hypothesized to contribute to this behavior. The survey will include items focused mechanisms of change, including self-efficacy, and on the current household gun storage (# and type of firearm; locked/unlocked, loaded/unloaded and location of ammo for each) and actions taken to support mental wellness for others in their home. Additionally, participants will also answer questions about their satisfaction with the FSN (acceptability, cultural responsiveness). For both comparison and intervention groups, the follow-up will capture a “snapshot” of current household firearm storage practices that day.

- a. Text message with link will say “Hello! Thank you for helping us out by doing this survey. When you participated in the Family Safety Net about a month ago, you gave us permission to send it. Please click on the link to access your personalized survey. You will receive \$30 for the time it took you to complete our survey: [<personalized link>](#)”
- b. If participants have not taken their survey, they will be contacted via phone about when they can take the survey.

- (9) Follow-Up Semi-Structured Interview Participants will additionally be invited at follow-up to take part in a 20-minute phone interview (semi-structured) also one month after their initial session. The follow-up semi-structured interview consists of questions around satisfaction with the program, what participants liked and didn't like, follow up questions on the mental health concerns they have in their home, and follow up on what they did with the home safety equipment they brought home and why as well as how the supplies worked for them. See Follow-Up Semi-Structured Interview Protocols.
- (10) Compensation: All participants will receive a \$30 cash equivalent (ie. gift card for their local store or Amazon, etc.) for completing the follow-up survey. All participants will receive an additional \$50 cash equivalent for completing the follow-up interview via phone.

3.1.3 DATA STORAGE AND MANAGEMENT

Participants will be assigned a study participant ID, which will be placed on all surveys and interview documents. This information will be kept in password-protected computers and on encrypted servers. All records will not include names, registration numbers, or other information that could link the information to the participants' names. This information will not be associated with participant answers.

Data will be collected using approved vendor software and will be uploaded using secure and UM authorized software over secure servers to either the ISR secure (encrypted) server and storage or other ISR approved storage.

Dr. Kate Comtois, University of Washington, serves in the role of Independent Safety Monitor (ISM) for the study. She is an independent expert with experience working in the area of health services, treatment development, and clinical trials research to prevent suicide for over 25 years. Dr. Comtois also has experience conducting research with Alaska Native people in Alaska. As the ISM, Dr. Comtois will provide independent monitoring of the pilot Family Safety Net clinical trial. She has reviewed the study protocol and has approved the Data and Safety Monitoring Protocols as of February 28, 2023.