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

NCT05657119

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UNIVERSITY OF MICHIGAN
CONSENT TO BE A PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Family Safety Net (FSN) - Aim 3: Randomized Clinical Trial
HUM#: HUM00225431
Principal Investigator: Lisa Wexler, PhD, MSW
Study Sponsor: National Institute of Mental Health R61 MH125757

You are invited to take part in a research study aimed at safe gun storage in Northwest Alaska. This form contains information that will help you decide whether to join the study.

Taking part in this research project is voluntary. You do not have to participate, and you can stop at any time. We will go over this entire form and invite you to ask questions before deciding whether to take part in this research project.

2. PURPOSE OF THIS STUDY

The purpose of this study is to create a widely used strategy to support home safety by reducing quick access to guns in homes, giving you gun storage materials and offering other resources to keep loved ones safe. By reducing easily accessed guns and giving other wellness resources, we hope to reduce the suicide and accidental deaths of youth and young adults in Northwest Alaska. The way we are doing this project is new and we need your help to learn how we can do this best. Your suggestions and feedback will help us create a quick plan to add to home safety throughout the region.

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study?

You may participate if you:

- Are 18+ years old
- Have lived in a Northwest Alaska town or village (i.e., Kotzebue, Point Hope, Kivalina, Noatak, Noorvik, Kiana, Ambler, Shungnak, Kobuk, Selawik, Buckland, Deering) for at least 5 years
- Are living in a household with at least 1 gun
- Have a phone that can receive texts
- Have young people (under 29) who spend time in your home

3.2 How many people are expected to take part in this study?

We estimate about 50 people will participate in Family Safety Net study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

In this study you *may* be invited to:

(1) Fill out a survey about your household, mental wellness, and gun storage;
(2) Participate in a short interview about the people in your home and about gun storage; we may audio record this conversation;
(3) Participate in a conversation with a research team member focused on home safety; we may audio record this conversation;
(4) Pick your choice of materials to enhance home safety and mental health;
(5) Receive 2-4 text messages per week for 4 weeks. These short messages are reminders and encouragement around home safety and the wellness of the people in your household

(6) In about a month, we hope to do a follow-up survey with you that is similar to the one you will fill out today with a few added questions about what you liked and didn't like about the whole Family Safety Net study.

(7) In about a month, we also hope to have a follow-up semi-structured interview with you to learn more about your experience.

4.2 How much of my time will be needed to take part in this study?
The survey, the interview, the conversation, and picking things to take home with you for safety will take approximately 30-40 minutes of your time. In the follow-up a month from now, we will invite you to do a survey again, which will take about 15 minutes of your time and an optional semi-structured interview that will take an additional 15 minutes.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
Potential risks of participating in this study are minimal. We will try to minimize these risks by being clear and efficient. In the study, we will ask questions related to the topic of guns and gun safety that you might not feel comfortable answering. We also ask about the mental wellness of people in your household. It is possible that talking about these issues—mental health, dangers of guns and suicide--may bring up bad feelings for you. You can skip any questions that you do not want to answer on the survey, in the Family Safety Net session or interviews. It is your choice to answer (or not) at all times. If you change your mind and no longer want to participate, you can stop participating at any time without any effects. Your relationship with Maniilaq and with UM researchers will be unchanged.

We will only collect your personal information on this consent form and your receipt, and this information will not be associated with your answers. The primary risk of this research is a loss of confidentiality. See Section 7 of this document for more information on how the study team will protect your confidentiality and privacy.

We will not be following up with you after the very end of the study. If you feel upset after completing the study or find that some of the questions or aspects of the study have triggered distress, talking with a qualified clinician may help. If you would like assistance, please contact Maniilaq Association's counseling and recovery services at (907) 442-7640 or 911 for an emergency or text/call 988 for the Suicide and Crisis Lifeline. Also, please feel free to check out the study website for local and national mental health information: https://fsn.isr.umich.edu/resources/ .

5.2 How might I or others benefit?
We are hoping that by participating in the Family Safety Net, adult family members, like yourself, will get ideas, home safety materials, tips to support young people's wellbeing, and reminders for keeping their loved ones safe at home. This study may also benefit others by building on the strength of families as an important unit for health and wellness efforts. We hope that your participation will help us make the Family Safety Net a useful way to engage family members in supporting home safety and ultimately offers a new way to protect young people and keep them safe.

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?

You are free to withdraw from the study for any reason, at any time with no penalty to you. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 9, "Contact Information". If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information. If you stop corresponding with the study team and do not inform a researcher of your decision to leave the study, you will not be withdrawn from the study, and the researchers will keep the information collected about you for the research.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for my taking part in this study?

YES! We want to compensate you for your time participating in the study

- $100-120 total for the whole study
    - Baseline survey = $20 today
    - Recruitment coupons = 2x$10 each, up to $20
    - Follow up survey (about 15 minutes) in about a month = $30
    - Optional follow up semi-structured interview (about 15 minutes) in about a month = $50

7.2 No one will profit or financially benefit from the study results.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information?

We will protect your confidentiality by using a study ID, not your name on the information you give us on the surveys and interviews. 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 you give to your name. We will only collect your personal information on this consent form and to pay you at the end, and this information will not be associated with your answers.

8.1.1 Special Protections

This research holds a Certificate of Confidentiality from the National Institutes of Health. This means that we cannot be forced to disclose any research information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. In general, we will use the Certificate to resist any demands for information that would identify you, except if you tell us that you are a danger to yourself or others, we may be required to report that information to the appropriate agencies to maintain safety. For example, we may disclose your information to the appropriate authorities if required by local or state law or if we suspect or learn about cases of child or elder abuse or neglect or endangerment of any vulnerable person, or that you may harm yourself or others.

We will disclose your information if the National Institutes of Health (NIH), the agency funding this research, requests information to audit or evaluate our procedures.

Please note that a Certificate of Confidentiality does not prevent you or a member of your family from

voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then we will not use the Certificate to withhold that information.

More detailed information about Certificates may be found at the NIH CoC webpage: https://humansubjects.nih.gov/coc/index

8.2 Who will have access to my research records?
There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- University, government officials, study sponsors or funders, auditors, and/or the Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.

8.3 What will happen to the information collected in this study?
Upon study completion your name or other information that can identify you directly will be destroyed. The results of this study could be published in an article or presentation but will not include any information that would let others know who you are without your permission.

8.4 Will my information be used for future research or shared with others?
We may use or share your research information for future research studies. If we share your information with other researchers it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

8.4.1 Special Requirements: A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by the National Institutes of Health (NIH). This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

9. CONTACT INFORMATION

Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Lisa Wexler, PhD, MSW
Email: lwexler@umich.edu
Phone: 1 (734) 764-7806

Study Coordinator: Kelsey Porter, MSW
Email: kaporter@umich.edu
Phone: 1 (530) 414-1162

Local Coordinator: Megan Leys, MSW
Email: mleys@umich.edu
Phone: 1 (907) 437-0351

We will not be following up with you after the study. If you feel upset after completing the study or find that some of the questions or aspects of the study have triggered distress, talking with a qualified clinician may help. If you would like assistance, please contact Maniilaq Association's counseling and recovery services at (907) 442-7640 or 911 for an emergency. Also, please feel free to check out the study website for local and national mental health information: https://fsn.isr.umich.edu/resources/ .

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)
2800 Plymouth Road
Building 520, Room 1169
Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933
Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

10. YOUR CONSENT

Consent to Participate in the Research Study

By checking the box below, you consent for the research staff to digitally audio record your session.

☐ ***I consent to research staff digitally audio recording my sessions***

☐ ***I DO NOT consent to research staff digitally audio recording my sessions***

Consent to Participate in the Research Study

By checking the box below and entering your name, you acknowledge that you are 18+ years old, have been living in the Northwest Alaska region for at least 5 years in one of the villages or towns stated in section 3.1, are living in a household with at least one gun, have young people under 29 who spend time in your home, have a cell phone that gets text messages, and you agree to be in this study. By consenting you agree to be contacted by the research team about this study including future participant recruitment.

Make sure you understand what the study is about before you consent. We will keep a copy of your consent with the study records. If you have any questions about the study after you consent, you can contact the study team using the information in Section 9 provided above.

☐ ***I consent to take part in this study. I understand what the study is about, and my questions so far have been answered.***

Your Name: _____

Date: _____