Va Meh Du Intervention

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Wake Forest University
School of Medicine

Department/Section of *Public Health Sciences*

VA MEH DU: AN INTERVENTION TO PROMOTE MENTAL WELLNESS AMONG KARENNI YOUNG ADULTS AND CHILDREN

Informed Consent Form to Participate in Research
Stephanie Daniel, PhD, Principal Investigator

SUMMARY

Your child is invited to participate in a research study. The purpose of this research is to promote mental wellness for Karenni children and young adults in Forsyth County, NC. Your child is invited to be in this study because they are a Karenni child aged 9-14 in Forsyth County. Your child's participation in this research will involve 6 months.

Participation in this study will involve your child taking part in a summer soccer program. All research studies involve some risks. All research studies involve some risks. The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life. There is the possibility that your child may benefit from participation in this study.

Your child's participation in this study is voluntary. Your child does not have to participate in this study if your child do not want to. There may be other choices available to your child. Some other choices may include not participating in this study. Your child will not lose any services, benefits, or rights your child would normally have if your child choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. Your child can ask any questions if your child need help deciding whether to join the study. The person in charge of this study is Stephanie Daniel, Principal Investigator. If your child have questions, suggestions, or concerns regarding this study or your child want to withdraw from the study his/her contact information is: [redacted].

If your child have any questions, suggestions or concerns about your child's rights as a volunteer in this research, contact the Institutional Review Board at [redacted].

INTRODUCTION

Your child is invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. Your child is being asked to take part in this study because your child is Karenni and lives in Forsyth County. Your child's participation is voluntary. Please take your time in making your decision as to whether or not your child wishes to participate. Ask your child's study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to improve mental wellness and physical activity for Forsyth County's Karenni community.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Up to 80 people who live in Forsyth County will take part in this study. Staff from the Karenni Community of Winston Salem (KnC of WS) (Htay Meh) or Wake Forest University's School of Medicine (Dr. Ana Sucaldito and Dr. Stephanie Daniel) may also be there.

WHAT IS INVOLVED IN THE STUDY?

If your child take part in this study, they will be asked to take part in a soccer program to increase mental wellness and physical activity in the community. If they choose to participate, they will be expected to attend soccer program activities (expected time: 1.5 hours a week for 5 months). They will also be asked short questions (15 – 30 minutes) about what they thought about the program and they will be asked for their gender and age. Sessions will be held in-person, virtually through WebEx, or by phone, in English or Karenni (Kayah). We will help you learn how to use these videoconferencing platforms.

As part of this research study, your child will be photographed/videotaped/audiotaped. This is being done *so that we can measure how much physical activity your child is doing and so that we can record their thoughts about the program.* You understand that your child may request the filming or recording be stopped at any time during the course of the research study. Your child can also withdraw his/her consent to use and disclose the photograph/videotape/audiotape before it is used. Your child should also understand that your child will not be able to inspect, review, or approve the photographs, videotapes, audiotapes or other media (including articles containing such) before they are used in this study.

Please choose one of the following regarding the use and disclosure of the photograph/videotape/audiotape used in this research study:

_____ I would like the photographs/videotapes/audiotapes of my child to be destroyed once their use in this study is finished.

____ The photographs/videotapes/audiotapes of my child can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use.

How Long Will I Be in the Study?

Your child will be in the study for about 6 months.

Your child can stop participating at any time. If your child decides to stop participating in the study we encourage Your child to talk to the investigators or study staff first to learn about any potential health or safety consequences. There are no consequences of leaving the study suddenly.

What Are the Risks of the Study?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life. You should discuss the risk of being in this study with the study staff. Your child may feel uncomfortable discussing some of the topics that come up during the focus groups or interviews.

Taking part in this research study may involve providing information that your child considers confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your child's information safe.

Are There Benefits to Taking Part in the Study?

If your child agrees to take part in this study, there may or may not be direct benefit to your child. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be an increase in physical activity, soccer skills, and mental health care skills.

What Other Choices Are There?

Your child does not have to participate in this study. This is not a treatment study. Your alternative is to not participate in this study.

What Are the Costs?

There are no costs to you or your child for taking part in this study. All the study costs will be paid for by the researchers.

Will Your child's Research Records be Confidential?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your child's identity and/or your child's personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of your child or others. There is always some risk that even de-identified information might be re-identified. Participant information may be provided to Federal and other regulatory agencies as required.

Audio and video recordings will be stored in a cabinet in a locked office or on a password protected computer and will be retained six years after the study is finished, then destroyed. During study activities, participants may request that recordings be stopped at any time. During focus groups, your child does not have to use their real name and those participants in group interviews or focus groups must agree to not share any information talked about in the group to protect the confidentiality of all participants.

Will You Be Paid for Participating?

You will receive no payment or other compensation for taking part in this study.

Who is Sponsoring this Study?

This study is being sponsored by Wake Forest School of Medicine. The researchers do not, however, hold a direct financial interest in the sponsor.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify your child. At most, the website will include a summary of the results. You can search this Web site at any time.

What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. Your child may choose not to take part or your child may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which your child are entitled. If your child decides to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your child's participation in the study at any time. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your child's willingness to continue to participate in the study.

Whom Do I Call if I Have Questions or Problems?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Stephanie S. Daniel, at 3[redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect

your child's rights. If you have a question about your child's rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, You should contact the Chairman of the IRB at [redacted]

You will be given a copy of this signed consent form.

What does my signature on this consent form mean?

Your signature on this form means that:

- You understand the information given to you in this form
- You have been able to ask the researcher questions and state any concerns
- The researcher has responded to your questions and concerns
- You believe you understand the research study and the potential benefits and risks that are involved for your child.
- You understand that even if you give your permission, you child may choose not to take part in the study.

Statement of Consent

I give my voluntary permission for my child to take part in this study. I will be given a copy of this consent document for my records.

Signature of Parent/Guardian_____ Date: _____Time:_____ am pm

Printed Name of Parent/Guardian:_____

Printed Name of Minor:_____

Statement of Person Obtaining Informed Consent

I have carefully explained to the parent of the child being asked to take part in the study what will happen to their child.

I certify that when this person signs this form, to the best of my knowledge, he or she understands the purpose, procedures, potential benefits, and potential risks of his or her child's participation.

I also certify that he or she:

- Speaks the language used to explain this research
- Reads well enough to understand this form or, if not, this person is able to hear and understand when the form is read to him or her
- Does not have any problems that could make it hard to understand what it means for his or her child to take part in this research.

Signature of Person Obtaining Consent:_____Date:_____ Time:_____am pm

Printed Name of Person Obtaining Consent:_____