A Scalable, Community-based Program for War and Refugee Trauma (ITH)
STUDY00015447, Elrha R2HC #70165
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UNIVERSITY OF WASHINGTON

CONSENT FORM
Islamic Trauma Healing: A Program for Community Reconciliation
Group Members

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Researchers' Statement
We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we are asking you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

This study will test an Islamic-focused group that is led by Somaliland community members. The group is designed to provide relief for people who are suffering after experiencing trauma, such as sexual assault, war, and torture. We will explore whether or not these groups reduce trauma-related distress, supports spiritual growth, and promotes community reconciliation. We will use the results to improve the program. We will also examine how well this program can be implemented in the community.

STUDY PROCEDURES

You are being asked to participate because you are a member of the Somaliland community who has experienced traumatic events and are wanting to reduce distress related to these events. If you have problems with wanting to hurt yourself or other people, use illegal drugs, or use alcohol at high levels, you will not be allowed to participate. Similarly, if you have difficulty thinking clearly (e.g., not being able to understand instructions well) or see or hear things that are not there (e.g., hallucinations; psychotic symptoms), you also will not be allowed to participate and

we will help you find other places to get help.

If you are eligible, your mosque will be randomly assigned (like a flip of a coin) to starting groups immediately or being asked to wait 6 weeks (1 ½ months) to start groups. This means that your mosque will have a 50% chance of being able to start right away. If you are asked to wait, you will fill out surveys and start your groups in approximately six weeks.

You will complete several surveys. These surveys will be done by trained assessors who will not reveal information you say to people outside of the study team. The assessors also will not know if your mosque will start now or start later.

These surveys will be given repeatedly over the course of the program to keep track of your progress. They will ask you about the type of trauma exposure, common reactions such as reliving the trauma and feeling depressed, beliefs about yourself and others, and how you are functioning in your daily life. They will also ask about thoughts of harming yourself. We will also ask about your expenses for attending the program. We will ask you to complete these surveys at the start, at three weeks, at six weeks, and at 3 months later. At the end of the group, we will ask you to tell us about your experience in the group and make an audio recording of it. Some of the assessor's interviews with you will also be recorded for quality control purposes.

You will meet with a group of approximately 5-7 individuals. This group will meet for 2 hours, each week for 6 weeks. There will be separate male and female groups. Two community members who have been trained will lead these groups.

Each group meeting will begin and end with readings and discussion based on Islamic teachings. In the meetings, the group will talk about common reactions to trauma. You will be asked to turn to Allah about what happened to you. You will also be asked discuss as a group what it is like to turn to Allah about these things. You will never be asked to talk about your personal history with other people in the group. You can choose to talk or not talk in the group.

You are not expected to share details of your traumatic experiences with others in the group. Your group leader will hear and know some of the details about what happened to you. Everyone in the group will be expected to keep anything they hear or see in the group within the group. That is, you are not to speak about what happened in the group to people who are not in the group.

Before and after group meetings, there will be drinks (e.g., tea or coffee) and time to talk together. Once you have finished the 6 group meetings, we will invite you to give comments about what the group was like. You may choose to give comments or not. You will also receive $20 USD ($11680 Somaliland Shillings) or $5 USD for each assessment (initial, 3 weeks, 6 weeks, and 3 months) for completing surveys at the 3-month follow-up.

If you do not want to answer any questions or no longer want to take part in meetings, you may choose to stop at any time.

RISKS, STRESS, OR DISCOMFORT

You may feel upset or distressed by some of the questions in the surveys.

Group meetings should help you to feel better. However, your trauma-related symptoms may not get better or may become worse while you are in this study. If you are waiting to start a group, your trauma-related symptoms may not get better or may become worse while you are waiting. If any of these things happen, we will help you to make contact with other sources of help.

We cannot promise that other people in the group will not share information about you or the group to other people. This is not allowed, and any person who does this will be removed from the group. All group members will be reminded of the importance of privacy at each meeting. It is also possible that the stored data you provide may be breached by others.

ALTERNATIVES TO TAKING PART IN THIS STUDY

You are free not to participate in this study, free to not answer questions, and free to stop being in the study at any time. As an alternative to this study, you may choose to receive counseling or therapy from another community provider. If you choose to do this, we will provide you with contact information for other counselors who work with survivors of trauma. This therapy is at your own cost.

BENEFITS OF THE STUDY

If you choose to take part in this study, you will receive 6 weeks of group meetings at no cost. The results of your progress in this study will be used to improve this group for other people who have similar experiences. Your trauma-related distress may improve as a result of your participation in this study and it may help reconciliation in your community. However, there is no guarantee of this.

SOURCE OF FUNDING

The study team is receiving financial support from Elrha.

CONFIDENTIALITY OF RESEARCH INFORMATION

All of the information you provide will be kept confidential. However, if we learn about abuse of children or elders, or that you intend to harm yourself or others, we must take steps to protect safety including reporting to the authorities or family members, within 72 hours, if appropriate. This may include identifying information you have given us.

We will ask for your name, age, phone number, and email to contact you about meetings with your assessor and with your group. At any time, you can ask us to remove this information.

You will be assigned an identification number, and this number will be used on all surveys. The surveys will not have your name on it. Any information on paper will be kept within a locked room at the University of Burao or SOYDAVO Offices. Survey data will be collected using a data management program with servers in the United States. Audio recordings will also be secured in the same place with no identifying information attached to them.

The results from this study may be used in publications, but there will never be any link published between you and your data. Data will be kept for 10 years following any publication of study results.

Information from this study may be shared with researchers to reanalyze the data. This shared will not include your name or other information that can identify you. Your study data will be assigned a code. The link between who you are and this code will not be shared.

University staff sometimes reviews studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy and the study records will not be used to put you at legal risk of harm.

A description of this clinical trial will be available on http://www.clinicaltrials.gov. 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.

We have a Certificate of Confidentiality from the United States the National Institutes of Health. These protections only apply to data held in the United States.

This helps us protect your privacy. The certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law in the United States. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the United States government who needs it in order to audit or evaluate the research;
- individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;
- to relevant authorities as required by other Federal, State, or local laws.

The Certificate expires when collection or use of identifiable, sensitive information concludes (i.e., when the study ends). Data collected prior to expiration will continue to be protected.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. You will receive phone calls or texts as a reminder for appointments. You will be responsible for any costs incurred from these communications to your device. Refreshments will be available for all group members at meetings.

Printed name of study staff obtaining consent Signature Date

Subject's Statement:

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at +1(206) 543-0098 or call collect at +1(206) 221-5940. I will receive a copy of this consent form.

Printed name of subject Signature of subject Date

Copies to: Researcher
Subject