

My Pathway to Healing

NCT04585906

5/27/2022



ADULT PARTICIPANT INFORMED CONSENT

Principal Investigator: Emily Haroz, PhD

Study Title: My Pathway to Healing: Adaptation and Testing of a Common Elements Treatment Approach to Address Trauma, Suicide Ideation, and Substance Abuse

IRB No.: 00009500

Sponsor/Supporter/Funded By: NARCH

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Key Information about the Study

Thank you for your interest in this study. The goal of this research study is to learn if a new program called My Pathway to Healing is useful and acceptable in the White Mountain Apache community. This program is intended to support Native American adults who struggle with suicidal thoughts or behaviors, self-injurious behaviors, or substance use. We are conducting this study to learn if this program is effective at supporting Native American adults and whether the program is acceptable and a good fit for the White Mountain Apache community.

- We are asking you to volunteer for a research study.
- You do not have to join the study; it is your choice and there is no penalty for not joining. Ask as many questions as you need to help you make your decision. Please review the details outlined in the rest of this consent document before deciding.
- You may be eligible for this study because you are between 25-65 years old and have had suicidal thoughts, attempt, self-injurious behavior, or binge substance use in the past 90 days. To be eligible for this study, you must also have had difficult experiences in your childhood and currently feel stress or anxiety related to those difficult experiences.
- If you join, we will ask you to participate in the following:
 - Respond to a screening questionnaire that will take 10-15 minutes to complete. Your responses to the questions will determine your eligibility to participate in the research study. Your responses will only be included in data analysis if you are eligible and decide to join the study.
 - Complete a baseline questionnaire in a private place of your choosing
 - Be randomized (chosen by chance) to participate in either enhanced case management or the My Pathway to Healing program
 - Engage in 4-8 one-hour visits with a community mental health specialist
 - These visits will include either enhanced case management services or the My Pathway to Healing program lessons, depending on which study group you are randomly assigned to. At the end of the study, if you have not received the My Pathway to Healing program and would like to, it will be available to you.
 - Complete four follow-up questionnaires, approximately 12 weeks, 16 weeks, 24 weeks, and 36 weeks after you have completed the baseline questionnaire, in a private place of your choosing
- If you join this study, you may benefit from sessions with the community mental health specialist. It is also possible that the sessions may make you uncomfortable or emotionally distressed. We will work with providers to make sure that these risks are minimized.
- You will be compensated for your time taking the five questionnaires with up to \$90 in gift cards.

Why is this research being done?

This study is meant to test a new intervention, the My Pathway to Healing program. We are trying to find out if this approach can help other adults in the community.

What will you do as part of this study?



1) Questionnaires: Complete five questionnaires: one at baseline, and four more approximately 12 weeks, 16 weeks, 24 weeks, and 36 weeks after you have completed the baseline questionnaire. These questionnaires are estimated to take up to 1 hour of your time and can be completed in a private location of your choice.

2) Random assignment: you will be randomly assigned (by chance) to receive either enhanced case management visits with a community mental health specialist, or lessons from the My Pathway to Healing program.

3) Visits with a community mental health specialist: you will have between 4 and 8 visits with a community mental health specialist, depending on your needs and schedule. These visits will either be enhanced case management visits or lessons from the My Pathway to Healing program. These visits will take between 1 and 1.5 hours of your time. These visits will occur after you have completed the baseline questionnaire and before you complete any other questionnaires. Possible visits with a community mental health specialist include:

- **Enhanced case management visits:** A Celebrating Life Program Educator will check-in with you to see how you are doing and may provide resources, lessons on coping skills, or other referrals to services depending on your needs.
- **My Pathway to Healing program visits:** A Celebrating Life Program Educator will teach you about wellness, balance, how to keep yourself safe from destructive behaviors, coping skills, and other related lessons. After completing the program, you would receive a small journal or activity book from the program educator.

Audio Recordings:

As part of this research, we would like your permission to audio record your visits with community mental health specialists to understand if they are doing the activities with you as intended. We will not use recordings for advertising or non-study related purposes.

You should know that:

- You may ask us to stop recording at any time.
- If you agree to allow the recording and then change your mind, just ask us to destroy that recording. If we have already removed identifiers from the recording, we may not be able to do this.
- Only members of this research team will have access to the recordings.
- Following completion of the study, the recordings will be destroyed.
- You can still participate in this study, even if you do not want us to record your sessions.

How long will you be in the study?

- We anticipate that you would be enrolled in this study for 6 months.

What happens to data that are collected in the study?

Johns Hopkins and our partners work to advance science and public health. If you join this project, you should understand that you will not own your data. The data collected from you will not be linked to your personal information (for example, your name). All data is collected anonymously and stored securely at the Johns Hopkins office. The project app used to complete questionnaires is not for clinical or public use but is restricted for this project only.

How will your data be shared now and in the future?

There are a few times when we will not be able to keep your information private. If someone tells us or we think that you are being hurt or that you may be hurting another person, we will have to tell the proper authorities. In addition, if you appear to be at risk for hurting yourself, we will need to refer you to the appropriate resource.

The data you provide in the questionnaires will be used to evaluate the My Pathway to Healing Program. Information about you will not be given to people that are not working on the project. The data from your questionnaires will not be linked to your personal information. No one will be able to look at the data and know that it came from you.



When we have all data analyzed, we may seek approval from the White Mountain Apache Tribe Health Board and Tribal Council to publish our results in an academic journal or present information at a conference. Although this data may be published and/or presented at research conferences, the data will be reported only in aggregate form, meaning that it will not be possible to identify any individual that participates in this study

What are the risks or discomforts of the study?

We anticipate minimal risk associated with this study. The main burden to you is the amount of time it will take to complete the study visits. The visits with a community mental health specialist will take between 4-8 hours total over 12 weeks. In addition, you will be asked to complete five questionnaires, which would result in an additional 5 hours of your time, for a maximum of 13 hours of participation over 9 months.

You may be uncomfortable completing the questionnaires. Some people may be uncomfortable talking about or reporting about their thoughts, feelings and behaviors. Our study staff are trained to discuss sensitive topics appropriately, be good listeners, keep your information private and confidential, and connect you to appropriate resources in the community.

Personal Privacy

The place where you do the questionnaires and all parts of this project will be a private place of your choosing. During the questionnaire, only you will be able to see your answers to the questions.

How will the confidentiality of your data be protected?

To keep your information private, we will assign you a number when you start the project. Any information we collect from you will only have this number on it. We will keep a separate list that identifies your name and number you have been assigned. This list will be private and all information about you will be stored in a locked file cabinet in the Johns Hopkins office. All electronic data will be stored on computers that are password protected.

Your information will be used to evaluate this project. You cannot be in the program unless you agree that the information can be used for this purpose. No identifying information will be included with the data that is analyzed. There will be no way to identify you in any publications or study results.

What is a Certificate of Confidentiality?

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means. It does not protect information that we have to report by law, such as child abuse. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help. This study is protected by a Certificate of Confidentiality that helps keep your information private when stored in the U.S.

What are the potential benefits to being in the study?

You may or may not benefit from participating in this study. You might benefit from visits with a community mental health specialist that are part of this study and can help you access additional services you may need. Your participation will also benefit your community and science by helping to understand if this type of program helps Native American adults.

What are your options if you do not want to be in the study?

You do not have to join and participate in this study. The alternative is not to participate in the study. If you are struggling with behaviors or thoughts related to suicide or substance use, there are other local resources that can support you if you do not wish to join this study. These resources include Apache Behavioral Health Services, Rainbow Treatment Center, The Whiteriver Indian Health Service Hospital, and the Celebrating Life system.

**Will it cost you anything to be in this study?**

No, it will not cost you anything to be in the study.

Will you be paid if you join this study?

Yes, you will be compensated for your time spent completing questionnaires if you join this study. You will not receive payments for the time you spend during the visits with a community mental health specialist. We will compensate you for your time with gift cards in the following amount for each study visit where a questionnaire is completed:

Questionnaire	Gift card amount
Baseline Questionnaire (when you start the study)	\$15
Endline Questionnaire (after your last visit with a community mental health specialist)	\$15
Questionnaire 1 month after endline	\$15
Questionnaire 2 months after endline	\$20
Questionnaire 3 months after endline	\$25

The Johns Hopkins Celebrating Life staff will not be responsible for lost or stolen gift cards and you will not receive another gift card should it be lost or stolen.

Can you leave the study early?

You may leave the study at any time without any penalty, including only stopping the program but continuing with the assessments and case management. Please note, if you decide to withdrawal from the study at any time, it will not affect the care you receive at Indian Health Service. Participants who stop all parts of the study early are able to continue case management through the Celebrating Life program. If we feel that it is not in your best interest to continue with the study, or if you relocate, you will not be expected to participate in the rest of the study.

Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You fail to follow instructions.
- The study is cancelled.

What is the Institutional Review Board (IRB) and how does it protect you?

This study has been reviewed by an Institutional Review Board (IRB), a group of people including scientists and community people, that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-955-3193 or jhsph.irboffice@jhu.edu.

What should you do if you have questions about the study, or are injured or ill as a result of being in this study?

- Call the principal investigator, Emily Haroz, PhD at 410-449-0051.
- If you wish, you may contact the principal investigator by letter:

JHCAIH Attn: Emily Haroz, PhD
415 N. Washington St., 4th Floor
Baltimore, MD 21231

If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3193.

Documenting Participant Choices



IRB Approval Date: May 27, 2022

Audio Recordings

You may agree to or decline our request to make and use the recording/images described above. Please indicate your decision below by checking the appropriate box.

YES NO

What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant (Print Name) Date/Time

Signature of Person Obtaining Consent (Print Name)
Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).