

**Forging New Paths: Building Interventions to Treat
Criminogenic Needs in Community Based Mental Health Settings**

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**University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants - Aim 2 RCT**

Consent Form Version Date: 3-8-2024

IRB Study # 22-0868

Title of Study: Forging New Paths: Building Interventions to Treat Criminogenic Needs in Community Based Mental Health Settings

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The goal of this study is to learn how well a new program called Forging New Paths (FNP) meets the needs of people with mental illness who have contact with the criminal justice system. We are enrolling up to 80 people. If you are interested in this study we will do an interview to see if you are eligible to participate. This interview will take about 30 minutes. If you are eligible you will be randomly assigned (like flipping a coin) to either receive Forging New Paths in addition to your usual mental health treatment or to continue receiving your usual mental health treatment. You will also be asked to complete three additional interviews over the next 7 months that will take about 30-45 minutes each to complete. Interviews will include questions about your mental health, substance use, coping skills and criminal justice system involvement. If you are assigned to receive Forging New Paths, your participation in this program will last for about 14 weeks. Your participation in this study will not influence any decisions by the criminal justice authorities. Your access to services at mental health and other treatment services will not be changed in any way by your participation in this study.

Your participation in this study will help us learn how well this new program meets the needs of people with mental illness. If you are interested in learning more about this study, please continue reading below.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without anything bad happening to you.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to develop a new program for people with mental illnesses and examine its effectiveness. The study is interested in learning how this new program can best meet the needs of people with mental illness who have contact with the criminal justice system.

Are there any reasons you should not be in this study?

You should not be in this study if you have an intellectual or developmental disability.

How many people will take part in this study?

Approximately 150 people will take part in this study.

How long will your part in this study last?

Your involvement in this study could last up to 9 months. You will be asked to participate in up to four research interviews (including your interview today) with a member of the research team. It is anticipated that each research interview will last approximately 30-45 minutes.

What will happen if you take part in the study?

If you agree to be in this study we will do an interview to see if you are eligible to participate in the study. If you are eligible and want to participate in this study you will be randomly assigned (like flipping a coin) to one of the following treatment groups: 1) Forging New Paths (FNP) and usual mental health treatment; or 2) usual mental health treatment. Everyone who is assigned to a treatment group will also be invited to participate in up to three additional research interviews. Your participation in this study will not influence any decisions by the criminal justice authorities. Your access to services at mental health and other treatment services will not be changed in any way by your participation in this study.

If you are assigned to the usual mental health treatment group, you will continue to receive the mental health services available to you both now and in the future. You will also be invited to participate in up to three additional research interviews described below. Staff at the community mental health agencies make all decisions about what usual mental health treatment services are provided and who is eligible to receive usual mental health treatment.

If you are assigned to the Forging New Paths and usual mental health treatment group, you will be invited to participate in the study intervention (FNP) while also continuing to receive the mental health services available to you both now and in the future. You will also be invited to participate in up to three additional research interviews described below. Staff at the community mental health agencies make all decisions about what usual mental health treatment services are provided and who is eligible to receive usual mental health treatment.

Forging New Paths (FNP) is a new mental health treatment that is delivered in a group setting. In order to participate in Forging New Paths, you must be eligible to participate in this study and randomly assigned to receive it. FNP will meet once a week for about 14 weeks. Each intervention session will last about 60 minutes. There will be up to 12 people in the group. You can participate in FNP in person or through a secure internet platform like Zoom. Participants in FNP will be reminded of the importance of keeping group members' information confidential. But we cannot guarantee that information you share with the group will remain confidential. Therefore, the treatment staff leading FNP will encourage you to be as honest and open as you can be in group and you will make your own decisions about how much personal information you share with the group.

Forging New Paths is designed to teach you different ways to think about behaviors and situations. It will also help you to learn and practice skills for managing disagreements and ways to solve problems you encounter. This project will help the research team understand how Forging New Paths can be most useful to people with mental illness. Do you have any questions about what will happen if you are eligible to participate in this study?

Everyone who is assigned to a treatment group in this study (Forging New Paths and usual mental health treatment or usual mental health treatment), will be asked to participate in up to four research interviews as part of this study. If you agree to participate in this study after providing informed consent, the first research interview can take place today. This interview will determine if you are eligible to participate in this study. If you meet study requirements and are assigned to one of the study treatment groups, you will be invited to participate in three more research interviews. We will schedule the second interview with you today. Then we will invite you to participate in a third interview 3 months from now and a fourth interview 6 months from now. We will also collect information about your experiences with the the criminal justice system and mental health services that you receive from agency records 9 months from now.

Research interviews will include questions about your mental health, drug use, and criminal justice involvement. During each interview you can choose not to answer a question for any reason. Each research interview will last approximately 30 - 45 minutes. You can also ask for breaks during an interview or end an interview at any point that you want. All interviews will occur in private spaces or on a secure virtual platform like Zoom. In total, you will be asked to participate in up to four research interviews. If you agree to participate in this study, we will ask you to sign a release form allowing us to obtain criminal justice system and mental health and health care records and use this information. In order for you to be in the study you will need to allow the researchers to have access to this information.

If you become incarcerated during your participation in this study, you will not be able to participate in research interviews or the study intervention while incarcerated. The permission you provide here will allow the research team to continue to collect information from agency records related to your criminal justice experiences and mental health and health care services while you are incarcerated. If you are released from incarceration while the study is still active, a member of the research team will contact you and invite you to participate in study activities that you remain eligible for according to study guidelines.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. There is little chance you will benefit from being in this research study.

What are the possible risks or discomforts involved from being in this study?

There may be uncommon or previously unknown risks. You should report any problems to the researcher. For example, loss of confidentiality (someone finding out things you said) is a risk whenever personal information is shared. All members of the research team receive training on how to keep study information private. Breach, or loss, of confidentiality, could cause you personal distress or other difficulties. The research team has taken steps to minimize these potential risks. Also, it is important for you to understand that any information you share with the research team will be kept completely confidential and private to the best of their ability.

Additionally, even though we will emphasize to all participants in the study intervention that information shared in group sessions should be kept confidential, it is possible that participants may repeat comments outside of the group at some time in the future. Therefore, we encourage you to be as honest and open as you can but remain aware of our limits in protecting confidentiality. It is also possible that by participating in this study people will learn that you have had contact with the criminal justice system. Protecting information you provide is very important to the research team.

The research interviews include questions about prior criminal justice system involvement and substance use. You can choose not to answer interview questions and you can end the interview at any time. This research is also covered by a Certificate of Confidentiality, which is described in more detail below. There is also a small possibility that you could become emotionally upset by questions asked by the research team. If you become upset, you can stop the interview. Also, a member of the research team can make a referral to treatment staff at the Center for Excellence in Community Mental Health if you need additional support or counseling.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?

We will make every effort to keep research records private. Your name will not be on any of your interview data. You will only be identified by a unique study number only (i.e., participant 001). The file connecting your name to your study number will be secured with a password on a secure UNC server. Only research staff working on this project will have access to project materials. All project data and information will be maintained by the School of Social Work at the University of North Carolina at Chapel Hill with access restricted to project staff.

Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

Under North Carolina law-

- researchers are required to report information about the abuse or neglect of a child or disabled adult to local or state authorities.
- confidentiality does not extend to certain communicable diseases, such as TB, HIV, hepatitis, or other illnesses that put others at risk. If the researchers become aware that subjects have such an illness, they are required to report it to state authorities

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used to prevent disclosure of information if you report having thoughts of hurting yourself or others. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you 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 the researchers may not use the Certificate to withhold that information.

You will be asked to sign a separate form ("HIPAA Authorization") to allow researchers to review your medical records.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?

You will receive a \$30 gift card for each research interview you participate in. In total you could receive up to \$120 in gift cards. Any payment provided for participation in this study may be subject to applicable tax withholding obligations

Will it cost you anything to be in this study?

It will not cost you anything to be in this study.

Who is sponsoring this study?

This research is funded by The National Institute of Mental Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-

related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

Signature of Research Participant

Date

Printed Name of Research Participant

Signature of Research Team Member Obtaining Consent

Date

Printed Name of Research Team Member Obtaining Consent