INFORMED CONSENT FORMS

Phase 1 Client Participant Consent Form – pp. 2-6
Phase 1 Staff Participant Consent Form – pp. 7-11
(Phase 2 Consent Forms not available due to study termination)

Title: Zero Suicide Implementation and Evaluation in Outpatient Mental Health (R56)

NCT05587530

Document Date: 11/08/2024 (Approved)

INFORMED CONSENT FOR PARTICIPATION IN RESEARCH

TITLE: Zero Suicide Implementation and Evaluation in Outpatient Mental Health (R56)

PROTOCOL NO.: AAAV1378
WCG IRB Protocol #20244449
AAAV1378

SPONSOR: Columbia University Irving Medical Center

INVESTIGATOR: Lisa Dixon, PhD, MD, MPH
Mailman School of Public Health
722 W 168th St. R244
New York City, New York 10032
United States

STUDY-RELATED PHONE NUMBER(S): 646-774-8420 (24 hours)

If you have questions, concerns, or complaints, or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

Key Information

- This is a research study and participation is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.
- The purpose of this study to better understand barriers and facilitators influencing people's decision to continue outpatient behavioral health care. We invite you to participate in a research project that involves a qualitative interview about your treatment experiences.
- If your treatment experience was a while ago, there will only be one interview. If you are just starting treatment, we will follow-up with you in three months to learn about your experiences.
- You can complete the interview from wherever you choose, as it will be conducted using teleconferencing software. Interviews will be one hour and audio-recorded.

- Risks include the possibility that answering the interview questions may be distressing to you. You can choose not to answer specific questions, take breaks, or have the interview stopped at any time. If your answers indicate an imminent problem that may jeopardize your safety or health, then the researchers may have to break your confidentiality to keep you safe in compliance with New York State law. If the researchers are concerned about your current safety, they will discuss options to ensure safety with you.
- This study was not designed to be of direct benefit to you. However, your participation may help improve care for clients in outpatient behavioral health clinics.

DETAILED RESEARCH INFORMATION

Purpose and Overview

We invite you to participate in a research project that involves participation in a qualitative interview about your treatment experiences. We are inviting clients currently or previously enrolled in outpatient behavioral health clinics for suicide-related reasons. The purpose of this study to better understand barriers and facilitators influencing your decision to seek treatment, remain in care, or discontinue care in outpatient behavioral health. We want to know your preferences for mental health treatment, how treatment can be improved, and your perceptions of current suicide prevention efforts. This study is funded by a grant from the National Institute of Mental Health.

In deciding whether you wish to enroll in this study, you should know enough about its risks and benefits to make an informed judgment. This consent form provides the essential details about this project. A member of the research team will also discuss the project with you and answer your questions. This discussion will go over all aspects of this study including: the purpose; the procedures; risks of the procedures; and the potential benefits and economic considerations of participating in this study. Once you understand the study, you will be asked if you are willing to participate. If so, you will be asked to sign this form.

Voluntary

Participation in this research study is voluntary. If you decide not to participate or if you later decide to stop participating, you will not lose any benefits to which you are otherwise entitled. A decision not to participate or withdraw your participation will not affect your current or future treatment or your relationship with Columbia University. If you withdraw from the study, you have the option to request that any information be made de-identified. You will be notified of any significant new findings about this kind of research that may affect your willingness to participate in this project.

Alternative to Participation

This is not a treatment study. Information being collected is for research purposes only and is to learn more about the perceptions of and preferences for outpatient behavioral health treatment, not about you personally. The alternative to participation in this study is to choose not to participate.

Study Procedures

You were contacted about this study because you enrolled in outpatient behavioral health services for a suicide-related reason. You will not be required to attend in-person to participate in this study.

Your participation will conducted remotely using the telephone or Health Insurance Portability and Accountability Act (HIPAA)-compliant video teleconferencing.

After eligibility is established, we will complete the informed consent process. Documentation of the informed consent will be provided to you via REDCAP, a HIPAA-compliant platform. Next, you will complete a qualitative interview via a HIPAA-compliant telehealth platform. This interview will ask about your history of suicidal thoughts or behaviors and your experiences in treatment. It will also discuss barriers and facilitators influencing your decision to seek treatment, remain in care, or discontinue care in outpatient behavioral health, your preferences for different types of mental health treatment, and how treatment can be improved. The interview will last approximately one hour and will be audio-recorded. Audio taping is required to participate. You may refuse to answer any of the interview questions if you feel uncomfortable. If your treatment experience was a while ago, you will complete one interview, whereas if you are just starting treatment, we will follow-up with you in three months to learn more about your experiences.

Audiotaping

Audiotaping is required for study participation. The purpose of the audiotaping is to allow the interview to be heard by research staff to study the interview. The recording(s) will be used for analysis by the research team. The recording will be accessed by study staff only, utilize a deidentified alphanumeric code, and stored electronically on a HIPAA compliant password protected, encrypted server. The recording(s) will be transcribed and original recordings will be destroyed upon completion of the study procedures and publication of study results. Consent may be withdrawn at any time. In addition, you may request that the taping be stopped at any time and portions and/or the entire recording may be erased either during or after your participation.

Risks

Since the interview is about your mental health treatment experiences and preferences, there is a possibility that you may become upset. You can choose not to answer specific questions or have your interview participation stopped at any time. It is also possible that you may become tired during the interview. If so, you may ask for breaks. Lastly, if your answers indicate that you maybe at imminent risk of suicide, then the researchers may have to break your confidentiality in order to keep you safe in compliance with New York State law. If the researchers are concerned about your current safety, they will discuss options to ensure safety with you.

Benefits

This study was not designed to be of direct benefit to you. However, your participation may help improve behavioral health treatment and care for clients at outpatient behavioral health clinics.

Confidentiality

All data will be kept strictly confidential by study staff. The interview will take place over HIPAA-compliant videoconferencing, and informed consent will be obtained via REDCap, a HIPAA-compliant platform. Anything you say during the audiotaped interview, as well as your name and other personal identifying information, will be stored in an electronic, secure database at the Columbia University.

All records from this study, including the audio recording of interviews, will only be available to the researcher staff, and to Federal, State, and Institutional regulatory personnel (who may review

records as part of routine audits). Data from this study may be shared with investigators at outside institutions. If data are shared, they will have no identifying information and will be sent either via secure email or a mail courier service to ensure their protection from theft or loss. Finally, in scientific reports of this study, neither your name or any other identifying information will be used or reported.

If your answers indicate that you may be at imminent risk of suicide, then the researchers may have to break your confidentiality in order to keep you safe in compliance with New York State law. If the researchers are concerned about your current safety, they will discuss options to ensure safety with you.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate *does not* stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate *cannot be used* to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate *does not* stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also *does not* prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Future Contact

We may contact you in the future about your interest in participation in other studies.

In Case of Injury

Federal regulations require that we inform participants about our institution's policy with regard to compensation and payment for treatment of research-related injuries. If you believe that you have sustained an injury as a result of participating in a research study, you may contact the Principal Investigator, Dr. Lisa Dixon at 646-774-8420 so that you can review the matter and identify the medical resources that may be available to you.

Compensation

If you decide to consent to this study, you are not responsible for any costs associated. As compensation for your participation in this study, you will receive a $50 check or gift card. You can choose whether you wish to be compensated via a gift card or a check. Gift cards will be sent by email, while checks will be sent by mail.

Questions

Please feel free to ask questions about any aspect of this form or this study that you do not understand. Take as long as you need to decide whether or not to participate in the study. The Principal Investigator, Dr. Lisa Dixon, will answer, to the best of her ability, any questions you may have now or in the future about the procedures involved in this study or your response to the procedures. Please feel free to contact her at 646-774-8420 (24 hours).

If you have any questions or concerns about your rights as a research participant, want to provide feedback, or have a complaint, you may call the Institutional Review Board (IRB). (An IRB is a committee that protects the rights of participants in research studies). You may talk to WCG IRB at 855-818-2289 or clientcare@wcgclinical.com during regular office hours.

You will be given a copy of this consent form to keep.

Documentation of Consent

I voluntarily agree to participate in the research study described above.

_____ _____

Signature Date

_____

Print Name

Person Designated to Obtain Consent

I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation. The participant has had an opportunity to ask questions and in my opinion is capable of freely consenting to participate in this research.

_____ _____

Signature of Person Obtaining Consent Date

_____

Print Name

INFORMED CONSENT FOR PARTICIPATION IN RESEARCH

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PROTOCOL NO.: AAAV1378
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SPONSOR: Columbia University Irving Medical Center

INVESTIGATOR: Lisa Dixon, PhD, MD, MPH
Mailman School of Public Health
722 W 168th St. R244
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Key Information

- This is a research study and participation is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.
- The purpose of this study to better understand barriers and facilitators influencing clients' decision to continue outpatient behavioral health care. We invite you to participate in a research project that involves a qualitative interview about your experiences working with clients enrolled in outpatient behavioral healthcare for suicide-related reasons.
- You can complete the interview from wherever you choose, as it will be conducted using teleconferencing software. Interviews will be one hour and audio-recorded.
- Risks include the possibility that answering the interview questions may be distressing to you. You can choose not to answer specific questions, take breaks, or have the interview stopped at any time.
- This study was not designed to be of direct benefit to you. However, your participation may help improve care for clients in outpatient behavioral health clinics.

DETAILED RESEARCH INFORMATION

Purpose and Overview

We invite you to participate in a research project that involves participation in a qualitative interview about your experiences working in outpatient behavioral healthcare. We are inviting behavioral health clinicians and peer specialists with experience working with clients enrolled in outpatient behavioral healthcare for suicide-related reasons. The purpose of this study to better understand barriers and facilitators influencing clients' decision to seek treatment, remain in care, or discontinue care in outpatient behavioral health. We also want to learn about client preferences for behavioral health treatment, how client treatment engagement and retention can be improved, and your perceptions of current suicide prevention efforts. This study is funded by a grant from the National Institute of Mental Health.

In deciding whether you wish to enroll in this study, you should know enough about its risks and benefits to make an informed judgment. This consent form provides the essential details about this project. A member of the research team will also discuss the project with you and answer your questions. This discussion will go over all aspects of this study including: the purpose; the procedures; risks of the procedures; and the potential benefits and economic considerations of participating in this study. Once you understand the study, you will be asked if you are willing to participate. If so, you will be asked to sign this form.

Voluntary

Participation in this research study is voluntary. If you decide not to participate or if you later decide to stop participating, you will not lose any benefits to which you are otherwise entitled. A decision not to participate or withdraw your participation will not affect your current or future employment or your relationship with Columbia University. If you withdraw from the study, you have the option to request that any information be made anonymous. You will be notified of any significant new findings about this kind of research that may affect your willingness to participate in this project.

Alternative to Participation

This is not a treatment study. Information being collected is for research purposes only and is to learn more about clients' perceptions and preferences for outpatient mental health treatment, not about you personally. The alternative to participation in this study is to choose not to participate.

Study Procedures

You were contacted about this study because you are either a behavioral health clinician or peer specialist with experience working with clients enrolled in outpatient behavioral health services for a suicide-related reason. You will not be required to attend in-person to participate in this study. Your participation will conducted remotely using the telephone or Health Insurance Portability and Accountability Act (HIPAA)-compliant video teleconferencing. After eligibility is established, we will complete the informed consent process. Documentation of the informed consent will be provided to you via REDCAP, a HIPAA-compliant platform.

Next, you will complete a qualitative interview. This interview will ask about your experiences working with clients enrolled in outpatient behavioral health care for a suicide-related reason. It will also discuss barriers and facilitators influencing clients' decisions to seek treatment, remain

in care, or discontinue care in outpatient behavioral health, and how client engagement and retention can be improved. The interview will last approximately one hour and will be audio-recorded. Audio taping is required to participate. You may refuse to answer any of the interview questions if you feel uncomfortable.

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Risks

Since the interview is about your experiences working with clients enrolled in behavioral healthcare for suicide-related reasons, there is a possibility that you may become upset. You can choose not to answer specific questions or have your interview participation stopped at any time. It is also possible that you may become tired during the interview. If so, you may ask for breaks.

Benefits

This study was not designed to be of direct benefit to you. However, your participation may help improve behavioral health treatment and care for clients at outpatient behavioral health clinics.

Confidentiality

All data will be kept strictly confidential by study staff. The interview will take place over HIPAA-compliant videoconferencing, and informed consent will be obtained via REDCap, a HIPAA-compliant platform. Anything you say during the audio-taped interview, as well as your name and other personal identifying information, will be stored in an electronically secure database at the Columbia University.

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Documentation of Consent
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_____ _____
Signature Date

_____
Print Name

Person Designated to Obtain Consent
I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation. The participant has had an opportunity to ask questions and in my opinion is capable of freely consenting to participate in this research.

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name