Date: 12/29/2021

National Clinical Trials #: NCT05330442

Study Title: Building Experience for Treating Trauma and Enhancing Resilience (BETTER)

PATIENT INFORMED CONSENT TO PARTICIPATE IN RESEARCH (WRITTEN)

You are being invited to take part in a research study because a health care provider referred you or because of your responses to questions asked by the Center Recruitment Coordinator. The Recruitment Coordinator will describe the study to you and answer all your questions. This paper will tell you about the study. Please read this paper and ask questions about anything you do not understand before deciding if you will take part in this study. It is your choice whether you want to take part in the study. Your medical care will be the same no matter which you choose,

WHAT IS THE PURPOSE OF THIS STUDY?

This study is called *BETTER*, which stands for *Building Experience for Treating Trauma and Enhancing Resilience*. The purpose of BETTER is to improve the care for patients who have experienced trauma or stressful experiences such as community or personal violence. We are inviting adults to participate in the study who are age 18 or older who may be experiencing symptoms related to trauma, which are sometimes called posttraumatic stress disorder or PTSD. Being invited to participate does not mean that you have PTSD. You and your health care provider can determine if that is the case together. We will include 720 people in the study across 12 health centers. Information from this study may help us learn how to improve health care for people who may have had similar trauma experiences.

The study is funded by the National Institute of Mental Health and is being conducted by Clinical Directors Network (CDN), the RAND Corporation, and the Boston University School of Medicine.

HOW DOES THE STUDY WORK?

If you agree to participate, we will ask you about 25 questions today to see if you are fully eligible for the study. We will give you a $10 gift card for the time you spend answering these questions even if you do not qualify.

If you qualify to participate in the full study, we will ask you to complete a survey today before you leave the health center or online within the next two days. The survey asks about your health, health care experiences, use of medical services, and your background. The survey will take about 20-30 minutes and we will give you a $20 gift card for your time. You will also be asked to take part in 2 more 20-30 minute surveys after the first survey. You will get a $30 gift card for completing the second survey (and a $40 gift card for completing the third survey.

Health centers taking part in this study have been assigned by chance (like the toss of a coin) to either continue providing care as they usually do or to offer an additional treatment for symptoms related to trauma.

We will tell your medical providers that you are eligible for the study because you are experiencing symptoms of stress related to trauma so that you and your providers can talk about your symptoms. If you need treatment for trauma-related stress, your providers will offer you the care that is available at your health center.

USUAL CARE VERSION: Your health center has been assigned to provide the usual care. There will be no change in the treatment being delivered at the health center. You can continue to receive the usual care offered at your health center.

INTERVENTION VERSION: Your health center has been assigned to have additional treatment available,. You can continue to receive your usual care and you will also have an opportunity to receive Written Exposure Therapy. This therapy has been shown to help decrease symptoms of PTSD. This therapy takes only 5 half-hour sessions and other patients have said that it has helped them. The sessions can be done in-person at the health center or remotely by video (like with Zoom). A Care Manager in your center will work with you and your other providers (medical provider and therapist) to see whether the treatment is a good option for you.

Regardless of which type of health center you are in, a Care Manager will help coordinate any additional follow-up care needed for the trauma-related stress you have experienced. After we finish talking, you will be connected with your assigned Care Manager. The Care Manager will conduct the first 20-minute visit (in-person or over the phone) where you will get information about problems caused by trauma, answers to any questions you may have, learn about different ways to handle trauma-related problems, and get connected to medical providers for treatment. The Care Manager will support your care by working with a medical provider and a therapist, if needed. After the first in-person or remote visit (by telephone or video), your Care Manager will schedule 2 additional telephone check-in calls with you over the next 3 months. These check-in calls will last about 10 minutes.

WHAT RISKS DO YOU FACE IF YOU DECIDE TO TAKE PART IN THIS STUDY?

There are few possible risks to you as a participant in the study. If someone learned that you were participating in a study about mental health, it could be embarrassing to you. We will keep your survey responses confidential, and we will not share your individual survey response with anyone outside of the research team. We will also keep your name separate from your survey responses at all times.

Answering some of the questions we are asking you today and again in 3 and 12 months or talking with the care manager or health care providers about the stressful event you have experienced may upset you. For example, remembering frightening or dangerous events may make you feel nervous, anxious, depressed, uncomfortable, or upset. You can skip any question or stop being in the study at any time. If you are feeling extremely upset, you will be referred to a provider in the health center.

HOW WILL THE PRIVACY AND THE CONFIDENTIALITY OF YOUR STUDY RECORDS BE PROTECTED?

At all times, we will do everything we can to protect your privacy.

Your confidentiality will be protected by assigning a participant identification number (ID) to your study records instead of using your name. All your answers from the interviews will be coded and stored in a secure database at CDN's and RAND's offices. A separate list of names, addresses, and telephone numbers, along with the ID's for each study participant will be stored in a secure file at CDN's offices. All information will be password-protected and locked away. The information we get will be used for the purposes of data analysis, and all analyses will be conducted by coded ID numbers only. The results of the study will be reported in the

form of summary statistics. Reports of study findings will never use your name or any other personally identifying information. We will protect your confidentiality.

At the end of the study, CDN will place general results of the study on its website – www.CDNetwork.org. Your name will not appear on the website or in any publications or presentations about the results of the study. All information is presented in the form of summary statistics to further protect your information. In addition, we will share a dataset with funder, the National Institute for Mental Health, so that other researchers can access it, but this dataset will be stripped of anything that can identify you.

As an additional layer of protection, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. Researchers with this Certificate may not disclose or use information that may identify you in any legal proceeding, for example, if there is a court subpoena, unless you have consented for this use. Information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except:

- if you have consented to the disclosure, including for your medical treatment.
- if it is used for other scientific research, as allowed by federal regulations protecting research subjects.
- if you tell study staff that you are about to harm yourself, or about to harm someone else, they may inform the appropriate authorities to ensure your safety, or the other person's safety.
- If you tell study staff that a child is being abused, they may tell the appropriate authorities about this so that the child is kept out of danger.

You may be concerned that someone may overhear you during the survey. We will make sure that the surveys are conducted in a private room or by video or phone.

All other study records will be kept for 7 years after the end of the study (2030) and then will be destroyed.

WHAT ARE THE POSSIBLE BENEFITS TO YOU FOR TAKING PART IN THIS STUDY?

You may not benefit from being in this research study. You will receive information about PTSD. The information may help you or someone you know.

WHAT ARE THE POSSIBLE BENEFITS TO SOCIETY FOR TAKING PART IN THIS STUDY?

We hope this study will help us learn about the best ways to improve health care for adults who may have experienced trauma.

WHAT IF YOU ARE ELIGIBLE TO PARTICIPATE?

Your participation in this research is **VOLUNTARY**. You don't have to take part in the study if you do not want to. Your choice about being in this study will not change the relationship with your health care provider or any other services or benefits you may get from your health center. Your choice will not affect your right to health care or other services that you can get. If you decide **not** to participate, you will continue to receive your health care as you usually do. If you decide **to** participate, you can skip any question or stop being in the study at any time. If you decide to stop the survey, the medical care you receive at this center will not be affected.

WHAT ARE THE COSTS OF BEING IN THIS STUDY?

There is no cost for being in this study.

The health-related information that we will receive about you in this study, including medical history information obtained during the care management and evaluation assessments and from your electronic health record, is personal. The research team is required by law to protect the privacy of information called "protected health information" or PHI. We will make every effort to protect the confidentiality of your PHI, which may be shared with others to support this research, to conduct public health reporting, and to comply with the law as required. Despite these protections, there is a possibility that information about you could be used or disclosed in a way that it will no longer be protected.

Your permission will expire 7 years after the completion of the study. You may withdraw or take away your permission to use and disclose your health information about you gathered after that date. However, information that has already been collected may still be used for this research study.

WILL YOU BE PAID TO PARTICIPATE IN THIS STUDY?

If you agree to participate in this research study, you will receive up to $105 in gift cards for your time and effort. This includes $15 ($5 for the first short screener & $10 for the longer screener) for determining that you qualify to participate, $20 for completing a survey about your health experiences today or within the next few days. You will also receive $30 for completing a survey in 3 months and $40 for completing a survey in 12 months.

AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION FOR THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

As a part of this study, we will be collecting health information about you. This information is "protected" because it is identifiable or "linked" to you.

Protected Health Information (PHI): By signing this consent document, you are allowing the study team and other authorized personnel to use your protected health information for the purposes of this research study. By signing the medical release form, you are authorizing the BETTER study staff to contact your healthcare providers to collect the information detailed above about your appointments, use of services, diagnoses, prescribed medications, and contact information. This information will be used only for research purposes.

All reasonable efforts will be made to protect the confidentiality of your PHI, which may be shared with others to support this research, to conduct public health reporting, and to comply with the law as required. Despite these protections, there is a possibility that information about you could be used or disclosed in a way that it will no longer be protected.

Right to Withdraw Your Authorization: Your authorization for the use of your health information for this research study shall not expire unless you cancel this authorization. Your health information will be used as long as it is needed for this research study. However, you may withdraw your authorization at any time if you notify the research team in writing. Please know that the research team will not have to destroy or retrieve any of your health information that has already been collected before your withdrawal is received.

You have a right to refuse to sign this form. Your health care, the payment for your health care, and your health care benefits will not be affected if you do not sign this form. If you do not sign this form, you will not be able to be part of this research study. This will not affect your medical treatment or your relationships with the health center staff in any way.

WHO CAN YOU CALL WHEN YOU HAVE QUESTIONS ABOUT THIS STUDY?

If you have any questions or concerns about this study, you may call either researcher who is in charge:

> Ms. Andrea Cassells of CDN at 212.382.0699, x227 or Dr. Lisa Meredith of RAND Corporation at 800.447.2631, x7365

If you have questions about your rights as a research participant or need to report a research-related injury or concern, you can contact RAND's Human Subjects Protection Committee toll-free at 866.697.5620 or by emailing hspcinfo@rand.org. If possible, when you contact the Committee, please reference Study #2021-N0253.

CONSENT TO PARTICIPATE IN THE BETTER STUDY

I have read the above information about the BETTER study. I have asked all the questions that I have today, and they have been answered. I have been told that I can ask other questions at any time. I agree to take part in this research study. I have been given a copy of this form for my own records. I understand that signing this form does not take away any of my legal rights.

_____

Participant's Name (Print)

_____

Participant's Signature Date

In my judgment, the participant is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research study.

_____

Person Obtaining Consent/Title Date

SCRIPT FOR ORAL CONSENT (PATIENT)

1. Recruiter	Hello - My name is _____. I am calling to invite you to participate in our research study: *BETTER*, which stands for *Building Experience for Treating Trauma and Enhancing Resilience*. You are being invited to take part in a research study because a health care provider referred you or because of your responses to questions asked by the Center Recruitment Coordinator. We will describe the study to you and answer all of your questions. It is your choice whether you want to take part in the study. Your medical care will be the same no matter which you choose. The purpose of BETTER is to improve the care for patients who have experienced trauma or stressful experiences such as community or personal violence. We are inviting adults to participate in the study who are age 18 or older who may be experiencing symptoms related to trauma, which are sometimes called posttraumatic stress disorder or PTSD. Being invited to participate does not mean that you have PTSD. You and your health care provider can determine if that is the case together. We will include 720 people in the study across 12 health centers. Information from this study may help us learn how to improve health care for people who may have had similar trauma experiences. The study is funded by the National Institute of Mental Health and is being conducted by Clinical Directors Network (CDN), the RAND Corporation, and the Boston University School of Medicine. If you agree to participate, we will ask you about 20 questions today to see if you are fully eligible for the study. We will give you a $10 gift card for the time you spend answering these questions even if you do not qualify. If you qualify to participate in the full study, we will ask you to complete a survey today before you leave the health center or online within the next two days. The survey asks about your health, health care experiences, use of medical services, and your background. The survey will take about 20-30 minutes and we will give you a $20 gift card for your time. You will also be asked to take part in 2 more 20-30 minute surveys 3 and 12 months after the first survey. You will get a $30 gift card for completing the 3-month survey and a $40 gift card for completing the 12-month survey. Health centers taking part in this study have been assigned by chance (like the toss of a coin) to either continue providing care as they usually do or to offer an additional treatment for symptoms related to trauma. We will tell your medical providers that you are eligible for the study because you are experiencing symptoms of stress related to trauma so that you and your providers can talk about your symptoms. If you need treatment for trauma-related stress, your providers will offer you the care that is available at your health center.
	IF THIS IS A USUAL CARE CENTER: Your health center has been assigned to provide the usual care. There will be no change in the treatment being delivered at the health center. You can continue to receive the usual care offered at your health center.
	IF THIS IS AN INTERVENTION CENTER: Your health center has been assigned to have additional treatment available. You can continue to receive your usual care and you will also have an opportunity to receive Written Exposure Therapy. This therapy has been shown to help decrease symptoms of PTSD. This therapy takes only 5 half-hour sessions and other patients have said that it has helped them. The sessions can be done in-person at the health center or remotely by by video (like with Zoom). A Care Manager in your center will work with you and your other providers (medical provider and therapist) to see whether the treatment is a good option for you.
	Regardless of which type of health center you are in, a Care Manager will help coordinate any additional follow-up care needed for the trauma-related stress you have experienced. After we finish talking, you will be connected with your assigned Care Manager. The Care Manager will conduct the first 20-minute visit (in-person or over the phone) where you will get information about problems caused by trauma, answers to any questions you may have, learn about different ways to handle trauma-related problems,

	and get connected to medical providers for treatment. The Care Manager will support your care by working with a medical provider and a therapist, if needed. After the first in-person or remote visit (by telephone or video), your Care Manager will schedule 2 additional telephone check-in calls with you over the next 3 months. These check-in calls will last about 10 minutes. Do you have any questions you'd like to ask me so far? [Note: If participant asks for guidance on standard clinical care, indicate that it would be best for the participant to contact the participant's primary care provider (PCP) and that the research team is not able to provide this type of information]
2. Participant	Yes, proceed to statement 3. No, proceed to statement 4.
3. Recruiter	Yes, I would be glad to answer your questions. Note: Answer any question that the participant has. Once the participant is satisfied, please continue.
4. Recruiter	There are few possible risks to you as a participant in the study. If someone learned that you were participating in a study about mental health, it could be embarrassing to you. We will keep your survey responses confidential and we will not share your individual survey response with anyone outside of the research team. We will also keep your name separate from your survey responses at all times. Answering some of the questions we are asking you today and again in 3 and 12 months or talking with the care manager or health care providers about the stressful event you have experienced may upset you. For example, remembering frightening or dangerous events may make you feel nervous, anxious, depressed, uncomfortable, or upset. You can skip any question or stop being in the study at any time. If you are feeling extremely upset, you will be referred to a provider in the health center. You may not benefit from being in this research study. You will receive information about PTSD. The information may help you or someone you know. We hope this study will help us learn about the best ways to improve health care for adults who may have experienced trauma. There is no cost for being in this study. Do you have any questions or concerns?
5. Participant	Yes, proceed to statement 6. No, proceed to statement 7.
6. Recruiter	Yes, I would be glad to answer your questions. Note: Answer participant to the fullest extent. Once the participant is satisfied, please continue.
7. Recruiter	At all times, we will do everything we can to protect your privacy. Your confidentiality will be protected by assigning a participant identification number (ID) to your study records instead of using your name. All of your answers from the interviews will be coded and stored in a secure database at CDN's and RAND's offices. A separate list of names, addresses, and telephone numbers, along with the ID's for each study participant will be stored in a secure file at CDN's offices. All information will be password-protected and locked away. The information we get will be used for the purposes of data analysis, and all analyses will be conducted by coded ID numbers only. The results of the study will be reported in the form of summary statistics. Reports of study findings will never use your name or any other personally identifying information. We will protect your confidentiality.

	At the end of the study, CDN will place general results of the study on its website – www.CDNetwork.org. Your name will not appear on the website or in any publications or presentations about the results of the study. All information is presented in the form of summary statistics to further protect your information. In addition, we will share a dataset with the funder, the National Institute for Mental Health, so that other researchers can access it, but this dataset will be stripped of anything that can identify you. As an additional layer of protection, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. Researchers with this Certificate may not disclose or use information that may identify you in any legal proceeding, for example, if there is a court subpoena, unless you have consented for this use. Information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except: • if you have consented to the disclosure, including for your medical treatment. • if it is used for other scientific research, as allowed by federal regulations protecting research subjects. • if you tell study staff that you are about to harm yourself, or about to harm someone else, they may inform the appropriate authorities to ensure your safety, or the other person's safety. • If you tell study staff that a child is being abused, they may tell the appropriate authorities about this so that the child is kept out of danger. You may be concerned that someone may overhear you during the survey. We will make sure that the surveys are conducted in a private room or by a secure, password protected video or phone connection. The health-related information that we will receive about you in this study, including medical history information obtained during the care management and evaluation assessments and from your electronic health record, is personal. The research team is required by law to protect the privacy of information called "protected health information" or PHI. We will make every effort to protect the confidentiality of your PHI, which may be shared with others to support this research, to conduct public health reporting, and to comply with the law as required. Despite these protections, there is a possibility that information about you could be used or disclosed in a way that it will no longer be protected. Your permission will expire 7 years after the completion of the study. You may withdraw or take away your permission to use and disclose your health information about you gathered after that date. However, information that has already been collected may still be used for this research study. All other study records will also be kept for 7 years after the end of the study (2030) and then will be destroyed. Do you have any additional questions or concerns?
8. Participant	Yes, proceed to statement 9. No, proceed to statement 10.
9. Recruiter	Yes, I would be glad to answer your questions. Note: Answer participant to the fullest extent. Once the participant is satisfied, please continue.
10. Recruiter	Your participation in this research is VOLUNTARY. You don't have to take part in the study if you do not want to. Your choice about being in this study will not change the relationship with your health care provider or any other services or benefits you may get from your health center. Your choice will not affect your right to health care or other services that you can get. If you decide not to participate, you will continue to receive your health care as you usually do. If you decide to participate, you can skip any question or stop being in the study at any time. If you decide to stop the survey, the medical care you receive at this center will not be affected.

	If you have any questions or concerns about this study or wish to cancel your authorization to participate, you may call either researcher who is in charge: Ms. Andrea Cassells of CDN at 212.382.0699, x227 or Dr. Lisa Meredith of RAND Corporation at 800.447.2631, x7365 If you have questions about your rights as a research participant or need to report a research-related injury or concern, you can contact RAND's Human Subjects Protection Committee toll-free at 866.697.5620 or by emailing hspcinfo@rand.org. If possible, when you contact the Committee, please reference Study #2021-N0253. Do you have any additional questions or concerns?
11. Participant	Yes, proceed to statement 12. No, proceed to statement 13.
12. Recruiter	Yes, I would be glad to answer your questions. Note: Answer participant to the fullest extent. Once the participant is satisfied, please continue.
12. Recruiter	Based on the information that you have been provided, are you willing to participate in this study and authorize the use and disclosure of your health information to researchers for the purposes described above?
13. Participant	Yes, Proceed to statement 10. No, Proceed to statement 11.
14. Recruiter	Thank you. I will continue.
15. Recruiter	Thank you again for your time. I can be reached at _____ if you happen to change your mind in the future. Have a great day.

CONSENT TO RECONTACT

May the study team, or someone from the study team, contact you in the future about using your information for research that is not described in this consent form?

____Yes ___No

May the study team, or someone from the study team, contact you in the future to see if you would like to participate in other research?

____Yes ___No

RESEARCHER'S STATEMENT

I have fully explained this study to the participant. As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the participant's satisfaction.

Name of participant who gave oral consent to take part of the BETTER Project:

_____ _____

Participant's Name Date of Oral Consent

_____

Person Obtaining Oral Consent: Name (Print) Signature Date