

University of California, Los Angeles

CONSENT TO PARTICIPATE IN RESEARCH

Mindful Self-Compassion to Address PTSD and Substance Use in Unhoused Women

Dana Rose Garfin, PhD from the Department of Community Health Sciences, in the Fielding School of Public Health at the University of California, Los Angeles is conducting a research study. This study is being funded by the U.S. Army Contracting Command (USACC). You were selected as a possible participant in this study because in our screening procedure you shared with us that you had experienced trauma, homelessness, and substance use and that you were interested in a study on stress reduction. Your participation in this research study is voluntary.

WHAT SHOULD I KNOW ABOUT A RESEARCH STUDY?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research study is to see if a short course of Mindful Self Compassion can help women who have experienced trauma, PTSD, and homelessness improve symptoms of PTSD, anxiety, depression, and substance use. We also want to find out if the mindful self-compassion program helps women with other problems such as helplessness and loneliness.

HOW LONG WILL THE RESEARCH LAST AND WHAT WILL I NEED TO DO?

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Participation will take a total of about 16 hours over four months. If you are in the Mindful Self Compassion group, you will participate in seven sessions over a six-week period, with six sessions being 1.5 hours and a longer session that will be 3 hours. If you are in the Psychology Survey group, you will complete the same number of sessions although they will not last as long.

You will also complete three interviews that will each last approximately 45-60 minutes.

If you are in the Mindful Self Compassion classes, you will be asked to attend weekly Mindful Self Compassion classes and complete home practices in between each session. Mindful Self Compassion classes teach core principles and practices that

enable us to respond to difficult moments in our lives with kindness, care, and understanding.

If you are in the Psychology Survey group (Treatment as Usual), you will have weekly sessions with us where you will fill out different psychological surveys.

More detailed information about the study procedures can be found under “**What Will Happen If I Take Part In This Study?**”

ARE THERE ANY RISKS IF I PARTICIPATE?

You should talk to the research team about any problems you experience while taking part in the study.

Risks and side effects related to Mindful Self Compassion are:

Likely

- None. We believe the risks associated with this study are rare.

Less Likely

- Anxiety or distress that arises as part of the mindfulness meditation instructions
 - You will be asked to sit still for a period of time, which can be hard for some people
- Anxiety or distress that arises as part of discussions with the group or trainer
 - Some people are anxious during group discussions, although we will take great caution to make the group environment a safe and comfortable space
- Loss of confidentiality (< 1%)
 - Since all your information will be uploaded onto a secure server on the UCLA server as you fill out the questionnaire and your responses will be recorded separately from your name, we think this is not very likely.
- Although we will not report your answers to anyone affiliated with your treatment facility or the court, you might be worried that some of your information will be disclosed.

Rare but serious

- We do not believe there are any serious risks associated with participating in this study

Psychological discomforts: Some of the procedures may cause embarrassment or anxiety, or the questions the researchers ask you may be upsetting or make you uncomfortable. If you do not wish to answer a question, you can skip it and go to the next question. If you do not wish to participate you can stop. You can still be in the rest of the study if you skip any part of it.

ARE THERE ANY BENEFITS IF I PARTICIPATE?

You may benefit from the study because taking part in this study may or may not make your health better. While researchers hope that mindfulness and other components of

Mindful Self Compassion may help people with PTSD, substance use and related problems, there is not proof of this yet.

If you are in the group that receives the Mindful Self Compassion and it proves to treat your PTSD, depression, anxiety, and substance use, you may benefit from participating in the study, but this cannot be guaranteed.

Benefits to Others or Society

The results of this study will help researchers learn more about mindfulness and self-compassion-related interventions and the benefit they could have to reduce PTSD and other outcomes. It is hoped that this information will help in the treatment of future patients with PTSD and trauma exposure.

What other choices do I have if I choose not to participate?

Your alternative to participating in this research study is to not participate.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

If you volunteer to participate in this study, the researcher will ask you to do the following:

Before you can participate in the main part of the study...

You will need to have “screening” procedures. The screening process helps the researchers decide if you meet the study requirements listed below. The screening procedures include filling out a short survey about your PTSD and trauma exposure and a measure of cognitive issues.

During the main part of the study...

If the screening exams, tests and/or procedures show that you can continue to be in the study, and you choose to take part, then you will have the following procedures and tests done. The main study tests and procedures include:

1. First session: complete an interview about your physical and mental health as well as your life experiences. We will take a picture of you to help us locate you for a follow-up session, although you can still be in the study if you don't want us to take your picture.
2. Sessions 2-8: you will participate in one of two groups: either Mindful Self Compassion classes or “Psychology Survey group (Treatment as Usual) where you will complete weekly psychological surveys.

You have been assigned to participate in the Mindfulness Self Compassion Group.

You will participate in 7 sessions that will consist of the following:

Session 1: What is Mindfulness Self Compassion?

Session 2: Practicing Self Compassion

Session 3: Discovering Your Compassionate Voice

Session 4: Self Compassion & Resilience

Session 5: Meeting Difficult Emotions

Living Deeply Half-Day Retreat:

Session 6: Making it Count

You will also be assigned brief homework assignments and participate in guided meditations (pre-loaded on a MP4 player) in between sessions.

Randomization: You will be assigned to a study group by chance (like a coin flip). This will depend on when you enroll in the program. Everyone who enrolls in the program at the same time will be in the same group. The group you are in may have different benefits for you. You will still be receiving the same care you would normally be getting through HealthRIGHT 360 at Prototypes. The program is extra to what you normally do as part of your treatment. Importantly, participation in this study will not impact your current treatment in any way. You will be receiving the same treatment and opportunities through HealthRIGHT 360 that you are already receiving or would receive in the future.

After you complete the main part of the study, you will again participate in an interview, which will occur right after session 7 or a few days later. Four months after the first session, you will participate in a final interview. The follow-up interview will be at Prototypes or a comfortable and private location that is convenient for you, including Zoom.

Since you have been assigned to the Mindful Self Compassion group, after the follow-up interview that will occur right after your final session or a few days later, you may have the opportunity to participate in an additional short qualitative interview. This will involve a short (10-20 minute) one-on-one conversation where we will ask you open-ended questions about your experiences, opinions, and perspectives about the Mindful Self Compassion intervention. This interview will help us understand more about your experiences in the study. Your responses will be audio-recorded for accuracy, but your identity will remain confidential. Participation in this interview is voluntary, and you can choose to stop at any time without penalty. You will be compensated \$10 for this interview. You can still be in the rest of the study and not participate in this qualitative interview. If you want, you can listen to the digital recording of the interview and then decide if you still want us to use this data in our analysis. If you do not want us to use this data, we will immediately destroy it with no penalty to you.

RETURN OF RESULTS

You will not be provided clinically relevant information as part of the study.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.

Use of personal information that can identify you:

Subject Identifiable Data

Identifiable information collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data. The reason that we link your actual name with a code is so that we can link all your data for the three assessments with each other. The list will be destroyed at the end of the study.

We will also take a picture of you and take down some information to help us find you for the follow-up assessments if you move away from Prototypes/ North County Serenity House. This is part of a Locator Guide but it will not be linked with your responses. It will be destroyed at the end of the study.

How information about you will be stored:

Data Storage

Research data will be stored electronically via REDCap, a data capture software program, on a secure server at the University of California, Los Angeles in an encrypted file with a password that only the Principal Investigator (Dr. Dana Rose Garfin) or senior research staff will have access to.

People and agencies that will have access to your information:

The research team, authorized UCLA personnel, and the study sponsor may have access to study data and records to monitor the study. Research records provided to authorized, non-UCLA personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.

Employees of the University may have access to identifiable information as part of routine processing of your information, such as lab work or processing payment. However, University employees are bound by strict rules of confidentiality.

How long information from the study will be kept:

The researchers intend to keep the research data indefinitely. However, the identifiable information that links you to your responses will be destroyed after the final data collection

USE OF DATA FOR FUTURE RESEARCH

Your data, including de-identified data, may be kept for use in future research, including research that is not currently known. If you do not want your data to be used for future research you should not participate in this study. Only deidentified data (that is, data that is not linked with any identifying information such as your name, picture, or contact information) will be used in this potential future research. All data that could possibly identify you (such as your name, picture, or contact information) will be destroyed at the end of the study.

WILL I BE PAID FOR MY PARTICIPATION?

You will be paid up to \$150 for your participation in the study, provided in cash or a Visa gift card. The payment breakdown is as follows:

- \$15 initial (baseline) interview
- \$10 for each of 7 group sessions (\$70 total)
- \$20 post intervention interview
- \$10 (optional) qualitative interview if you are in the Mindful Self Compassion group
- \$30 four-month follow-up interview

If you are no longer living at Prototypes, we will reimburse you for any out of pocket expenses you incur as part of your transportation back to the site to complete the study procedures.

You will also receive a certificate of completion if you attend at least 5 of the sessions. If you come to all seven sessions will receive an additional certificate for your perfect attendance. You will get materials that are associated with the sessions (for example, MP4 players).

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?

You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately.** The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study or your safety and welfare are at risk.

If you experience any severe symptoms that we did not anticipate or that are listed above or your health worsens you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety

and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

If you withdraw or are removed from the study, the researcher may ask you to return for the follow-up visits if you would like to complete those assessments.

If you elect to withdraw or are withdrawn from this research study, the researchers will discuss with you what they intend to do with your study data. Researchers may choose to analyze the study data already collected or they may choose to exclude your data from the analysis of study data and destroy it, as per your request.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

The research team:

If you have any questions, comments or concerns about the research, you can talk to the one of the researchers. Please contact: Dr. Dana Rose Garfin at dgarfin@ucla.edu or 415-407-9497.

UCLA Office of the Human Research Protection Program (OHRPP):

If you have questions about your rights as a research participant, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may contact the UCLA OHRPP by phone: (310) 206-2040; by email: participants@research.ucla.edu or by mail: Box 951406, Los Angeles, CA 90095-1406.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

- You can choose whether or not you want to be in this study, and you may withdraw your consent and discontinue participation at any time.
- Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled.
- You may refuse to answer any questions that you do not want to answer and still remain in the study.

You will be given a copy of this information to keep for your records.

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

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SIGNATURE OF THE PARTICIPANT

Name of Participant

Signature of Participant

Date

SIGNATURE OF PERSON OBTAINING CONSENT

Name of Person Obtaining Consent

Contact Number

Signature of Person Obtaining Consent

Date

Treatment As Usual

University of California, Los Angeles

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3. First session: complete an interview about your physical and mental health as well as your life experiences. We will take a picture of you to help us locate you for a follow-up session, although you can still be in the study if you don't want us to take your picture.
4. Sessions 2-8: you will participate in one of two groups: either Mindful Self Compassion classes or Psychology Survey group (Treatment as Usual) where you will complete weekly psychological surveys.

You have been assigned to participate in the Psychology Survey group.

You will participate in 7 sessions where you will take psychological surveys. You will also receive an MP4 player that you can listen to music on.

Randomization: You will be assigned to a study group by chance (like a coin flip). This will depend on when you enroll in the program. Everyone who enrolls in the program at the same time will be in the same group. The group you are in may have different benefits for you. You will still be receiving the same care you would normally be getting through HealthRIGHT 360 at Prototypes. The program is extra to what you normally do as part of your treatment. Importantly, participation in this study will not impact your current treatment in any way. You will be receiving the same treatment and opportunities through HealthRIGHT 360 that you are already receiving or would receive in the future.

After you complete the main part of the study, you will again participate in an interview, which will occur right after session 7 or a few days later. Four months after the first session, you will participate in a final interview. The follow-up interview will be at Prototypes or a comfortable and private location that is convenient for you, including Zoom.

RETURN OF RESULTS

You will not be provided clinically relevant information as part of the study.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.

Use of personal information that can identify you:

Subject Identifiable Data

Identifiable information collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data. The reason that we link your actual name with a code is so that we can link all your data for the three assessments with each other. The list will be destroyed at the end of the study.

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House. This is part of a Locator Guide but it will not be linked with your responses. It will be destroyed at the end of the study.

How information about you will be stored:

Data Storage

Research data will be stored electronically via REDCap, a data capture software program, on a secure server at the University of California, Los Angeles in an encrypted file with a password that only the Principal Investigator (Dr. Dana Rose Garfin) or senior research staff will have access to.

People and agencies that will have access to your information:

The research team, authorized UCLA personnel, and the study sponsor may have access to study data and records to monitor the study. Research records provided to authorized, non-UCLA personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.

Employees of the University may have access to identifiable information as part of routine processing of your information, such as lab work or processing payment. However, University employees are bound by strict rules of confidentiality.

How long information from the study will be kept:

The researchers intend to keep the research data indefinitely. However, the identifiable information that links you to your responses will be destroyed after the final data collection

USE OF DATA FOR FUTURE RESEARCH

Your data, including de-identified data, may be kept for use in future research, including research that is not currently known. If you do not want your data to be used for future research you should not participate in this study. Only deidentified data (that is, data that is not linked with any identifying information such as your name, picture, or contact information) will be used in this potential future research. All data that could possibly identify you (such as your name, picture, or contact information) will be destroyed at the end of the study.

WILL I BE PAID FOR MY PARTICIPATION?

You will be paid up to \$140 for your participation in the study. The payment breakdown is as follows:

\$15 initial (baseline) interview

\$10 for each of 7 group sessions (\$70 total)
 \$20 post intervention interview
 \$30 four-month follow-up interview

If you are no longer living at Prototypes, we will reimburse you for any out of pocket expenses you incur as part of your transportation back to the site to complete the study procedures.

You will also receive a certificate of completion if you attend at least 5 of the sessions. If you come to all seven sessions will receive an additional certificate for your perfect attendance. You will get materials that are associated with the sessions (for example, MP4 players).

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?

You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately.** The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study or your safety and welfare are at risk.

If you experience any severe symptoms that we did not anticipate or that are listed above or your health worsens you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

If you withdraw or are removed from the study, the researcher may ask you to return for the follow-up visits if you would like to complete those assessments.

If you elect to withdraw or are withdrawn from this research study, the researchers will discuss with you what they intend to do with your study data. Researchers may choose to analyze the study data already collected or they may choose to exclude your data from the analysis of study data and destroy it, as per your request.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

The research team:

If you have any questions, comments or concerns about the research, you can talk to the one of the researchers. Please contact: Dr. Dana Rose Garfin at dgarfin@ucla.edu or 414-407-9497.

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If you have questions about your rights as a research participant, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may

contact the UCLA OHRPP by phone: (310) 206-2040; by email: participants@research.ucla.edu or by mail: Box 951406, Los Angeles, CA 90095-1406.

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- You may refuse to answer any questions that you do not want to answer and still remain in the study.

You will be given a copy of this information to keep for your records.

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Name of Participant

Signature of Participant

Date

SIGNATURE OF PERSON OBTAINING CONSENT

Name of Person Obtaining Consent

Contact Number

Signature of Person Obtaining Consent

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