UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title	DREAMER: Defining stress REsilience And Mindfulness Effects in Rheumatoid Arthritis
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Clinicaltrials.gov National Clinical Trial (NCT) Number	*NCT06276387*

1. Why have I been given this document?

To see if you are interested in taking part in a research study. A research study is a planned project done to learn more about a topic.

2. Do I need to take part in this research study?

No. Taking part in research is voluntary. If you don't want to take part there will be no penalty and you will not lose your current benefits. The Principal Investigator, or another member of the study team, will explain the study to you. Please ask questions. Take your time deciding if you want to be in this study. You can talk with your health care team, your family, and friends before deciding.

3. This section describes key information to consider about this study

3.1 Why is this study being done?

This study is being done to learn how stress, resilience to stress, and a mindfulness program affect symptoms and inflammation among people with rheumatoid arthritis (RA).

3.2 How long would I be in this study? How many study visits are there?

You would be in this study for about 3 months and visit the research site about 2 times. During this time, you would also complete surveys online, and you may attend online mindfulness classes weekly for 8 weeks.

3.3 What are the procedures with the most risk in this study?

The procedures with the most risk in this study are:

- Blood draw (venipuncture)
- Survey or interview questions about sensitive topics
- Loss of privacy

3.4 What risks and discomforts are most severe? What risks and discomforts are most common?

Possible risks and discomforts of this study that are most severe are:

- Blood drawing (venipuncture) risks
- Loss of privacy

Possible risks and discomforts of this study that are most common are:

- Randomization risks
- Emotional or psychological discomfort (e.g., from answering survey or interview questions about sensitive topics or learning mindfulness skills)

We will tell you more about risks and discomforts later in this form.

3.5 Are there benefits to taking part in this study?

You may or may not benefit from participating in the study. The information learned from this study may help others in the future.

3.6 What are my other options if I don't want to take part in this study?

Your other options may include:

- Getting care without being in this study
- Taking part in another study if you are interested and one is available

4. How many people will take part in this study?

About 20 people will take part in this phase of the study. About 48 people will take part in all phases of the study.

5. Who is paying for this study?

This study is being paid for by National Institutes of Health.

6. Do any UCSF researchers of this study have financial interests that I should know about?

No.

7. What are the research procedures of this study?

Before you begin the main part of the study...
You will complete an eligibility screening survey to see if you qualify for the main part of the study.

Study procedures
If you qualify for the study, you will complete the following procedures.

- Online questionnaires about your health, mood, and symptoms. These will take approximately 20 minutes to complete.
- Two in-person study visits (at baseline and follow-up), each lasting up to one hour, that will include:
    - A brief joint exam by a study rheumatologist that will take roughly 5 minutes.

- **Blood drawing (venipuncture):** A blood sample will be taken by inserting a needle into a vein in your body. Each sample will be about 3 tablespoons. A total of about 6 tablespoons will be taken for the whole study.

Randomization: This study has different groups. You will be put into a group by chance. How your group is chosen is like flipping a coin or rolling dice. Your chance of being put into one group might be higher depending on the design of the study.

- **If you are in group 1** ...
  - You will be enrolled in a mindfulness program called Mindfulness-Based Stress Reduction (MBSR), offered by the UCSF Osher Center for Integrative Health. The MBSR course takes place over 8 weeks, and all components will be held over Zoom or completed remotely. It is a well-studied program that has been shown to improve sleep, stress, and the ability to cope with pain. The MBSR course includes the following:
    - An Orientation / Introduction to Mindfulness (2.5 hours)
    - A private interview with the MBSR instructor before beginning the program (30 minutes)
    - Eight weekly mindfulness group sessions via Zoom (2.5 hours each)
    - One daylong virtual retreat (7 hours)
    - Home mindfulness practices (about 40 minutes a day)
  - Each week during the 8-week course, you will complete a brief (5-minute) online survey about your home practice and whether you attended class that week.
  - After the MBSR course, you will also be asked to attend a focus group about your experience participating in the MBSR course. The focus group will take up to 90 minutes, and it will be held virtually over Zoom. The focus group will include 5-10 other research participants who also have RA, in addition to a trained facilitator who will ask questions. During the focus group you will *not* be required to answer any questions that make you feel uncomfortable or that you prefer not to answer. The feedback and comments you provide during the

focus group will be used to develop future mindfulness programs for people with RA and related conditions.
    - The focus group will be recorded so that we can use your feedback to improve the MBSR experience for future MBSR participants with RA. You will be notified when the recording starts at the beginning of the focus group. The researchers will ask you and the other people in the group to use only first names during the group session, and they will also ask you not to tell anyone outside the group what any particular person said in the group. At the end of the focus group, researchers will write down all of the focus group discussion for analysis. Any information that links your identity to the recording will not be included in that written file. Recordings will be reviewed by study personnel and will be destroyed upon the completion of all data analyses.
    - All of the above procedures are specific to the study and not part of routine care. However, while participating in this study, you will also continue the medications and other treatments prescribed by your regular treating healthcare provider for your RA.
- **If you are in group 2** …
    - You will continue the medications and other treatments prescribed by your regular treating healthcare provider for your RA.
    - You will be asked not to begin any new mindfulness practices during your participation in the study.

Follow-up procedures

The study team will follow up with you to see how you are doing. Approximately 2-3 months after enrollment, you will repeat the same assessments you completed at the beginning of the study, including:

- Online questionnaires about your health, mood, and symptoms. These will take approximately 15 minutes to complete.
- An in-person study visit, lasting up to one hour, including:
    - A brief joint exam by a study rheumatologist
    - **Blood drawing (venipuncture)**

Medical records review: If you are an existing UCSF patient, study staff may access your medical record to confirm certain health information, such as current medication use, RA diagnosis, and recent disease activity.

Collection and storage of blood specimens: Some of your blood will be sent to Quest laboratories immediately to check on levels of inflammation in the blood (e.g., C-reactive protein, erythrocyte sedimentation rate). Some of the blood that is collected from you will be stored at UCSF for research tests for this study. These stored samples will be used to learn more about the link between stress and the immune system. Storing blood for these tests is a required part of the study. If you choose to leave the study early, you can request that your stored samples be destroyed by contacting study staff or Dr. Patterson at any time. After you complete the study, you can also request that any remaining samples be destroyed. All specimens will be coded, and only study staff will have access to the key that links your name with your study code.

- After all tests needed for your medical care are done, your leftover specimens will not be thrown away. Instead, we will save them in what is called a "specimen bank." This bank will store your specimens in case they are needed for future research. We do not know if your specimens will be used, but they might be used in research about autoimmune or other diseases.
- Your specimens will be kept for approximately 30 years. If you decide later that you do not want your specimens and information to be used for future research, tell the Principal Investigator. This person's contact information is on Page 1 of this form. The study team will destroy any data they still have that can be linked to you. We cannot destroy data that has already been shared with other researchers.

7.1 Where do the procedures happen?

The in-person study procedures will be done at one of two UCSF locations: the UCSF Parnassus campus or the UCSF Osher Center for Integrative Health on the Mount Zion campus. The MBSR sessions and focus group will be done over Zoom.

8. What are the risks of this study?

Risks and side effect related to this study include:

- **Randomization risks**: You might be put into a group that receives something that is not as helpful as another group. You might have more side effects than people in another group or people who don't join this study.
- **Blood drawing (venipuncture) risks**: Drawing blood may cause discomfort from the needle stick. It may cause bruising, infection, and fainting.
- **Emotional or psychological discomfort**: Some of the questions in the questionnaires may make you feel uncomfortable or distressed. You are free to stop these questions at any time. If you are in the mindfulness group, you may find the coursework to be mentally or psychologically difficult. If you attend the focus group, it is possible that you may feel uncomfortable or anxious responding to questions in front of others.
- **Loss of privacy**: There is a risk of loss of privacy if another participant breaches the agreement to keep discussions in the focus group private.
- **Unknown risks**: The study treatment (MBSR) may have side effects that no one knows about. The study team will let you know if they learn anything that might make you change your mind about taking part in the study.

For more information about risks and side effects, ask one of the researchers.

9. Will I be paid if I take part in this study?

In return for your time and effort, you will be paid up to $210 for taking part in this study, depending on which group you are assigned to.

You will receive $75 for completing baseline assessments, including study surveys, in-person visit, and blood draw. At follow-up, you will receive $25 for completing online surveys, and $75 for completing an in-person visit and blood draw. If you are assigned to the MBSR group, you will be invited to participate in a focus group after the MBSR course is complete; if you participate in this focus group, you will receive $35. Thus, if you are assigned to the MBSR group, you could receive a total of $210 if you complete all study procedures. If you are assigned to the TAU group, you could receive a total of $175 if you complete all study procedures.

You will be paid in cash after each of the in-person visits (i.e., at baseline and follow-up). If you are in the MBSR group and complete the online focus group, you will be paid by Amazon e-gift card, which will be emailed to you approximately 1-2 weeks after the group. If for some reason you are unable to be paid in cash at baseline or follow-up (e.g., because you completed the online surveys but did not attend the in-person visit), you will be paid via Amazon e-gift card.

At each of your in-person visits for this study, we will reimburse for public transportation or provide parking validation at a nearby UCSF garage.

9.1 Will I share in any profits from this study?

No. Your specimens or information obtained from your specimens may be used for commercial use. If this happens, you will not share in any profits.

10. Will I be reimbursed for expenses if I take part in this study?

You will be reimbursed for expenses if you take part in this study, including public transportation and parking. At each of your in-person study visits, we will provide validation for a nearby UCSF parking garage.

11. How will my information be used?

Researchers will use your information and specimens to do this study. Once the study is done, we may use your information and specimens for other research studies in the future. We may share them with other researchers to be used in their studies. We will not share your name or other information that could identify you. We cannot promise that this will prevent future researchers from figuring out who you are. We will not ask you for additional permission to share this de-identified information.

11.1 Genetic testing statement

Researchers may use your specimens to look at your DNA. DNA contains information that determines things like eye color, height, or disease risk that are passed on from parent to child.

11.2 How will my genetic information be shared?

We may use your genetic information and some medical record data to do research in the future. We will remove your name and other personal information before sharing it with other researchers. We may share this information with other scientists or companies not at UCSF. This information may be put into an unrestricted or controlled access government health research database. Even though no personal information will be included, we cannot guarantee that no one will ever be able to use this information to identify you.

12. How will information about me be kept confidential?

If you take part in this study, there may be some loss of privacy. We will do our best to make sure information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records may be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form will be added to your UCSF medical record. People involved with your future care and insurance may become aware that you participated in this study. They may see information added to your medical record. Study tests and information obtained from you will be part of your research records. Your personal information may be given out if required by law. Information from this study may be published or presented at scientific meetings. If it is, your name and other personal information will not be used.

If you take part in the focus group, the researchers will ask you and the other people in the group to use only first names during the group session, and they will also ask you not to tell anyone outside the group what any particular person said in the group. However, the researchers cannot guarantee that everyone will keep the discussions private. At the end of the focus group, researchers will write down all of the focus group discussion for analysis. Any information that links your identity to the recording will not be included in that written file. Recordings will

be reviewed by study personnel and will be destroyed upon the completion of all data analyses.

12.1 Who may review my research information?

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the University of California
- Representatives of the National Institutes of Health

13. Does this study involve testing of diseases and conditions that must be reported to the public health department?

No, this study does not involve testing for reportable conditions.

14. What happens if I am injured or feel harmed because I took part in this study?

It is important to tell the Principal Investigator if you feel you have been injured or harmed because you took part in this study. The contact information for this person is on the first page of this form.

15. Are there any costs to me for taking part in this study?

No. There is no cost to you or your insurer if you take part in this study. However, you may need to pay for items such as parking and transportation.

You or your insurer will be billed for the costs of any usual medical care you receive outside of this study. You will also be responsible for any deductibles or co-payments for these usual medical care costs.

16. Can I stop being in the study if I want to?

Yes. You can decide to stop at any time. If you are thinking about stopping, tell the study team so they can discuss any risks of stopping with you. They can tell

you what follow-up care and testing could be most helpful. The study team will help you stop your participation safely.

If you stop being in the study, any data or specimens we have already collected will remain part of the study records. The study team may still get information from your medical records if it is important to the study. This information may include information like laboratory results, treatment courses, or health outcomes. If you do not want this information to be collected after you decide to stop being in the study, you must tell the study team.

17. Can I be removed from the study by the Principal Investigator?

Yes. The Principal Investigator may stop you from taking part in this study at any time. This could happen without your permission. It could be because it is in your best interest, if you did not follow the study rules, or the study has been stopped.

18. What are my rights if I take part in this study?

You may choose to take part or not to take part in this study. It's your choice. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

19. Who can answer my questions about this study?

You can contact the study team with any questions, concerns, or complaints you have about this study. The contact information is on the first page of this form.

UCSF has an office that can answer questions about your rights as a research participant. This office is called the Institutional Review Board (IRB). The IRB is available to talk about any problems or concerns you have about the study. The UCSF IRB's phone number is 415-476-1814.

19.1 Where can I get more information about this study?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The National Clinical Trial (NCT) number for this study will be listed on the first page of this form. If the NCT number is not yet available, the study team will give it to you when it is available.

20. Consent

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

You will also be given the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to say “No” to this study now or at any point without penalty.

If you wish to take part in this study, please sign below.

_____	_____
Date	Participant's Signature for Consent
_____	_____
Date	Person Obtaining Consent