Exploring the Concepts of Bio-experiential Spaces
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STUDY INFORMATION:

Study Title: Exploring the Concepts of Bio-experiential Design

Study site(s): Icahn School of Medicine at Mount Sinai, Mount Sinai Hospital

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SUMMARY OF THIS RESEARCH STUDY:

This document explains a research study you might be interested in joining. Participation in the study is voluntary. You can agree to join or not. Your decision will not limit your ability to receive care at Mount Sinai. You should only agree to take part if you understand the study and if all of your questions about the research study are answered. If you do join the study, the research team must share any new information with you that may change your mind about taking part.

The purpose of this study is to investigate how spending time in an immersive bio-experiential space affects the well-being, resilience, and different measures of mental health of someone who is regularly exposed to stressful environments, such as healthcare workers.

If you choose to take part, you will be asked to complete eight (8) surveys which will be completed online at week 1, week 2, week 4, week 6, and week 12. These surveys address multiple variables related to physiological and mental health. You will be required to be in-person at the Recharge Room at week 1 and week 4.

At week 1 and week 4, before and after you experience the room, the study team will use a pulse oximeter device to measure your oxygen saturation and heart rate, and an automatic blood pressure cuff to measure your blood pressure. Additionally, you will be asked to wear an Electroencephalogram (EEG) cap and a device to measure your sweat response or galvanic skin response for the duration of the experience. You will also be asked to roll sterilized laboratory glass beads in your hands for 60 seconds prior to and after their study sessions to give another measure of sweat response.

If you choose to take part, the main risks to you are potential minor emotional discomfort when answering the questionnaires.

You may benefit from taking part in this research. Some potential benefits are improvement in mental health and well-being.

If you are interested in learning more about this study, please continue to read below.

STUDY PARTICIPATION:

You may qualify to take part in this research study because you are an employee of Mount Sinai Hospital or the Icahn School of Medicine at Mount Sinai.

Your participation in this research study is expected to last 12 weeks.

There are 60 people expected to take part in this research study at Mount Sinai.

Funds for conducting this research study are provided by the Cullman Institute.

DESCRIPTION OF WHAT IS INVOLVED:

If you agree to take part in this research study, here is what may be involved:
1) Screening/Baseline Forms (DAY1): may take up to one (1) hour in which the study's purpose as well as its potential risks and benefits will be explained to you in more detail. The following activities and forms will be conducted during this visit:

a. Demographic Form: Accessed through a REDCap link sent to your email

b. Cognitive and Mental Health Surveys: Research study staff will administer ten (10) questionnaires which you will access through a REDCap link sent to your email:

i. Generalized Anxiety Disorder 7 (GAD7)
ii. Patient Health Questionnaire (PHQ-9)
iii. Insomnia Severity Index (ISI)
iv. Fatigue Severity Scale (FSS)
v. Brief Resilience Scale (BRS)
vi. Satisfaction With Life Scale (SWLS)
vii. Physician Well-being Index
viii. Maslach Burnout Inventory-Human Services Survey
ix. Social Connectedness Scale- Revised
x. Awe Scale

c. Physiological Testing: Research study staff will use a pulse oximeter, automatic blood pressure cuff, Galvanic Skin Response device, EEG cap, and glass beads. The research assistants will test you prior to and after having the recharge room experience.

i. Oxygen saturation
ii. Heart rate
iii. Blood pressure

iv. Galvanic skin response
v. EEG
vi. Sweat collection from hands with glass beads

2) Recharge Room Experience (4-weeks):

You will enter the room and experience the room for as long as you would like. The time spent in the room will be accounted for. You will be encouraged to utilize the Recharge Room as frequently as you would like, but at least three (3) times per week.

3) Midpoint- (week 2):

a. Cognitive and Mental Health Surveys: Research study staff will administer ten (10) questionnaires which you will access through a REDCap link sent to your email:
   i. Generalized Anxiety Disorder 7 (GAD7)
   ii. Patient Health Questionnaire (PHQ-9)
   iii. Insomnia Severity Index (ISI)
   iv. Fatigue Severity Scale (FSS)
   v. Brief Resilience Scale (BRS)
   vi. Satisfaction With Life Scale (SWLS)
   vii. Physician Well-being Index
   viii. Maslach Burnout Inventory-Human Services Survey
   ix. Social Connectedness Scale- Revised
   x. Awe Scale

5) Post-intervention Visit- After week 4, the study team will collect the same information as at the first visit. This may take up to one (1) hour and the following activities will be performed:

a. Mental Health surveys: A new REDcap link will be sent to you via email to complete the eight (8) mental health questionnaires
   i. Generalized Anxiety Disorder 7 (GAD7)
   ii. Patient Health Questionnaire (PHQ-9)
   iii. Insomnia Severity Index (ISI)
   iv. Fatigue Severity Scale (FSS)
   v. Brief Resilience Scale (BRS)
   vi. Satisfaction With Life Scale (SWLS)
   vii. Physician Well-being Index
   viii. Maslach Burnout Inventory-Human Services Survey
   ix. Social Connectedness Scale
   x. Awe Scale

c. Physiological Testing: Research study staff will use a pulse oximeter, automatic blood pressure cuff, Galvanic Skin Response device, and EEG cap. The research assistants will test you prior to and after having the recharge room experience.
   i. Oxygen saturation
   ii. Heart rate

iii. Blood pressure
iv. Galvanic skin response
v. EEG
vi. Sweat collection from hands with glass beads

USE OF YOUR DATA AND/OR SAMPLES:

In addition to being used to complete this research study, your personal information (such as, name, date of birth, or email address), study data may also be used and shared for additional (future) research. Before anything is shared, all of your identifying personal information will be removed, and it will be replaced with a code. Researchers are not planning on giving you the details of any of this future research nor the results. That means that a research project might be done that you would not consent to if provided with the details of that research project. If you do not want any future research to be done with your data and/or samples, even with your identity removed, please do not sign this consent form or take part in the study.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, you will be responsible for the following things:

1) Your own health and well-being by truthfully providing accurate answers to the questionnaires as well as informing the research team of any side effects, etc.
2) Understanding the time commitment required for the assessments, agreeing to attend scheduled visits, and arranging your own travel to and from study visits.
3) Notify the research team if you need to stop the session or if you feel uncomfortable answering any questions.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for taking part in this study. Being in this study will not cost you anything extra.

POSSIBLE BENEFITS:

There is a chance this study may benefit you, but this is not guaranteed. Others may benefit from what researchers learn from the study. Possible benefits to you include improvement in mental health and well-being.

POSSIBLE RISKS AND DISCOMFORTS:

- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk

OTHER OPTIONS TO CONSIDER:

You may decide not to take part in this research study. If you decide not to take part, this will not affect the clinical care you receive at Mount Sinai. The choice is totally up to you.

IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you believe that being in this research study has harmed you, you should contact the Lead Researcher. Their contact information is listed at the beginning of this consent form.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this study at any time. No matter what you choose, your care and benefits through Mount Sinai will not be negatively impacted.

If you decide to stop being in the study, please contact the Lead Researcher or the research staff.

You may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page. Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you decide you don't want your data and/or samples to be used for research anymore, you can contact the researcher and ask to have your data and/or samples withdrawn or labeled so that they will not to be used in additional projects or shared. If your data and/or samples have already been shared with researchers, those researchers will be asked to stop using them. However, if any data and/or samples have already been shared without your identity or a linking code, it won't be possible to retrieve them. Data and/or samples that have already been used will not be affected by your decision. If your data and/or samples have already been deposited in an external repository, the study team will request that your data and/or samples be removed.

Withdrawal without your consent: The Lead Researcher, the funder or Mount Sinai may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the research team have not been followed, the Lead Researcher believes it is in your best interest, or for any other reason. If data and/or samples have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT INFORMATION:

If you have any questions, concerns or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Lead Researcher at phone number 212-241-8454

DISCLOSURE OF FINANCIAL INTERESTS:

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are encouraged to talk to the Lead Researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As part of this study, some of your private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.

What is protected health information (PHI)?
PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.

Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information.

What PHI is collected and used in this research study, and might also be shared with others?
As part of this study, the research team at the hospital(s) involved in the research will collect your:

- Name and email address

During the study, the researchers will gather information by:

- Completing the tests, procedures, questionnaires, and interviews explained in the description section of this consent.

Why is your PHI being used?

Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who you are, unless you give separate permission to do so.

Who, outside Mount Sinai, might receive your PHI?
As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your PHI, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Lead Researcher.)

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).

In all disclosures outside of Mount Sinai, you will not be identified by name or email address unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Lead Researcher will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board (IRB) allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, *OHRP, as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access.* The results of this research may be published. However, your name and other identifying information will be kept confidential.

For how long will Mount Sinai be able to use or disclose your PHI?
Your authorization for use of your PHI for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will have access to your medical record and any study information that is part of that record. The research team is not required to release research information to you that is not part of your medical record.

Do you need to give the researchers permission to obtain, use or share your PHI?

NO! If you decide not to let the research team obtain, use or share your PHI, you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment, or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?
If you decide to stop being in the study, please contact the Lead Researcher or the research staff. The research team may ask you whether they can continue to collect information from your medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page.

Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If researchers are reviewing your medical records or asking questions about your medical history or conditions, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you. If researchers are not reviewing your medical records or asking questions about your medical history or conditions, then you may ignore the following section.

Notice Concerning HIV-Related Information
If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 416-0197. These agencies are responsible for protecting your rights.

How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

ADULT PARTICIPANT:

Your signature below documents your permission to take part in this research study and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

Signature of Participant	Printed Name of Participant	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of Consent Delegate	Printed Name of Consent Delegate	Date	Time

WITNESS SECTION:

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

Signature of Witness	Printed Name of Witness	Date	Time