

CONSENT TO BE A RESEARCH SUBJECT

STAYING WELL: A CLINICAL TRIAL OF MINDFULNESS-BASED STRESS
REDUCTION AND EDUCATION GROUPS FOR HIV

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PURPOSE AND BACKGROUND

Dr. Susan Folkman and Dr. Frederick M. Hecht at the UCSF Osher Center for Integrative Medicine are doing a research study to examine the effects of mindfulness based stress reduction (MBSR) and education groups on HIV infection. This study is funded by the National Institutes of Health. Some of the key areas of interest include comparing the effects of MBSR and education groups on the following:

- CD4 T-lymphocyte cell counts and viral load levels.
- depression and quality of life.
- stress hormones.

I am being asked to participate in this study because I am HIV positive and I am not on anti-retroviral therapy.

PROCEDURES

If I agree to participate in this study, the following will occur:

Overview: I will speak to a study staff member to see if I may be eligible to participate. I will be told what the study involves, and will answer questions about my current CD4 T-cell count, viral load, antiretroviral history, current medications, and substance use. If it appears that I am eligible to participate, I will be told more about the study and what is involved in participating in either the mindfulness based stress reduction (MBSR) or the Information/Education (Inform) group. If I am interested in participating, I will have a screening visit to determine if I am eligible to participate. This visit will take about 1 hour. I will complete a questionnaire, and will have a blood draw to confirm my eligibility. I will also be given a home saliva sampling kit and instruction about how to complete this prior to my baseline visit. If I am eligible to participate in the study based on my screening visit and blood draw, I will be scheduled for a baseline visit. At the baseline visit, I will have my blood drawn and complete questionnaires. This visit will last about 1.5-2 hours. I will be randomly assigned to participate in either an MBSR group or an Inform group for eight weeks. I will have follow-up visits at 3, 6 and 12 months, each lasting 1.5-2 hours. I will also have a short visit at month 9 to have my blood drawn to measure CD4 T-cell counts and viral load. Total time required for study visits, not including class participation, is approximately 6-9 hours over 6 visits. I will have my blood drawn at the UCSF Mt. Zion General Clinical Research Center (GCRC) a total of six times. About 2 tablespoons of blood will be taken at the screening visit and month 9 visit, 5 tablespoons at the month 6 visit, and 9 tablespoons at the baseline, 3 month and 12 month visits. Each month during the study (12 times total), I will complete (by email or the phone) a short questionnaire about whether I have been experiencing cold-type symptoms. More information about what tests will be done and what will happen at study visits is

described below. After one year, if I participate in the Inform group, I will have the option of taking a MBSR class free of charge.

1. Location: Study visits will take place at the Mount Zion GCRC, located at 1600 Divisadero Street, 6th floor. The MBSR and Inform group visits will take place at the Osher Center for Integrative Medicine located at 1701 Divisadero Street, Ste. #150. .
2. Screening visit / enrollment / consent: I will be asked to bring my CD4 T-cell count and viral load test results, if available, to this meeting. These will be used to help check if I am eligible to participate. If it appears that I am eligible for the study, study staff will review the consent form and HIPAA (health information privacy) form with me. If I am interested in participating in this study I will sign these forms. I will complete a brief questionnaire and have a blood draw (about 2 tablespoons) for CD4 T-cell and viral load testing. The CD4 T cell count and viral load will be used to confirm that I am eligible for the study. It will take about a week to get these test results. Study staff will call me when the results are done to tell me the results and whether I am eligible for the rest of the study. I may go through this screening and not be eligible for the study.

I will be given a home saliva sampling and dexamethasone suppression test (DST) kit and instructions about how to use the kit. I will be called and reminded when to start the saliva collection. I will complete a logbook to record the time of my home-based saliva collections, as well as my mood, at each sample. I will also record my daily use of tobacco, alcohol, and other health behaviors as well as my stress level and how I coped with stress each day. I will take 3 saliva samples (waking, 30 minutes post-waking, and bedtime) on 4 consecutive days prior to my baseline visit. On the evening of the third day of saliva sampling, I will take a low dose (0.5 mg) dexamethasone pill (a synthetic hormone similar to cortisol, a hormone my body produces naturally). These tests will be used to check my body's regulation of stress hormones. I will collect my saliva by drooling through a straw into a small plastic labeled tube. The saliva will need to be stored in my home freezer until I bring it in. This visit will take about 1 hour.

3. Baseline visit: I will bring my saliva kit back with me on this visit. This visit will usually happen 1 to 6 weeks after the screening visit. I will complete study questionnaires. I will have my blood drawn (140 cc, about 9 tablespoons). My blood pressure, heart rate, heart output, and perspiration will be monitored for about 15 minutes. This monitoring is described more below in Section 10. This visit will take about 1.5-2 hours.
4. Randomization- I will be assigned a group by chance. The two groups are (a) MBSR group or (b) Inform group. I will have a 50/50 chance (like flipping a coin) of being placed in one of the two groups. Neither study staff nor I will make the choice.
5. Mindfulness Based Stress Reduction: If I am assigned to the MBSR group I will participate in the following: (1) an individual pre-program intake interview with the course director, lasting 45-50 minutes; (2) eight weekly group classes lasting 2.5 to 3 hours; (3) an 8-hour silent retreat during the sixth week of the program; (4) daily home assignments of 45 minutes per day of formal mindfulness practice 6 days per week for the entire duration of the course. Each week, I will be asked how many minutes I practiced MBSR during the past week. The total in-class contact is about 30 hours, the total home assignments are a minimum of 42-48 hours, and total individual interview time is about 1 hour. If I am assigned to the MBSR group, I will

spend a total of approximately 80 hours over the course of the one-year study period. There will be about 15-25 other people with HIV in the group.

6. Inform Group: If I am assigned to the Inform group I will participate in eight weekly group classes. These will last about 1.5 hours each. They will cover a variety of educational topics about managing HIV infection. There will be about 15-25 other people with HIV in the group. The total in-class contact is about 12 hours. If I am assigned to the Inform group, I will spend a total of approximately 20 hours over the course of the one-year study period. After the one-year study observation period is complete, I will be eligible to participate in a regularly scheduled 8-week MBSR group at the Osher Center at no cost to me.
7. Follow-up visits: I will have follow-up visits 3, 6, 9 and 12 months after my baseline visit. At 3, 6 and 12 months I will answer study questionnaires, have my blood drawn (about 9 tablespoons at 3 and 12 months and 5 tablespoons at 6 month), and have my blood pressure and heart rate taken (see section 10 for details). These visits will take about 1.5-2 hours each. I will have a short visit for a small blood draw (approximately 2 tablespoons) at month 9 to assess CD4 T-cell and HIV viral load only. This visit will take approximately 15 minutes. I will be paid \$10 in cash for the completion of this visit. If I prefer, I can choose to have my blood drawn at one of several Quest labs in the community. I will be given a form to take with me to the lab for this blood draw. If my blood is drawn at a Quest lab in the community, I will receive the \$10 payment by check in the mail. If I move out of the Bay Area or otherwise am unable to come for a follow-up study visit at 3, 6, or 12 months, study staff may want to work with me to complete questionnaires by mail and have a small blood draw (approximately 2 tablespoons to measure CD4 t-cells and HIV viral load). I will receive a \$15 payment by check in the mail for completing these study assessments. At months 3 and 12, I will again do the home saliva sampling, logbook and dexamethasone suppression test (DST). I will be given a test kit for this. I will be called and reminded when to start the saliva collection.
8. Long Term Follow-up: Study participation is currently planned to last one year. I may be asked to participate in longer-term follow up. If I wish to participate in the long-term follow-up, I will sign a separate consent form.
9. Collection of blood: I will have my blood drawn at the screening visit, baseline visit, and follow-up visits at 3, 6, 9 and 12 months. At the screening visit and 9 month visit about 30cc (about 2 tablespoons) of blood will be drawn and tested for CD4 t-cell count and viral load level. About 140 cc (about 9 tablespoons) of blood will be drawn at the baseline and 3 and 12-month follow-up visit to examine my stress hormones and CD4 levels; viral load levels will also be measured at each follow-up visits, but not at the baseline visit. About 75 cc of blood (5 tablespoons) will be drawn at the 6-month visit.
10. Other physiological testing: At the baseline visit and follow-up visits, I will have my blood pressure and heart rate taken. I will have a number of sensors placed on my skin for about 5 minutes while I am resting. These sensors are like those used for EKG recordings. Sensors will be attached to my arms, legs, neck chest, and fingertips in order to measure heart rate, blood pressure, the amount of blood pumped by my heart on each beat, and perspiration from my fingertips. At the baseline and 3-month visit, I will have these things measured for about 10 minutes while doing a breathing exercise and other tasks, in addition to 5 minutes while resting. I will have to lift my shirt enough to allow placement of the sensors.

11. Questionnaires: At baseline and 3, 6, and 12 month study visits, I will complete questionnaires on a computer. These questionnaires will take about an hour to complete. The questionnaires will be about health, mood, stress, use of recreational/illegal drugs, and my physical and emotional well-being. There will be staff available to help if I have questions. Each time I do home saliva sampling (three times) I will complete a logbook to record the time of my home-based saliva collections, as well as my mood, at each sample. Each month during the study (12 times total), I will complete (by email or the phone) a short questionnaire about whether I have been experiencing cold-type symptoms.
12. Blood and Saliva Storage: Some of the blood and saliva collected from me will be stored at the UCSF AIDS Specimen Bank for research tests related to this study. These stored samples will be used to learn more about my immune system and stress, including cell aging. Storing blood and saliva for these immune and stress-related tests is a required part of the study. If I choose to leave the study early I can request that my stored blood and saliva samples be destroyed by contacting study staff or Dr. Hecht at any time. After I complete the study, I can also request that any remaining specimens be destroyed.
13. Optional storage of blood or saliva for future research: If I agree, any of my blood or saliva that is not required for already planned research tests may be stored at the UCSF AIDS Specimen Bank and used for future research, including new tests that become available. Results of any future tests will not be given to me unless the test results are thought to be important to my medical care. Blood and saliva specimens will be kept for up to 30 years after the end of the study unless I ask to have them destroyed. I can ask to have stored specimens destroyed after I am finished participating in the study by contacting either study staff or Dr. Hecht. These samples will not be sold or used directly to produce commercial products. Having samples saved for future research is voluntary. If I choose not to allow this, it will not affect my participation in the study. I should circle my choice and initial at the end of this form to indicate whether or not I am willing to allow storage of my blood and saliva for future research.
14. Genetic Testing: Researchers might do tissue typing (HLA) on my blood using genetic testing if I agree. HLA typing is needed to do many tests of the immune system, such as cytotoxic T lymphocytes (CTL). HLA and CTL testing is not planned now as part of the study. Researchers may want to do this testing if future funding is available however. In addition, other types of genetic testing may become available that help understand the relationship between stress and the immune system. I am being asked if this type of genetic testing can be done on my blood specimens in the future. This testing would not be done to affect my health care and the researchers do not plan on telling me the results of genetic tests. However, the researchers will inform me or my doctor if knowing the test results would allow me to get treatment that could prevent or ameliorate a serious medical condition. Genetic testing is optional and will only be done if I agree. If I agree now but change my mind in the future, I can notify study staff and withdraw this agreement. If I do this, no further genetic testing will be done. I should circle my choice and initial at the end of this form to indicate whether or not I am willing to agree to genetic testing.
15. Contact details: Study staff will need to contact me by phone or mail about my study appointments. All contact will be done as confidentially as possible. I will be asked to complete a form with my contact details.

16. Sub-study: I may be asked if I am willing to participate in a sub-study. The sub-study will look at stress reactions during a thinking task. Participation in the sub-study is optional and I will be asked to sign a separate consent form.
17. Use of Anti-Retroviral Therapy (ART): I am being asked to participate in this study because I am not on ART and do not currently have plans to start ART in the next year. However, I am free to begin ART at any time. This is a decision should be made with my physician, and should be completely independent of my participation in this study. If I start ART during the course of the study, I can continue to participate in the study.

RISKS/DISCOMFORTS

Blood drawing: Blood drawing may cause some discomfort, bleeding, bruising and, rarely, infection where the needle enters the skin. Rarely, fainting may occur.

Saliva sample: There are no significant risks involved in giving a saliva sample.

Dexamethasone Suppression Test (DST): Low dose dexamethasone typically has no side effects or interactions with medications.

Physiological testing: These tests are not painful and will cause me no physical harm. The sensors are applied, and feel like, band-aids. Redness or irritation of the skin may occur when they are removed. This generally goes away within a few hours. A skin cream will be available for me to use when the sensors are removed to reduce any irritation. If I begin to have discomfort such as redness or itching while wearing the sensors, I may choose to end the test. I may feel anxious or uncomfortable doing the breathing and other tasks. I may refuse to do the tasks or stop the testing at any time. If I feel uncomfortable at any time during the physiological testing, I should tell the study staff immediately so that they can either correct the problem or stop the testing.

Interviews / Questionnaires: I may feel anxious and uncomfortable answering some of the interview questions that I feel are personal. I may refuse to answer any questions. The questionnaires may take a long time and may be boring.

Randomization: I will be assigned to a treatment group by chance. I may not be assigned to the group I would prefer. The type of group I participate in may not be as helpful as the other group. This will not be known until after the study is completed and the data analyzed.

Mindfulness meditation: During the meditation practices, I may experience restlessness or become aware of distressing emotions. If this happens, I can stop the exercise and speak to the instructor.

Confidentiality: Participation in research will involve a loss of privacy, but information about me will be handled as confidentially as possible. A UCSF medical record may be created as a result of my participation in this study. My consent form will be included in this record. A brief medical history and notes by Mt. Zion GCRC nursing staff during my research visits at the GCRC may also be included in this record. Therefore, other UCSF doctors may become aware of my participation. Hospital regulations require that all health care providers treat information in medical records

confidentially. My CD4 and viral load tests will not be sent to this medical record. Because this study is limited to people with HIV, my HIV status will be known to the other individuals in my study group. The researchers will ask me and the other people in the group to use only first names during the group session. They will also ask us not to reveal the identity of group members to anyone outside of the group or 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.

Research records will be kept as confidentially as possible. Individual names will be known only to study staff. All specimens as well as data collected will be coded (no names will be used). No names will be used in any published reports resulting from this study. If I indicate during the study that I am experiencing suicidal thoughts and am thought to be at risk of harming myself, study staff may be ethically required to break confidentiality in order to assure safety. In order to verify the study data, representatives from the National Institutes of Health/National Center for Complementary and Alternative Medicine and the UCSF Committee on Human Research, may need to review my records. In this study I will be asked about drug use. The researchers will keep information about me as confidential as possible but complete confidentiality cannot be guaranteed. To help protect my privacy, researchers have obtained a Certificate of Confidentiality from the National Institutes of Health. With this certificate, the researchers cannot be forced to disclose information that may identify me, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the certificate to resist any demands for information that would identify me, except as explained below.

The certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

A Certificate of Confidentiality does not prevent me or a member of my family from voluntarily releasing information about myself or my involvement in this research. If an insurer, employer, or other person obtains my written consent to receive research information, then the researchers may not use the certificate to withhold that information.

The results of my study questionnaires will be kept confidential and will not be shared with my physician. They will be used only for the study and will not become part of my medical file. Laboratory tests such as my CD4 and viral load results will not be sent to my physician unless I request this. If I wish to receive copies of my CD4 and viral load results and/or have them sent to my physician, I can request these from study staff at any time. If I request it, study staff will send me results from my home saliva testing at the end of the study.

Treatment and compensation for injury: If I am injured as a result of being in this study, treatment will be available. The costs of such treatment may be covered by the University of California depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, I may call the office of the Committee on Human Research at (415) 476-1814 or write: Committee on Human research, Box 0962, University of California, San Francisco, CA 94143.

BENEFITS:

There may be no benefit to me for participating in this study. I may learn information about HIV or how to cope better with HIV. Knowledge from this study may help researchers and health care providers learn more about how to slow the advance of HIV infection.

ALTERNATIVES:

Participation in this study is voluntary. If I chose not to participate in this study, I can attend MBSR as a paid course (\$300) at the UCSF Osher Center and other sites in the San Francisco Bay Area. If I decide not to participate in this study, it will not affect my ability to get medical care at any UCSF affiliated site.

COSTS:

There will be no costs to me or to my insurance carrier for participating in this study.

PAYMENT:

I will be given \$25 to cover transportation and the inconvenience of attending each of 4 evaluation sessions (baseline, 3, 6 and 12 months). I will receive these payments in cash at the end of each study visit. At each of these visits, I will be given the option to also receive either vouchers to cover my parking expenses for these visits, or a \$5 gift certificate to a local merchant. The parking vouchers I receive are valid only at the 1635 Divisadero Street parking garage (entrance is on Sutter Street between Divisadero and Broderick). I will be given \$10 in cash for the blood draw at the 9 month visit. If I chose to go to a community Quest lab for the 9 month blood draw, I will receive the \$10 payment by check in the mail. If I am unable to come to UCSF for a follow-up visit and complete questionnaires by mail and blood draw at a Quest lab in my community, I will receive the \$15 payment by check in the mail. If I am paid by check I will need to provide my social security number. I will be given \$20 to cover the inconvenience of completing and returning a home saliva sampling kit three times during the study (baseline, 3 and 12 months). I will receive these payments in cash when I return a completed kit and logbook.

If I complete all study visits (baseline, 3, 6, 9 and 12 month) I will receive a \$35 bonus payment at my 12 month visit. If I complete the baseline, 3 and 12 month visit, I will receive a \$15 bonus payment at my 12 month visit. If I turn in all three home saliva kits and logbooks, I will receive an additional \$15 bonus payment at the 12 month visit. So, I could receive a total bonus of \$50 if I complete all study visits and saliva kits, and a total of \$220 throughout the study. I will not be paid to attend the weekly classes. If I need bus tokens to attend class, I should speak to a staff member.

QUESTIONS:

This study has been explained to me by Dr. Frederick Hecht or the person who signed below and my questions have been answered. If I have further questions about the study, I may call Dr. Hecht at 415.476.4028, extension 431 or Dr. Patty Moran at 415.353.9745.

If I have any comments or concerns about participation in this study, I should first talk with the researchers. If for some reason I do not wish to do this, I may contact the Committee on Human Research, which is concerned with the protection of volunteers in research projects. I may reach the committee office between 8:00 and 5:00, Monday through Friday, by calling (415) 476-1841, or by writing: Committee on Human Research, Box 0962, University of California, San Francisco/San Francisco, CA 94143.

CONSENT:

PARTICIPATION IN RESEARCH IS VOLUNTARY. I am free to decline to be in this study, or withdraw at any point. My decision as to whether or not to participate in this study will have no influence on my present or future status as a patient at UCSF. The director of the study reserves the right to release me from the study at any time if he/she deems it appropriate.

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

If I wish to participate in the study, I should sign below. I have read and been given a signed copy of this document and a copy of the Experimental Subject's Bill of Rights to keep.

I agree do not agree to have any of my leftover blood and saliva stored for future research.

Patient's Initials _____

I agree do not agree to have genetic testing.

Patient's Initials _____

Signature of Study Participant

Date

Printed name of Participant

Signature of Study Member Obtaining Consent

Date