Title: Mindfulness training for anger, conflict, and aggression: The VCU Stress Reduction Study

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RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: **Virginia Commonwealth University Stress Reduction Study**

VCU IRB NO: **HM20012124**

This consent form may contain words that you do not understand. Please speak with or email the study staff to explain any words that you do not clearly understand. You may print an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

You are being invited to participate in a research study. It is important that you carefully think about whether being in this study is right for you and your situation. Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

Why is this study being done?

This research study seeks to understand how stress reduction training influences neural responses (brain activation) and behavior related to stress, including emotions, desires, and reactions to adverse events such as social conflict. You are being asked to participate in this study because you expressed interest in participating in the VCU Stress Reduction Study. The full research project will be conducted over approximately 4-6 weeks, and will consist of two data collection sessions on the VCU campus, one before and one after a 14-day stress reduction training course conducted via a smartphone that you provide. This course entails instructor-facilitated stress reduction exercises previously shown to reduce stress and improve well-being. Participants will be randomly assigned to a mindfulness course or an active coping course. Both of these courses – mindfulness training (MT) and coping training (CT) – involve expert-facilitated mental wellness techniques. MT emphasizes mindfulness-based techniques to reduce stress and promote well-being, whereas CT emphasizes reframing and reappraisal techniques to reduce stress and promote well-being. Regardless of which course you are randomly assigned to participate in, you can receive up to $300 for your participation in this study, in addition to the free, evidence-based stress reduction training. Participation is voluntary, and all of your responses will remain strictly confidential.

What are the risks and benefits of participating?

The physical risks involved in this study are minimal and are related to participation in the empirically validated stress reduction courses as well as the laboratory activities. The stress reduction courses described earlier have been used previously in research and have been associated with personal benefits such as stress reduction and mood improvements.

The questionnaires and emotion regulation tasks to be used in this study may make you feel uncomfortable or stressed, but they have been used many times by many researchers with no adverse effects. Some study activities involve loud noises.

There are no known long-term effects from MRI scanning. The MRI scanner is shaped like a tube in which only the head is encircled; yet it may make some people feel claustrophobic. The machine also makes noise, which may make some people anxious. You will wear earplugs and headphones to protect your ears from the scanner noise. Your head will be held still in a foam-cushioned holder, which may feel a little stiff. You will not be sedated at any point during this study. The MRI Technologist will be in communication with you throughout the scanning period and you can ask to end the scan at any time. The Technologist will monitor you for signs of discomfort and will offer a break or will terminate the scan at any time if you appear to be very distressed.

People with any aneurysm clips, metallic implants, infusion pumps, cardiac pacemakers, defibrillators, or some braces cannot have MRI scans. All metal or magnetic objects must be removed before entering the MRI scan room (for example, watches, coins, jewelry, credit cards, hair pins). The MRI Technologist will carefully screen you for these items prior to entering the MRI room.

In addition, there is a risk to you concerning the possibility of your identity being linked with your study data. However, we take many precautions to keep all information we collect from you strictly confidential. The study data will be stored with an anonymous study ID number, without a name, and kept in a secure VCU location. The anonymous study ID number and associated study data will be stored in password-protected computer files. All research analyses will be done without names attached to data, and data will only be reported in aggregate form, so individuals will not be identifiable from any research report. Your identity will not be revealed in any publication or presentation that may result from this study.

In sum, there is a minor risk of loss of confidentiality; however, the information about you will be kept as confidential as possible.

If you qualify and choose to participate in the remainder of the study, to be conducted on different days, you will be asked to complete measures of your personality, behavior, and emotional well-being, and you may experience feelings of distress while completing these measures. You will also complete emotion regulation tasks in the fMRI scanner. All of these tasks have been used extensively in psychological research across the country. The study risks are not greater than the risks associated with daily living. However, if participating in this study causes you to feel upset or you become concerned about your psychological state or your current life situation, the study staff will provide you with contact information for resources available on the VCU campus (the latter two are freely available if you are a student at VCU) that can help you address these issues, including:

• Center for Psychological Services and Development, which offers counseling services on a sliding fee scale; phone 828-8069.
• Commonwealth Counseling Services, which offers counseling services throughout the Greater Richmond area; phone 730-0432
• University Counseling Services, which offers free counseling for VCU students; phone 828-6200 (Monroe Park Campus) or 828-3964 (Medical Campus).
• University Student Health Services (also free for VCU students); phone 828-8828 (Monroe Park Campus) or 828-9220 (Medical Campus).

Should you need services other than those provided by VCU University Counseling Services or University Student Health Services, fees for such treatment will be billed to you or to appropriate third party insurance.

There is prospect of direct benefit to you by participating in this study. Specifically, you could receive a free stress reduction course. In addition to direct benefit to you, the study is likely to yield generalizable knowledge to further society's understanding of the processes under study.

What will happen if I participate?
If you decide to be in this research study, and qualify to participate in all parts of the study, you will be asked to complete the following study activities, in this order:

- An initial visit to our laboratory to introduce you to the study.
- The at-home completion of a computer-based packet of questionnaires concerning your personality traits and social interaction styles, behavior regulation, emotions, and stress.
- The completion of brief smartphone-based surveys in your day-to-day life. The brief surveys concern your current emotions, desires, and stress experiences, and we will ask you to complete them three times per day over the course of 7 days. These “experience sampling” surveys can be completed during your normal waking hours and they will have little interference in your daily activities. Completion of the surveys will require use of a smartphone that you provide.
- Following this, we will ask you to visit VCU’s Collaborative Advanced Research Imaging (CARI) facility to complete a brief emotion identification task and a self-description task in an MRI scanner while we record your brain activity in a completely nonintrusive way. The first task involves a series of images to which you will be asked to respond using a small set of buttons. The second task involves identifying personality traits that describe you. At this session, women between the ages to 21 and 60 years will first be asked to provide a urine sample for pregnancy testing, as MRI scanning can present safety risks to pregnant women.
- Then you will begin one of two stress reduction courses. Each course will last 14 days, during which time you will be asked to listen to 20 minute lessons each day plus complete brief (3 to 10 minute) exercises daily via a smartphone that you provide. Each course will involve mental exercises to

reduce stress in your daily life, along with direct instruction from the course leader to help in learning and applying the stress reduction techniques. To avoid any biases regarding who participates in which course, all participants will be randomly assigned to one course.

- After the course we will ask you to complete smartphone-based experience sampling, in which we will again ask you to complete brief surveys three times a day for 7 days.
- Finally, we will ask you to complete two brief emotion regulation tasks in an MRI scanner at the CARI facility. The first of these tasks involves a series of images to which you will be asked to respond using a small set of buttons. The second task is a competitive reaction time task playing against another person.

If you agree to participate in the full study following receipt of study information in the initial laboratory visit, you will be notified soon thereafter about whether or not you will be enrolled.

If you are enrolled, you will be asked complete at-home computer-based survey measures, as outlined above, as well as 7 days of smartphone-based experience sampling. Then you will be asked to report to a private laboratory space at the CARI facility (203 East Cary St., Richmond VA) for the pre-course brain imaging session. You will complete the task outlined above in a functional Magnetic Resonance Imaging (fMRI) brain scanner. After you have successfully completed your 14-day stress reduction course, we will ask you to complete a second 7 days of smartphone-based experience sampling. Then you will be asked to complete two tasks, as outlined above, in an fMRI brain scanner at the CARI facility.

The fMRI procedure does not alter or disrupt brain activity in any way. A VCU MRI Technologist will operate the MRI scanner to take images of your brain while you are resting and while completing the emotion regulation tasks. If you are a woman between 21 and 60, you must complete a urine pregnancy test before you complete the procedures in the MRI scanner. If the results of this test indicate that you are pregnant, you will not be able to participate in the study. An MRI technician will complete another MRI safety screening (identical to the one you already completed during the screening measures) to ensure nothing has changed and you are safe to complete the MRI scan. Once in the fMRI room you will be positioned in the scanner and the procedures will be explained. The MRI Technologist may need to repeat a scan if a technical issue is encountered. If you are uncomfortable, the VCU MRI Technologist will stop, and you will be removed from the scanner. A trained member of our research team will also attend each scanning session. At both the pre- and post-course brain imaging sessions, the time in the MRI scanner will be about 50 minutes.

The brain images acquired in this study are not designed to make clinical diagnoses and will not be made available to anyone to assist with clinical

matters. No MRI images will be released to the participant at any time for any reason. However, if any possible brain abnormality is observed, study staff will inform you so that you may consult with your primary care physician.

You do not have to answer any questions you do not wish to answer or participate in any activities you don't wish to, and you may withdraw from the study at any time without penalty. The first (pre-course) CARI-based session, including the MRI procedure, is expected to take about 90 minutes. However, this data collection session is not useful for us unless you continue in the study. The second (post-course) CARI-based session, including the MRI procedure, is also expected to take about 90 minutes. Participation in both of these laboratory sessions is very important to the study. Therefore, you will be compensated up to $150 after completing the pre-course, smartphone-based experience sampling and MRI session, and up to $150 in addition after completing the post-course, smartphone-based experience sampling and MRI session. In addition, you will receive a free stress reduction course and a personalized report of selected responses that you made in the study.

If any part of the study should make you feel too uncomfortable to continue, you are free to immediately withdraw your participation and leave without giving up payment for the completed portion of the study. There is a two-way communication system installed in the laboratory and fMRI rooms and you can discontinue the study at any time by simply telling the experimenter to stop. To be clear: you do not have to answer any questions you do not wish to answer or participate in any activities you do not wish to, and you may withdraw from the study at any time without penalty. All of your data will be kept strictly confidential and will be viewed by the research study personnel only.

We plan to enroll 25 adults in our study. Significant new findings developed during the course of the research which may relate to your willingness to continue participation will be provided to you.

COMPENSATION

Qualifying participants who participate in the full study will receive a minimum of $260, with a possibility to earn up to $300 (you can earn up to $40 for completing at least 90% of the smartphone-based experience sampling records). You will receive money in full at the end of the study. Payment will be pro-rated if you withdraw from or are asked to leave the study early; in those cases you will receive $10 for the initial laboratory visit, $10 for completing the at-home questionnaires, $30-$50 for each week of completing experience sampling surveys, and $100 for each MRI session. Payment will be made by check. If you complete the study you will also receive a personalized report of selected responses that you made during the study. This report will be delivered via e-mail to an address you provide.

COSTS
Completion of the experience-sampling surveys and the stress reduction course requires use of a smartphone that you provide. These activities are internet-based and thus may incur data usage charges that you will be responsible for. The study also requires time you will spend for data collection procedures and the stress reduction course.

CONFIDENTIALITY
The data collected in this study will not be directly connected to any personally identifiable information such as name or birth date. Data is being collected only for research purposes, identified only by an anonymous study ID number, and stored separately from the consent form in a locked research area. All personal identifying information will be kept in password protected electronic files and will be deleted after all data has been collected. Hard copy consent forms will be kept in a locked file cabinet for 3 years after the study ends and will be destroyed at that time. Electronic files of the study data will be kept indefinitely. Access to all data will be limited to study personnel.

We will not tell anyone the answers you give us; however, information from the study and the consent form signed by you may be looked at or copied for research or legal purposes by the sponsor of the research, or by Virginia Commonwealth University. Personal information about you might be shared with or copied by authorized officials of the Federal Food and Drug Administration, or the Department of Health and Human Services (if applicable). What we find from this study may be presented at meetings or published in papers, but your name will not ever be used in these presentations or papers.

As indicated in the “Compensation” section above, if you complete the study you will receive a personalized report of selected responses that you made during the study. If we find something of medical importance to you, we will inform you although we expect that this will be a very rare occurrence.

The information and samples collected as part of this study will not be used or distributed for future research studies, even if identifiers are removed.

IF AN INJURY OR ILLNESS HAPPENS
Virginia Commonwealth University and the VCU Health System (also known as MCV Hospital) do not have a plan to give long-term care or money if you are injured because you are in the study. If you are injured because of being in this study, tell the study staff right away. The study staff will arrange for short-term emergency care or referral if it is needed. Bills for treatment may be sent to you or your insurance. Your insurance may or may not pay for taking care of injuries that happen because of being in this study.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
You do not have to participate in this study. Choosing not to participate will

involve no penalty or loss of benefit to which you are otherwise entitled. If you choose to participate, you may stop at any time without any penalty. You may also choose not to answer particular questions or participate in tasks that are part of the study. Withdrawal from the study will not affect your present or future University relationship. You can withdraw your study data by writing to the PI.

Your participation in this study may be stopped at any time by the study staff without your consent. The reasons might include:
• the study staff thinks it necessary for your health or safety;
• you have not followed study instructions;
• administrative reasons require your withdrawal.

QUESTIONS
In the future, you may have questions about your participation in this study. If you have any questions, complaints, or concerns about the research, contact:

Kirk Warren Brown, PhD
Virginia Commonwealth University
806 W. Franklin Street
Box 982018
Richmond, VA 23284
Telephone: 804-828-6754
E-mail: kwbrown@vcu.edu

If you have any questions about your rights as a participant in this study, you may contact:

Office for Research
Virginia Commonwealth University
800 East Leigh Street, Suite 3000
Box 980568
Richmond, VA 23298
Telephone: 804-827-2157

You may also contact this number for general questions, concerns or complaints about the research. Please call this number if you cannot reach the research team or wish to talk to someone else. Additional information about participation in research studies can be found at http://www.research.vcu.edu/irb/volunteers.htm.

CONSENT

I have been given the chance to read this consent form. I understand the information about this study. Questions that I wanted to ask about the study have been answered. My signature below says that I am willing to participate in the rest of the study. I will receive a copy of the consent form once I have agreed to participate.

Participants Name (Print)

_____

Participants Signature

Date (MM/DD/YYYY)

_____ _____

Name of Person Conducting Informed Consent Discussion (Print)

_____

Signature of Person Conducting Informed Consent Discussion

Date (MM/DD/YYYY)

_____ _____

Principal Investigator Signature (if different from above)

Date (MM/DD/YYYY)

_____ _____