



Consent to Participate in a Research Study

IRB Approval
11/19/2020
IRB # 47465
IRB1

KEY INFORMATION FOR DAHLiA II

You are being invited to take part in a study called DAHLiA II about how patterns of daily experience influence health.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?

The purpose of this study is to link daily life – especially the amount and quality of different activities – to aspects of psychological and physical health. By doing this study, we hope to learn that some kinds of activity may help people with chronic pain to improve their mental and physical health. We also hope to be able to tell what kinds of activity are most helpful for different kinds of people.

You will be asked to complete an on-line diary for 14 days. The diary will ask about things like your goals for that day, your physical activity, your health symptoms, and your psychological well-being. At the beginning and end of each week, your diary will contain some additional questions. Your participation in this research will last about 7 hours over 14 days.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You might choose to volunteer to help us enrich the knowledge in the DAHLiA Study. For a complete description of benefits, refer to the Detailed Consent. As thanks for your participation, you will receive \$10 for each diary completed between 8 pm and 2 am every evening.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You might not want to participate in this study if you feel it would be too much of a burden. For a complete description of risks, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE SUBSTUDY?

You do not. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is Suzanne Segerstrom, Ph.D., M.P.H., of the University of Kentucky, Department of Psychology. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, her contact information is:

859-257-4549 (phone)

segerstrom@uky.edu (email)

859-257-2207 (lab phone)

dahliastudy@uky.edu (lab email)

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity

(ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer at: (859) 323-1184.

[Click here to continue to the detailed consent.](#)

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You do not qualify for this study if you participated in the first phase of DAHLiA.

Because this study follows on DAHLiA I, people in DAHLiA II are asked to meet the same criteria to participate. You should not take part if you have any of the following:

- You are severely overweight (your BMI is greater than 40).
- You have taken or received oral, inhaled, or injected corticosteroids (e.g., prednisone) within the past 3 months.
- You have a pacemaker.
- You have an active, serious mental disorder such as major depression or schizophrenia.
- You have a serious medical condition such as autoimmune disease.
- You have a heart condition, such as a recent heart attack, angina, or severe arrhythmias, or very high blood pressure (> 200/100).
- You have any condition that prevents the ability to exercise on a treadmill.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted online. You will be asked to fill out daily questionnaires on the internet for 14 days. Each day's assessment may take up to 30 minutes. The total amount of time you will be asked to volunteer for this study is 7 hours over 2 weeks.

WHAT WILL YOU BE ASKED TO DO?

You will be asked to complete an on-line diary for 14 days. The diary will ask about things like your goals for that day, your physical activity, your health symptoms, and your psychological well-being. At the beginning and end of each week, your diary will contain some additional questions.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The risks in this study are no greater than those you would encounter in daily life. Because this is a long study, you may be inconvenienced related to the time involved. Answering questionnaires could cause mental stress or distress.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

You will not get any personal benefit from taking part in this study.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs associated with taking part in this study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private. We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. All of your data will be identified only by a code and not by your name, email address, or other identifying information.

You should know that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to share your information with:

- authorities, if you report information about a child being abused, if you pose a danger to yourself or someone else; and/or
- Officials of the National Institutes of Health or the University of Kentucky may look at or copy pertinent portions of records that identify you.

We will make every effort to safeguard your data, but as with anything online, we cannot guarantee the security of data obtained via the Internet. Third-party applications used in this study may have Terms of Service and Privacy policies outside of the control of the University of Kentucky.

This diary will use REDCap, a secure, web-based program to capture and store data at the University of Kentucky. Please be aware, while we make every effort to safeguard your data once received on servers via REDCap, given the nature of online surveys, as with anything involving the Internet, we can never guarantee the confidentiality of the data while still en route to the server.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study. If you choose to leave the study early, data collected until that point will remain in the study database and will only be removed if you ask us to remove it. The individuals conducting the study may need to withdraw you from the study. This may occur if you are not able to follow the directions they give you, if they find that your being in the study is more risk than benefit to you, or if the agency funding the study decides to stop the study early for a variety of scientific reasons.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

As thanks for your participation, you will receive \$10 for each diary completed each evening. A diary is considered completed if you respond to it after 8 pm on the day you are invited or before 2 am on the subsequent day. For example, if you receive a diary invitation on Tuesday, it is considered completed if you respond to it after 8 pm on Tuesday and before 2 AM on Wednesday morning.

With a few exceptions, study payments are considered taxable income reportable to the Internal Review Service (IRS). A Form 1099 will be sent to you if your total payments for research participation are \$600 or more in a calendar year.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

You will be informed if the investigators learn new information that could change your mind about staying in the study. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study. Information about the DAHLiA study, including a copy of this detailed information, can be found at <https://psychology.as.uky.edu/scsege0/dahlia-study>

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS/SURVEYS?

Generally, surveys done for research purposes are not meant to provide clinical information/diagnoses.

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 350 people to do so.

The National Institute on Aging is providing financial support and/or material for this study.

FUTURE USE OF YOUR IDENTIFIABLE INFORMATION OR SAMPLES:

All identifiable information (e.g., your name, clinical record number, or date of birth) will be removed from the information or samples collected in this study. After we remove all identifiers, the information or samples may be used for future research or shared with other researchers without your additional informed consent.

Your information will not be shared with any University of Kentucky (UK) investigators or investigators outside of UK not affiliated with the DAHLiA Study.

By giving my full name and continuing to the survey page, I

(1) give my consent to participate and

(2) confirm that I have accessed a copy of this information, available at <https://psychology.as.uky.edu/scsege0/dahlia-study>