Consent for Participation in a Research Study
Northwell Health

Campus: Zucker Hillside Hospital/Feinstein Institute for Medical Research

Title: Understanding Daily Fluctuations in Self-Regulation

Principal Investigator: Frederick Muench, Ph.D.

Sponsor: Robert Wood Johnson Foundation

Introduction

You are being asked to join a research study called, "Understanding Daily Fluctuations in Self-Regulation." The purpose of a research study is to answer specific questions about your experiences and how they vary over time to help improve our understanding of health and wellbeing.

This consent form will explain:

- the purpose of the study
- what you will be asked to do
- the potential risks and benefits

Why is this research study being done?

The purpose of this study is to understand whether using a mobile health application that you download onto your mobile will help you and us understand how your levels of concentration, self-regulation and control vary throughout the day and in different circumstances, like when you are feeling happy or sad or in the morning or evening. Although mobile phone apps have been made to help people monitor their behavior, we still do not know whether they work to improve your health. In this study, we ask you to come into our offices to fill out questionnaires and then use the mobile application in your daily life.

In the first part of our research, you will come into our offices for a 2 hour research appointment and complete questionnaires along with computer and mobile game like tests. Once you complete these tests, you will download a mobile app and use it twice a day for about 10 minutes per day (5 minutes in the morning and 5 minutes in the evening). You can base your app usage around your schedule. We want to see if we can execute this study solely by phone and to study how well the mobile app features work. We will use information about how you use the app to make the app better, but also provide you feedback on how your scores on the mobile tasks differ depending on certain factors, like time of day and mood.

Why is this research?

This is a research study because we are asking you to provide information on your mood, thoughts and impulses both in a clinic setting and while you are in your natural environment.

How many people will take part in this study?

This research study hopes to enroll 100-150 men and women.

How long will you be in this study?

If you choose to take part in this study, the study period will last for a total of 3 weeks from the time you enroll in the study, but you will be able to use the mobile application for longer if you wish.

What will happen in this research study?

You have already provided preliminary consent to be pre-screened using the web-form or in a telephone interview. We are requesting written informed consent for your participation in this study, including confirming your eligibility. If you agree to participate in this study, you will undergo an assessment in order to confirm your eligibility for this study and determine if this study is appropriate for you. For example, this study is looking at people's fluctuations in mood or risk taking and you need to be willing to complete all the daily questionnaires. The assessment that you will receive after signing this consent will determine if you are eligible.

You may withdraw from the study at any time. If you choose to participate in this study and at any time you feel that what is offered in this study is not addressing your needs sufficiently, you will be provided with referrals to community organizations or private practitioners.

At your only in-person appointment will undergo a first study visit where you will complete questionnaires about yourself, feelings and behavior, and computer and mobile game like tests lasting about 2 hours. After this appointment you will download a mobile application, complete a 5 minute morning survey and game, and complete a 5 minute evening survey and game for the next 3 weeks (14 morning surveys of 5 minutes each and 14 evening surveys of 5 minutes each). You will also be asked to complete a 10 minute 2 week survey on the internet. You only have to come to the clinic one time. Below is a list of the procedures for this study:

- Complete internet screening form
- Review consent form
- Schedule your one in-person appointment
- Come to the office for a 2 hour assessment
- Watch a video on completing your mobile assessments
- Download the mobile assessment and feedback application
- Complete the mobile app sign-up process
- Complete daily 5 minute morning surveys for 3 weeks
- Complete daily 5 minute evening surveys for 3 weeks
- Complete a 10 minute survey after 3 weeks

Contents of In-person Research Assessments: During your research assessment, you will be asked about your feelings, thoughts, behaviors, and other aspects about yourself. Some of these questions will be asked by a staff member and other questions will be presented on a computer. Computer questions will involve responding on the computer keyboard and/or to online assessments. We will also ask you to complete computer and mobile game like tests. For example, we will ask you to pump-up a digital balloon to try to receive points or digital currency, or choose your preference between two options presented on the computer or mobile phone. This will take approximately 2 hours total for all assessments.

Mobile Phone Data Collection

Your mobile phone will be used for this study. You will download the mobile application where you will complete the questionnaires and mobile games and tests. The application will also collect data on your phone usage and activity. We will send notices on your phone asking you to complete these tasks and surveys at specific times via push notifications through the mobile application. You can use the notification settings on your phone to control your notifications. We will inform you of these options during the study consent and review process.

Daily online questionnaires: You will be asked to complete some questions on your mobile phone at the in-person assessment and you will also be asked to complete two mobile questionnaires each day for at least the next 3 weeks. The questions will be about your mood, thoughts and behaviors over the recent past. In addition you will be prompted to complete at least one game like mobile task each time you complete the questionnaires. This will last 3 weeks.

Text Message Data: You will also be asked a few questions via text message about your experiences in the study. This data is separate from the mobile phone application data collection.

Daily mobile phone data: The app will track your use of the app and features in the app. This way the researchers can find out more about how often the app is typically used by participants, which specific features of the app are used, etc. In addition, we will collect other information about your mobile phone use such as when your phone is in use, when it is not, when you are using applications, the number of text messages sent and received, and your activity and movement. It is important to note that we do not collect the content of your interactions with others, but rather when and how many things are happening on your phone. **We will NOT access your personal contacts, text message content, personal photos, or websites visited, only the frequency and timing of your interaction with your phone.** During the training, we will show you these data collection features visually. This functionality is critical to the study, and these tracking devices are strictly necessary in order for you to use the app and to participate in the study. However, you may change your preference from time to time during the study, should you wish to do so by calling the researcher.

Three week 10 minute survey: At the end of the three week period we will ask you to complete one final mobile questionnaire, which includes questions about your experiences during the study period along with the full version of the game like tasks. This will take about 10 minutes.

Chart Review: If you were recruited from the GAP study (PI: Gregerson), we ask you to give consent to review your data from that study to help us understand how genetics may influence self-regulation.
I consent to obtaining my data from the GAP study. Please circle

• Yes • No Initials _____ Date _____

In case we have trouble contacting you: To be in the study, we will ask you to provide the name and contact information of one person. The only reason we will contact them is to help us locate you if you move or are otherwise non-responsive to our outreach. No other information about you will be given to them nor will we ask your contacts any questions.

Permission to contact you once the study is over (optional):

Sometimes, once the study is over, we realize we may have additional questions about your experience of change and being in the study. We are asking your permission to re-contact you after the study to ask you questions about your experience of change and being in the study. You may withdraw permission at any time, as it will not affect your participation in the study.

I consent to being re-contacted after my participation in the study is completed. Please circle

• Yes • No Initials _____ Date _____

What are the risks of the research study? What could go wrong?

There are some risks associated with this study. You may feel uncomfortable in answering some questions about your feelings, completing the tests about concentration, or discussing issues that are distressing when with the researcher. If you feel uncomfortable, you may choose to refuse to answer questions that you find hard to answer or talk about.

You may also feel some discomfort from completing questionnaires on your mobile phone when you are going about your day to day routines. You may get a notification at a time you don't want one which can be bothersome.

It is also possible that someone may know you are participating in a study about mood, concentration, and self-regulation through either the notifications or if you keep the application open on your phone. Even though there is no disease or condition identified in this study, someone may learn you are participating in a study. This could cause some embarrassment or self-consciousness. The mobile app will also upload data from your smartphone. While it is minimal, it may slightly increase your data usage which may be subject to increased charges depending on your plan. Be safe. Do not do study tasks while driving. Wait until you are in a safe place to perform tasks.

You may have concerns about data security, privacy and confidentiality. Your study data, including this consent, will be maintained in an encrypted database. Only a limited number of researchers will have access to any personally identifying survey or device information. Although we will use state-of– the-art technology to protect your information, there is a slight risk of loss of confidentiality. This is low risk because we separate your personal information (information that can directly identify you, such as your name or phone number) from the app use data that you provide to respect your privacy. However, even with removal of this information, it is sometimes possible to re-identify an individual. This risk, while very low, should still be considered before enrolling. Participation in this study may involve risks that are not known at this time.

If you have any questions or believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator of the study, Dr. Fred Muench at telephone number (516) 837-1668.

What are the benefits of this research study?

The possible benefits you may experience from this study include monitoring your moods and thoughts, and identifying the times of the day, moods, thoughts and behaviors associated with when you are able to concentrate the least and most; however, this cannot be guaranteed. Information we learn about your condition may help others in the future as we hope to enhance this mobile application to help others.

How do we protect confidentiality?

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information. In order to protect your privacy, we will use a random code instead of your name on all of your study data. This unique code cannot be used to directly re-identify you. Any survey or device data that identifies you (including name, birthdate, mobile phone number, etc.) will be removed before the data is transferred to researchers for the study.

We will combine your study data, including survey response and task measurements, with those of other study participants. The combined data will be transferred to a computer program where all of the information can be used by researchers who have obtained permission to use the DMT Study data. Your study data may be shared with other researchers outside of the Northwell Health without survey or device information that can be linked to identify you. We will not share your information with any advertisers or other commercial third parties. Data will be stored in a manner that maintains strict information technology procedures to safeguard participant information and to prevent improper access.

If you do not want to take part in this research study, what are your other choices?

Your involvement in this research is entirely voluntary, and you can stop or withdraw from the study at any time. You do not have to participate in this study to receive information about your moods and feeling and how they relate to your concentration and self-regulation.

Are there any costs for being in this research study?

There is no cost of using the mobile application in this study or the feedback you will receive. Because you will be receiving text messages as part of this study and may complete assessments using your smartphone, you may be subject to data overage usage charges per your smartphone data plan if you are using your own smartphone and one has not been provided to you by a member of the study team.

Will you receive any payments for participating in this research study?

As part of the study, we will provide you with payment as a way to compensate you for your time, effort, phone usage and travel expenses. We will provide you with a payment of $50 to complete the baseline in-person 2 hour assessment, regardless of your eligibility for the study. If you are enrolled in the study, we will provide you with an additional $25 for completing the daily mobile assessments and an additional $25 bonus if you complete at least 80% and your 14-day assessment.

All participants, regardless of treatment condition, will be entered into a raffle for the opportunity to win an iPad or iPad mini. There will be opportunities during the weeks that you complete the mobile surveys to earn raffle tickets to be entered into the drawing. During the first 12 weeks of the study, in addition to compensation for the daily morning surveys, you will earn a raffle ticket for completing each randomly timed survey, one for each completed survey. Once 85 participants have enrolled in the study, we will have the first of three raffles. There will be two additional raffles—each of which will contain around 86 participants.

What happens if you are injured while participating in this study?

If you are hurt from being in the study, you will receive medical care and treatment as needed from Northwell Health. However, you will be responsible for the costs of such medical treatment, directly or through your medical insurance or other forms of medical coverage. No money will be given to you.

What are your rights as a research participant?

Your participation in this project is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study.

If you do not join the study, you will not be penalized or lose benefits to which you are entitled. If you join the study you may withdraw at any time without prejudice to your future care at Northwell Health. Follow-up examinations may be needed to assure your well-being.

Could you be taken off the study before it is over?

It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher, study sponsor or the Institutional Review Board (IRB, the committee that oversees research at this institution).

Reasons for withdrawal may include:

- failure to follow instructions,
- failure to show up for study visits,
- it is not in your best interest to continue on this study, or
- the study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data already collected will continue to be used. However, no new data will be collected.

What happens if new information is learned?

Any new information that develops during this study, which might affect your decision to participate, will be given to you immediately. Your consent to continue to take part in this study may be obtained again.

What information will be collected and used for this study?

If you agree to be in this study, we will collect health information that identifies you, such as your name, location, telephone numbers, birth date, or e-mail/internet protocol (IP) addresses, device ID, and other information. Your identifying information will be stored separately from the data collected during the tests, questionnaires and interviews. We will only collect information that is needed for the research.

During the study the researchers will gather information by: taking a medical history (including current and past medications or therapies, conditions or symptoms, etc.) and obtaining data from the questionnaires and tests explained in the description section of this consent. If you have come from another study within Northwell, researchers will also obtain your medical history data from that study or practice with your permission.

This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization.

Your personal contact information will only be accessed by the study team if necessary and will not be shared outside the study team. Your de-identified study data such as survey results, which does not include any identifying personal information, may be shared with other researchers who Northwell has approved to receive the study data.

The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

Who else will see your information?

Study records that identify you will be kept private.

The following reviewers may access your study and medical records to make sure that this study is being done properly:

- Representatives from federal and state government oversight agencies, such as National Institutes of Health, US Department of Health and Human Services (DHHS), or the New York State Department of Health
- Representatives from the Northwell Health Institutional Review Board (IRB, the committee that oversees research at this institution)

We will do our best to protect the privacy of your records but it is possible that once information is shared with people listed on this form, it will be released to others. In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do, we will not identify you.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Will you be able to access your records?

If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment, and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, or for any questions related to your health information, you may contact the Research Privacy Officer at (516) 321-2100.

How long will your health information be kept?

There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

Can you change your mind?

If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you must send an email or letter to the Principle Investigator at the following address:

Dr. Frederick Muench

1010 Northern Boulevard, Suite 311
Great Neck, NY 11021
fmuench@northwell.edu

Your letter must state that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those who stay in it

Will information about this study be available to the public?

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

Does the investigator of this study receive money if you take part?

Funding for this research study is provided by the Robert Wood Johnson Foundation, with technology support from Cornell University and Sage Bionetworks. The funding is used to support the activities of the Division of Psychiatry Research and to pay back the Division for the costs of the study personnel. Compensation is *not* based upon the number of people enrolled in the study. If your doctor is an investigator for this study, s/he is interested in both your healthcare and the conduct of this research. You do not have to take part in a research study conducted by your doctor.

Who can answer your questions about this study?

If you have any questions about the study, you may call the Principal Investigator, Dr. Frederick Muench at (516) 837-1668. If you need emergency care, dial 911 or go to the nearest Emergency Room. If you have questions about your rights as a research participant, concerns about being in the study, or would like to offer input, you may contact the Office of the Institutional Review Board (IRB, the committee that oversees research at this institution) at (516) 321-2100. A signed copy of this consent form will be given to you.

A note from the study team:

Because you are completing this consent away from our offices, we use the following questions to make sure that you fully understand what we are asking you to do as a participant in this research project. We will review this consent form and quiz with you in your first assessment. We wish to underscore that this quiz is not designed to challenge your commitment to the study or your treatment goals, but to ensure your safety and eligibility to participate.

Please read the following questions and select True or False:

1. I will be compensated for my participation in this study.

True **False**

2. Once the study begins, I cannot drop out no matter what the circumstances.
   True **False**

3. If the researchers believe I pose a risk to myself or others, they may call the appropriate authorities to keep me and others safe.
   True **False**

4. My data is being collected on a mobile application via questionnaires and tasks.
   True **False**

[Signature Page Follows]

Summation/Signature

I have read the above description of the research study. I have been told the risks and benefits involved and all my questions have been answered to my satisfaction. A member of the research team will answer any future questions that I may have. I voluntarily agree to participate in this research study described above, and I know that I can withdraw from the study at any time without penalty. By signing this form, I have not given up any of my legal rights.

_____ _____

Signature of Participant Date

_____ _____

Printed Name of Participant Date

I have discussed the proposed research with this participant and, in my opinion, this participant understands the benefits, risks and alternatives (including non-participation) and is capable of freely consenting to participate in this research study.

_____

Printed Name of Witness

_____ _____

Signature of Witness Date

Investigator's Statement

In addition to advising the above participant of other forms of treatment and therapy which are appropriate, I have offered an opportunity for further explanation of the risks and discomforts which are or may be associated with this study, and to answer any further questions relating to it.

_____ _____

Investigator's Signature Date

_____

Investigator's Printed Name