Memorial Sloan Kettering Cancer Center
IRB Number: 11-204 A(37)
Approval date: 30-Aug-2023

# Verbal Informed Consent for Clinical Research

**Study title for participants:** Fear of Cancer Recurrence: An Intervention Development Study Phase 4, Part 3

**Official study title for internet search on http://www.ClinicalTrials.gov:** Attention and Interpretation Modification (AIM) for Fear of Breast Cancer Recurrence: An Intervention Development Study

**Lead Researcher:** Christian Nelson, PhD (646) 888-0030

**Directions for the consenting professional:**
- You can attempt to contact the potential participant **only 3 times**.
- Do not leave a voicemail message unless you have received IRB approval to do so.

## Introduction

Hello, may I speak with (potential participant's name)?

### If NO:

- **Do not** leave your name or number to call back. Say that you will call back another time and ask for a good time to reach the potential participant.

### If YES:

- Continue with discussion.

My name is (consenting professional), and I am calling from the Department of Psychiatry and Behavioral Science at Memorial Sloan Kettering Cancer Center. I am contacting you about our research study, Fear of Cancer Recurrence: An Intervention Development Study. We are asking you to take part in this study because you have been diagnosed with rare melanoma or skin, gynecological, long-term adult pediatric, or other rare cancer.

Would this be a good time to speak with you about this study? Our conversation will take about 20-30 minutes.

### If NO:

- Ask when a better time might be to call and record his/her availability.
- If the potential participant is not interested in hearing more: Thank the potential participant for his/her time and end the call.

### If YES:

- Continue with discussion.

## Overview of the Consent Discussion

During this call, I will explain the study and its risks and benefits, and we will discuss any questions you have. After that, I will ask if you would like to take part in the study. It is important to know that a research study is completely voluntary. You can choose whether to take part, and you can change your mind at any time. Whatever choice you make, your medical care will not be affected. Please take your time to make your decision. If you have questions at any time, please feel free to ask me for more information.

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## Study Information

The purpose of this study is to pilot test, customize, and personalize a mobile app-based intervention program intended to help cancer survivors cope with fears of cancer recurrence. We have developed an app called iThrive and an additional symptom tracking app based on results from our pilot study, which you may have taken part in previously. We will test how "user-friendly" and helpful the apps are by having you use either one or both apps for about four weeks and provide feedback to us about your experience. You will need to come in to Memorial Sloan Kettering Cancer Center two times (at the beginning of the study and about three months after you have completed using the app) for an EEG (electroencephalogram) assessment to participate in this study. All other activities for this study can be completed from your home.

If you decide to take part in this study, you should expect to do the following:

- Complete questionnaires online, over the phone, or in person.
    - Demographics (i.e., age, sex, ethnicity), medical, and mental health information
    - You may be asked to complete the first set of questionnaires a second time if you have not started using the apps within two weeks of completing the questionnaire.
- Download one or two new mobile-apps (iThrive and iTrack or iTrack alone, depending on randomization) developed to assist with fear of cancer recurrence and to track your fear of cancer recurrence symptoms on your iOS mobile device.
- Complete an EEG assessment two times during the study: once at the beginning of the study before you begin using the app(s), and again about three months after you have completed using the app(s). Information from the EEG assessments will be used to learn more about fear of cancer recurrence related to neural activity.
    - You will be invited to an MSK office where you will meet with a study team member who will take a measurement of your head and fit you with the appropriate cap. They will then attach electrodes to the cap, which are connected to the EEG machine.
    - The EEG machine will measure electrical activity in your brain while you complete a word-association exercise and attention exercise on a computer or an iPad. You should not feel any pain or discomfort during the EEG assessment.
- Use mobile app(s) for four weeks based on your assigned study group
    - iTrack: This app has been developed by Curiosity Health Inc.,and requires self-report of psychological symptoms related to fear of cancer recurrence. If you choose to take part, you will complete questions to track your fear of cancer recurrence symptoms for two times a week for 4 weeks. You will be instructed to complete each session within 24 hours of starting it.
    - iThrive App: This app was also developed by Curiosity Health Inc. and provides a personalized word-association exercise that is intended to help reduce fear of cancer recurrence. If you choose to take part and are randomized to one of the iThrive groups, you will complete 8 or 16 10-minute personalized sessions on the iThrive app two times a week for 4 weeks (iThrive-8), or four times a week for 4 weeks (iThrive-16). Participants can complete a given day's 10-minute session in one or two sittings.
- Provide feedback about the user-friendliness, design and helpfulness of the apps.
- Complete a questionnaire online, over the phone, or in person after all sessions are completed in the app. The questionnaire will take no more than 20 minutes to complete and asks about the following:
    - Questions about fears of cancer recurrence and what triggers these fears
    - Questions about your attention and concentration
- Participate in follow-up questionnaires and assessments for 3-months post-app use.
- After you have completed the follow-up questionnaires and assessments, you may keep the

app on your device for up to one year from when it was downloaded. Afterwards, the app will deactivate. We may evaluate your usage of the app during this time.
- If you were assigned to receive iTrack alone, you will be offered the opportunity to download iThrive when you have completed the follow-up questionnaires and assessments.

Please remember that any information reported through iThrive or iTrack will NOT be communicated to your medical team. These apps are not intended to serve as a substitute for professional medical advice. Please continue to follow your medical team's guidance on symptom reporting and medical follow-up throughout the study participation.

You will not receive the results of this research study.

About 267 people will take part in this study at MSK. About 90 people will take part in this portion of the study.

**Do you have any questions about this study so far?**

## Risks and Benefits

There are both risks and benefits to taking part in this study. If you choose to take part in this study, there is a risk that:

- You may lose time at work, school, or at home, and you may spend more time than usual in the hospital or doctor's office
- You may be asked sensitive or private questions that you do not usually discuss
- You may become upset by some of the questions asked or items in the app intervention

You may ask the study team (lead researcher and research staff) any questions you may have about risks.

Taking part in this study may not benefit you directly, but what we learn from this research may help cancer patients.

## Alternatives to Participation

If you decide not to take part in this study, you may choose to treat your fear of cancer recurrence through counseling. Sometimes a doctor may recommend taking medications, or you may choose to take part in a different research study if one is available.

## Ending Participation

You can decide to stop participating in this study at any time. If you decide to stop, let the study team know as soon as possible. We will not be able to withdraw information about you that has already been used or shared with others.

The study team will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study. The lead researcher may remove you from the study if it is no longer in your best interest or you do not follow the study rules.

## Conflict of Interest

This study is sponsored by Cycle for Survival. Researchers at MSK invented the mobile app-based intervention being studied in this research. This intellectual property is owned by MSK. MSK has licensed this intellectual property to Blue Note Therapeutics, and also has an ownership interest (such as stock or stock options) in the company. These financial interests might be affected by the

results of this study; this means that MSK could gain or lose money depending on the study results.

In addition, one of the investigators involved in this study is an inventor of the mobile app-based intervention. This means that the investigator could gain or lose money depending on the results of this study.

If you would like to know more about the steps MSK has taken to protect your best interests while you are in this study, please contact the MSK Patient Representative Department at 212-639-7202.

## Costs of Participation

You will not be charged for the mobile-app intervention program while you are taking part in this study. The intervention will be provided by Curiosity Health, Inc. You and/or your health plan/insurance company will have to pay for all the costs of treating your cancer while you are participating in this study.

It is possible that the mobile-app intervention program may not continue to be supplied while you are on the study. This possibility is unlikely, but if it occurs, your study doctor will talk with you about your options.

This research may lead to the development of new tests, interventions, or other products for sale. If it does, you will not receive any payment from the sale of these products.

You will receive $50 in the form of cash, gift card, or money order at the completion of the study.

**Do you have any questions?**

## Privacy and Security Information

Your privacy is very important to us, so I would like to end by explaining who will have access to your information and how your information will be used.

In the future, any information that identifies you may be removed. Your data may be assigned a unique code, and the list that links the code to your name will be stored separately from your data. Your information may be used for research that has not been described in this consent form, and they may be shared with another investigator for future research. You will not be asked if you agree to take part in future research studies.

If your information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. It is possible that your de identified information from this study will be shared with other researchers outside of MSK, and may be stored in public databases. All requests for data sharing will be reviewed by the study sponsor, and if individual results are included in the data, they will not contain any identifiable information about you, such as your name, address, telephone number, or social security number. Your privacy is very important to us and we use many safety procedures to protect your privacy. However, we cannot guarantee that no one will ever be able to use your information to identify you.

MSK must get your permission before using or sharing your protected health information for research purposes. Your protected health information includes your medical and research records, which could include HIV-related or genetic information.

The main reasons for using or sharing your information are to do the study, to check your health status, and to find out the research results. We also want to make sure the research meets legal and institutional requirements.

Your protected health information may be shared with and used by the following:

- The study's lead researcher and the research team
- People and offices that deal with research oversight, quality assurance, and/or billing, if applicable.
- MSK and the sponsor's research collaborators, business partners, subcontractors and agent(s) working to conduct the study, to monitor the study, or to analyze the study information for this study or for other research about the study.
    - Once your data is shared, it may not be as well protected as it is at MSK.
    - Your information may also be shared with federal and state agencies, and other domestic or foreign government bodies including:
        - the Office for Human Research Protections of the US Department of Health and Human Services
        - the National Cancer Institute /National Institutes of Health

If your information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. Your information may be given out, if required by law. However, the researchers will do their best to make sure that any information about you that may be released will not identify you.

If you agree to take part in this study, you give us permission to share your protected health information. If you do not agree to let us share your information, you will not be able to take part in this study. However, it will not affect your ongoing medical treatment or healthcare coverage.

## Contact Information

You can talk to the study team about any questions or concerns that you may have about this study. You may also contact the lead researcher, Dr. Christian Nelson at 646-888-0030. More information about this study may be available at ClinicalTrials.gov.

For questions about your rights while you are participating in this study, call the MSK Institutional Review Board (IRB) at 212-639-7592. If you have concerns, complaints, or input on research, or if you would like more information about the informed consent process, please contact the MSK Patient Representative Department at 212-639-7202.

## Additional studies:

This part of the consent form describes optional studies that you can choose to take part in. You will not get health benefits from any of these studies. The doctors leading this research hope that the results of these studies will help other people with cancer in the future.

The results of these studies will not be added to your medical records, and you will not be informed of the test results.

You will not be billed for these optional studies. You can still take part in the main study even if you do not participate in some or all of the optional studies. If you sign up for but cannot complete any of the optional studies for any reason, you can still take part in the main study.

### Optional salivary cortisol collection

If you choose to take part in this study, you will be asked to have optional salivary collection two times during the study: once at the beginning of the study before you begin using the app(s), and again about three months after you have completed using the app(s). For the salivary collection, you will be mailed collection tubes, prepaid shipping materials, and detailed instructions. We will ask you to collect saliva samples within 10 days prior to using the app(s) at four times throughout each day: upon wakening, 30 minutes post-wakening, 8 hours post-awakening, and before bedtime. You will then repeat this procedure for two days about three months after you have completed using the

app(s). As sample collection timing is critical, the app(s) will include reminder alarms and ask for a time-stamped picture to confirm sample collection.

Researchers will use the information from salivary collection to try to learn more about fear of cancer recurrence related to cortisol.

The results of the salivary collection will be used only for research, and not to guide your medical care.

Please check Yes or No. Your medical care will not be affected, no matter what you decide to do.

I agree to have the optional salivary collection:

❑ Yes ❑ No

**Based on our discussion, do you voluntarily agree to participate in this study?**

## If NO:

- Thank the participant for his/her time. Do not complete the below participant and consenting professional information. Add a note to the medical record/research file indicating that he/she declined to participate.

## If YES:

- Continue.

Thank you so much for your time and for agreeing to participate in this study.

| Participant Information | |
|---|---|
| **Participant Name** | |
| **MRN/Study ID** | |

| Consenting professional must personally sign and date | | |
|---|---|---|
| **Consenting professional's signature** | | **Date:** |
| **Consenting professional's name (Print)** | | |