Confidential

Informed Consent Form

This form explains our study and asks you to agree to partiicpate. Please read the form carefully. A member of our study team will talk with you over Zoom to explain the study. Thank you so much for your interest in our study!

BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK
THE BURKE NEUROLOGICAL INSTITUTE

SUBJECT INFORMATION AND INFORMED CONSENT

Project Title: Home-Based Exercise for People with Chronic Neurological Impairments
Principal Investigator: Kathleen Friel, PhD
Institution Name: Burke Neurological Institute
Institution Address: 785 Mamaroneck Ave, White Plains, NY 10605
Telephone: 914-368-3116, 646-351-9063 (24 hour)
Protocol # TELEX

ABOUT VOLUNTEERING FOR THIS RESEARCH STUDY
You are invited to participate in a research study. The purpose of the study is to determine the effect of a home-based exercise program on cardiovascular fitness and your quality of life. We will assess your motivation, enjoyment and compliance to either a live or pre recorded exercise class on Zoom.

You are eligible for this study because you have a neurological impairment that you've had for at least six months. A neurological impairment is weakness in your arms and/or legs that was caused by a stroke, brain injury, spinal cord injury, or any other condition that affects your brain or spinal cord.

WHY IS THIS STUDY BEING DONE?
Scientists at The Burke Neurological Institute (BNI) are partnering with the Sabrina Cohen Foundation (SCF) to test whether a home-based exercise program can improve cardiovascular health and quality of life in people who have had a chronic neurological impairment. We designed this study after the onset of COVID-19 in the United States. Since COVID-19 limits accessibility to gyms and other types of exercise venues, we hope to learn and understand the physiological and behavioral aspects of this rehabilitation strategy to optimize wellness after a neurological injury. You were selected as a possible participant in this study because you've had a neurological impairment for at least six months.

WHAT WILL I DO IF I AGREE TO BE IN THIS STUDY?
If you agree to be in the study, you will participate in 36 at-home, Zoom-based exercise classes. Classes will be held three times a week, for twelve weeks. You will be randomized to either a live class with other video participants, or a pre-recorded class that you will take on your own.

Before the first class, we will review your medical history with you to be sure it is safe for you to be in the study. If you qualify for the study, we will send you a kit that contains items you will need for the study, including a heart rate monitor, blood pressure cuff and adjustable wrist weights. We will also send you some surveys that ask about your ability to do everyday activities, such as dressing and cooking.

After you receive your home exercise kit, we will have an orientation Zoom class. You will meet the other people in the exercise class. During the orientation, the study team will teach you how to use the heart rate monitor. If you cannot put on the heart rate monitor, we will ask that a caregiver be present to assist you during each class.

You will download one applications onto your phone or computer that will allow us to access the information from your heart rate monitor. No one but the research team will be able to see this information aside from you.

Each exercise class will take approximately one hour. Each session will begin with instructions and questions from the study team regarding your pain level, level of motivation, and blood pressure. The exercise portion of the class will take 45 minutes. At the end of the class, the study team will ask you additional questions, such as how hard you worked, pain level, level of motivation and blood pressure.

The class instructor will tailor exercises to different abilities, so everyone can be active and safe. The entire class will be done in a seated position.

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Approximately 100 people will be enrolled in the live class, and 100 in the pre-recorded class.

After the 18th class, which is midway through the study, we will send you another set of the same surveys you completed before the first class. We will send you a third set of surveys after the final class.

RISKS AND INCONVENIENCES OF THE STUDY
Your participation in the project might involve the following risks:

The largest risk in this study is the risk of fatigue and muscle aches. These symptoms are common with exercise. The instructor will offer modifications of each exercise, to offer easier or more difficult options. You will always be welcome to use a modification, request an additional modification, or rest.

The risk of fall in this study is small, since you will be seated. If you normally have trouble with stability of your torso while you are seated, we will ask that a caregiver be present in case a fall occurs.

There is a risk that your personal health information be disclosed in error. For this study, we are using secure Zoom settings from an academic medical center, and we will require a password for each class, to mitigate this risk. The app containing your heart rate information will also be secure.

PERMISSION FOR PHOTOGRAPHY
We will record each live class, video and audio. Since we are not together in one space, we need to record each class for purposes of data collection. Therefore, we require each participant to agree to being recorded. We want to make sure that you understand this.

Do you agree to be photographed in this study?
◯ Yes
◯ No

Please initial here to confirm your choice about being photographed during the study:

_____

NEW INFORMATION
You will be told about any new significant findings developed during the course of the study that might affect your willingness to continue in the research.

COST OF STUDY TO PARTICIPANTS
There is no cost to you for participating in the research study.

BENEFITS OF THIS STUDY
Participation in this study is not guaranteed to benefit you. This study is only for the purpose of research. You may feel stronger by the end of the study, but there is no guarantee that this will occur. However, the information learned from this study may help other people in the future.

ALTERNATIVES TO STUDY PARTICIPATION
You do not have to participate in this research study to receive treatment for your condition. Your participation in this study is voluntary. If you decide to participate, you are free to discontinue participation at any time. Your participation in this study may be terminated without your consent by the study team or regulatory authorities, in certain circumstances, such as, if the investigator determines it is in your best interest, you cannot adhere to the study procedures, or in the event the study is terminated.

IN CASE OF INJURY
In accordance with Federal regulation, we are obligated to inform you about our policy in the event injury occurs. For medical emergencies, call 911. If, as a result of your participation, you experience injury from known or unknown risks of the research procedures as described, emergency medical care and treatment will be provided on our premises to the extent possible. We will assist you in obtaining additional medical care, as needed, but you will be responsible for the costs of such further medical treatment, either directly or through your medical insurance and/or other forms of medical coverage. No other compensation will be offered by or Burke Neurological Institute or the Biomedical Research Alliance of New York. Further information can be obtained from Dr Kathleen Friel (914 368-3116). You are not waiving any legal right to seek additional compensation through the courts by signing this form.

CONFIDENTIALITY
To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study will be submitted to the study sponsor and to the U.S. Food and Drug Administration. It may be submitted to governmental agencies in other countries where the study product may be considered for approval. Medical records, which identify you and the consent form signed by you, will be looked at by the sponsor or the sponsor's representatives and may be looked at by the FDA and other regulatory agencies, the Institutional Review Board, and the Biomedical Research Alliance of New York. While these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this research project may be presented at meetings or in publications; however, you will not be identified in these presentations and/ or publications.

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you. If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health, including:

• Past and present medical records
• Research records
• Records about phone calls made as part of this research
• Records about your study visits
• Information obtained during this research about laboratory test results
• Results from diagnostic and medical procedures including but not limited to X-rays, physical examinations and medical history
• Billing records

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study. Your information may be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor. Information about you and your health which might identify you may be given to:

• The U.S. Food and Drug Administration
• Department of Health and Human Services agencies
• Governmental agencies in other countries
• Biomedical Research Alliance of New York (BRANY)
• The Institutional Review Board
• Accrediting agencies

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the U.S. federal privacy laws. However, these groups are committed to keeping your personal health information confidential. If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose. The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

This authorization does not have an expiration date. If you do not withdraw this authorization in writing, it will remain in effect indefinitely.

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. You do not have to sign this consent form. If you choose not to sign this consent form, you will not be able to be in this research study. Your decision not to sign this consent form will not have any effect on your medical care and you will not lose any benefits or legal rights to which you are entitled. You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you may not be allowed to look at or copy your information until after the research is completed.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor at the address on the front of this informed consent form. If you withdraw your permission, you will not be able to continue being in this study, but you will not have any penalty or loss of access to treatment or other benefits to which you are entitled. When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Notice Concerning HIV-Related Information: HIV-related information that either is collected as part of the research or that may already exist in your medical record might be accessed for the research by the research staff and the study sponsor, but will not be shared with others without your authorization, unless federal or state law requires the disclosure. You have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights or New York City Commission on Human Rights. These agencies are responsible for protecting your rights.

QUESTIONS ABOUT THIS STUDY
If you have any questions or requests for information relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, or if you have a study related injury, you may contact Dr. Friel at 914-368-3116, 646-351-9063 (24 hour).

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research.

You will be given a copy of this form to keep.

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

You are making a decision as to whether or not to participate. Your signature indicates that the above information has been reviewed with you and that you have decided to participate. You may withdraw at any time without prejudice after signing this form should you choose to discontinue participation in this study.

Signature: _____

Date: _____

Time: _____

Upload a copy of informed consent here, if the participant chose to provide consent on paper