INFORMATION ABOUT A UNIVERSITY OF WASHINGTON RESEARCH STUDY

Exercise to Treat Depression after TBI: The *InMotion Study*

Why are we asking you to be in this study?

We are asking you to participate in this study because you are enrolled in the Traumatic Brain Injury (TBI) Model System study and you reported some symptoms such as low mood or lack of enjoyment after TBI. Mood changes and even depression are common after TBI. People with low mood or depression may also have poor sleep, low energy, difficulty concentrating, changes in appetite, and feeling bad about oneself. These symptoms can make living with TBI much more difficult than it needs to be.

Doctors will often recommend antidepressant medications or counseling to treat these symptoms. However, these treatments do not always work and not everyone wants to try them. An alterntive approach is to use exercise to treat these symptoms. In people without TBI we know that exercise can improve mood, enjoyment, sleep, energy, thinking ability, how people feel about themselves, and quality of life. So far, no one has determined whether exercise also can improve mood, depression, and these other symptoms in people with TBI. That is exactly what this study is designed to do.

We want to learn whether people like you will feel significantly better if they have access to a telehealth coach who helps them become more physically active. The coach will help participants gradually take part in physical activities that they enjoy and can do in their daily lives such as brisk walking, jogging, swimming, playing sports, or even weight-lifting or dancing! We will determine whether this treatment program, called *InMotion,* improves mood, enjoyment, energy, sleep, pain, anxiety, and quality of life.

What will you be asked to do?

If you decide to join the study, we will assign you either to the *InMotion* intervention group or to the Wait List group. Which group you are assigned to will be random, like the flip of a coin. If you are assigned to the Wait List group, you will be able to participate in the *InMotion* intervention 12 weeks later.

The physical activity coach will work with you using the HIPAA-compliant video platform, Zoom, or by phone. The sessions will be scheduled at times convenient for you. There will be eight Zoom calls spread over 12 weeks. The coach will find out what types of physical activity you want to do more of and work with you to meet your goals. The goal of the treatment is to help you gradually build up to a healthy dose of exercise, which is 150 minutes of moderate to vigorous physical activity each week. You will be asked to wear a Fitbit® fitness tracker on your wrist to help measure your progress. (We will send you the Fitbit® and will include a postage paid

envelope for you to send back to us once you complete the intervention.) The amount of exercise will increase gradually over the weeks at a rate that is doable for you. We will ask you questions about your mood, enjoyment, sleep, energy, pain, anxiety, and quality of life before the treatment begins, after the intervention treatment ends at 12 weeks, and at a post treatment follow-up (at 24 weeks for those in the Intervention group and at 36 weeks for those in the Wait List group). The entire study will take place by Zoom or by phone.

We will ask to audio record the sessions to make sure the physical activity coach is following study procedures. If you don't want us to record the audio, you can still participate in the study. You can ask us to delete any or all portions of the recordings by contacting us.

PROCEDURES	*InMotion* Intervention Group	Wait List Group
Contacts - We will get names and contact information for people who can help us find you if we are unable to reach you during the study	X	X
TBIMS Data Collection – We will get your information from the National Data Statistical Center Traumatic Brain Injury Model Systems database. This data includes age, sex, ethnicity/race, education level, employment status, marital status, details about your TBI	X	X
Baseline Phone Assessment – You will have a 45 minute phone or video call with study staff. They will ask you questions about your mood and whether it affects your activities, any pain your are having, medications you are taking, your satisfaction with life, and whether you have feelings of hurting yourself.	X	X
Group Assignment – You will be assigned to either the intervention or wait list group	X	X
***InMotion* Intervention Sessions –** Week 1, 2, 3, 4, 6, 8, 10, 12	X	
Week 12 Phone Assessment – Procedures are the same as at baseline	X	X
Week 12 – Wait list group begin intervention		X
***InMotion* Intervention –** Week 13, 14, 15, 16, 18, 20, 22, 24		X
Week 24 Phone Assessment – Procedures are the same as at baseline	X	
Week 36 Phone Assessment – Procedures are the same as at baseline		X

Why might you want, or not want, to participate?

You may want to take part in the study because the intervention may improve your mood, enjoyment, energy, sleep, pain, and other symptoms as well as quality of life. Even if you don't benefit directly, your participation will us help us learn more about future treatments for low mood and depression in people with TBI.

While taking part in this study, we encourage you to continue any medications or therapies that you are already using. You can continue to get treatment for low mood or depression as you normally would.

You may not want to take part in the study if you will be uncomfortable discussing depression and your mood with us. You may find some of the questions personal or sensitive. We will ask you questions like, "How satisfied are you with the level of motivation to do things?" "In the last two weeks, how often have you been bothered by thoughts you would be better off dead, or of hurting yourself?" "What medications are you currently taking?" You can choose not to answer any questions you don't want to answer and can stop any study procedures at any time.

Some people get an itchy rash from the band of the Fitbit®. It can be treated with lotion. If the Fitbit® isn't positioned right, it can cause bruising, irritation or rubbing which may require you to reposition the device. If you have a history of skin irritation from plastic wristband or if you have problems during the study, please tell us.

We do not expect you to experience negative side effects from the assessments or exercise sessions, but if you do, you can talk to Dr. Bombardier who is the Principal Investigator and a licensed clinical psychologist. He can give you referral information or other help, if needed. His phone number is: **206.744.3665**.

There are other ways to treat low mood or depression. These other ways include medications and counseling. You can speak with your doctor about the different options that are available to you outside this study.

How will we protect the information you provide?

We will protect your confidentiality. We will store your name and other identifiable information separate from the study data. Access to your identifying information will be limited to certain members of the study team and any individuals from the UW or other agencies that may need to audit study records. When we publish the results of this study, we will not use your name. If we learn you intend to harm yourself or others, we must report that to the appropriate authorities. Using a FitBit® may involve additional confidentiality risks because FitBit® stores the data collected from the device. We advise you to read the FitBit® user agreements and let us know if you have any questions or concerns about it.

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information and then use it for future research studies or give it to other investigators without getting additional permission from you. If we want to use or share study information/specimens that might identify you, a review board will decide whether or not we need to get additional permission from you. We will share your study data with the TBI National Data and Statistical Center.

We have a Certificate of Confidentiality from the U.S. Federal National Institutes of Health which allows us to keep your identifiable research information confidential from legal proceedings or in response to a legal request unless you give us permission to release it. You or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection, including mandatory reporting, institutional monitoring and others as listed elsewhere in this consent form.

The Certificate expires when the study ends. Data collected prior to expiration will continue to be protected.

Other information about this study.

Participation is voluntary. This means that you can refuse to participate. It also means that if you do enroll, you can decide to stop participating at any time without penalty.

We are receiving financial support from the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR).

You will not have to pay anything directly to be in the study. But you will need to have a working phone and internet connection for the exercise sessions and assessments. You will also need a device like a computer or smart phone to communicate with the Fitbit®.

We will compensate you $30 to complete each of the three assessments for a total of $90. The compensation will be in the form of a Visa gift card, by check or using the electronic payment system called, Zelle. We will send this within 3 weeks of completing each assessment.

A description of this clinical trial will be available on https://clinicaltrials.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 search this Web site at any time.

What can you do if you want more information?

Talk to the study team. We are here to help you understand the study. Feel free to ask us any questions you may have, even about things that are not in this document. It is our responsibility to give you the information you need to make a decision and to give you time to think about whether or not you want to sign up. If you feel you have been harmed by participating, you can contact us about that too.

Talk to someone else. If you want to talk about the study with someone who is not part of the study team, talk about your rights as a research subject, or to report problems or complaints about the study, contact the UW Human Subjects Division at: hsdinfo@uw.edu or 206.543.0098.

Study Team	206.744-3665	Charles Bombardier, PhD, Principal Investigator
	206.897.6322	Erica Wasmund, Research Coordinator
	206.228.8380	Mary Curran, MSW, Interventionist
	206.543.0219	Silas James, MPA, Research Asssistant