Mass General Brigham

Research Consent Form
General Consent Form Template
Version Date: February 2021

Subject Identification

Protocol Title: Toolkit for Optimal Recovery after Concussions (TOR-C)

Principal Investigator: Jonathan Greenberg, Ph.D.

Site Principal Investigator: N/A

Description of Subject Population: College-aged individuals with a recent concussion who experience some worry

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within Mass General Brigham now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

The purpose of this study is to compare two brief live video mind-body treatments for the unique needs of college-aged individuals with recent concussion (Toolkit for Optimal Recovery after Concussion; TOR-C) to prevent persistent symptoms of concussions.

How long will you take part in this research study?

If you decide to join this research study, it will take you about 4 months to complete the study. During this time, we will ask you to participate in 3 assessments: one before the program begins, one after the 4 program sessions, and one 3-months after completion of the program. All study procedures will be entirely remote, meaning you will participate from the comfort of your own home or another safe and private area over a video platform.

What will happen if you take part in this research study?

If you choose to participate in this study, we will ask you to sign this consent form before we do any study procedures.

Once you sign this consent form and agree to participate in this study, you will complete the first set of study questionnaires. After that, you will be randomized (like flipping a coin) into one of 2 programs (TOR-C 1 or TOR-C 2). There is no way to predict which of the two programs you will in. Both programs will receive 4 weekly sessions, 45 minutes each, that are delivered by a trained clinician via secure live video with Zoom. You will meet with the clinician from the comfort of your home at a time that is convenient for you. You will be asked to participate from a private, quiet space. Both programs aim to provide guidance around maximizing recovery. We do not know right now which program will be more effective. Once randomized to a program, you will not know the content of the other program. With your permission, we may ask to send you text messages to remind you of specific assignments related to the treatment and encouragements depending on your group assignment.

All participants will be asked to complete surveys at 3 time points: (1) before the study begins, (2) approximately 4 weeks, and (3) approximately 3 months after the intervention ends. Surveys will ask questions about your injury, your pain, stress, mood, coping and about your ability to engage in activities of daily living. We anticipate that it will take about 30 minutes to complete the surveys.

Why might you choose to take part in this study?

We cannot promise any benefits to you from taking part in this research study. However, possible benefits may include your ability to cope with pain and improve their mood, pain, and disability. Others with a concussion and anxiety may benefit in the future from what we learn in this study.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully.

There are no foreseeable physical risks from this research study. You may feel uncomfortable completing study questionnaires.

Other things to consider are the time you are required to commit to this study. All participants in this study will be asked to participate in 3 assessment visits over the course of 4 months, each lasting about 30 minutes. You will also be asked to attend 4 sessions over live video each lasting 45 minutes. We may also send you text messages to remind you of specific assignments related to the treatment and encouragements.

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?"

What other treatments or procedures are available for your condition?

You will be able to continue with routine care as determined by your medical team. You will participate in this study in addition to all other medical care you are receiving.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Jonathan Greenberg, PhD is the person in charge of this research study. You can call him at 617-643-9402 M-F 9-5.

If you have questions about the scheduling of appointments or study visits, call Nadine Levey M-F 9-5 at 617-724-8431.

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

Why is this research study being done?

In this research study we aim to test novel programs aimed at optimizing recovery after concussion among young adults who experience some worry or anxiety (Toolkit for Optimal Recovery after Concussion).

Who will take part in this research?

We are asking you to be part of this research study because you are 18-35 years of age, have a recent diagnosis of a concussion, and have answered questions that show that you would benefit from support in order to recover quicker and better.

About 50 people will take part in this phase of the research study.

The National Center Complementary and Integrative Health is paying for this study.

What will happen in this research study?

If you choose to participate in this study, we will ask you to sign this consent form before participating in any study activities. If you choose to take part in this research study and sign the consent form, you will receive 4 weeks of a free support program sessions using Zoom. Zoom is a free for you and secure online videoconferencing software program that is currently used to provide care for patients at MGH. We will help you install Zoom on your computer, tablet or smartphone and will teach you how to use it before you start the program. You will have one session per week, for 4 weeks. Each session will last approximately 45 min. Once you log in from a webcam-equipped computer, the Zoom program will allow you to see and hear the study staff clinician in real-time, while participating from your home or another independent location. You

will need to be in a private, quiet location. Study staff may schedule one brief Zoom meeting with you to ensure that you are comfortable with using the software.

Setup and Baseline (pre-program) Assessment (1/2 hour)

During this portion of the study, you will fill out several questionnaires online, through a secure system. The survey questions will ask you about your injury, your pain, stress, mood, coping and about your ability to engage in activities of daily living. You will complete these questionnaires from your own home or another private location.

You will also meet with study staff to learn whether you have used Zoom before, whether you need help installing it and to ensure that you are comfortable with the Zoom software and are ready to start the study sessions. We will also schedule your first Zoom video session with one of our study staff instructors. We will also provide you with a study manual.

Visits 1-4: Program Sessions

You will participate in visits 1-4 for the Toolkit for Optimal Recovery-Concussion support program. Each of the 4 visits will be 45 minutes long, will be conducted via secure Zoom, and will be led by a clinician. The program sessions will be audio-recorded.

With your permission, we would like to send you text messages to coordinate your participation, remind you of sessions and specific assignments related to the treatment, and encouragements depending on your group assignment.

Text messages by mobile/cell phones are a common form of communication. The Toolkit for Optimal Recovery after Concussion research study involves sending you text messages that are relevant to the research study. Texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier.

Below are some important points about texting in this research study.

- Text messages are not encrypted, and therefore carry security risks. This research study and Mass General Brigham are not responsible for any interception of messages sent through unencrypted text message communications.

- You will be responsible for all fees charged by your carrier's service plan for text

messaging. This research study and Mass General Brigham are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts.

- Text messages will only be read by study staff during regular business hours. Texts sent on evenings or weekends will not be read until the next business day.
- Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.

- You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number a text message that says "Stop Research Text."

- Your agreement applies to this research study only. Agreeing to other texts from Mass General Brigham, for example appointment reminders, is a separate process. Opting out of other texts from Mass General Brigham is a separate process as well.

- It is your responsibility to update your mobile/cell phone number with this research study in the event of a change.

I have had the chance to ask questions about texting with staff associated with this research study. I have been informed of the risks and other information covered above and consent to the use of unencrypted text communications associated with this research study.

Please indicate with your initials whether you consent to correspond with us over text:

Yes: _____ No: _____

Post Program Assessment (1/2 hour)

Approximately 4 weeks after the study intake you will participate in the post-program assessment. You will complete survey questionnaire (same as the study intake) and can complete these questionnaires on a personal computer at home or another private location.

Follow-Up Assessment (1/2 hour)

This portion of the study will occur 3 months after you complete the intervention and will be the final study activity. You will complete survey questionnaire (same as the study intake) and can complete these questionnaires on a personal computer at home or another private location.

Place of Visits: You can attend the online program sessions from your home or any other private place with a personal computer or smartphone. The personal computer or smartphone must be equipped with a webcam and Zoom videoconferencing software.

Withdrawal: Participation in this study is voluntary. You can refuse to answer any questions, and you can withdraw from the study at any time. Refusal to participate in the study will in no way impact their medical care.

Confidentiality: Your research study information will only be identified with the study number available only to the study staff. The information will be stored electronically in a file that is only accessible to study staff. Confidentiality will only be suspended in the case of a psychological emergency. If a member of the study staff is concerned that you may cause harm to yourself or others, the study psychologist and principal investigator, Dr. Jonathan Greenberg, will be immediately informed.

How may we use and share your samples and health information for other research?

The information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example, your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

You should not expect to get information about the results of the research study or the results of your individual participation in the research study. We will study and obtain information from many people. It could take years before anyone knows whether the results have any meaning. There is a small chance that we could find out something from the study that might be important to your health. If this happens, we may contact you to find out if you would like to learn more.

However, even if we find something important to your health, we cannot guarantee that you will be contacted.

What are the risks and possible discomforts from being in this research study?

There are no foreseeable physical risks from this research study. You may feel uncomfortable completing study questionnaires.

Other things to consider are the time you are required to commit to this study. All participants in this study will be asked to participate in 3 assessment visits over the course of 4 months, each lasting about 30 minutes. You will also be asked to attend 4 sessions over live video each lasting 45 minutes. We may also send you text messages to remind you of specific assignments related to the treatment and encouragements.

What are the possible benefits from being in this research study?

We cannot promise any benefits to you from taking part in this research study. However, possible benefits may include your ability to cope with concussion symptoms, pain, anxiety, mood, and returning to daily activities. Others with a concussion and anxiety may benefit in the future from what we learn in this study.

What other treatments or procedures are available for your condition?

You will be able to continue with routine care as determined by your medical team. Participation in this research study does not mean that you cannot seek other forms of treatment for orthopedic injury and related pain, including medications or other forms of support. In fact, we ask that you continue your regular medical treatment with your physician in addition to taking part in this research study

Can you still get medical care within Mass General Brigham if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Mass General Brigham now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

We respect your time and we will reimburse you $20 for the first survey, $30 for the second (post-program) survey, and $40 for a survey 3-months after completion of the program, for a total of up to $90.

What will you have to pay for if you take part in this research study?

There will be no cost to you for any study visits. All of the program sessions and study assessments will be paid for by study funds.

The study will not provide you with a computer or cellphone. In addition, you will be required to download and install Zoom videoconferencing software in order to participate in the online sessions. This software is available for download, and study staff will give you specific instruction on how to locate and install it onto your computer.

What happens if you are injured as a result of taking part in this research study?

The risk of injury in this study is very low. We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example,

if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Mass General Brigham to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why they may need to do so:

- Mass General Brigham researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Mass General Brigham ethics board or an ethics board outside Mass General Brigham that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Mass General Brigham who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers

- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other:

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your identifiable information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your identifiable information for any mailing or marketing list. However, once your identifiable information is shared outside Mass General Brigham, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify

the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Person Obtaining Consent:

Statement of Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent | Date | Time (optional)

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