Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

Title of Research Study: The impact of yoga-based physical therapy on heart rate variability for individuals with traumatic brain injury: a pilot study

Investigator: ***Dr. David Ripley, MD, MS***

Supported By: This research is supported by the Shirley Ryan AbilityLab (SRALab).

Financial Interest Disclosure: The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

If your doctor is also the person responsible for this research study, please note that he is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Key Information:

The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you have had a traumatic brain injury, are currently undergoing rehabilitation in a hospital setting, and are appropriate to participate in a physical therapy yoga group.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.
- Participation in the study will in no way affect your treatment or the care you are being provided as part of your rehabilitation.

Why is this research being done?

The purpose of this study is to determine whether there is a beneficial effect of an hour-long yoga-based physical therapy group on heart rate, anxiety, sleep, fatigue, and agitation. Agitation will only be assessed if agitation is present. The study will involve using body-worn sensor technology to help therapists track changes in heart rate on three occasions for one hour each; the three occasions include a yoga-based physical therapy session, a typical physical therapy session, and seated rest in a calming environment. The study will also involve wearing an activity monitor from as early as the time of consent until the morning after the last of three therapy sessions to track potential changes in sleep. The ability to monitor changes in heart rate, sleep, anxiety, fatigue, and agitation may help identify people who might benefit from yoga as an adjunct to traditional physical therapy approaches.

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You should not participate in this study if you are under the age of 18, if you are pregnant, if you have cardiac conditions such as arrhythmias, if you have other neurological conditions (such as multiple sclerosis, Alzheimer's disease, Parkinson's disease, etc.), if you have any powered, implanted devices for monitoring or supporting heart function (i.e.pacemaker, defibrillator, or LVAD), if you have skin irritation or wounds near your chest, if you have trouble accurately expressing your thoughts or feelings, or if you have aphasia.

How long will the research last and what will I need to do?

If you consent to participate, you will be in this research study during your inpatient stay at Shirley Ryan AbilityLab. There will be three days in which you participate in a one-hour research study session, and approximately 7-14 days that you will wear an activity monitor wristband.

You will participate in an hour-long yoga-based physical therapy group, an hour-long typical physical therapy session, and an hour-long seated rest in a calming setting on the 25th floor. You will be asked to wear 3 sensors on your chest during each session which will measure changes in your heart rate. You will also be asked to wear an activity monitor wristband from as early as the time of consent to the morning after the last research session for the study. The activity monitor may be removed throughout the day for short periods (for example, when showering), but it is recommended to keep the monitor on as much as possible to capture activity and sleep levels, and to minimize the chances of it being forgotten to put back on or lost. Depending on the day you potentially agree to participate in the study relative to the day the group occurs on, the time that you would wear the monitor could range from 7-14 days. You will be asked to fill out questionnaires regarding your anxiety and fatigue before and after each session. If you require physical assistance to fill out the questionnaires, this will be provided to you. If you are being regularly assessed by the nursing staff for agitation, your agitation will also be measured.

Is there any way being in this study could be bad for me?

There is a risk of skin irritation during and after wearing the sensors, a risk of falling during the exercises, and of muscle soreness during and after the exercises. Please see below for more detailed information on how researchers will reduce these risks.

Will being in this study help me any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits may include: changes in your heart rate that can positively impact overall health or improvements in your anxiety or sleep quality. These potential benefits may not carryover after participation in the yoga group has ended. Potential benefits to others include increased awareness about benefits of yoga to treating people with traumatic brain injuries during their hospital stay.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, it will not be held against you, and it will not affect the rest of the care you receive. You may still participate in the yoga group without data being collected for the purposes of the research study. Your participation in the study will not affect your treatment or care provided during your rehabilitation in any way.

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Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team by contacting Dr. David Ripley, (312) 238-1000.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 30 people at SRALab who have experienced a traumatic brain injury will be in this research study.

What happens if I say "Yes, I want to be in this research"?

If you consent to participate, you will participate in an hour-long yoga-based physical therapy group on one day, 1 hour of a normal physical therapy session on another day, and 1 hour of seated rest in a calming environment on another day.

For each session, we will measure:

1) Heart rate variability, or millisecond to millisecond changes in heart rate, during the session with the sensors placed on your chest
2) Self-reported anxiety, immediately before and after the session
3) Sleep quality, as measured by wristwatch-sized activity monitors
4) Self-reported fatigue, immediately before and after the session
5) Observation-based agitation, immediately before and after the session (only if you are being regularly assessed by the nursing staff for agitation)

The yoga-based physical therapy session will take place in an enclosed, quiet space to minimize outside noise or distraction. The lights will be dimmed, and light, instrumental, calming music will be played throughout to contribute to a relaxing ambience which is atypical of a standard physical therapy session. The group will consist of 2-5 individuals. The session will begin with an introduction to posture, foundational breath-based exercises, and instruction on proper recruitment of core musculature, followed by approximately 45 minutes of physical postures/poses. The postures will be modified according to your physical abilities to optimize safety and ensure the postures are appropriately challenging. For example, you may be instructed to perform some postures from a seated position and others in standing, if appropriate and safe. The basic elements of postures are similar to that of traditional physical therapy balance exercises, but cues will be provided throughout to pair appropriate breath cycles with appropriate postures consistent with a standard yoga program; for example, exhaling when flexing the trunk downwards and inhaling when reaching upwards. You will also

be regularly cued for appropriate core engagement and posture. Rest breaks will be provided as needed. The session will close with a 4-5 minute *savasana*, which consists of progressive relaxation and guided meditation.

The typical physical therapy session will be as stated; a typical physical therapy session that is no different than a standard treatment you would receive if you were not in a research study. Some examples of what you might do in this session include, but are not limited to: walking, stairs, balance, or strenghtening exercises.

The seated rest in a calming environment will occur in the same enclosed, quiet space as the yoga-based session. The lights will be dimmed and the same gentle, instrumental, calming music will be played throughout to contribute to a relaxing ambience. You will be instructed to rest for one hour.

Which of the three conditions you participate in first will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get first. You will be asked to not eat or drink caffeine within 1 hour before participating in each of the three conditions.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to participate in three, one-hour long sessions on three consecutive days while wearing 3 chest sensors: a yoga-based physical therapy group, a typical physical therapy session, and a seated resting session in a calming environment. The researchers will place the sensors on you immediately before the session and take them off immediately after, for a total wear time of approximately 1 hour and 5 minutes for each session. You will also wear an activity monitor for one to two weeks. You will be required to fill out the above stated anxiety and fatigue assessment immediately before and immediately after the sessions. If you are being regularly assessed by the nursing staff for agitation, your agitation will also be measured immediately before and after the sessions.

What happens if I say "Yes", but I change my mind later?

You can leave the research at any time; it will not be held against you.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

What are the risks of participating in this research study?

There is a risk of muscle soreness due to increased physical activity during testing sessions. All subjects will work with trained researchers and clinicians. Adequate rest will be given and subjects will be monitored for verbal or visual signs of fatigue or discomfort. The risk of soreness is similar to that during any clinical inpatient therapy session.

There is a risk of falling during clinical and exercise assessments. The risk of falling will be reduced by having each participant supervised during training and testing by a clinician or researcher trained in all testing procedures. During these assessments, the participant will use a gait belt for safety. The risk is similar to that during any clinical inpatient physical therapy session.

There is a risk of irritation to the skin from wearing the sensors. This risk will be reduced by minimized by excluding people who have a known allergy and discontinued use if skin irritation

occurs.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any additional costs to you. You and your insurance company will only be charged for the health care services that you would ordinarily be responsible to pay.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include changes in medical condition (i.e. new arrhythmias, implantation of a pacemakers, etc.) or changes in behavior, alertness, or cognitive function that preclude/prevent you from being capable of participating in therapy in a group setting.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

Shirley Ryan AbilityLab and MC10, Inc. (the manufacturer of the sensors and the associated software) will take appropriate measures to protect your information. Every participant will be assigned a random number, which will substitute for any identifiable information. The only place your name is maintained is in a locked cabinet to which only the principal investigator and lead researcher have access to. Any information collected by the heart rate sensors and theactivity monitors , which is sent to a cloud-based storage system, will only be connected to the number, not your idenitifable information.There is no identifiable information translated to MC10 or activity monitor.

The data collected in this study includes the data collected by the sensor devices, as well as information about your height, weight, age and gender, and any information you and the study staff share via the app. This non-identifiable data will be shared with MC10, Inc. MC10, Inc. may use aggregated data to answer additional scientific questions, for product development purposes, to market or promote its products and services, or it may sell the data to interested audiences. MC10 may keep the data indefinitely.

Please be advised that these sensors have not been tested on the following groups: pregnant women, individuals with pacemakers or other sensitive devices, and individuals under 18 years of age.

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If you become ill or are injured as a result of this study, your attending physician will be notified and will address your injury or illness as appropriate.

The hospital or researchers will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

If you are interested in hearing the results of your collected data, this information can be shared with you by Dr. David Ripley, at (312)-238-1000, or Kelly Krese, PT, at (312)-238-5938 at any time.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- All information in a medical record
- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study devices

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire 08/01/2020.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

David Ripley
Medical Director, Brain Injury Medicine & Rehabilitation
Associate Professor, Northwestern University Feinberg School of Medicine
Shirley Ryan AbilityLab
355 E. Erie St.
Chicago, IL 60611
Ph: (312) 238-1000
Email: dripley@sralab.org

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

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A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may audio or video record me to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team.
_____	_____	The researcher may audio or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although the researcher will attempt to limit such identification. I understand the risks associated with such identification.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

My signature below documents that the information in the consent document and any other written and information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

_____ _____
Signature of Witness to Consent Process Date

_____
Printed Name of Person Witnessing Consent Process

Your signature documents your permission for the named participant to take part in this research.

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_____	
Printed Name of Participant	
_____	_____
Signature of Legally Authorized Representative	Date
_____	_____
Printed Name of Legally Authorized Representative	Date
_____	_____
Signature of Person Obtaining Consent	Date
_____	_____
Printed Name of Person Obtaining Consent	Date