MONASH University

EXPLANATORY STATEMENT

Project ID: 40295
Project title: Aerobic exercise as a therapeutic intervention for women who have experienced intimate partner violence (IPV).

Sandy Shultz
Department of Neuroscience
Phone: 99030268
email: Sandy.shultz@monash.edu

Georgia F. Symons
Department of Neuroscience
Phone: 0434910441
email: Georgia.fullersymons1@monash.edu

You are invited to take part in this study entitled *Aerobic exercise as a therapeutic intervention for women who have experienced intimate partner violence (IPV)*. Please read this Explanatory Statement in full before deciding whether or not to participate in this research. If you would like further information regarding any aspect of this project, you are encouraged to contact the researchers via the phone numbers or email addresses listed above.

1 What is the purpose of this research?

Intimate partner violence (IPV) is a serious societal and medical issue worldwide that has severe and long-term impacts on the lives of women. Of the many challenges faced by IPV survivors, post-traumatic stress disorder (PTSD) is one of the most prevalent. Similarly, concussion (a form of brain injury) is known to have short- and long-term impacts and is also understudied.

This research project aims to initially identify exercise tolerance in women who have experienced intimate partner violence. Secondly, to examine the effect of aerobic exercise on PTSD symptomology and quality of life compared to passive stretching. Secondary to this, this project will also examine the effect of this intervention in women who have experienced previous IPV brain injury (IPV-BI) with persistent post-concussion symptoms (PPCS)

2 Why were you invited for this research?

You are invited to take part in this research project because you have been identified as someone who has experienced intimate partner violence.

3 What does the research involve?

Study Design

If you agree to participate, you will be asked to provide signed informed consent prior to the initiation of the study. The study will involve an initial screening visit at visits to Monash University on Level 6 of the Alfred Centre, 99 Commercial Road Melbourne. If recruited to the study you will be prescribed your intervention which involves weekly exercise and diarising for 4 weeks, depending on which group you are assigned to. In addition, you will be asked to return to Monash University (Level 6 of the Alfred Centre, 99 Commercial Road Melbourne) every week. These visits will have a duration of approximately 2 to 3 hours.

During your baseline assessment, you will be randomly allocated (by chance) to either the passive stretching intervention or the graded exercise intervention. Briefly, if you are assigned to the aerobic exercise intervention, you will be instructed to perform aerobic exercise each day on a stationary bike, at home or in a gym at the prescribed target heart rate (HR), wearing a provided HR sensor (Fitbit inspire 3) to monitor HR for 20min/daily. You can walk or jog if you do not have access to exercise equipment.

If you are assigned to the passive stretching group, you will be instructed to follow a prescribed stretching program. You will be provided with a booklet containing a gentle, whole-body, progressive stretching program (with pictures and instructions) to perform for 20min/daily. You will also be required to wear a provided HR sensor (Fitbit Inspire 3) to monitor HR.

Study Activities

You will complete the following assessments in this study.

- **Informed consent (Baseline visit only):** Before you begin the study, you will be given detailed information about the study and any other relevant information by research staff. If you decide to participate, you will be asked to sign this information sheet and consent form before any procedures are completed.
- **Eligibility Criteria Review (Baseline visit only):** The study research staff will ask you questions and complete tests to assess if you are eligible for the study.
- **Medical history and demographic details (Baseline visit only):** The research staff will ask you about your medical history, including any previous brain injury history, other medical conditions that you might have, and other demographic factors such as age, ethnicity/race, sex and highest level of education obtained. There will also be sections to assess previous history of IPV.
- **Medications and treatments (during entire study):** You will be asked about the medications and treatments that you have taken in the 7 days prior to the baseline study visit, and between the start of the study until your final study visit. This includes medications such as over-the-counter medicines, vitamins, herbal remedies or other alternative treatments and treatments such as acupuncture, occupational therapy, physical therapy, vestibular therapy, visual therapy, cognitive behavioural therapy, chiropractic therapy, and other therapies.
- **Adverse Events (during the entire study):** You will be asked how you are feeling if you have had to visit a hospital or have been seriously ill.

- **Biopsychosocial questionnaires (all visits):** You will complete questionnaires related to PTSD, quality of life post-concussive symptoms, mood, drug and alcohol use, sleep, and quality of life will also be administered. The biopsychosocial questionnaire tests are administered on an iPad and should take approximately 30 minutes.

- **Cognitive tests (first and final visit):** Tests will assess key cognitive functions known to be affected by PTSD and concussion such as slowed information processing speed, reduced attention and working memory, and impaired new learning and recall. These tests will be administered via computer, iPad and/or pen and paper. The duration to complete all components of the cognitive assessment will be approximately 45 minutes. This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way.

- **Blood collection (all visits):** A trained individual will insert a needle into your arm vein, and blood will be collected into a small tube (approximately 60 ml or 12 teaspoons). This will take approximately 5 minutes.

- **Saliva collection (all visits):** You will provide a 5ml saliva sample into a collection tube (DNA Genotek Inc., Ottawa, ON). You will be required not to eat or drink anything 30 minutes prior to this collection. This will take approximately 5 minutes.

- **Exercise tolerance test (All visits):** Exercise tolerance will be assessed using the Buffalo Concussion Bike Test (BCBT). During this test, participants are asked to cycle on a stationary seated bike. Every two minutes, the exercise intensity will increase for a maximum of 30 minutes. Every 2 minutes, participants will also indicate their symptom severity using the Visual Analogue Scale (VAS) and perceived exertion on Borg Ratings of Perceived Exertion (RPE) 6–20 (lowest to highest). Heart

rate will be recorded with the Fitbit (Inspire 3) and electrocardiogram (ECG) to determine heart rate variability. This test identifies the heart rate (HR) at which symptom exacerbation occurs (i.e., Heart Rate Threshold [HRt]). This takes a maximum of 30 minutes.

- **Exercise Intervention (daily):** Participants assigned to aerobic exercise intervention will be instructed to perform either 4 weeks of aerobic exercise (20 mins) daily at home or in a gym at the prescribed target HR (STAE or SAE), wearing a provided HR sensor (Fitbit Inspire 3) to monitor HR. Participants will be instructed to stop their exercise session if their symptoms increase by 2 or more points from their pre-exercise symptom level (on a 10-point visual analogue scale) or at 20 minutes, whichever comes first. Participants will be encouraged to perform 5 minutes of chosen warm-up and cool down. You also must not smoke, drink alcohol or consume caffeinated or sugary drinks for 1 hour prior to each daily exercise or stretching session and avoid showering wearing the heart rate monitor. You should rest apart from the prescribed exercise and not participate in other physically engaging activities. Participants will be asked to return every week to re-evaluate their exercise tolerance.

  Sub-symptom threshold aerobic exercise (STAE)
  If assigned to the STAE group, you will be required to exercise at a prescription target HR of 80% of the HR achieved at symptom exacerbation on the BCBT at the most recent visit. You will be asked to return every week to re-calculate the HR prescription.

  Standard aerobic exercise (SAE)
  If assigned to the SAE group, you will be required to exercise at a prescription target HR of 65% of your age-predicted maximum heart rate.

  On completing the 4 weeks, participants will be offered to continue for an additional 4 weeks.

- **Passive stretching intervention**: Participants assigned to the placebo-like passive stretching group will be instructed to follow a prescribed stretching program and given the same instructions about resting as the exercise group. This group will be provided with a booklet containing a gentle, whole-body, progressive stretching program (with pictures and instructions) that does not considerably elevate HR to perform for 20 minutes/daily for 4 weeks. You also must not smoke, drink alcohol or consume caffeinated or sugary drinks for 1 hour prior to each daily exercise or stretching session and avoid showering wearing the heart rate monitor. Participants will be asked to return every week to re-evaluate their exercise tolerance. Following 4 weeks of passive stretching intervention, participants will be re-evaluated for exercise intolerance and offered to participate in 4 weeks of either STAE or standard exercise intervention.

- **Re-evaluation (every week):** Every week, irrespective of group, all participants will return and be re-evaluated on the BCBT, biopsychosocial questionnaires, and fluid biomarkers. You do not need to complete your intervention prescription on this day. Participants in the STEA will receive an updated HR prescription if they are able to exercise to a HR greater than that of their baseline assessment. In addition, the study, exercise compliance, PTSD and PPCS symptoms, quality of life, medications and therapies will be assessed at the weekly follow-up appointment.

4 Source of funding

This research project is being conducted by Professor Sandy Shultz and the other Associate Investigators. The research is funded by the Australian National Health and Medical Research Council.

5 Consenting to participate in the project and withdrawing from the research

If you decide you want to participate in this research, you will complete and sign a consent form stating that you have read and understood this explanatory statement. You will be given this Explanatory Statement and Consent Form to sign and you will be given a copy to keep if you wish. Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you decide to withdraw from this research, you may request to have your data withdrawn.

6 What are the possible benefits of taking part?

It is possible that you won't receive any benefits from this research. Your participation in this study, however, may help develop important scientific knowledge that could contribute to the treatment of patients with concussion in the future.

7 What are the possible risks and disadvantages of taking part?

Medical interventions can be associated with side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Many side effects go away shortly after the intervention ends. However, sometimes side effects can be serious, long-lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. If you experience a side effect, contact your study doctor who will discuss the best way to manage the side-effect.

In the event that any incidental findings are identified, the study doctor will advise you of the appropriate course of action. We cannot guarantee that we will find any/all unusual features.

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

Exercise: The risk caused by undertaking exercise that is gradually increased in intensity or passive stretching is minimal.

- When you perform the Buffalo Concussion Bike Test, you may experience tiredness, faintness, be unsteady on your feet or find it difficult to continue the test, at which point the test will be terminated. You will be assessed and monitored by appropriately trained staff during the test, who will ensure that any risks associated with the study, including exercise are minimised. Your care will be adjusted if any risks become apparent.
- You may experience strained ligaments or joints or other musculoskeletal injuries as a result of exercising.
- You may experience an adverse cardiac event while exercising which may cause chest pain. If you experience these symptoms, you should call an ambulance. However, such events are extremely rare.
- It is highly encouraged that you only participate in this study if you have ambulance cover/insurance as, unfortunately, in the unlikely event that you require an ambulance whilst exercising, the research team is unable to cover the call-out cost of the ambulance. Please note the proximity of the Alfred Centre, 99 Commercial Road Melbourne, is next door to the Alfred Hospital, hence it is unlikely that an ambulance is required.

Blood Tests: Having a blood sample taken may cause some discomfort or bruising. Sometimes, the blood vessel may swell, or blood may clot in the blood vessel. Some people may feel faint when having blood

taken, and may occasionally faint. Rarely, there could be bleeding or a minor infection. If this happens, it can be easily treated.

Questionnaire Completion: It is unlikely that you will experience discomfort while completing the questionnaire. However, you are not obliged to answer any questions that makes you uncomfortable or anxious. There is a minimal but potential risk for re-traumatisation.

9 Services on offer if adversely affected

Given the sensitive nature of this research project, we have provided a range of support services at the end of this document if required.

10 What will happen to information about me and my biospecimens?

If you voluntarily agree to participate in this study, a unique 'Study ID' number will be provided, and all information collected about you will be associated with this ID. The study IDs will be stored in Monash University's REDCap, a secure, password-protected database accessible only to the study investigators.

All blood and saliva samples will be coded (i.e., re-identifiable) and stored at -80 degrees freezers in labs within the Shultz lab within the Department of Neuroscience, Monash University until they are analysed. These freezers will be locked, and access is restricted to the study investigators. All blood and saliva samples collected will be with a unique Study ID number, and access to data will be restricted to only the investigators of the study.

11 Payment

There are no additional costs associated with participating in this research project, nor will you be paid, but for each visit, you will receive a $50 e-voucher (to use at 200 stores across Australia).

If you accidentally damage the heart rate monitor, you are not liable for the cost of this, and you will be provided with a replacement. Unfortunately, at the conclusion of the study, you will be required to return the Fitbit to the research team.

12 Confidentiality

All participants will be assigned a de-identified study ID to maintain the anonymity of participation. All data will be stored under this code on Monash University's REDCap, a secure password-protected database. This can only be accessed by study investigators.

The findings of this study will be non-identifiable (i.e., not revealing individual information) and published in a widely accessible journal.

During the study, you will be required to wear a FitBit (Inspire 3) activity tracker. The device must be paired to your mobile phone and synced to the research platform Fitabase. Only data related to steps taken, activity intensity, calories burned, sleep rating, and heart rate will be collected. No other data from your mobile phone or daily life will be exported to the institute. It is important to note that the collected data will be used solely for the purposes of the study and will be kept confidential.

13 Storage of data

Data collected on iPads will be securely stored on Monash University's REDCap, a secure password-protected database. This can only be accessed by study investigators. Any hardcopy cognitive assessments or consent forms will be stored in a locked filing cabinet at the Alfred centre.

All hard copy data will be kept for a minimum of 5 years and destroyed at the completion of the study period. Secured digital data will be stored indefinitely.

14 Use of data for other purposes

The data collected for this study is intended to be used solely for the outcomes of this study. The use of de-identified data in any future studies would only occur where ethics approval has been granted, along with consent from the participant. In accordance with data-sharing guidelines, de-identified data may be made available upon request for use by other researchers. Any shared data will not include your identifying details.

15 Results

The individual participants of this study will not be able to get the identified results of their individual tests. Participants will be only able to access all published, de-identified data in journal publications. A lay summary of overall study findings, along with the abstract of any publications, will be communicated to you if you wish to receive this by email or post.

16 Complaints

Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Executive Officer, Monash University Human Research Ethics Committee (MUHREC):

Executive Officer
Monash University Human Research Ethics Committee (MUHREC)
Room 111, Chancellery Building D,
26 Sports Walk, Clayton Campus
Research Office
Monash University VIC 3800

Tel: +61 3 9905 2052 Email: muhrec@monash.edu Fax: +61 3 9905 3831

Thank you,

Sandy Shultz

Help lines

If you are at risk

If you, or someone you know, is in immediate danger, call 000.

National

1800RESPECT
(1800 737 732)
The National Sexual Assault, Family & Domestic Violence Counselling Line for any Australian who has experienced, or is at risk of, family and domestic violence and/or sexual assault.
24 hours, 7 days a week.
www.1800respect.org.au

Lifeline
(13 11 14)
A national number which can help put you in contact with a crisis service in your state.
24 hours, 7 days a week.
www.lifeline.org.au

Victoria

Safe Steps Family Violence Response Centre
(1800 015 188)
Victorian statewide service providing telephone support, information, referral, safety planning and risk assessment for women and children experiencing family violence.
24 hours, 7 days a week.
www.safesteps.org.au

Sexual Assault Crisis Line (1800 806 292)
A statewide confidential, telephone crisis counselling service for people who have experienced both past and recent sexual assault.
24 hours, 7 days a week.
www.sacl.com.au

Support for families

Relationships Australia
(1300 364 277)
Support groups and counselling on relationships, and for abusive and abused partners.
www.relationships.com.au

Support for people with disability

National Disability Abuse and Neglect Hotline
(1800 880 052 / TIS : 13 14 50 / NRS : 1800 555 677)
An Australia-wide telephone hotline for reporting abuse and neglect of people with disability
9am to 9pm weekdays and 10am to 4pm weekends and public holidays.

Support in your language

Translating and Interpreting Service
(131 450)
Free phone service to gain access to an interpreter in your own language.
24 hours, 7 days a week.
tisnational.gov.au