

EXPLANATORY STATEMENT

Project: #MindinBody. An investigation into persistent pain from a psychobiological perspective: A mixed-methods intervention study

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You are invited to take part in this study. 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 Alison Flehr via the phone number or email address listed above.

What does the research involve?

The purpose of this study is to investigate a link between persistent pain and stress in women with a history of trauma and the impact of two different types of physical activity on this link.

If you agree to be in this study, the following will occur:

- As a part of the screening process you will undergo a face to face psychiatric diagnostic interview (The MINI International Neuropsychiatric Interview), which may take up to 45 mins. Furthermore, should the MINI indicate a possible mental health condition, this outcome will be passed on to the appropriate clinicians; that is, the Psychiatrist on the research team and your GP.

To ensure the well-being of the participants', if through the screening process the researchers identify a possible mental health condition that might put the participant at risk of harm due to participation in this study, that participant will not be invited to take part in the study, for further clarification please email Alison.flehr@monash.edu.

- You will be randomly assigned to one of two types of physical activity; Bikram Yoga practice (90 mins), or Adrenaline HIT training (45 mins) and you will be required to attend classes for your allocated activity, 3 times (only) per week for 8 weeks.
- Before and after your 8 week program you will be required to
 - Complete a range of questionnaires and psychological inventories online. In addition to basic demographics, these include a quality of life and health survey (SF-36 Medical Outcomes Survey [SF-36 MOS]), a persistent pain assessment (Brief Pain Inventory [BPI]), a depression, anxiety and stress scale (Depression, Anxiety and Stress Scale [DASS-21]), traumatic stress scale (Self-report Inventory for Disorders of Extreme Stress [SIDES-SR]), a coping self-efficacy scale (Coping Self-Efficacy Scale [CSE]), a mindfulness scale (Five Facet Mindfulness Questionnaire [FFMQ]), and a history of traumatic events scale ((Life Stressor Checklist-Revised [LSC-R]). Completion of these tests will take approximately 2 hours each time.
 - Attend the Baker IDI (99 Commercial Rd, Prahran) between the hours of 9am to 11am to provide an overnight fasting blood sample, resting ECG and blood pressure measurement, which may take up to one hour each visit.



- Upon your first visit to the service provider you will be required to fill out your personal details as per their membership requirements
- After the completion of the 8 week program you may be invited to attend a one hour focus group (comprised of 10 study participants of the same physical activity type). Anonymous quotes from the focus group discussions may be utilized for the reporting of study outcomes.
- You will also need to provide written medical permission from your GP before you are able to participate in this study.

Why were you chosen for this research?

You are being asked to participate in this study because you are a female, aged 20 to 50 who suffers from persistent pain and has a history of trauma. Your contact details were obtained after you contacted the student researcher.

Consenting to participate in the project and withdrawing from the research

In order to participate in this study you will be required to sign and return the consent form to Alison Flehr.

You have the right to withdraw from further participation at any stage by contacting Alison Flehr.

If you do decide to withdraw from the study you may also request that your data be withdrawn.

Possible benefits and risks to participants

Benefits

You will likely experience many physical and psychological benefits from participation in this study including improvements to pain and stress levels.

Risk/Discomforts

Bikram Yoga is a challenging form of yoga and exercise.

- It is practiced in a room heated to 40 degree Celsius, which may be unpleasant initially.
- Some of the postures can make the novice participant feel nauseous. It is important that you assess your own discomfort, and if necessary, sit down until you feel able to continue.
- Some of the postures are quite physically challenging therefore participants' are encouraged just to perform the yoga to the best of their personal ability, and according to how they feel that day.
- If a particular pose is painful (versus uncomfortable) and you do not wish to perform it at that time, you may stop a pose at any time.
- If at any time during the 8 week period:
 - you experience any pain of concern, or injury,you should immediately seek medical advice and notify Alison Flehr.
- If at any time during the 8 week period:
 - you do not wish to continue the yoga classes; or
 - your GP advises you to stop the yoga classes,you should immediately stop attending the yoga classes and notify Alison Flehr.

Adrenaline HIT is a challenging high intensity workout program.



- The high intensity program may make the novice participant feel nauseous. It is important that you assess your own discomfort, and if necessary, sit down until you feel able to continue.
- Some of the activities are quite physically challenging therefore participants' are encouraged just to perform them to the best of their personal ability, and according to how they feel that day.
- If a particular activity is painful (versus uncomfortable) and you do not wish to perform it at that time, you may stop that activity at any time.
- If at any time during the 8 week period:
 - you experience any pain of concern, or injury,
 you should immediately seek medical advice and notify Alison Flehr.
- If at any time during the 8 week period:
 - you do not wish to continue the Adrenaline HIT classes; or
 - your GP advises you to stop the Adrenaline HIT classes,
 you should immediately stop attending the Adrenaline HIT classes and notify Alison Flehr.

Fasting Blood Sample

How are the blood samples taken?

You will be asked to lie down and we will take a blood sample (30 ml, or around 2 tablespoons) from a vein in your arm. Qualified and experienced personnel will take the sample using an aseptic technique and sterile equipment. Some people find giving blood slightly uncomfortable. Following collection of the sample there is a slight chance of bruising. Avoiding heavy lifting or vigorous arm movements for 24 hours following collection reduces the chances of this occurring.

What are the possible risks and disadvantages of taking part?

- 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 doctor or contact Alison Flehr.

Side Effect	How often is it likely to occur?	How severe might it be?	How long might it last?
Infection from blood test	Very rare	Can result in hospitalisation, usually easily treated	Days to weeks
Bruising from blood test	Very unlikely (<1%)	Mild pain	A few days

- There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your doctor immediately about any new or unusual symptoms.
- Many side effects go away shortly after the procedure ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your doctor may need to stop your participation in the study. Your doctor should discuss the best way of managing any side effects with you.

Resting ECG Assessment

How is resting ECG Assessed?

You will be asked to remove any jewellery or other objects that may interfere with the procedure and to remove your clothing from the waist up, it is okay to leave your bra on (you will be covered with a sheet or gown with only the necessary skin exposed to ensure your privacy). You will be asked to lie down and not talk or move during the assessment. Electrodes will be attached to selected sites on the chest arms and legs and the ECG will be started, it



usually takes around ten minutes to twenty minutes to complete and generally, there is no special care after an ECG. You will still be eligible to participate in the study if you do not wish to undertake a resting ECG assessment.

What are the possible risks?

ECG is a safe and non-invasive procedure with no known risks.

Blood Pressure Test

How is blood pressure tested?

You will be asked to sit with your back supported and legs uncrossed, any long sleeve clothing will be removed so the upper arm is exposed. The blood pressure device cuff will be placed around your upper arm and then pumped up to restrict the blood flow in the arm, this squeezing may feel a little uncomfortable but only lasts a few seconds. The pressure cuff is slowly released and the pressure in the cuff is recorded at two points as the blood starts to return to your arm. Generally, there is no special care after a blood pressure test. You will still be eligible to participate in the study if you do not wish to undertake the blood pressure test.

What are the possible risks?

A blood pressure test is a safe and non-invasive procedure with no known risks.

Services on offer if adversely affected

- If you suffer any injuries or complications as a result of this research project, please refer to the Participant Emergency Numbers and Support Information attached to this document or contact the Alison Flehr to assist you with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.
- If you become upset or distressed as a result of your participation in the research, please refer to the Participant Emergency Numbers and Support Information attached to the end of this document or contact Alison Flehr who 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.
- In the event of loss or injury, the parties involved in this research project have agreed to adhere to advice of Monash University Governance in mediating between the participant and the Institution
- Should any future genetic testing of your blood sample identify a medically significant result and you have indicated on the consent form that you wish to be notified of such a result, you will be contacted through a telephone call from one of the researchers and be advised to visit your GP, to whom you can send the results, and also provide information of other support services if appropriate.
- Should the resting ECG assessment indicate any potential heart problem you will be advised to visit your GP, to whom the results will be sent, for follow up.
- Should the blood pressure test provide a blood pressure reading of concern, you will be advised to visit your GP, to whom the results will be sent, for follow up.

Payment

- Participants will receive a \$10 gift voucher pre and post intervention for completing their online questionnaires each time.
- Participants will receive a \$10 gift voucher pre and post intervention in lieu of the cost of travel/parking to the Baker IDI to supply a blood sample each time.



- Participants will receive their Bikram Yoga/Adrenaline HIT classes free of charge. They will also receive a 10 class pass to the alternate activity after completing the study.
- For the participants attending the post intervention focus groups, they will receive \$10 gift voucher in lieu of the cost of travel/parking and \$20 gift voucher for their participation in the focus group

Confidentiality

Any information obtained in connection with this study and that can identify a participant will remain confidential. In any publication, information will be given in such a way that the participant's identity will be protected. Only the principal and associate investigators, or in the event of an audit, the auditors, will have access to personal identifying information. Information collected will be used only in the manner for which approval has been given and security procedures will be applied to maintain confidentiality. In general this will involve the removal of personal identifying information from data collection forms. No data capable of association with a particular individual will be published. Intervention related data will be stored under the participant ID code, focus group data will be coded under the participant's first name or preferred pseudonym.

Storage of data

Paper based data (consent forms) will be scanned and stored digitally, the original paper version will be shredded. Scanned consent forms will be stored using LabArchives.

<https://www.monash.edu/library/researchdata/eln>

Electronic data (questionnaires) will also be stored using LabArchives. Access to data will be available only to the limited number of individuals directly involved with this project. No data capable of association with a particular individual will be published.

Blood samples will be stored in a locked freezer at the Baker IDI. These samples will be labeled with a code, study name and date of collection. The Institute has a high level of security and only research staff associated with this project will have access to the stored samples. The laboratory freezers are not accessible by non-lab staff. Blood samples will be stored indefinitely, and after a maximum of ten years they will be destroyed.

Use of data for other purposes

Blood is being collected for future analysis and will be stored indefinitely to be analysed in future research related to this project. A portion of it will be spun down to plasma and stored in the Baker freezers for future analysis which might include the analysis of things like cortisol, oxytocin, noradrenaline, and inflammatory markers, for example. Also, a portion will be sent to Flinders University in Adelaide for analysis by Dr. Sarah Cohen-Woods of different genetic and epigenetic variations, including DNA methylation and microRNA's. You will still be eligible to participate in the study if you do not wish to provide the blood samples.

Otherwise, only aggregate de-identified data may be used for other projects where ethics approval has been granted.

Results



The results of the present study might be published as a peer reviewed journal article, as book chapter, and in a thesis, they might also be and presented at a conference, after which all participants will received a standard letter with a summary of the study findings and a copy of the overall peer-reviewed published study findings. In addition, participants will be informed of all their results at their request. Electronic/paper copies of their results will be made available to them at their request at the end of their study participation when they will receive a standard email/letter outlining their individual results.

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 (MUHREC):

Executive Officer
Monash University Human Research Ethics Committee (MUHREC)
Room 111, Building 3e
Research Office
Monash University VIC 3800

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

Thank you,



Associate Professor Jan Coles



Participant Emergency Contact Numbers and Support Information

Public Hospital Emergency Departments

Click on the below link for Melbourne Metropolitan Emergency Department Information

<http://edstatus.health.vic.gov.au/Home/Emergency-department-status.aspx>

Nurse on Call

A Victorian Government health initiative, is a phone service that provides immediate, health advice and information from a registered nurse, 24 hours a day, 7 days a week; [1300 60 60 24 - Nurse on Call](tel:1300606024)

24-Hour helplines and online support

Lifeline - 13 11 14 (confidential 24/7 counselling and referrals)

Suicide Call Back Service 1300 659 467

The suicide call back service provides free nationwide professional telephone and online counselling for anyone affected by suicide. www.suicidecallbackservice.org.au

SuicideLine 1300 651 251

SuicideLine is a free 24/7 telephone counselling service offering professional support to people at risk of suicide <http://www.suiceline.org.au/>

National Sexual Assault, Family and Domestic Violence 1800 RESPECT (737 732)

A 24 hour crisis line for people experiencing sexual assault or domestic and family violence, can provide the names and contact details of agencies and support groups throughout Australia. www.1800respect.org.au (online counselling available)

PTSD and Trauma help and information resources

- [Center for the Study of Traumatic Stress](#)
- [National Child Traumatic Stress Network \(NCTSN\)](#)
- [Posttraumatic Stress Disorder Evidence Based Information Resource](#)
- [Trauma Pages](#)

Anxiety and Depression - Several organisations offer access to information, resources and services, including:

- www.beyondblue.org



- www.crufad.unsw.edu.au
- bluepages.anu.edu.au
- depressioNet
- www.moodgym.anu.edu.au

Ongoing Counselling Resources

The Better Access to Psychiatrists, Psychologists and General Practitioners through the Medicare Benefits Schedule (Better Access) initiative. Medicare rebates are available for up to ten individual and ten group allied mental health services per calendar year to patients with an assessed mental disorder who are referred by:

- A GP managing the patient under a GP Mental Health Treatment Plan or
- Under a referred psychiatrist assessment and management plan or
- A psychiatrist or paediatrician

<http://www.health.gov.au/internet/main/publishing.nsf/content/mental-ba-fact-pat>

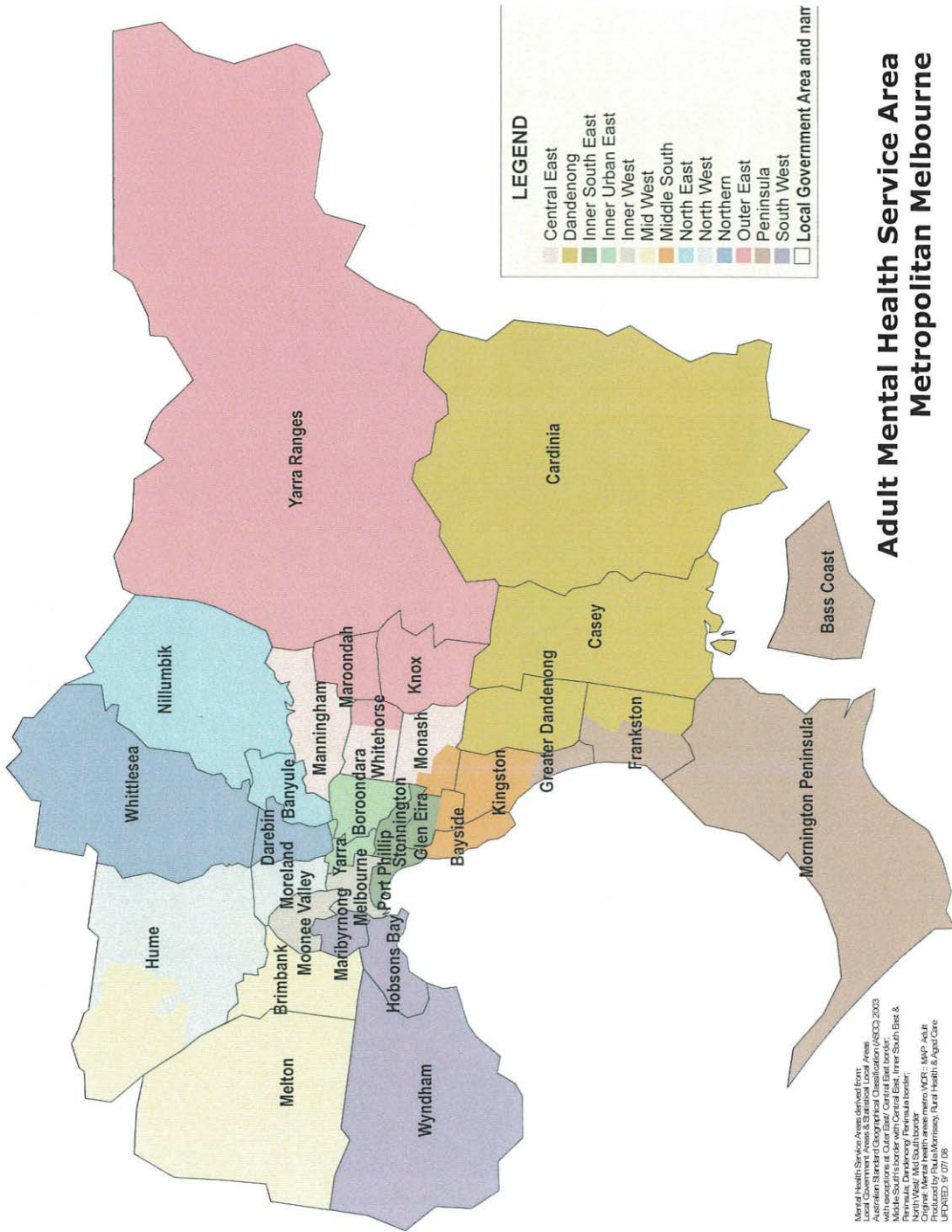
Psychologists - The Australian Psychological Society (APS) maintains a register of psychologists, listing their specialities. Call **1800 333 497** or search the list on their website; <http://www.psychology.org.au/>

Emergency Psychological/Psychiatric Support Services

Area Psychiatric Triage Service (note: some services share contact numbers)

Central East	Monash, Waverley, Box Hill, Nunawading-West	1300 721927
Dandenong	Dandenong, Casey, Cardinia, Frankston-East	1300 369 012
Inner South East	Port Phillip, Stonnington, Glen Eira, Caulfield	1300 363 746
Inner Urban East	Yarra, Bundoora	1300 558 862
Inner West	Mooney Valley, Melbourne	1300 874 243
Mid West	Melton, Brimbank	1300 874 243
Middle South	Bayside, Kingston	1300 369 012
North East	Nillumbik, Banyule	1300 859 789
North West	Hume, Moreland	1300 874 243
Northern	Whittlesea, Darebin	1300 874 243
Outer East	Maroondah, Knox, Yarra Ranges, Nunawading-East	1300 721927
Peninsula	Mornington, French Island, Frankston-West	1300 792 977
South West	Wyndham, Hobsons Bay, Maribyrnong	1300 657 259





Metropolitan Melbourne Areas which include:
 Local Government Areas & Statistical Local Areas
 Australian Standard Geographical Classification (ASGC) 2003
 with exceptions of Outer East, Central East border,
 Peninsula, Dandenong, Thornbury border,
 North West / Mid South border
 Produced by Public Health / Rural Health & Aged Care
 UPDATED 09/07/08

