Research Project Information Sheet
Novel trauma technique for PTSD

Ethics Approval Number: **S231842**

Research Team Contact Details

This project is being undertaken by a team of researchers led by Dr Zack Shan (Chief Investigator) at the University of the Sunshine Coast's –Thompson Institute (12 Innovation Pkwy, Birtinya QLD 4575).

Chief Investigator

Dr Zack Shan
Email: zshan@usc.edu.au
Phone: (07) 5456 3951

Research Investigator/Psychologist

Stephanie Price
Email: stephanieprice1@research.usc.edu.au
Phone: 0417 269 733

Please read this information carefully. We encourage you to ask any questions or clarify anything you don't understand with one of our research team. Before deciding to take part, you might wish to discuss your possible participation with a family member, friend or medical practitioner.

This research project information sheet explains what's involved in this project and should help you decide if you'd like to take part. If you decide to participate in this project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Have understood what you have read
- Consent to take part in this research project
- Consent to the use of your information as described

Project Description/What is this project about?

- Most people are likely to experience a traumatic event in their lifetime, and there is the potential for these events to result in more significant mental health issues, including but not limited to Post-Traumatic Stress Disorder (PTSD).
- The purpose of this research project is to understand the impact of a cutting-edge trauma therapy (flash technique) on PTSD symptomology, and the brain mechanisms involved to provide vital information for the treatment of trauma.
- The research investigator is a registered psychologist who is experienced in delivering trauma therapy in clinical practice. Flash technique will require participants to think of a target memory i.e., a traumatic memory that still causes high distress of at least a 6/10, when 0=no distress and 10=highest distress. Examples of a target memory include, but are not limited to:
    - a negative medical experience,
    - a motor vehicle accident,
    - an assault,
    - a disturbing experience,
    - a near miss,
    - a frightening altercation,
    - death or loss,
    - injury or hospitalisation,
    - nightmares
    - natural disaster.
- Flash technique therapy will require participants to briefly remember the target memory and rate it out of 10 (to indicate current level of distress associated with the memory) before engaging in a pleasant distraction (such as playing a game) and blinking when prompted.
- Previous research has established the technique as effective, pleasant and safe, yet little is known about how it affects brain functioning, to reduce distress relating to trauma memories.

- You are invited to participate in this research if:
    - you have a current or suspected diagnosis of PTSD, **OR** you are otherwise healthy, but have a traumatic/disturbing memory you would like to work on,
    - are willing and able to undergo magnetic resonance imaging (MRI), and undertake neuropsychological assessments,
    - you feel you can tolerate this therapy (flash technique),
    - you do not have any of the exclusion criteria listed on our website.

* A traumatic/disturbing memory may be obvious to you if you find yourself avoid certain situations that may remind you of that memory, you might acknowledge a heightened sense of anxiety when thinking about the memory or when reminded of it by similar circumstances. If you are unsure if you have a traumatic memory this will be confirmed with our research team during the initial steps of participation, such as the pre-screening interview phone call.

**Due to the novel nature of the technique, flash technique will only be available as part of this study, where your participation can be supported by our team of researchers and a psychologist.

Participation/What will I be expected to do?

- If you agree to participate in this research project, you will be asked to do any or all of the following: provide demographic details, complete our self-report questionnaire pack (2-3 times), engage in neurocognitive assessments, undergo MRI and engage in flash technique therapy. Please see details below.
- Initially you will be asked to review our website, read our inclusion/exclusion criteria, read this form, sign the consent section, and input your demographic details for contact.
- A research team member will then contact you (via phone call) to commence a short pre-screening interview to confirm you meet criteria for the study.
- Once your eligibility is confirmed, you will be asked to complete our self-report questionnaire pack (taking approx. 15mins) which will be emailed to you. Based on your responses, you will be allocated to a participant group. There are two participant groups available, including those with PTSD (Phase 1) and those without PTSD (Phase 2). Each group will differ in regards to time commitments and assessments.
- **Phase 1** participants (those with current or suspected PTSD) will be asked to attended the Thompson Institute on three separate occasions over a 6-week period for assessment, including baseline/first visit (T1), post-intervention/second visit (T2) and follow-up/third visit (T3) timepoints. An example of an assessment day schedule is as follows:

    10:15am – Arrive at Thompson Institute
    10:30am - Neurocognitive assessments (approx. 1.25hrs)
    12:00pm - Lunch break
    12:30pm - MRI safety check and flash technique preparation (approx. 45mins)
    1:00pm - MRI scanning (the first occasion will include flash technique in the scanner/instructions will be provided, the second and third visit to the Thompson Institute will not include flash technique) and check in with researcher/first flash technique home session if first visit to the Thompson Institute (approx. 45mins)
    2:00-2:30pm – Finish
    After the first assessment day (baseline/T1), participants will engage in 10 more flash technique sessions in total at home on your own computer, 5 per week over two weeks. The links for the sessions will be emailed to you. Participants then return to the Thompson Institute for post-intervention assessment/second visit (T2), and 4 weeks later for follow-up assessment/third visit (T3). A similar schedule for each visit to the Thompson Institute will be followed as indicated above. The self-report questionnaire pack will be emailed to participants to complete prior to second (T2) and third (T3) visits to the Thompson Institute. The follow-up assessment (T3) will complete your participation in this study.
- **Phase 2** participants will be asked to attend the Thompson Institute on one occasion and engage in flash technique once while in the MRI scanner. The schedule for phase 2 participants may look similar to the following:

    8:30am – Arrive at Thompson Institute

8:45am – MRI safety check and flash technique preparation (approx. 45mins)
9:15am – MRI scanning (includes flash technique while in the scanner/instructions will be provided in the scanner) and final check in with researcher/ questions (approx. 45mins)
10:00-10:30am – Finish
One week after attending the Thompson Institute you will be emailed a link including the self-report questionnaire (taking approx. 15mins), this will complete your participation in this study.

- **Participation is voluntary. Participants can change their minds and withdraw from the study at any time prior data analysis**. **Beyond this point it will not possible to exclude your de-identified data from our data analysis. Should you wish to withdraw please send an email with your name and participant ID to the researchers listed on this form.**
- **Your participation, or not, will not affect your relationship with UniSC, members of the research team, your employer, or any associated organisation. Please note that your participation will remain anonymous to these bodies, no information will be shared with them at any time, and your confidentiality will be held to the highest standard.**
- If you agree to take part in this study, you will be asked to sign the consent form available along with this information sheet (links available on our website INSERT LINK HERE). We will be alerted that you have completed the form and will subsequently call you for the pre-screen interview.

A breakdown of your participation is presented in the below.

Phase 1: Summary of Assessments

What will you do?	**Self-Report Questionnaire**	**Neurocognitive Assessment**	**Magnetic Resonance Imaging (MRI)**	**Intervention**
Time Required (Approximate)/Number of Repeats	15 minutes (X 3 = 45 minutes)	1.25 hours (X 3 = 3.75 hours)	Scan 1 =1 hour, 30-minutes (45-minutes preparation (including flash technique practice and 45-minutes in the MRI) Scan 2 and 3 = 45 minutes (15-minutes preparation and 30-minutes in MRI per session thereafter (X 3 = 3 hours)	First intervention (flash technique) is incorporated in MRI time 15 minutes for at home flash technique interventions thereafter (X 10 = 2.5 hours)
Data collection	Online questionnaire (link emailed)	Neurocognitive assessments administered on an iPad at UniSC's - Thompson Institute	One-on-one intervention preparation with researcher if first visit. MRI preparation. Resting state MRI and task-based MRI with a staff member or researcher at the Thompson Institute. Pulse rate will be taken to measure changes throughout flash technique.	Flash Technique requires a 0-10 rating of distress relating to the target memory (link emailed)
Example questions/activities	In the past month, how much were you bothered by	Coloured crosses will appear on the iPad screen, you	We are looking to see what your brain is doing, and in what areas, whilst engaging	On a scale of 0-10 (10=highest distress) how distressing is that

	repeated, disturbing, and unwanted memories of the stressful experience?	will be required to select the crosses on the screen as quickly and accurately as possible.	in flash technique and what happens to your brain overtime	target memory now?
Consent	Written consent form	Written consent form	Written consent form	Written consent form
Withdrawal	At any time/up to the point at which data is analysed.	At any time/up to the point at which data is analysed.	At any time/up to the point at which data is analysed.	At any time/up to the point at which data is analysed.

Phase 2: Summary of Assessments

What will you do?	**Self-Report Questionnaire**	**Magnetic Resonance Imaging (MRI)**	**Intervention will be undertaken within the MRI**
Time Required (Approximate)/Number of Repeats	15 minutes (X 2 = 30 minutes)	1 hour, 30- minutes (45-minutes preparation (including flash technique practice and 45-minutes in the MRI)	Incorporated in MRI time.
Data collection	Online questionnaire (link emailed)	Flash technique and MRI preparation. Resting state MRI and task-based MRI with a staff member or researcher at the Thompson Institute. Pulse rate will be taken to measure changes throughout flash technique.	Flash Technique requires a 0-10 rating of distress relating to the target memory (link emailed)
Example questions/activities	In the past month, how much were you bothered by repeated, disturbing, and unwanted memories of the stressful experience?	We are looking to see what your brain is doing, and in what areas, whilst engaging in flash technique	On a scale of 0-10 (10=highest distress) how distressing is that target memory now?
Consent	Written consent form	Written consent form	Written consent form
Withdrawal	At any time/up to the point at which data is analysed.	At any time/up to the point at which data is analysed.	At any time/up to the point at which data is analysed.

Information about Magnetic Resonance Imaging (MRI)

This is a non-invasive procedure that requires participants to lay in a confined cylinder-like space while images of brain structure and function are recorded. The MRI procedure requires participants to lie still on a bed inside the cylinder while resting (not sleeping) or while engaging in an activity (flash technique) while images are taken. MRI obtains images via a magnetic field and radio waves. (Please note: a non-invasive procedure means that it **does not** require the administration of any contrast dye and it **does not** use radiation like CT scans or x-rays.) All participants will undergo a safety check and briefing prior to each MRI, MRIs will be run by a trained technician. If you are concerned about anxiety or claustrophobia, please discuss this with one of our research team members. An MRI technician will be present to check in with you during the scan.

Consent

Consent is for your data and information to be collected in an identifiable format, stored in a re-identifiable format, and used in analysis and publications in a de-identifiable format.

Consent is sought for this project and for related activities, ethics-approved, projects that may be undertaken by this research team.

Risks and Benefits

Risks: There are minimal to medium risks associated with your participation, which may include:

- Sometimes thinking about the themes discussed in the questionnaire can create uncomfortable or distressing feelings. You are not required to answer any questions you don't want to and you may discontinue or pause the questionnaire at any time if required. Participants may experience some distress while engaging in assessments and treatment within this study, however, the technique is specifically designed to assist with high distress. No adverse incidents have been recorded in previous research or in the clinical experience of the researcher/psychologist. The technique has been shown to be safe, effective, and pleasant. Furthermore, researchers are trained to provide support during these situations and will ensure your comfort at all times. If you need to talk to someone you may wish to contact family or friends, your General Practitioner, your Employee Assistance Program, UniSC Student Wellbeing (5430 1226), Lifeline (131114), Beyond Blue (1300 224 636), or Mental health access line (1300 642 255 or 1300 MH CALL).
- If you experience an adverse/or serious reaction to the treatment the research team will make contact with your GP to provide feedback and follow-up. You will be informed prior to this contact being made.
- In the event incidental abnormalities (such as potential brain disease or/illness), the research team will contact your GP to provide feedback and request your clinician follow up with you. This may also lead to you being withdrawn from the study. You are welcome to re-engage in the future if your situation changes.
- If you have a known diagnosis of PTSD, it is strongly recommended that you speak with your currently treating medical practitioner about your participation in this study.
- Anxiety may arise about being in the MRI. In instances of claustrophobia or where the participant has indicated distress/discomfort during the MRI, the participant will be closely monitored. Imaging protocols will be followed to mitigate any risks associated with the MRI procedure.
- Some participants may experience some anxiety about flash technique due to it being novel, to them. The researcher is a psychologist with 10 years clinical experience, specialising in trauma treatment. She has advanced training in flash technique and will be able to manage any distress that may arise. Should a participant no longer meet selection criteria or experience an escalation of risk/deterioration of mental health, the UniSC's - Thompson Institute's escalation of care plan will be followed. The escalation of care plan will be followed in the event of an adverse event/or unexpected serious negative event that impacts participants. The Chief Investigator will record any such events internally and report to the approved human research ethics committee to ensure participants' safety needs are addressed and future adverse events are mitigated.

- Participants may incur costs in accessing transport to and from UniSC's - Thompson Institute. A $20 gift voucher will be offered to assist with travel costs.
- Participants may be inconvenienced by giving up the time required to participate in this research project. If employed, participants may forgo hours worked in order to attend assessments. The research team will do their best to accommodate participants in scheduling assessments to suit time restrictions.
- You may discontinue participation at any time if you feel uncomfortable. Following magnetic resonance imaging you may wish to engage in a short debrief where you can speak about any issues or ask any questions about the technique or project with a trained team member. During phase 1/applicable to phase 1 participation only, a team member will make contact with participants during home flash technique practice to allow for any questions, feedback or issues. A list of helpful resources and services on the Sunshine Coast will be provided to you when you agree to participate in this study.

Benefits:

- Flash technique was specifically designed for highly distressing memories, and the technique utilises a small window of exposure before immediately engaging in a distraction to improve tolerance and decrease distress over time.
- This study will contribute to and extend the current literature regarding the neurobiological underpinnings of trauma/PTSD and novel treatment approaches such as flash technique. Participants may gain a better understanding of the neurological basis of trauma memory processing through a technique that has been described as safe and pleasant.

Who is the research team?

This study will be carried out at the Thompson Institute with collaboration with other experts:

- Dr Zack Shan – Chief Investigator, Associate Professor, Thompson Institute, Sunshine Coast, QLD
- Stephanie Price – Research Investigator, Psychologist, Thompson Institute, Sunshine Coast, QLD
- Dr Christina Driver – Co-Investigator, Lecturer in Mental Health and Neuroscience, Thompson Institute, Sunshine Coast, QLD
- Dr Luke Ney – Co-Investigator, Postdoctoral Research Fellow, Queensland University of Technology, Brisbane, QLD
- Dr Jacob Levenstein, Co-Investigator, Research Fellow, Thompson Institute, Sunshine Coast, QLD
- A trained MRI technician, Thompson Institute, Sunshine Coast, QLD
- A data scientist, Thompson Institute, Sunshine Coast, QLD

Privacy, Confidentiality and Results

Any data collected as a part of this research project will be stored securely as per UniSC's Research Data Management Procedures and retained for at least 15 years after final publication. All comments and responses will be treated confidentially unless required by law.

The research team will be able to identify if you choose to participate. However, data will be de-identified and stored in a re-identifiable format. Participation status or individual comments will not be shared with funding bodies, employers or organisations. The results of this research project may be presented at external or internal conferences or meetings, or by publication. If you would like a summary of findings of this research project, please contact the Chief Investigator (listed above).

If immediate and serious harm to self or others is expressed at any time during this study the research team will need to follow up with the risk and safety manager, UniSC legal and make an emergency/crisis referral on your behalf so you can be supported.

Concerns or Complaints

If you have any concerns or complaints about the way this research project is being conducted you can raise them with the Chief Investigator (listed above). If you prefer an independent person, you may contact the Chair of the UniSC Human Research Ethics Committee: (c/- Office of Research, University of the Sunshine Coast, Maroochydore DC 4558; telephone (07) 5430 2823; email humanethics@usc.edu.au).

Please save the information above if you choose to participate.