

Plain Language Statement

Melbourne School of Psychological Sciences



Project: A Type II Hybrid Effectiveness-Implementation, Randomised Control Trial of Left Write Hook for Female and Gender Diverse Adult Survivors of Child Sexual Abuse and Other Gendered Violence

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Introduction

Thank you for your interest in participating in this research project. The following few pages will provide you with further information about the project, so that you can decide if you would like to take part in this research.

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Alfred Hospital Ethics Committee and the University of Melbourne Human Research Ethics Committee. This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2023). This statement has been developed to protect the interests of people who agree to participate in human research studies.

Please take the time to read this information carefully. You may ask questions about anything you don't understand or want to know more about.

Your participation is voluntary. If you don't wish to take part, you don't have to. If you begin participating, you can also stop at any time. There will be no change to the regular Left Write Hook program if you choose not to take part in the research.

What is this research about?

We invite you to participate in a project that will explore the influence of the Left Write Hook program on physical and psychological wellbeing. The aim of the project is to understand potential mental health benefits of completing Left Write Hook, relative to exercise only, which has already been shown to help mental and physical health.

What will I be asked to do?

Should you agree to participate, you will be randomly assigned (i.e. by chance) to complete 8 weeks of either the Left Write Hook group, or a boxing-only group (which does not involve any writing component). You will not be able to choose which group you are assigned to.

If you are assigned to the Left Write Hook group, you will complete 8 x weekly group sessions involving expressive writing and non-contact, trauma-informed boxing. Sessions will run for approximately 2 hours.

If you are assigned to the boxing group, you will complete 8 x weekly group non-contact, trauma-informed boxing sessions led by a boxing facilitator. Sessions will run for approximately 45 minutes. If you like, you will have the opportunity to complete the Left Write Hook programme at the end of the study.

In addition, you will be asked to complete pre- and post-program assessments, as well as a follow-up assessment one month after you finish the program. In these assessments, you will be asked to complete an online questionnaire asking about some basic demographic information (e.g. age, gender) and some questions about your mental wellbeing and physical health. These online assessments take 20-30 minutes to complete on 3 occasions (pre-program, post-program, and one-month follow-up). You will also complete some short fitness tasks in person: blood pressure assessment (cuff is placed around your arm), a sit-and-reach task, and a grip strength task (where you squeeze a hand device tightly), 3-minute step test (stepping on and off a box), and 4-step balance test (balance in 4 positions). These tasks will be completed individually, with a program facilitator, to ensure the program is tailored to be delivered to you safely. These in-person assessments take 15-20 minutes to complete on 2 occasions (pre-program, post-program).

We know that trauma has a lasting impact on the body. In particular, childhood and sexual trauma causes lasting changes in stress hormones, which can negatively impact your own physical and mental health, and might also be passed down to any children you may have. To better understand if Left Write Hook might improve these hormones, there will also be an option to provide a hair sample to measure your stress hormones (50mg / 2cm). This is entirely optional, and your choice won't impact your participation in the rest of the program.

What are the possible benefits?

Past research shows that both boxing and Left Write Hook are likely to offer benefits for your wellbeing. Both the Left Write Hook program and 8-weeks of group boxing sessions usually cost \$300-400. You will also get the additional benefit of taking part for free. This research benefits the community by helping us to understand the extent to which Left Write Hook improves mental and

physical health. This information will be used to help us offer Left Write Hook to other survivors in the future. You will also be compensated for your time completing the research surveys.

What are the possible risks?

The questionnaires will ask you to reflect on your mental and physical health, which we know can be uncomfortable. You can choose to complete the questionnaires wherever you feel most comfortable – in the presence of the facilitator at the end of a session, or at home. Appropriate supports are available to you at all times throughout and after participation in the study. In the case of any distress after group sessions, Dr Emma Veltman (Clinical Psychologist) and Dr Hitchcock (Clinical Psychologist) will be available to debrief, as will your regular facilitator, and regular mental health support provider. If the Clinical Psychologist on the research team believes you might benefit from additional support during the trial, they may contact your GP and/or other mental health supports. In this instance, they will reach out to you to discuss this before any contact is made. If you require immediate support, you are also able to call Lifeline on 13 11 14. Lifeline is a 24 hour, 7 days per week telephone crisis counselling service. More information about available supports can be found at the bottom of this form.

Do I have to take part?

No. Participation is completely voluntary. You are able to withdraw at any time and to withdraw any unprocessed data previously supplied. This means you can withdraw your data up until study results are published in an academic journal at the end of the trial. After study results have been published, unfortunately your individual data points can no longer be identified and removed. Withdrawing from the research will not carry a penalty or affect your rights. To be clear, your participation in Left Write Hook is completely unaffected if you choose not to participate in the research. If you wish to withdraw from the study, please email Dr Emma Veltman (emma.veltman@unimelb.edu.au) or any of the researchers listed at the start of this form.

Will I hear about the results of this project?

Yes. Once analysis has been completed, we will email you a summary of the results. We will also host (and invite you to) a seminar, where we will discuss the results. We will write a paper based on this project for a peer-reviewed journal and share these results verbally at conferences for mental health professionals.

What will happen to information about me?

We use password-protected servers to store your data. We keep your identifiable, personal information (eg name) in a separate folder to your research data. We may be required by law to break confidentiality, if we are concerned for either your own safety or that of someone else. If this happens, we will contact you first, before doing anything. Your identifiable data will be kept securely for 15 years and then destroyed, as per legal regulation. Your deidentified data (e.g., a spreadsheet of numbers with any personal details removed) will be kept for perpetuity. You can ask us to view or delete your data at any time. We might share data that does not include any of your identifiable information with other researchers to use in ethics-approved research projects in the future. For example, at the end of the study, a spreadsheet containing deidentified data may be uploaded onto a record of research datasets, so that it can be used for any future research. The use of data in a separate

future study will not be covered by this projects' approval (i.e. researchers will apply for a new ethics approval from an ethics committee, to ensure your data is being used ethically). In publications, we will only show results in a summarised fashion and will not share individual responses. In the instance that quotes are shared from interviews with the program facilitators, we will remove all identifiable information. We will also contact you if your responses indicate you might be experiencing significant emotional distress, to discuss this with you and help connect you to support if needed. If you choose to provide a hair sample, will be kept for up to one year, or until analysis has taken place (whichever is sooner). After analysis hair samples will be safely destroyed and disposed using secure laboratory waste processes.

Who is funding this project?

This project has received \$599,820 in funding from the Medical Research Future Fund. As reimbursement for your participation, you will receive a \$20 Giftpay voucher for completion of each questionnaire (for a total of up to \$60).

Are there any conflicts of interest?

Dr Donna Lyon is both a member of the research team and the founder of Left Write Hook. Dr Lyon also sits on the board of the Left Write Hook charity. It is standard for those who develop an intervention to be the first to evaluate the efficacy of the intervention. Moreover, principles of co-production and collaboration are particularly important when working with survivors. Dr Lyon's conflict will be declared on the trial publication and all sharing of results.

Where can I get further information?

If you would like more information about the project, please contact the lead researcher; Dr Caitlin Hitchcock, Caitlin.hitchcock@unimelb.edu.au.

Who can I contact if I have any concerns about the project?

This project has human research ethics approval from The University of Melbourne (Project ID 28998) and the Alfred Hospital Ethics Committee (Project ID 110810). If you are participating in the trial through a community group and have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Research Integrity Administrator, Office of Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 1376 or Email: research-integrity@unimelb.edu.au. All complaints will be treated confidentially. In any correspondence please provide the name of the research team and/or the name or ethics ID number of the research project. If you are participating through a site partner (i.e. Alfred Health) and have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact: Reviewing HREC Office/Complaints contact person
Position: Complaints Officer, Office of Ethics & Research Governance, Alfred Health
Telephone: (03) 9076 3619
Email: research@alfred.org.au
Please quote the following Project ID Number: 110810

Feeling distressed? Support is available.

If you are feeling sad or upset after completing the questions in this study, we want to support you. If you need immediate support, you can contact Lifeline (13 11 14) or 1800RESPECT (1800 737 732) 24 hours, 7 days a week. A clinical psychologist, Dr Caitlin Hitchcock, is also available to support you. You can email her at any time (caitlin.hitchcock@unimelb.edu.au), and she will contact you as soon as possible. For ongoing support, we recommend you reach out to your GP.