Participant Information Sheet

A coping skills group programme for people experiencing persisting symptoms after a concussion.

Hello. My name is Victoria Holetic, and I am a trainee clinical psychologist at Canterbury Christ Church University. I would like to invite you to take part in a research study. I am looking to find out whether a new group intervention helps people to cope better or improve their persisting symptoms after a concussion.

Before you decide whether to take part, it is important that you understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss with others if you wish.

This research is supervised by Dr. Alexandra Garfield (Principal Supervisor, Consultant Clinical Psychologist), Dr. Robert Solway (Principal Clinical Psychologist) and Dr. Jerry Burgess (Director of Neuropsychology Programmes).

- Part 1 tells you the purpose of this study and what will happen to you if you take part.
- Part 2 gives you more detailed information about the conduct of the study.

Please ask me if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Part 1

What is the purpose of the study?
There is currently little support available to those experiencing persisting symptoms after a concussion. As a result, there are many people struggling with these symptoms and long-term problems after concussion. We are conducting a research project to develop and test a new group programme to help support people to cope with and manage their symptoms.

This project aims to explore whether the group programme is possible to run, if people find it helpful and if it works to support people with their symptoms. If the results show that the group programme is useful and worth trying, we will hope it will lead to more research and possibly more support for people with persisting concussion symptoms.

Why have I been invited and who can take part?
We are inviting adults aged 18-65 years old who have suffered a head injury which has resulted in a concussion and are still experiencing symptoms after 3 months or longer since their injury.

We are also inviting anyone who has been told they are experiencing post-concussion syndrome or PCS. If you are not sure whether you are experiencing concussion symptoms, you can complete a questionnaire. We ask that you have access to a computer, tablet or mobile phone to attend the group virtually.

Unfortunately, if you meet any of the below criteria, we kindly ask that you do not take part in this study. This is partly to ensure consistency with the data and also because we are not able to provide support in these areas while you take part in this study.

- If you are currently struggling with alcohol or substance use
- If you are currently admitted to hospital
- If you are currently receiving treatment for your mental health
- If you are currently struggling with significant mental health difficulties (e.g., difficulties with self-harm or suicidal thoughts)
- If you have any physical health conditions where the symptoms of another condition are seen as the priority to the concussion symptoms
- If you are currently in ongoing litigation relating to your concussion
- If you have suffered previous brain or head injuries (not including concussion)
- if you have a diagnosis of dementia or other neurological disorders

Do I have to take part?
No, participation in this project is entirely voluntary and it is up to you to decide whether to join the study. If you agree to take part, we will then ask you to sign a consent form.
If you wish, we can discuss the study in more detail with you and answer any questions you may have. You are free to withdraw your participation at any point in the project without giving a reason.

Randomised Controlled Trial (RCT)
This project will use a randomised controlled trial (RCT) design. If you sign up for this study, you will be randomly assigned to either take part in the group programme or to continue your usual routine and not take part in the group during the project. We will then compare the outcomes of participants from the two groups to see if the programme was successful.

What will happen to me if I take part?

1. If you would like to participate in this project and you meet the eligibility criteria, you will be asked to complete a sign up survey and you will be asked to provide your contact details. You will receive a copy of this information sheet by email.

2. You will be invited to speak with me either on the telephone or video call and I will confirm with you that you are eligible to take part in this project. You will be asked to sign a consent form saying that you would like to take part in the research project.

3. You will then be randomly allocated to either take part in the group programme or to continue your usual routine.

4. If you are randomly allocated to the group programme, you will be asked to complete questionnaires on the symptoms you are experiencing, your quality of life, and your mood, at the beginning and at the end of the group programme.

If you are randomly allocated to not take part in the group programme, then we will ask you to complete the same questionnaires at the same time as the group programme. You have an equal chance of being put into either group.

5. The concussion group programme will take place every week over 6 weeks. Each session will last for an hour and a half with a 10-minute break halfway through. The group programme will take place online using Microsoft Teams, which is free to use.

The group will have up to 12 people who are all experiencing persisting concussion symptoms and 2 group facilitators who will deliver the group programme. This will be myself and another healthcare professional.

Alternatively, if you are randomly allocated to not take part in the group programme, we encourage you to continue your usual routine and continue managing your persisting concussion symptoms however you wish.

6. Both groups will be asked to complete questionnaires during the project. A set of questionnaires will be emailed to you before the group programme begins and at the end of the group programme. Some demographic information will also be collected at the beginning of the study.

At the end of the group programme, I will also ask you to complete a survey which asks for feedback of what you thought about the programme and how you found taking part. This will help us to improve the programme for future use.

Alternatively, if you would prefer to complete a paper copy of these or via the telephone with a researcher, we can support you with this.

Expenses and payments
As a token of our appreciation for taking part in the research study, there will be a prize draw where 4 x £20 amazon vouchers can be won.

What are the possible disadvantages and risks of taking part?
We think the risks associated with taking part in this research are low.

However, if you find looking at a screen difficult, where you may feel your symptoms getting worse (for example, headaches, light sensitivity or other symptoms), you are welcome to complete the questionnaires on the telephone.

During the online group, you are also welcome to turn your screen brightness down and listen to the material to engage with the group without needing to look at the screen. We can also send you a paper copy of the group materials to refer to during the group. If you feel that it would be challenging to take part in an online group, we ask you not to participate to avoid exacerbating your symptoms.

If at any time during the study you find a topic sensitive or upsetting you are welcome to take a break or leave the session. Should it be the case you need to leave the group, you are welcome to do so and a facilitator will contact you to check-in.

What are the possible benefits of taking part?
There may be no direct benefit from taking part in the study. We cannot promise the study will help you, we hope that you may be able to take away some coping techniques and that building awareness around the difficulties after a head injury will be of help to you in coping with some of the struggles you experience.

By taking part, you are contributing to our understanding of whether an intervention can support people living with persisting symptoms after a concussion injury to cope better with their difficulties.

What if there is a problem?
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed the detailed information on this is given in Part 2.

Will information from or about me from taking part in the study be kept confidential?
Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. There are some rare situations in which information would have to be shared with others. The details are included in Part 2.

This completes Part 1 of the information sheet.
If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?
You can stop being part of the study at any time without giving a reason. It may not be possible to withdraw the information about you that we have already collected. This is because we would like to use the data collected up to your withdrawal and will need to manage your data in specific ways for the research to be reliable. This means we won't be able to let you change the data we hold about you. If you withdraw from the study, this will not affect any current or future care you receive for your concussion.

What if there is a problem?
Any concerns or complaints made by you will be taken very seriously and reviewed by the lead researcher, and if necessary, Canterbury Christ Church University.

Concerns and complaints
If you have a concern about any aspect of this study, you can speak with the lead researcher for this study, who will do their best to address your concerns. Contact via email can be made to: v.holetic196@canterbury.ac.uk.

If you remain unhappy, or wish to make a formal complaint, you can speak with Dr. Fergal Jones (Clinical Psychology Programme Research Director at Salomons Institute for Applied Psychology) at fergal.jones@canterbury.ac.uk or call 01227 927110.

Will information from or about me from taking part in the study be kept confidential?
All personal information which is collected from or about you during the course of the research will be kept strictly confidential. The only time when I would be obliged to pass on information from you to a third party would be if, because of something you told us, we were to become concerned about your safety or the safety of someone else. We will always try to discuss this with you first.

How will we use the information we collect about you?

- We will collect information from you for this research project. This information will include your name, contact details, details of your GP, some demographic information, and your answers to questionnaires asking you about your concussion injury, your symptoms, quality of life and mood. If you are allocated to the group programme, it will also include your answers to questions about your experiences of the group.

- This data will be stored in a password-protected spreadsheet and your personal identifiable information will be stored separately in a password-protected spreadsheet.

- An anonymous coding system will be used so that only the lead researcher can link your personal information to the data you have provided.

- After we have analysed the results, we will write our reports in a way that no one will identify you took part in the study, your information will be made anonymous.

- We will keep the responses you provide for up to 10 years after the research has finished (as according to the Medical Research Council) to enable researchers to continue analysis of the study data in future projects. After this time, your data will be deleted.

- Other authorised people such as the study's supervisors (Dr. Alexandra Garfield, Dr. Robert Solway, and Dr. Jerry Burgess) will have access to your data for monitoring the quality of the research.

- Participants have the right to check the accuracy of data held about them and correct any errors.

- Please refer to the Canterbury Christ Church University Privacy Note for further information at https://www.canterbury.ac.uk/services/governance-and-legal-services/data-protection/privacy-notices/research-privacy-notice

What will happen to the results of the research study?
The results of this research will form the lead researcher's Major Research Project. The project could also be published in scientific journals and related media and presented to interested parties. The results will be anonymised in every report that we write, you will not be identified. We may use anonymised quotes from your responses in our feedback survey in our published report to show others what participants' thought of the group intervention.

If you do not wish for your quotes to be use in any report, please let us know on the consent form. If you would like to receive a copy of the results after the study has finished, please let us know on the consent form.

Who is sponsoring and funding the research?
Canterbury Christ Church University is the sponsor for this study.

Who has reviewed the study?
This study has been reviewed and given favourable opinion by The Salomons Ethics Panel at Salomons Institute for Applied Psychology, Canterbury Christ Church University.

Should you wish to take part, you will be given a copy of the information sheet and a copy of your signed consent form to keep for your records.

Further information and contact details
If you would like to speak to me and find out more about the study or ask any questions, you can get in touch by emailing me at v.holetic196@canterbury.ac.uk

If you would like to speak with a researcher supervising the study who is experienced in this field please contact Dr. Jerry Burgess who is the lead contact supervisor for this research on jerry.burgess@canterbury.ac.uk

Thank you for taking the time to read this information sheet.