AlfredHealth

MONASH University

Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

The Alfred Hospital

Title	INtegrative approaches for Optimizing Recognition, Management and Education of concussion at the community sports level
Short Title	INFORMED-1
Project Number	128/23
Project Sponsor	Monash University
Coordinating Principal Investigator/ Principal Investigator	Prof. Biswadev Mitra (Emergency & Trauma Centre, The Alfred Hospital, Melbourne; Department of Epidemiology & Preventive Medicine, Monash University, Melbourne)
Associate Investigator(s)	Dr Alexander Olaussen (Department of Paramedicine, Monash University, Melbourne; National Trauma Research Institute, Melbourne; Ambulance Victoria, Melbourne; Department of Epidemiology & Preventive Medicine, The Alfred Hospital / Monash University, Melbourne) Dr Stuart McDonald (Monash Trauma Group, Central Clinical School, Monash University; Alfred Research, The Alfred Hospital, Melbourne) Prof. Jennie Ponsford (School of Psychological Sciences, Monash University, Melbourne) Associate Prof. Sandy Shultz (Department of Neuroscience and Central Clinical School, Monash University, Melbourne) Associate Prof. Catherine Willmott (AFL House, Melbourne) Prof. Terence J. O'Brien (Alfred Brain and Alfred Research, The Alfred Hospital, Melbourne; Central Clinical School, Monash University, Melbourne) Prof. Michael O'Sullivan (Centre of Clinical Research, University of Queensland, Queensland) Dr. Michael Makdissi (AFL House, Melbourne) Dr Jonathan Reyes (AFL House, Melbourne, Monash University, Melbourne) Dr Zhibin (Ben) Chen (Monash University, Melbourne) Dr Jennifer Makovec-Knight (Monash University, School of Psychological Sciences, Melbourne; Psychology Services, Alfred Health) Madison Essery (Alfred Health Emergency Services, Melbourne) Abha Somesh (Alfred Health Emergency Services, Melbourne) Cassandra Yankoff (Alfred Health Emergency Services, Melbourne) Christine Koolstra (Alfred Health Emergency Services, Melbourne) Natalie Linke (Department of Epidemiology & Preventive Medicine, Monash University, Melbourne)

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you have sustained a head injury within the previous seven days. The research project is testing a new telehealth program treatment for diagnosing and managing potential concussions. This new telehealth program run by neuropsychologists, physiotherapists, emergency physicians and neurologists, is called INFORMED-1.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to have the tests and treatments that are described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

Telehealth is an emerging way of assessing and managing patients, particularly after the COVID-19 pandemic. The role of telehealth in concussion diagnosis and management is not fully researched yet, therefore in this trial, we are in the first instance testing the effectiveness of the diagnostic ability of a telehealth program. After two years at the conclusion of the trial, the research findings will be emailed to all participants with the aggregate summary data findings.

The results of this research will be used by the Study Coordinator Dr Alexander Olaussen to obtain a Doctor of Philosophy (PhD) degree.

This research has been initiated by the Coordinating Principal Investigator, Professor Biswadev Mitra.

This research has been funded by the Medical Research Future Fund (MRFF) MRFF 2021 Traumatic Brain Injury Grant Opportunity (APP 2016112).

3 What does participation in this research involve?

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random).

You have a one in two chance of being allocated to the telehealth program. The program is meant to assess whether telehealth increases the number of diagnoses.
This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no additional costs associated with participating in this research project, nor will you be paid. All tests and medical care required as part of the research project will be provided to you free of charge.

Given the study is conducted via telehealth, there are no costs expected to be incurred by the participant.

It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

The Initial steps for eligibility and participation in this study.

Step 1	You have recently suffered a head strike during a sporting activity (either matches or training).
Step 2	Go to website www.informedtbi.org on information regarding a number of our trials.
Step 3	Go to "For patients" tab and click on "Head Injury within the last 7 days" if appropriate to you.
Step 4	You will now see the tab "INFORMED-1".
Step 5	Check whether you are eligible to participate and if so, submit your contact details and sign a consent form.
Step 6	Within one business day a research nurse will contact you to obtain baseline details.
Step 7	Based on this information, the nurse will confirm your trial eligibility.
Step 8	If eligible, the nurse will then randomise you to one of two possibilities.
Step 9	Depending on which possibility you are randomised to, either: a) a neuropsychologist/neurologist or physiotherapist will be in touch with you OR b) you will be provided with the most current and available concussion/head injury advice.
Step 10	Regardless of which option you are randomised to, you will be contacted on day 7 and day 14 post head injury regarding your clinical symptoms.
Step 11	If you are randomised to the telehealth arm, you will be contacted on day 30 post head injury to assess your satisfaction and feedback regarding the telehealth program.

The telehealth program takes about 45min. If further assessments, medical opinions, tests and/or consultations are considered necessary, then more time will be required.

4 What do I have to do?

If you are eligible to take part in the study and are randomised to the telehealth arm, you will be attending an online virtual video based telehealth consultation. This will require access to technology (such as computer/smart phone) to enable this. The video consultations will not be recorded to maximise your security and privacy.

There will be no restrictions in terms of lifestyle or your regular medications or behaviours.

In terms of return to play, both arms of the study will be encouraged to adhere to the AFL Return To Play (RTP) guidelines.

5 Other relevant information about the research project

This trial is running for 2 years and is available to all players in any sporting activity and will enrol at least 500 head-injured patients with suspected concussion.

It is a Monash University sponsored study and run out of Alfred and Monash University.

6 Do I have to take part in this research project?

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 do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Alfred Health, Monash University, your club or sporting Association.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. Other options are available; these include sourcing available evidence regarding what to do with concussion and suspected concussion, see your GP or using our website www.informedtbi.org for further information.

Your research nurse will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

Please note that this program cannot clear you of concussion. Players are required to follow existing guidelines, including the need to *"obtain a written medical clearance from a Medical Practitioner (i.e. General Practitioner, Sports Doctor, Neurologist) to return to training and playing. The medical clearance must state that the player has been cleared from a concussion injury"*

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include:

In the interventional arm, earlier, more accurate and more personalised diagnosis of concussion, as well as access to our online resources relating to concussion.

In the standard of care arm, introduction to online resources relating to concussion.

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

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.

10 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

If you are randomised to the telehealth arm and during the assessment, the neuropsychologist or physiotherapist are concerned for you, they can seek advice from rostered on medical specialists (emergency physicians or neurologists) who will be virtually co-located for urgent assessment of symptoms related to the head injury outside the scope of a possible concussion.

In addition, should the telehealth team feel the need for in-person assessment and management, including physiotherapy or occupational therapy for example, this will be facilitated for you.

Furthermore, regardless of which option you are randomised to, if you have persistent symptoms on day 14, you will be offered to enrol in the iRecover trial, which is a 12-week intensive multidisciplinary treatment to minimise long term symptoms of concussion.

11 Can I have other treatments during this research project?

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

12 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you and all exsiting data will be deleted.

13 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for if the decisions is made in the interests of the study sponsor or by local regulatory/health authorities.

14 What happens when the research project ends?

The current neuropsychologist telehealth assessment is only available in this trial setting. However, if this is found to be successful we will attract funding and this trial will go a long way towards achieving such funding to setting up this program to be available for all participants with potential concussion, not just in sporting activities, but any sports related head injury in both contact and non-contact sports.

Part 2 How is the research project being conducted?

15 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential.

If eligible, you will be randomised by the critical care nurse who is doing the phone triage and you will be assigned a study number. The Research Coordinator will compile a study enrolment log, which will link the study number to your name. Subsequent data will be identified by the study number. The video consultations will not be recorded to maximise your security and privacy. The enrolment log and study data will be kept separately. Your follow-up details will be collected including name, address and contact telephone numbers for the purpose of contacting you for subsequent reviews. The contact details will be forwarded to the coordinating centre. Study data will be entered into The Alfred Hospital Red-Cap database specifically designed for the study with restricted access via authenticated login using an email address and password combination. Furthermore, to further protect your privacy, your contact details (i.e.: name, phone number, email etc) will be kept electronically in a secured database in Red-Cap **separately** to your clinical information.

The study number will hold the clinical information data, and as such your symptoms cannot be directly related to your name. There will be no hard copies stored physically. The data will be retained indefinitely.

Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you will NOT be obtained from your health records held at this and other health services for the purpose of this research.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Only aggregate data, that cannot be traced back to the individual participant will be presented.

Information about your participation in this research project will NOT be recorded in your health records. It is however encouraged that you discuss the outcomes of your involvement in this trial with your club trainers, medical personnel and your GP.

In accordance with relevant Australian and Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project described in this Section 15 that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

16 What if I get injured in the research?

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. As 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.

In the event of not being cleared to return to play, it is the responsibility of the participant to communicate this with the club and adhere to the current guidelines.

17 Who is organising and funding the research?

This research project is being conducted by Professor Biswadev Mitra on behalf of Alfred Health and Monash University.

This research project is being sponsored by Monash University and is being funded Medical Research Future Fund (MRFF) MRFF 2021 Traumatic Brain Injury Grant Opportunity (APP 2016112).

Alfred Health and/or Monash University may benefit financially from this research project if, for example, the project assists Alfred Health and/or Monash University to obtain approval for a new telehealth program.

You will not benefit financially from your involvement in this research project even if, for example, your clinical information (or knowledge acquired from analysis) prove to be of commercial value to Alfred Health and/or Monash University

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Alfred Health and/or Monash University, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries. Neither Alfred Health nor Monash University will benefit financially from your involvement in this research project directly.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

The funding provided by Medical Research Future Fund (MRFF) MRFF 2021 Traumatic Brain Injury Grant Opportunity (APP 2016112) is purely to enable the research project to be conducted.

18 Who has reviewed the research project?

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 has been approved by the Alfred Hospital Ethics Committee.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

19 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on +61 3 9904 4544 or any of the following people:

Clinical contact person

Name	Dr Alexander Olaussen
Position	Lead Investigator/Study coordinator
Telephone	+61 3 9904 4544
Email	alexander.olaussen@monash.edu

Or

Complaints contact person

Name	Carly Talarico
Position	Research Assistant, Alfred Health Emergency
Telephone	+61 3 90762782
Email	carly.talarico@alfred.org.au

If you 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

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Consent Form - *Adult providing own consent*

Title	INtegrative approaches for Optimizing Recognition, Management and Education of concussion at the community sports level
Short Title	INFORMED-1
Project Number	128/23
Project Sponsor	Monash University
Coordinating Principal Investigator/ Principal Investigator	Prof. Biswadev Mitra (Emergency & Trauma Centre, The Alfred Hospital, Melbourne; Department of Epidemiology & Preventive Medicine, Monash University, Melbourne)
Associate Investigator(s)	Dr Alexander Olaussen (Department of Paramedicine, Monash University, Melbourne; National Trauma Research Institute, Melbourne; Ambulance Victoria, Melbourne; Department of Epidemiology & Preventive Medicine, The Alfred Hospital / Monash University, Melbourne) Dr Stuart McDonald (Monash Trauma Group, Central Clinical School, Monash University; Alfred Research, The Alfred Hospital, Melbourne) Prof. Jennie Ponsford (School of Psychological Sciences, Monash University, Melbourne) Associate Prof. Sandy Shultz (Department of Neuroscience and Central Clinical School, Monash University, Melbourne) Associate Prof. Catherine Willmott (AFL House, Melbourne) Prof. Terence J. O'Brien (Alfred Brain and Alfred Research, The Alfred Hospital, Melbourne; Central Clinical School, Monash University, Melbourne) Prof. Michael O'Sullivan (Centre of Clinical Research, University of Queensland, Queensland) Dr. Michael Makdissi (AFL House, Melbourne) Dr Jonathan Reyes (AFL House, Melbourne, Monash University, Melbourne) Dr Zhibin (Ben) Chen (Monash University, Melbourne) Dr Jennifer Makovec-Knight (Monash University, School of Psychological Sciences, Melbourne; Psychology Services, Alfred Health) Madison Essery (Alfred Health Emergency Services, Melbourne) Abha Somesh (Alfred Health Emergency Services, Melbourne) Cassandra Yankoff (Alfred Health Emergency Services, Melbourne) Christine Koolstra (Alfred Health Emergency Services, Melbourne) Natalie Linke (Department of Epidemiology & Preventive Medicine, Monash University, Melbourne)

Consent Agreement

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Monash University concerning my injury and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Declaration - for participants unable to read the information and consent form
See Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 Section 4.8.9. A legally acceptable representative may be a witness*.
Witness to the informed consent process
Name (please print) _____

Signature _____ Date _____
* Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†
I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.
Note: All parties signing the consent section must date their own signature.

Consent via telehealth or telephone

- ❒ Consent was obtained using Red-CAP e-consent platform
- ❒ Consent was discussed with *[Participant]* via telephone on *[insert date]* and received signed consent form on *[insert date].* Signed by *[Investigator].*

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Form for Withdrawal of Participation - *Adult providing own consent*

Title	INtegrative approaches for Optimizing Recognition, Management and Education of concussion at the community sports level
Short Title	INFORMED-1
Project Number	128/23
Project Sponsor	Monash University
Coordinating Principal Investigator/ Principal Investigator	Prof. Biswadev Mitra (Emergency & Trauma Centre, The Alfred Hospital, Melbourne; Department of Epidemiology & Preventive Medicine, Monash University, Melbourne)
Associate Investigator(s)	Dr Alexander Olaussen (Department of Paramedicine, Monash University, Melbourne; National Trauma Research Institute, Melbourne; Ambulance Victoria, Melbourne; Department of Epidemiology & Preventive Medicine, The Alfred Hospital / Monash University, Melbourne) Dr Stuart McDonald (Monash Trauma Group, Central Clinical School, Monash University; Alfred Research, The Alfred Hospital, Melbourne) Prof. Jennie Ponsford (School of Psychological Sciences, Monash University, Melbourne) Associate Prof. Sandy Shultz (Department of Neuroscience and Central Clinical School, Monash University, Melbourne) Associate Prof. Catherine Willmott (AFL House, Melbourne) Prof. Terence J. O'Brien (Alfred Brain and Alfred Research, The Alfred Hospital, Melbourne; Central Clinical School, Monash University, Melbourne) Prof. Michael O'Sullivan (Centre of Clinical Research, University of Queensland, Queensland) Dr. Michael Makdissi (AFL House, Melbourne) Dr Jonathan Reyes (AFL House, Melbourne, Monash University, Melbourne) Dr Zhibin (Ben) Chen (Monash University, Melbourne) Dr Jennifer Makovec-Knight (Monash University, School of Psychological Sciences, Melbourne; Psychology Services, Alfred Health) Madison Essery (Alfred Health Emergency Services, Melbourne) Abha Somesh (Alfred Health Emergency Services, Melbourne) Cassandra Yankoff (Alfred Health Emergency Services, Melbourne) Christine Koolstra (Alfred Health Emergency Services, Melbourne) Natalie Linke (Department of Epidemiology & Preventive Medicine, Monash University, Melbourne)

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Alfred Health, Monash University, my club or sporting Association.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.