



Participant Information Sheet – General (Extended)

NICM Health Research Institute

Project Title: A randomised feasibility study assessing an Active Virtual Reality Gaming intervention to promote physical activity and mood in young men with mild-moderate depression.

Project Summary:

You are invited to participate in a research study being conducted by Dr Mike Armour, Mrs Fiona Hargraves, (PhD Candidate) from NICM Health Research Institute, Western Sydney University, Australia; Dr Freya MacMillan, Dr Emma George and Dr Sandra Garrido from Western Sydney University, Australia; Dr Joseph Firth from The University of Manchester, England; and Professor Kerry Sherman, Macquarie University, Australia.

Young adulthood can be a busy and stressful time with many lifestyle changes. Physical Activity is known to be beneficial for stress, anxiety and improving mental health but it can also be difficult to find the time and motivation to exercise, especially with low mood or when feeling stressed. In addition, the recent COVID-19 pandemic has limited access to many community recreation and fitness centres and opportunities for physical activity have declined. Meanwhile, there is a rising interest in e-health and digital strategies for increasing physical activity.

We are interested in investigating whether playing active virtual reality games on the Oculus Quest 2 device can promote physical activity adherence and enhance mood in young Australian men. This information will help us better understand the role of alternative modes for involvement in physical activity, rather than attending a fitness centre in person and whether active virtual reality gaming (AVRG) is potentially an acceptable and feasible strategy to help guide future research and practice in accessible physical activity interventions for mental health.

You do not need to be currently undertaking any structured physical activity or gaming to participate.

How is the study being paid for? This study is part of a PhD funded by The Blackmores Institute.

What will I be asked to do?

This trial is open to participants Australia wide.

To be eligible to be part of this trial you need to:

- Be a male aged between 18-29 years
- Willing and physically able to participate in active VR gaming
- Have reliable wifi internet connection, access to a smartphone to for screening and outcome apps, willing to use a Facebook account to log into an Oculus Quest 2 device.
- Have a safe and clear 2 x 2m space at their place of residence in which to operate the gaming device.
- Willing to provide informed consent and adhere to the protocol.

- Not currently be taking any pharmaceutical medication (such as an antidepressant prescribed by your doctor) or any herbal medicines (like St Johns Wort) that are designed to improve your mood.

You will be asked to fill in an online survey to determine eligibility for the trial. You will be asked about your background (such as your age, which state you live in, employment status), current lifestyle (physical activity, sleep, habits), experience with exercise, preferences for exercise involvement, mood and stress (mental health).

If eligible, you will be randomised into one of two groups, who are both involved in the same gaming intervention (one group has a delayed start) and undertake baseline measures consisting of online surveys after which you will receive an Oculus Quest 2 device on loan to use at home through your Facebook account and receive orientation for use. You will participate in an eight-week program of AVRG, in which you can choose to play any or all of three provided games: Pistol Whip, Thrill of the Fight and Beat Sabre/Audio Trip. While playing on the Oculus Quest, you will wear a provided heart rate monitor linked to the VR Exercise app to track usage and physical exertion.

After eight weeks, you will return the device to us and complete online surveys of outcome measures. And then a short survey online four weeks after that to follow up.

How much of my time will I need to give?

Participation in the study will involve:

- Initial baseline measures: around 30 minutes
- AVRG for 8 weeks: at least three thirty-minute sessions each week.
- Outcome measures: around 30 minutes
- (Four-week follow up survey: 10 minutes)
- (Post-trial interview: 30 minutes)

What benefits will I, and/or the broader community, receive for participating?

There is existing evidence that physical activity can enhance both both mental and physical health and you also get the opportunity to learn and participate in some popular, fun virtual reality games with excellent user reviews. The findings from this trial may be used to direct future research on physical activity via AVRG and mental health in young men.

Will the study involve any risk or discomfort for me? If so, what will be done to rectify it?

We do not foresee any major risk to you from participating in this study. For online surveys, we do not use cookies or collect your IP address and all information collected is stored in the REDCap clinical trials software system as a number you will be allocated once randomised. There are risks involved in participating in physical activity and we will provide safety recommendations aligned with the use of the gaming equipment. We recognise that some people feel uncomfortable when talking about matters relating to physical and mental health.

If any of the topics raised in this trial cause distress, or for more information about stress, mood or mental health please consider contacting one of the support services listed below:

Lifeline: 13 11 14 (<https://www.lifeline.org.au/>)

Beyond Blue: 1300 22 4636

Suicide Call Back Service - 1300 659 467

The Suicide Call Back Service provides immediate support to anyone feeling suicidal. In addition, they can provide ongoing support through up to six 50-minute telephone counselling sessions that will provide you with longer term support. The Suicide Call Back Service also offers online counselling.

How do you intend to publish or disseminate the results?

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 the participant cannot be identified, via summaries of what we found, rather than individual data.

Will the data and information that I have provided be disposed of?

Please be assured that only the researchers will have access to the raw data you provide. However, your data may be used in other related projects for an extended period of time, such as helping inform future clinical trial design on physical activity and mental health interventions.

Can I withdraw from the study?

Participation is entirely voluntary, and you are not obliged to be involved. If you do participate you can withdraw at any time. We will retain data collected up to the point of withdrawal for analysis because this is important information in a feasibility study. Whatever your decision, it will not affect your relationship to anyone involved in this study. If you withdraw from the study, we will try to contact you to make sure it was not due to an adverse event.

Can I tell other people about the study?

Yes, you can tell other people about the study by providing them the link to this information sheet. If they would like more information, they can then contact Dr Armour to discuss their participation in the research project.

What if I require further information?

Please contact Dr Mike Armour should you wish to discuss the research further before deciding whether or not to participate

Dr Mike Armour, Chief Investigator, email m.armour@westernsydney.edu.au

What if I have a complaint?

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through Research Engagement, Development and Innovation (REDI) on Tel +61 2 4736 0229 or email humanethics@westernsydney.edu.au.

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

This study has been approved by the Western Sydney University Human Research Ethics Committee. The Approval number is H14118.

What will happen with my information if I agree to it being used in projects other than this one?

Thank you for considering being a participant in a University research project. The researchers are asking that you agree to supply your information (data) for use in this project and to also agree to allow the data to potentially be used in future research projects.

This request is in line with current University and government policy that encourages the re-use of data once it has been collected. Collecting information for research can be an inconvenience or burden for participants and has significant costs associated with it. Sharing your data with other researchers gives potential for others to reflect on the data and its findings, to re-use it with new insight, and increase understanding in this research area.

You have been asked to agree to Extended consent.

Extended consent

When you agree to extended consent it means that you agree that your data, as part of a larger dataset (the information collected for this project) can be re-used in projects that are

- an extension of this project
- closely related to this project
- in the same general area of this research.

The researchers will allow this data to be used by our research team at NICM Health Research Institute to inform future research in this area.

To enable this re-use, your data will be held at the University in its data repository and managed under a Data Management Plan. The stored data available for re-use *will not* have information in it that makes you identifiable. The re-use of the data will only be allowed after an ethics committee has agreed that the new use of the data meets the requirements of ethics review.

The researchers want to keep the data for *15 years* for possible re-use. After this time the data will be securely destroyed.

You are welcome to discuss these issues further with the researchers before deciding if you agree. You can also find more information about the re-use of data in research in the [National Statement on Ethical Conduct in Human Research](#) – see Sections 2.2.14 - 2.2.18.

<https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018>