



## Participant Information Sheet – General (Extended)

**Project Title:** *Active Breed: Improving men's health in South-Western Sydney*

### Project Summary:

The *Active Breed* program is a 12-week two-arm randomised controlled trial comparing a men's health intervention with a wait-list control group (to receive a delayed intervention). Participants will engage in an education and exercise program, focusing on increasing physical activity, improving dietary intake, reducing weight, enhancing mental health and social support, discussing the role men can play in violence prevention, improving relationships and making healthy choices.

You are invited to participate in this research study being conducted by Western Sydney University, the Canterbury-Bankstown Bulldogs Rugby League Club, and the South Western Sydney Primary Health Network.

To be eligible to participate in this program, you must be male, aged 35-64 years, with a BMI of  $\geq 25\text{kg/m}^2$ , available to attend program sessions at Belmore Sports Ground and not participating in any other weight loss programs or interventions. If you have recently participated in a weight loss program or intervention in the previous 6 months, you are not eligible to participate in this program.

### How is the study being paid for?

The study is being funded by the Canterbury-Bankstown Bulldogs, the South Western Sydney Primary Health Network and Western Sydney University. The study is also supported in-kind by the Bulldogs, Western Sydney University, the South Western Sydney Primary Health Network and White Ribbon Australia.

### What will I be asked to do?

Before the program begins, you will be asked to complete a pre-exercise screening assessment and a demographic questionnaire to provide information on factors including your age, socio-economic status, history of disease, ancestry, country of birth, physical activity levels, dietary intake, smoking status, social support, perceptions of domestic and family violence and health literacy. You will also be asked to wear a lightweight waist-worn physical activity monitor (accelerometer) for a one-week period at baseline (pre-program), at the end of the program (week 12) and at a further 12-week follow-up (week 24). Trained research staff will also take measurements including your height, weight, waist circumference and blood pressure at each of the three time points.

You will be randomly allocated into one of two groups. The first group will participate in the 12-week program starting in July 2019, and the second group will be placed on a wait-list to participate in the program in January 2020. Both groups will have the same data collected at all three time-points.

The program will involve participation in weekly education and exercise sessions that will last for 90 minutes per session. The program will focus on topics including increasing physical activity, improving dietary intake, reducing weight, enhancing mental health and social support, raising awareness of domestic violence and gender equality and making healthy choices. At the end of the 12-week program, you may be asked to participate in a survey or discussion about the program to help identify positive aspects of the program and aspects for improvement. This valuable information will help improve the program.

You will also be asked to provide your consent to use photographs, videos and direct quotes taken during the sessions for promoting the Active Breed program.

### **How much of my time will I need to give?**

Each measurement session will take around 30 minutes of your time and will be held at Belmore Sports Ground. These sessions will be held before the program (baseline), at the end of the program (week 12) and again a further 12 weeks later (week 24). You will have the option to complete questionnaires online, prior to attending the measurement sessions. The education and exercise sessions will be held once weekly for 12 weeks, and will each run for 90 minutes.

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

By delivering a program designed specifically for men and by targeting key health behaviours and outcomes, we anticipate that participants will experience improvements in physical and mental health. Throughout the program, men will be involved in education sessions and will gain knowledge about improving their physical and mental health by changing behaviours and learning new skills. For example, men will learn about improving/strengthening relationships, becoming more active, being role models for their children or younger family members, and eating well.

We anticipate that this program will result in improvements in some of the following health behaviours/outcomes: physical activity levels, sedentary behaviour, dietary intake (fruit and vegetable consumption, sugar sweetened beverages, excess fat), mental health, and levels of social support.

This program may reach a large number of participants across the greater Western Sydney region, enhancing community spirit and knowledge about community engagement programs being developed and implemented for men.

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

Every measure will be taken to minimise harm or discomfort, however, if you feel uncomfortable at any time during the program, you may opt to withdraw from specific aspects of the program, or to withdraw from the program altogether. All education and physical activity sessions will be tailored to cater for men of all ages, fitness and skill levels to reduce the risk of discomfort, but participation in all aspects of the program is not compulsory.

Should you decide to withdraw at any time, there will be no consequences associated with your decision.

### **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, except with your permission. Only the research team will have access to the data you provide, and data will be stored securely during and after the completion of the study. All data will be de-identified prior to dissemination.

Any photo or video footage taken of you will only be used if you provide your consent, and written quotes will only be used if you provide your consent. Your personal information (name and age) will only be included in video footage, photos or in writing (e.g., in media articles) if you provide your consent. You may withdraw your consent at any time without consequence. Photographs and video taken during the program sessions will be available for participants to view prior to being used for promotional purposes, and any written quotes will be available for review prior to publishing.

### **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. Other related projects may include future iterations of the Active Breed men's health program, or assessments of long-term health behaviour change in Active Breed participants. There are a number of government initiatives in place to centrally store research data and to make it available for further research. For more information, see <http://www.ands.org.au/> and <http://www.rdsi.uq.edu.au/about>. Your data will be stored securely and it will be de-identified before it is made available to any other researcher.

### **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 without giving reason.

If you do choose to withdraw, any information that you have supplied will be aggregated and retained for analysis. You can withdraw from the study by emailing the research team at [activebreed@westernsydney.edu.au](mailto:activebreed@westernsydney.edu.au) or contacting the lead investigator (please see details below).

### **What if I require further information?**

Please contact Dr Emma George should you wish to discuss the research further before deciding whether or not to participate.

Dr Emma George

Phone: +612 4736 0052

Email: [activebreed@westernsydney.edu.au](mailto:activebreed@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](mailto:humanethics@westernsydney.edu.au).

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

If you agree to participate in this study, you may be asked to sign the Participant Consent Form. The information sheet is for you to keep and the consent form is retained by the researcher/s.

This study has been approved by the Western Sydney University Human Research Ethics Committee. The Approval number is H11914.