

**UNIVERSITY OF CALGARY**

**CONSENT TO PARTICIPATE IN RESEARCH**

**TITLE:** A **BE**havioural **WE**ight **L**oss Intervention delivered in Cardiac Rehabilitation for patients with Atrial Fibrillation and obesity: The **BeWEL** IN CR–AF Study

**SPONSOR:** University of Calgary

**FUNDER**: Canadian Institutes of Health Research (CIHR)

INVESTIGATORS**:**

Tavis Campbell, PhD, Principal Investigator

Department of Psychology, University of Calgary

Telephone: (403) 210-8606

Email: campbet@ucalgary.ca

Stephen Wilton, MD, Principal Investigator
Department of Cardiac Sciences. University of Calgary

Telephone: (403) 210-8606

Email: sbwilton@ucalgary.ca

**CO-INVESTIGATORS:**

Dr. Sandeep Aggarwal, MD

Dr. Lesley Lutes, PhD

Dr. Codie Rouleau, PhD

Dr. Ross Arena, PhD

# INTRODUCTION

Dr. Tavis Campbell andassociates from the Department of Psychology at the University of Calgary are conducting a research study.

This consent form is only part of the process of informed consent. It should give you a basic idea of what the research is about and what your participation will involve. If you would like more detail about something described here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form for your records.

You were identified as a possible participant in this study because you have a diagnosis of atrial fibrillation (“AFib”) and higher body weight (i.e., body mass index ≥30 kg/m2). You may have also previously enrolled in a cardiac rehabilitation (CR) program through TotalCardiology Rehabilitation™. Your participation in this research study is voluntary.

**BACKGROUND**

People with AFib who also have higher body weight can get relief from their symptoms if they lose about 10% of their weight. Research shows that one way to lose a moderate amount of weight and keep it off is by participating in *behavioural weight loss treatment* (BWLT). BWLT is a group-based therapy program that uses psychology to teach people how to better manage their eating, increase their physical activity, and maintain other healthy behaviours.

**WHY IS THIS STUDY BEING DONE?**

The purpose of this research study is to test if a BWLT program modified for people with AFib will result in a greater amount of CR patients losing 10% of their body weight compared to CR patients that receive treatment as usual. We also want to know if people who take part in BWLT experience any changes in AFib symptoms, related health outcomes, and psychological health.

Typical CR programs often do not include a dedicated weight loss component, which is especially important for patients with higher body weight. This study will help determine the most appropriate treatment for people with both AFib and higher body weight.

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

About 120 people will take part in this study. All of the people who take part will be completing the study through the University of Calgary.

**WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?**

If you join this study, you will be randomly chosen to participate in either the 12-week TotalCardiology Rehabilitation (TCR) program or a 24-week virtual BWLT program in addition to the 12-week TCR program.

The cardiac rehabilitation program at TCR is an exercise and education-based model where you will learn how to safely exercise and gain control of your cardiac risk factors over a 12-week period. The program begins with a graded exercise stress test, where if safe, you can begin weekly supervised aerobic exercise for 6 weeks. These exercise sessions will take place at the MNP Community & Sport Centre Gym (located at 2225 Macleod Trail SE, Calgary), range from 15-60+ minutes based on your fitness level, and involve aerobic-based exercises using machines like treadmills, ellipticals, and bicycles. Concurrently, you will be encouraged to partake in virtual classes reviewing exercise, heart healthy eating, understanding medications, and stress management. For the remaining 6 weeks of the 12-week program, you will exercise from home and meet virtually once a week for patient-led group discussions on topics such as sleep hygiene and progressing your exercise. Following the 12 weeks of cardiac rehab, you will be invited to complete a 12-week stress test to evaluate your progress. You will also be invited to complete stress tests at 24-weeks, 1-year, and 2-year timepoints to monitor your progress over time.

While participating in the cardiac rehabilitation program, you will be asked to keep a log of your structured exercise activity daily and send this log to the study team weekly. The study team will review your TCR medical chart to monitor your progress while in the TCR program and obtain data from your stress tests to measure the program's impact on your cardiac fitness. Other data from your TCR medical chart, such as blood pressure, lipid profile, BMI, waist circumference and CRF collected by TCR medical staff as standard of care, may also be used further to analyze the impact of the cardiac rehabilitation program. The final analyses will de-identify all data obtained from your TCR medical chart.

The BWLT program consists of twelve 2-hour group-based weekly sessions that are provided virtually using Zoom videoconferencing software. You will need to have a computer or smartphone with a camera and microphone to take part. After the first 12 weeks, there will be six biweekly follow-up sessions. These sessions will alternate between individual phone-based sessions and group-based sessions, for an additional 12 weeks. You will also need to be physically within the province of Alberta while you take part in the BWLT sessions. The BWLT sessions will cover nutrition, physical activity, sleep, stress, body image, and more. In each session, you will be asked to set health goals and make small changes to your health habits to encourage weight loss. You will also be asked to weigh yourself weekly using a smart scale and wear a fitness tracker so that we can track your daily step count. **A FitBit Aria Air scale and Fitbit Charge 5 fitness tracker will be provided to you if you are randomized to the BWLT program, and will be yours to keep at the end of the study.** In order to use these devices, you will be required to download the FitBit app and the study team will setup FitBit accounts on your behalf. The study team will have access to data that is collected through the FitBit Aria Air scale and Charge 5 fitness tracker.

**Everybody participating in the study will also be given an AliveCorTM KardiaMobile device for daily heart monitoring.** You will be instructed on its use, which will involve recording two separate 30-second electrocardiograms (ECGs) twice a day for 1 year starting from the day you complete baseline assessments. The purpose of these recordings is to measure your AFib burden. In order to use this device, you will be required to download the Kardia app. The study team will provide instructions on creating Kardia accounts, and will have access to the data that is collected by the KardiaMobile device. **This device will be yours to keep at the end of the study.**

Additionally, you will be asked to complete a series of questionnaires three times during this study: before you start the 12-week BWLT program or treatment as usual, at the end of the first 12-weeks, and at the very end of the study (approximately 24-weeks). The questionnaires will ask about your mood, your AFib symptoms, your eating habits, and your quality of life. The questionnaires also ask for some personal information (e.g., marital status, income, race) so we can describe the group of people who completes this study. Each questionnaire package will take about 25 minutes to complete. If you joined this study after being referred from TotalCardiology, the study team may also obtain or verify information about your diagnosis, rehabilitation, risk factors, and treatments from your TotalCardiology Rehabilitation medical chart.

All participants in the study will also be completing a sociodemographic questionnaire at the beginning of the study to determine data such as age, sex, gender identity, race/ethnicity, income, and education.

**WHAT WILL HAPPEN WHEN I AM FINISHED THE STUDY?**

At the end of the full 24-week program you will be asked to fill out the same questionnaires that you completed at the start of the study, and answer some questions about your satisfaction with the BWLT program. Afterwards, you will only need to continue to complete two 30 second ECG tracings use the provided KardiaMobile device twice daily until a year has passed since you first started the program. If you found the BWLT beneficial, you are free to use the materials to continue the exercise and eating habits you learned on your own.

**HOW LONG WILL I BE IN THIS STUDY?**

You will be in this study for about 1 year, or until the final follow questionnaires have been completed.

**ARE THERE ANY POTENTIAL RISKS OR DISCOMFORTS THAT I CAN EXPECT FROM THIS STUDY?**

There are very few risks to taking part in this study. You may be asked to talk about your weight or physical and emotional problems you are experiencing. This can be uncomfortable or distressing to some people. You may pass on any question you do not feel comfortable answering. If you have health questions beyond the scope of this study, the researcher will connect you to other resources (as appropriate) which might include your CR team, your doctor, emergency services, and/or community supports.

In terms of physical risks, you may feel physical stress or fatigue while taking part in the TCR program. Medical supervision of CR exercise sessions is a key component of the TCR program. Given the professional instruction and supervision that you will receive when performing exercises, the risk for injuries is extremely low. Should any injuries or health concerns arise, the researcher will connect you to other resources (as appropriate) which might include your CR team, your doctor, emergency services, and/or community supports.

If you experience any distress as a result of this study, there are a number of resources you may find helpful, such as the Alberta Mental Health Hotline (1-877-303-2642 - toll-free). If you feel particularly distressed and need emergency services, please go to the nearest hospital emergency department. You can also call the Calgary Distress Centre (403-266-1605).

**ARE THERE ANY POTENTIAL BENEFITS IF I PARTICIPATE?**

If you agree to take part in this study, you may feel better emotionally or lose a moderate amount of weight. Weight loss has been shown to improve AFib symptoms in past studies, therefore you may experience some relief from your AFib symptoms. It is possible you will not experience any benefits.

**WHAT OTHER CHOICES DO I HAVE IF I CHOOSE NOT TO PARTICIPATE?**

If you chose not to take part in this study, you will continue to receive the usual standard of care from your medical team. Your medical care will not be affected in any way if you choose to not take part or if you withdraw your consent later. You can also choose to continue with your CR program on its own and not take part in the BWLT classes provided by this study. CR alone has been shown to provide some benefits to people with AFib.

**CAN I STOP BEING IN THE STUDY?**

Yes. You can decide to stop at any time. Tell the study coordinator if you are thinking about stopping or decide to stop. There are no risks to you if you decide to stop the study.

# WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT ME?

During the study, the researchers could learn something about you that they didn’t expect. For example, the researchers may identify other arrhythmias using the KardiaMobile device or identify ischemic heart disease during the stress tests that happen during CR. The researchers will consult with medical experts as needed to evaluate the findings and will then share these results with you. You will be helped with arranging appropriate follow up and care.

I consent for the researchers to share findings with me:

❑ YES

❑ NO

**WITHDRAWAL OF STUDY DATA**

If you withdraw from the study, you can ask to have your data removed from our records at any time before the final data analysis is complete. If you wish to have your data removed, please tell the study coordinator when you stop the study. Your information cannot be withdrawn from the study after the final data analysis is complete.

**WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?**

You will not be paid for your participation in this research study. You do not have to pay to take part in this study, and there are no anticipated parking costs. You will not be reimbursed for any out-of-pocket expenses. The research team is not responsible for any costs you might incur related to technology, internet, mobile phone charts, parking, or transportation fees. You are encouraged to check with your Internet and phone plan to avoid unexpected costs from the Zoom videoconferencing sessions.

**WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?**

The researchers will do their best to make sure that your private information is kept confidential, unless required by law. Information about you will be handled as confidentially as possible, but there is always the potential for an unintended breach of privacy. We will conduct the group sessions using Zoom, accessed through a password-protected university account. Zoom has high-level security precautions built in so your confidentiality is protected. We will record the sessions using the Zoom recording feature. Electronic recording files will be encrypted, password protected, and stored on a secure University of Calgary server. The recordings will be reviewed by our research team and permanently deleted 5 years following the completion of the study.

Any data acquired from your Total Cardiology Rehabilitation (TCR) medical chart will be de-identified before it is extracted from TCR’s electronic medical record system and stored on an encrypted, password-protected server at the University of Calgary.

Data from both the Fitbit Charge 5 fitness trackers and Fitbit Aria Air scales will be synced to online password-protected accounts managed by our study team. Data from each account will only be linked to a Study ID, meaning that none of your identifiable information will be linked to the account. The study team will disable geolocation and heart rate monitoring features on the device, and instruct you on disabling geolocation when connecting the device to the Fitbit app on your phone. You will be encouraged to remove the Fitbit when sleeping to ensure that your sleep data is not recorded. In combination, these measures will ensure that your data is anonymized to everyone except the study team. Fitbit also has high-level security precautions built in so your confidentiality is protected. Weight and step-count data will be exported and saved in our secure REDCap database, while any other data will be discarded. Our team will delete all participants’ Fitbit accounts after the completion of the study, at which point Fitbit will discard the data between 30 – 90 days of the request. Further details regarding Fitbit’s privacy policy can be accessed on their website (<https://www.fitbit.com/global/en-ca/legal/privacy-policy>).

Additionally, data from the AliveCor KardiaMobile EKG device will be accessible to the study team through online password-protected Kardia accounts. AliveCor has high-level security and privacy precautions in place to ensure that your confidentiality is protected. Identifiable information will only be shared with the study team and healthcare professionals, and EKG tracings will be downloaded and saved in secure password-protected University of Calgary servers. Further details regarding the AliveCor privacy policy can be accessed on their website (<https://www.kardia.com/privacy/en>).

The research team will handle data according to the Data Management Plan as outlined below:

Only the research team will have access to the information you provide. Your name and other identifying information will not be linked with the data we gather. You will not be identified as an individual in any report coming from this study. Only group summary information will be used in presentations or publication of results. Any paper forms that have your name will be stored in a separate locked cabinet so it cannot be linked to your interview or questionnaire answers. All study forms will be kept in a locked cabinet in a secure office within the Department of Psychology at the University of Calgary (2500 University Dr. NW, Calgary, AB).

**HOW LONG WILL INFORMATION FROM THE STUDY BE KEPT?**

After data collection for the study is complete, de-identified data will be stored indefinitely on an encrypted drive. Data with identifying information will be retained for 5 years and then destroyed. All data obtained from this study may be used for future analysis without obtaining further consent from you. However, each study arising as a result of information obtained in this study will be submitted for ethics approval. The University of Calgary Conjoint Health Research Ethics Board (CHREB) will have access to the records. Authorized representatives from the University of Calgary and the Conjoint Health Research Ethics Board may look at your identifiable medical/clinical study records held at the University of Calgary for quality assurance purposes.

**USE OF DATA FOR FUTURE RESEARCH**

My deidentified research data may be kept for use in future research to learn about, prevent or treat other health-related problems.

\_\_ YES \_\_ NO

**CONTACT FOR FUTURE RESEARCH**

University of Calgary researchers may contact me in the future to ask me to take part in other research studies.

\_\_ YES \_\_ NO

**WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?**

**The Research Team:**

You may contact Jasleen Kaur at (403) 702-5295 with any questions or concerns about the research or your participation in this study.

**Conjoint Health Research Ethics Board (CHREB):**

If you have any questions concerning your rights as a possible participant in this research, please contact the Chair, Conjoint Health Research Ethics Board, University of Calgary at (403) 220-7990.

**HOW CAN I FIND OUT ABOUT THE STUDY RESULTS?**

If you are interested in learning about the results of the study, please let the research coordinator know before you finish the study. When the study is complete, the research coordinator will email you a summary of the results.

**WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?**

Taking part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you.

* You have a right to have all of your questions answered before deciding whether to take part.
* Your decision will not affect the standard medical care you receive [or your education or employment, as relevant]
* If you decide to take part, you may leave the study at any time.

# HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

Typing your name in full on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate as a participant. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care.

**YES, I consent to participate in the study.**

Your full name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Today’s date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

You may print out a copy of this signed consent form for your reference.

This study has been approved by the University of Calgary Conjoint Health Research Ethics Board (REB22-0976).