

Participant Information Sheet

Study title: *Evaluating BBM Motivation: a community-based,
Pacific-driven approach to health*

Locality: Auckland

Ethics committee ref.: 21/STH/122

Lead investigator: Fa'asisila Savila

Contact phone number: 027 635 8829

Kia ora and warm Pacific greetings. You are invited to take part in research evaluating the value of BBM Motivation for the health and wellbeing of the community it serves. Participation is voluntary (your choice) and you may withdraw from the study at any time without giving a reason. Non-participation or withdrawal will not affect your health care or your relationship with BBM Motivation.

This Information Sheet will help you decide if you'd like to take part. We will guide you through the information and answer any questions you may have. You do not have to decide to participate today. Feel free to talk about the study with other people, such as family/whānau, friends, or healthcare providers.

If you agree to take part, you will be asked to sign a Consent Form. You will be given a copy of both forms to keep. Please make sure you read and understand all the information. Only individuals able to give independent full informed consent will be enrolled into the study.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to understand the clinical value of BBM's **From The Couch** programme for its members. Information from this study will help BBM improve its programmes to improve long term health benefits for staff and members.

This study has been approved by the Health & Disability Ethics Committee on 30 June 2021.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Taking part involves answering some questions about your quality of life (wellbeing) and will have your height and weight measured. This will all take approximately 15 minutes. We ask your permission to use all information already collected by BBM since the time you registered to join BBM. We will invite you to answer the same questions and be measured in 12 weeks, six months, one year and two years' time.

We will also ask you to provide your National Health Index (NHI) number to access health information from National Health Datasets and your doctor. **We also ask your permission to access your health information in one year and in two years' time.** This will give us a better understanding of your health conditions, medications, and events, which will allow us to study health changes in relation to your engagement with BBM.

You will be provided with a small koha/token at study completion, to acknowledge your time given for the study.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

We do not foresee there being any risks with taking part in this study. However, some people may find answering questions about physical and mental health an emotional process, see ***Who do I contact for more information or if I have concerns*** on the page 3 below.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small but may increase in the future as people find new ways of tracing information.

Possible benefits of taking part in this study may only be indirect by helping BBM improve their systems and programmes for members. Findings from this study may also inform health benefits for the wider community.

WHAT WILL HAPPEN TO MY INFORMATION?

Information that could identify you (identifiable data) will include your name, contact details, NHI number and medical history. Your identifiable data will be used only for this study. Once you sign the consent form, an identification (ID) code will be assigned to your name. Information collected using your NHI will have identifying data removed (de-identified). The de-identified data will be placed against your ID code and entered into a database (coded data).

All of your digital information will be stored in a password protected folder on a secure university network drive and only accessible by research staff on this study. Coded data will be summarised, so it does not show your personal data in any reports, publications, or discussions about the study. All coded data may be used for future research about the BBM programme and other health related research. If you withdraw from the study, you may also withdraw any information collected about you.

All data recorded on paper including information linked to your ID code will be kept in a locked filing cabinet at the university and only the head researcher will have access to it. The consent form will only be accessed if the university, an ethics committee, or other monitoring body needs to check that the study has been carried out appropriately. Hard copy data will be destroyed after 10 years of storage.

WHO PAYS FOR THE STUDY?

This study is funded by the New Zealand Health Research Council.

WHAT ARE MY RIGHTS?

You have the right to accurate information about your health and to access any information collected about your involvement in the study. Your personal information will be kept confidential and unnamed; it will be summarised, so it does not show your identity in any reports, publications, or discussions about the study. If you withdraw from the study, you may also withdraw any information collected about you.

If you were injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

Your information will be stored securely for up to 10 years after which it will be destroyed. Dr Fa'asisila Savila will be responsible for the storage and erasing of your information at the end of this period. Dr Savila will also

Medical Programme

ID: _____

arrange for you to see the results of the study; these are likely to be available about one to two years after the start of this study.

If you agree to taking part now, but change your mind later, you can pull out of the study at any time.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns, or complaints about the study at any stage, you can contact:

Dr Fa'asisila ('Sila') Savila

OR

Georgina James

Phone number: 027 635 8829

Ph: 027 492 4837

Email: f.savila@auckland.ac.nz

Email: jorja@thebbmprogram.com

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050

Fax: 0800 2 SUPPORT (0800 2787 7678)

Email: advocacy@hdc.org.nz

For Māori health support please contact:

Dr Matire Harwood

Phone: +64 9 923 7866

Email: m.harwood@auckland.ac.nz

For Pacific health support please contact:

Dr Vili Nosa

Phone: +64 9 373 7599

Email: v.nosa@auckland.ac.nz

Consent Form



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Please tick to show that you consent to the following:

I have read, or have had read to me, in my first language, and I understand the Participant Information Sheet.

I have been given sufficient time to consider whether to participate in this study.

I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.

I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.

I understand that my taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care or my relationship with BBM.

I consent to the research staff collecting and processing my information, including medical history about my health.

I understand that my participation in this study is confidential and that no material, which could identify me or my family, will be used in any reports on this study.

I understand the compensation provisions in case of injury to myself during the study.

I know who to contact if I have any questions about the study in general.

If I decide to withdraw from the study, I agree that the information collected about myself up to the point when I withdraw from the study may continue to be processed.

I consent to my family doctor or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.

I wish to receive a lay summary of the results from the study.

Declaration to take part: I hereby consent to take part in this study.

Full name:	
Signature:	Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____