THE UNIVERSITY OF AUCKLAND
Te Whare Wānanga o Tāmaki Makaurau
NEW ZEALAND

MEDICAL AND HEALTH SCIENCES

PARTICIPANT INFORMATION SHEET

Project title: **The use of Nutrigenomics in Sport Nutrition**

Principal Investigator: Dr Andrea Braakhuis (The University of Auckland)
Research Team: Lillian Morton (Sport Nutritionist, Lillian Morton Nutrition), Tyla Goodsell-Matthews (The University of Auckland)

Research introduction and aim
Individual genetic variation can affect how people respond to food, beverages and supplements they consume. Some research shows athletes may be more motivated to adopt healthy dietary change when given specific information about their genes than when given general population-based advice.

Project description and invitation
You have been invited to participate because you are a regularly competing athlete who is interested in receiving sport nutrition advice. This study will involve you working with a research sport dietitian to support you to follow a healthy diet. You will be provided nutrition support based on current best practise guidelines which may or may not include the use of genetic test results. You will be placed into one of two groups, which will receive either the standard nutrition support for sport performance based on population-based evidence (standard care), or nutrition support which is personalised, genetic-based advice for sport performance (NSN). If you chose to participant in the study it will be random as to which group you are placed.

Nutrigenomix testing is a safe and non-invasive saliva collection kit developed for use by healthcare professionals to provide their clients with comprehensive, reliable, genomic information with the ultimate goal of improving the client's health and performance through the provision of personalised nutrition and physical activity recommendations. The Nutrigenomix test kit involves saliva collection, testing of the participant's DNA for specific nutrition-related markers, and generation of a personalised nutrition and fitness report. The test analyses variations in 70 genes that impact nutrient metabolism, eating habits, weight management and body composition, food intolerances and physical activity. The accuracy of the genetic test results is between 99.7 – 100%.

Project Procedures
In the first session, a dietary assessment (food frequency questionnaire) and body composition will be completed. A saliva test will be taken for the genetic testing. You may receive standard sport nutrition advice, OR sport nutrition advice tailored to your genetic test results.
Two weeks after the initial consultation all participants will be provided written dietary information based off the International Olympic Committee sport nutrition guidelines, but tailored to the individual circumstances. Results of the genetic test will be provided at this time. The results of the genetic test will be put into context and dietary advice adapted accordingly.
The intervention phase will be two months and will require weekly 24-hr recalls on different days of the week. At the end of the two month trial, a dietary assessment (FFQ) and body composition will be taken. Body composition will be assessed using skinfolds which estimates the percentage of body fat by measuring skinfold thickness at specific locations on the body.

The thickness of these folds is a measure of the fat under the skin, also called subcutaneous adipose tissue. Measurements will be taken in accordance with International Standard practice guidelines (ISAK) by certified measurers.
Any questions or concerns about the study will be discussed via email or phone prior to commencing. You will be provided information about the study, if you are satisfied with everything and agree to take part, we will ask you to sign the consent form (below) prior to testing. The provision of nutrition support will finish following the 2 month intervention.

Saliva
Your saliva sample will be used in analysis of various genetic markers related to nutrition and physical activity. The sample will be sent to the Nutrigenomix laboratory (Australia) for the genetic test.

The information collected in this study will only be used for this study and will be kept safe and securely for a total of 6 years. Your samples will be kept until the end of the analysis. At the end of this time a medical waste contractor will dispose of your tissue. Your samples analysed by Nutrigenomix will be destroyed. You can request a karakia be said at the time of your tissue disposal.

Many iwi, hapu, and whānau disagree with transport of saliva samples due to issues with the loss of rights to your whakapapa. However, it is acknowledged that individuals have the right to choose. These concerns may also apply to non-Māori. We encourage you to consult with your family or whānau before agreeing to participate, if you think this might apply to you.

Detection limitations
Nutrigenomix testing is not intended to prevent, mitigate, or cure disease. Nutrigenomix does not provide medical advice, diagnosis or treatment. The test looks at 70 genes that have been shown to modify response to dietary intake and/or to impact nutrition and physical activity recommendations. The development of chronic diseases can be influenced by many factors, including genetics, diet and lifestyle. Following the recommendations provided does not guarantee absence of disease. The test results are based upon probabilities, and may not provide a 100% definitive conclusion to either elevated or typical risk.

What if Something Goes Wrong?
The risks of participation are low and every precaution will be taken for your safety. If there happens to be a physical injury resulting from your participation in this study, you will be advised to visit a treatment provider to make a claim to ACC as soon as possible. ACC cover and entitlements are not automatic and your claim will be assessed by ACC in accordance with the Accident Compensation Act 2001. If your claim is accepted, ACC must inform you of your entitlements, and must help you access those entitlements. Entitlements may include, but not be limited to, treatment costs, travel costs for rehabilitation, loss of earnings, and/or lump sum for permanent impairment. Compensation for mental trauma may also be included, but only if this is incurred as a result of physical injury.

If your ACC claim is not accepted you should immediately contact the researcher. The researcher will initiate processes to ensure you receive compensation equivalent to that to which you would have been entitled had ACC accepted your claim.

You may have your friend, family, or whānau support help you understand the risks and/or benefits of this study or any other explanation you require. You are also welcome to have a friend, family, or whānau support with you during every session.

Right to Withdraw from Participation

You have the right to withdraw from this study at any time. Your contribution is entirely voluntary and if you chose to withdraw any remaining samples and data will be destroyed at that point, but data or samples that have already been collected and processed will continue to be used.

Anonymity, Confidentiality and Risks

Saliva samples will be coded and recorded against a randomly generated code to keep your identity confidential. Coding will be numerical and you will not be identifiable by this code. Each saliva sample is anonymized using a barcode and this is entered into a password protected online system. Nutrigenomix uses a Secure Socket Layer (SSL) protocol to encrypt information that is transmitted over the Internet. This technology uses 256-bit encryption, which ensures that confidential information and transactions cannot be viewed, intercepted or altered. Nutrigenomix will never reveal client information or genetic data to a third party except as required to provide the services requested, or as required by law. The only person able to link the code with your name is Dr Andrea Braakhuis who will keep the coding list in a locked filing cabinet. When the analysis is completed the researchers will analyse the whole group's data and report on averages. This data will be used for scientific publication and presentations. No person will be identifiable from the analysis. There is a risk that your data is delinked if The University of Auckland electronic systems are comprised and data from testing laboratories are linked to your identification.

Contact Details

For more information please contact:

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For concerns of an ethical nature, you can contact the Chair of the Auckland health Research Ethics Committee at ahrec@auckland.ac.nz, or at 373 7599 x83711, or at Auckland Health Research Ethics Committee, The University of Auckland, Private Bag 92019, Auckland 1142.

If you require Māori cultural support, talk to your whānau in the first instance. Alternatively, you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext 2324.

If you have any questions or complaints about the study, you may contact the Auckland and Waitematā District Health Boards Māori Research Committee or Māori Research Advisor by phoning 09 4868920 ext 3204.

APPROVED BY THE AUCKLAND HEALTH RESEARCH ETHICS COMMITTEE ON 3/3/2021 FOR THREE YEARS. Reference Number AH21599

CONSENT FORM
THIS FORM WILL BE HELD FOR A PERIOD OF 6 YEARS

Project title: The use of Nutrigenomics in Sport Nutrition

Principal Investigator: Dr Andrea Braakhuis (The University of Auckland)
Research Team: Tyla-Goodsell-Smith (The University of Auckland)

- I have read the Participant Information Sheet, have understood the nature of the research and why I have been selected. I have had the opportunity to ask questions and have them answered to my satisfaction.
- I agree to take part in this research.
- I have had the opportunity to use support from a family (whānau) member or a fried to help me ask questions and understand the research.
- I understand that I am free to withdraw participation at any time
- I understand that the saliva sample will be collected and used for research.
- I understand that samples will be sent to Australia for analysis and disposed of at the end of the study
  - I wish for a karakia said at the time of my tissue disposal (*please circle*). *Yes* *No*
- I wish to receive the summary of findings. I understand that there may be a delay between data collection and the publication and availability of the research results (*please circle as appropriate*). *Yes* *No*
- I understand that the results from this study will be used for scientific publication and presentations.

Name _____

Signature _____ Date _____

E-mail for the purposes of providing general study results:

_____

Researcher's Signature_____ Date _____

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