

Department of Psychology

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**Anxiety and Micronutrients:**

**A double blind, randomised controlled trial with zinc and vitamin B6**

**Consent Form for Participant**

* I have read and I understand the Participant Information Sheet
* I have had time to consider whether to take part.
* I understand what is required of me if I agree to take part in the research.
* I know who to contact if I have any questions about my rights or about the study.
* I have been given the opportunity to discuss the study with the investigator or anyone else I wished to speak to. I am satisfied with the information that has been provided and I have a copy of this consent form and information sheet.
* I understand that all information and samples that I provide and my participation in this study is confidential. I understand that no information that could be used to identify me will be used on any reports.
* I understand that my GP will be informed about whether or not I am eligible and participating in the study.
* I consent to my GP being informed of any significant outcomes that may arise.
* I understand the risks associated with taking part and how they will be managed.
* I understand that my participation in this study is voluntary and I understand that I can withdraw from the study at any time without any disadvantage.
* I understand that I can contact the researcher (Ben Warren 027 589 2006) or supervisor (Julia Rucklidge 03 369 4398) for further information.
* I know who to contact if I have any questions about the study, if I experience any side effects related to the study intervention, if I have any upcoming medical procedures or have been prescribed new medication, if anything occurs which I think would be a reason to withdraw from the study or if I experience an increase in symptoms.
* I agree to provide blood and urine samples and understand that the urine sample may be sent overseas for analysis.
* I understand my responsibilities as a study participant, the provisions which will be made for the reimbursement of expenses involved in this study and the compensation provisions in case of injury during the study.
* I understand that the intervention will be stopped if it should appear harmful to me.
* I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
* If I have any complaints, I can contact the Chair of the University of Canterbury Human Ethics Committee, Private Bag 4800, Christchurch ([human-ethics@canterbury.ac.nz)](mailto:human-ethics@canterbury.ac.nz)).

|  |  |
| --- | --- |
| I wish to receive a summary of the results from the study | Yes/No |
| I consent to the use of my data for future related studies, which have been given ethical approval from the Health and Disability Ethics Committee. | Yes/No |
| I consent to my name being placed in a separate database so that I can be contacted in the future should there be other studies which I might like to participate in, with the understanding that I can choose whether to participate in such studies or not. | Yes/No |
| If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed. | Yes/No |
| If I decide to withdraw from the study, I agree to being contacted one year after I started the study to collect follow up information. | Yes/No |

GP contact details:

Name:

Phone:

Surgery address (if known):

* By signing below, I agree to participate in this research project.

Name: Signed:

Date:

Email address (if you would like a copy of the results):

**This will be completed by the principal investigator after completion of your phone screening interview.**

**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.**

|  |  |
| --- | --- |
| **Yes 🞏** | **No 🞏** |

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

|  |  |
| --- | --- |
| **Yes 🞏** | **No 🞏** |

|  |  |
| --- | --- |
| Researcher’s name: | |
| Date: |  |

**ACTIVE CONDITION INGREDIENTS LIST**

|  |  |  |  |
| --- | --- | --- | --- |
| **Ingredient** | **Quantity per capsule** | **Quantity per serve** | **Serving size** |
| Zinc (as picolinate)  Vitamin B6 (as pyridoxine) and Vitamin B6 (as pyridoxal-5-phospate) | 25mg  100mg/50mg | 100mg  100mg/50mg | 5 capsules |

**PLACEBO CONDITION INGREDIENTS LIST**

|  |  |  |  |
| --- | --- | --- | --- |
| **Ingredient** | **Quantity per capsule** | **Quantity per serve** | **Serving size** |
| Maltodextrin, potato starch and cocoa | 500mg | 2500mg | 5 capsules |