

## **NUTRIMUM Trial: Study overview**

### **What is the purpose of the study?**

The Mental Health and Nutrition Research Group | Te Puna Toiora are conducting a clinical trial to see whether a vitamin and mineral (multi-nutrient) supplement can improve the wellbeing of pregnant women and the general health outcomes of their child.

The product being studied has been researched previously and has shown to have beneficial effects on low mood, anxiety, stress, bipolar disorder, insomnia, ADHD, autism, and post-traumatic stress symptoms in both children and adults who are not pregnant. The benefits of this particular formula have not yet been scientifically shown in pregnant people.

### **What product is being used in the study?**

The product used in this study is called *Daily Essential Nutrients* which contains a blend of various vitamins, minerals, amino acids and anti-oxidants, also known as multi-nutrients. The ingredients are typically consumed in a well-balanced diet.

In order to determine whether or not the multi-nutrients work, they are being compared to an iodine supplement. Both the multi-nutrient and iodine products are consumed orally, usually at a dose of four capsules, three times per day (a totally of 12 capsules per day). Each contain the New Zealand Ministry of Health recommendation of supplemental iodine during pregnancy and lactation.

### **How is the product being studied?**

In order to show the effect of the micronutrients, this study will use the best method of investigation known as a double-blind randomised controlled trial. This means that participants will be randomly allocated to take either the multi-nutrient or iodine capsules and therefore have a 50 % chance of receiving either supplement. Since the study is double-blind, this means that neither the participant nor the researchers involved in the study will know which supplements participants are taking until the study has finished.

### **What does participation involve?**

Participants will take either the micronutrient or iodine capsules for 12 weeks. After 12 weeks, **all** participants have the opportunity to try out the multi-nutrient product which will be provided either until birth or up to 6 months after birth.

Throughout the duration of their pregnancy, participants will be required to complete assessments over the phone/video calling and via an online every four weeks and complete a brief 10 minute online questionnaire two weeks later. The researchers would also like to follow up with all participants one month, six months and twelve months after their baby has arrived.

### **What are the risks?**

The multi-nutrient product being used in this study has been shown to be safe in children and adults with very little side effects, if any. For those who do report side effects, the most common include nausea and headaches; however these can be avoided by taking the capsules on with food. We therefore suggest that you *always take your capsules with food and plenty of water.*

Like anything consumed during pregnancy, the ingredients contained in the study supplements will be exposed to the foetus. No adverse effects on the foetus or mother have been reported in previous research using doses of single nutrients that are similar or higher to the doses contained in the supplements being studied. Furthermore, taking the nutrients from the second trimester onwards reduces the risk of congenital abnormalities and other foetal complications as the foetus has already gone through its most vital stages of development.

### **What are the benefits?**

There may or may not be any benefit to you as a result of taking part in this study. Previous research has shown beneficial effects of multi-nutrient formulas on mood and anxiety in children as well as in adults who are not pregnant. The research suggests that symptoms of low mood and anxiety may improve as a result of taking the product; however, there is no guarantee that your symptoms will improve and you may experience an increase in your symptoms. Some people find that having their symptoms monitored over time can in itself be therapeutic.

### **Does it cost to participate?**

Participation in this study will not incur any costs to you. Both the micronutrient and iodine supplements are provided free of charge. You will receive a \$10 petrol voucher for any visit to the university in order to reimburse transportation costs. As a thank you for taking part and congratulations on the arrival of your baby, you will be gifted a mothers and babies gift package.

### **Who is eligible to take part?**

A diagnosis of depression or anxiety is **NOT** required for entry into this study.

We are looking for pregnant women who are:

- 16 years of age or older
- 12 - 24 weeks pregnant
- Having one baby
- Living in New Zealand
- Feeling low in mood, anxious, irritable, overwhelmed, worried or on edge.\

## How do I take part?

If you're interested in taking part, you first need to register your interest via an online questionnaire which can be found on the following link or on the NUTRIMUM webpage.

[http://canterbury.qualtrics.com/jfe/form/SV\\_5auSZkmA4hqbwod](http://canterbury.qualtrics.com/jfe/form/SV_5auSZkmA4hqbwod)

The questionnaire will assess your eligibility to take part in the trial and should take approximately 10 minutes to complete. There is an option to save your responses and return to the questionnaire at a later time should you wish. After completing the questionnaire, a researcher will contact you regarding your eligibility to participate in the trial.

For more information about the trial or if you have any questions, please don't hesitate to contact the research co-ordinator, Hayley Bradley on the following details:

Phone: 03 369 2386

Email: [hayley.bradley@pg.canterbury.ac.nz](mailto:hayley.bradley@pg.canterbury.ac.nz)

*This study has been given ethical approval by the Southern Human and Disabilities Ethics Committee and the Standing Committee on Therapeutic Trials (Medsafe). The study has also received approval from the Human Ethics Committee and the Ngāi Tahu Consultation and Engagement Group at the University of Canterbury and the research committee at the New Zealand College of Midwives.*

## Ingredients: Micronutrient formula

Ingredients:	1 capsule	12 capsules
Vitamin A (as retinyl palmitate)	480 IU	5,760 IU
Vitamin C (as ascorbic acid)	50 mg	600 mg
Vitamin D (as cholecalciferol)	250 IU	3,000 IU
Vitamin E (as d-alpha tocopheryl succinate)	30 IU	360 IU
Vitamin K (75% as phylloquinone; 25% as menaquinone-7)	10 mcg	120 mcg
Thiamin (as thiamin mononitrate)	4 mg	60 mg
Riboflavin	1.5 mg	18 mg
Niacin (as niacinamide)	7.5 mg	90 mg
Vitamin B6 (as pyridoxine hydrochloride)	5.8 mg	69.9 mg
Folate (as L-methylfolate calcium)	66.8 mcg	801 mcg
Vitamin B12 (as methylcobalamin)	75 mcg	900 mcg
Biotin	90 mcg	1080 mcg
Pantothenic acid (as d-calcium pantothenate)	2.5 mg	30 mg

Calcium (as chelate)	110 mg	1,320 mg
Iron (as chelate)	1.15 mg	13.8 mg
Phosphorus (as chelate)	70 mg	840 mg
Iodine (as chelate)	17 mcg	204 mcg
Magnesium (as chelate)	50 mg	600 mg
Zinc (as chelate)	4 mg	48 mg
Selenium (as chelate)	17 mcg	204 mcg
Copper (as chelate)	0.6 mg	7.2 mg
Manganese (as chelate)	0.8 mg	9.6 mg
Chromium (as chelate)	52 mcg	624 mcg
Molybdenum (as chelate)	12 mcg	144 mcg
Potassium (as chelate)	20 mg	240 mg

**Proprietary blend ingredients:**

Choline bitartrate, Alpha-lipoic acid, Mineral wax, Inositol, Acetyl-L-carnitine, Grape seed extract, Ginkgo biloba leaf extract, L-methionine, N-acetyl-L-cysteine, Boron (as chelate), Vanadium (as chelate), Lithium orotate (as chelate), Nickel (as chelate)

**Other ingredients:**

Vegetarian capsule (hypromellose), Microcrystalline cellulose, Magnesium stearate, Silicon dioxide, Titanium dioxide

**Ingredients: Iodine formula**

<b>Ingredients:</b>	<b>1 capsule</b>	<b>12 capsules</b>
Riboflavin	0.1 mg	1.2 mg
Potassium Iodide	12.5 mcg	150 mcg
Silicon dioxide	2.5 mg	30 mg
Magnesium stearate	5 mg	60 mg
Microcrystalline cellulose	500 mg	6 g

**Thank you for your interest in this study**