

Evaluation of the psychoneuroimmunological state of healthy humans following intramuscular injection of the influenza (FluQuadri™) vaccine, a two-way crossover double-blinded placebo-controlled trial

ACTRN12623000650695

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| Status | RECRUITING |
| Sponsor | Australian Government, Department of Defence (Defence Science and Technology Group, DMTC) |
| Enrollment | 40 participants |

Plain Language Summary

When we get sick, our body goes through a series of changes — in how we feel, think, move, and communicate — that are the early warning signs of illness. This study is trying to map these changes precisely by tracking a range of measures in the hours after the immune system is triggered by a flu vaccine. By understanding what normal immune activation looks like across physical, cognitive, and emotional dimensions, researchers hope to develop better tools for detecting illness early.

Healthy volunteers will receive a standard flu vaccine (or a placebo injection at a separate visit) and be monitored intensively for up to 8 hours afterward, undergoing tests of physical performance (walking, sit-to-stand), cognitive tasks, eye tracking, speech and voice analysis, and brain activity measurements using EEG — all while vital signs are recorded.

You may be eligible if you are a healthy adult aged 18 to 40, are a non-smoker (or have not smoked for 3 months), have a BMI between 18.5 and 29.9, are willing to receive the flu vaccine, and do not have any neurological or mental health conditions. People with a history of severe allergic reactions to vaccines, egg allergy, or who are pregnant or trying to conceive are not eligible.

Key Eligibility Criteria

Inclusion (6)

- Healthy participants aged between 18 and 40 years.
- No history of seizures, head injury or head physiognomy (head shape) that would preclude EEG cap placement.
- Able to provide written and informed consent in English.
- Are willing to receive the influenza vaccination during the trial.
- Body weight greater than 50 kg (minimum blood donation weight set by the Red Cross Blood Bank); BMI index between 18.5-29.9.

... and 1 more (see full listing online)

Exclusion (13)

- Have been diagnosed with neurological conditions or neurodegenerative diseases, such as depressive, anxiety or post-traumatic stress disorder, sleep conditions, or Attention Deficit Hyperactivity Disorder (ADHD) and Autism Spectrum Disorder.
- week exclusion for vaccination of any type, if infected with Covid or influenza during the testing period, adjustments will be made to the testing protocol to allow for recovery from infection.
- Have received an immunisation for the influenza strains contained within the current year's influenza vaccine formulation.
- Participants have had a positive test response for active influenza infection during the same season.
- Have medical conditions which preclude them from having an influenza vaccination.

... and 8 more (see full listing online)

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12623000650695>

Locations (1 total)

SA, Australia