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## AU-ARROW

*(AU-ARROW full title: The AUstralian-Multidomain Approach to Reduce dementia Risk  
by prOtecting brain health With lifestyle intervention study.)*

### General background and study summary

Despite decades of medical research, there are currently no effective treatments for Alzheimer's disease symptoms, or to stop the advance of the disease. More recently, the focus of research has shifted to prevention. In the case of Alzheimer's disease, it is now known that the disease develops for many years in the brain before symptoms are experienced – this information has been discovered due to specific brain imaging tests that can now pick up the damage many years before symptoms start. Slowing down the development of Alzheimer's disease would delay the time at which symptoms appear or even prevent the occurrence of this disease, thus improving the quality of life of an affected person, as well as that of their family and friends.

Many recent studies have shown that simple lifestyle changes can improve brain function, and may also delay the onset or reduce the risk of cognitive decline and dementia. Although individual lifestyle changes have been shown to provide such benefits, the most effective improvements have been seen when combinations of lifestyle changes have been implemented (multidomain lifestyle changes). For example, studies which have looked at the effect of increasing exercise levels, *in combination* with regular brain training, have found that the improvements to brain function are greater when compared to only increasing exercise, or doing regular brain training, on their own.

One recent multidomain lifestyle study carried out in Finland combined regular exercise, dietary changes, online brain training and regular health monitoring. Participants in this study were monitored for two years, and the main aim of the study was to determine if the combination of those four lifestyle changes could significantly reduce decline in brain function, and promote brain health, as well as overall health and functioning. The participants were healthy older adults who would otherwise be at higher-than-average risk of significant memory problems and later dementia. The clinical trial was known as the "Finnish Geriatric Intervention Study to Prevent Cognitive Impairment and Disability (FINGER) study", and its success has led to the world-wide collaboration aimed at testing whether similar positive results can be obtained in other countries and cultures around the world. A similar study led by the United States known as the US-POINTER (U.S. Study to Protect Brain Health Through Lifestyle Intervention to Reduce Risk) study began in 2019. This AU-ARROW study is the Australian version of the FINGER study and is closely aligned to the study in the US. Other countries or regions which have already carried out or are in the process of setting up similar studies include China, Singapore, Taiwan, Japan, Germany, Canada, Latin America, and Spain.

### AIM OF THE AU-ARROW STUDY

In this study, we aim to investigate whether changes to lifestyle factors in combination with regular health monitoring can have a positive influence on specific brain functions including memory. A positive outcome would give more evidence that lifestyle changes that are relatively easy to adopt can help to prevent or delay brain function decline and dementia, such as Alzheimer's disease dementia, in an Australian population.

## STUDY OVERVIEW

This 2-year study is investigating whether a combination of specific lifestyle changes, and regular health monitoring, will help to preserve brain function and reduce the chance of developing Alzheimer's disease. There are no medications or drugs being tested in this trial, just changes in lifestyle and regular health monitoring.

If you are enrolled in the study, you will be RANDOMLY ALLOCATED to one of two groups, these are described below:

### Group 1: Multidomain Lifestyle Intervention Group

If you are in this group, you will be asked to adopt specific lifestyle changes which include:

- increased physical activities,
- dietary changes,
- brain training exercises,
- increased social engagement and
- the regular monitoring for risk factors that are related to Alzheimer's disease such as heart disease, diabetes type 2, and hypertension.

In the Multidomain Lifestyle Intervention group, you will also attend regular group meetings, which involve information sessions and/or group discussions. If you are allocated to this group, there is a considerable time commitment, you will need to allocate approximately 2 hours per day, 5 days a week to the activities of the study.

In the Multidomain Lifestyle intervention group, you will be introduced slowly to specific lifestyle changes over the first 16 weeks, in a group of 15-20 people, with the goal of maintaining these lifestyle changes for the remaining 20 months of the trial. The changes will include regular physical exercise at a gym, dietary improvements, and computer-based brain training. You will also be encouraged to monitor some health risk factors regularly, such as your blood pressure.

Following the start of these changes, monthly meetings with your group will then occur. At these monthly meetings, we will provide with further information on the benefits of the various aspects of the lifestyle intervention and how they will reduce your risk of cognitive decline. The meetings will involve talks and/or group discussions with either a trial research assistant, exercise physiologist or dietitian, to discuss your progress and challenges along the way. Other support will also be available over the 2 years of the trial via phone or email, to provide information and encouragement.

### Group 2: Health Education and Coaching Group

If you are allocated to the Health Education and Coaching group in the study, you will be asked to attend group meetings which involve information sessions and group discussions. The group meetings of 15-20 people will occur every 3-5 months to provide general health education and coaching to promote the benefits of exercise, diet and cognitive activity, and to discuss potential goal-setting. Other support will also be available over the 2 years of the trial via phone or email, to provide information and encouragement.

### For Both Groups

No matter which group you are in, you will receive routine blood tests every 6 months, to test for general health indicators, such as blood cholesterol levels and glucose levels. You will also undergo a physical assessment, and you will be asked to undergo 6-monthly assessments of your memory and thinking skills, and to fill out questionnaires about your lifestyle, activities, sleep, mood and quality of life. Once the blood test results are available, you will be given a consultation with a clinician to discuss your results. The clinician meetings will happen 6-monthly for the Multidomain Lifestyle intervention group, and yearly for the Health Education and Coaching intervention group. You will also be provided with activity trackers (Fitbits).

You will also be asked to fill out 3 questionnaires online at the 3, 9, 15 and 21-month time points, that will cover aspects of your diet, physical, social and mentally stimulating activities, and any medication changes. This brief review of any lifestyle changes does not require any visit to the study site, and will take approximately 30 minutes to complete.