# EXPLANATORY STATEMENT

**Stroke patients – male and female volunteers**

**Project ID: 37746**

**Project title: Nut supplementation to mitigate post-stroke cognitive decline (NUT-me): a pilot study**

**Chief Investigator**

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You are invited to take part in this study. Please read this Explanatory Statement in full before deciding whether or not to participate in this research. If you would like further information regarding any aspect of this project, you are encouraged to contact the researchers via the phone numbers or email addresses listed above.

**What is the aim of the study?**

Stroke is a strong risk factor for dementia, with up to 80% of individuals having lower cognitive function 5 years after a stroke event. However, having a stroke does not need to result in declining cognition if we can identify effective strategies to reduce the risk of post-stroke dementia. Diets containing nuts can reduce the risk of both dementia and stroke, but have not been tested in stroke survivors. Therefore, this pilot study aims to determine whether eating nuts regularly reduces post-stroke cognitive decline and dementia. The NUT-me pilot study will supplement the diet of stroke survivors with a mix of nuts containing walnuts, hazelnuts, almonds and Brazil nuts for 3 months and assess the effects on cognition and health markers.

**What does the research involve?**

The research will involve you attending the Be Active Sleep Eat (BASE) facility on four occasions, two of them for a short session (30 min) and two for a long session (3 hours). In the first visit, you will be randomised into one of the study groups: Nut or Control. Participants in the Nut group will be asked to consume 30g of a mix of nuts containing 1 Brazil nut, walnuts (15g), hazelnuts (7g), and almonds (7g) daily for 90 days. The nuts will be provided by the research team, so you don't need to buy anything. Participants in the Control group will be asked to not consume nuts for the period of the study. Regardless of the group you are allocated in, you will receive two 1:1 dietary counselling on how to improve your diet to follow the Australian Dietary Guidelines. You will be asked to perform a battery of cognitive tests using an Ipad in the first and the fourth visit for comparison of the results.

The four visits will be as follows:

Visit 1: You will be asked to fill out three questionnaires asking about some demographic information, medical history, physical activity and how you feel in general. The researcher will measure your blood pressure, body composition, height and weight. You will be asked to complete the cognitive tests. You will receive instructions to fill

out the 3-day 24h dietary recalls and will receive the first 1:1 dietary counselling session. The Nut group will receive bags with daily portion of nuts for 45 days. You will be at the BASE facility for around 3 hours.

Visit 2: this visit should happen within a week of the first one. You will be asked to arrive fasted in the morning and the researcher will collect a sample of your blood. You will return the 3-day 24h dietary recall. You will be at the BASE facility for around 30 minutes.

Visit 3: This visit should happen between days 35 and 44 of the study. You receive the second 1:1 dietary counselling session. If you are in the Nut group, the researcher will check your compliance by counting the returned nuts and will give you a second allotment of nuts for the second half of the study. You will be at the BASE facility for around 30 minutes.

Visit 4: This visit should happen between days 90 and 100 of the study. You will be asked to arrive fasted in the morning for a second blood collection. The researcher will measure your blood pressure, body composition and weight. They will also ask you to bring the second 3-day 24h dietary recall and to answer the some questionnaires. You will also perform the cognitive tests.

The research team may contact you in between visits to confirm your appointments.

**Criteria for inclusion in the research**

We are looking for people who have had a stroke in the last 6 months. To ensure that only suitable participants are included, we have a number of criteria that must be met. Please advise the researcher if you do not meet any of the following criteria:

- ≥ 18 years;
- do not have allergy to nuts
- have severe disability denoted by premorbid modified Rankin scale (mRS)>4
- not consuming nuts (>2 servings/wk) habitually in the previous 2 months
- not taking alpha-linolenic acid supplements (fish oil, flaxseed oil, and/or soy lecithin)
- no dementia or psychiatric disease
- no mastication issues
- can give consent
- speak English

**Blood samples**

We will collect a sample of blood at the start of the study and another at the end. The blood samples will be stored in de-identified tubes in a freezer until analysis – after analysis, they will be disposed of. These samples will be used to measure glucose, insulin, blood lipids and inflammatory markers.

**Consenting to participate in the project and withdrawing from the research**

In order to participate in this study the written consent form must be read, signed and returned to the researchers. Participation in this research is voluntary. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you choose to leave the study early, we would like to know your reason for discontinuing.

**Possible benefits and risks to participants**

Participating in this study brings no direct benefit to you, but knowledge generated from this study will help the researchers understand if nut is a feasible strategy to mitigate post-stroke cognitive impairment. You may also gain a sense of satisfaction from generating new knowledge by participating in this study.

The risks of this study are minimal as most measurements are going to be taken by using non-invasive methods. There is a chance that bruising may occur from blood sample collection but this risk is minimised as blood collection will be conducted by trained personnel.

**Confidentiality**

Any information obtained in connection with this project that can identify you will remain confidential. This information will only be disclosed with your permission or as required by law. Your name will be assigned a code, which will be used in discussing data, so that your identity is not disclosed. Only de-identified results will be presented in meetings, conferences, as part of a thesis or published in scientific journals or reports.

**Storage of data**

The data will be stored for at least 5 years on secure Monash University servers accessible only to members of the research team (current and future).

**Use of data for other purposes**

In accordance with National Health and Medical Research Council Statement on Data Sharing, de-identified data may be made available for use by the other researchers. This data will be held on secure public repositories and may be a requirement of some journals prior to publication. Any shared data will not include your identifying details.

**Results**

If requested, participants will be given their body composition results at the end of the study. If you would like to receive a report of the research findings please contact Barbara Cardoso, using the contact details listed above. The findings are accessible for 6 months following completion of the study.

**Complaints**

Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Executive Officer, Monash University Human Research Ethics Committee (MUHREC):

Executive Officer
Monash University Human Research Ethics Committee (MUHREC)
Office of Research Ethics and Integrity
Room 116, Administration Building B (3D)
26 Sports Walk, Clayton Campus
Monash University VIC 3800

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Thank you,

Dr Barbara R Cardoso