

Royal North Shore Hospital and the University of Sydney

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

**INTERVENTIONAL STUDY**

**Determining the effects of statins on cognition in older adults**

**Invitation**

You are invited to participate in a research study, looking at the effects of cholesterol-lowering medications, called statins, on memory (cognition) in older adults living with dementia. Currently, information about the use of statins is unclear and this study aims to generate evidence surrounding the suitability of using this class of drugs in older adults living with dementia.

This study is being conducted by:

* Dr Danijela Gnjidic, Research Fellow and Lecturer, University of Sydney
* Professor Sarah Hilmer, Professor of Geriatric Pharmacology and Aged Care Specialist, University of Sydney and Royal North Shore Hospital
* Professor Sharon Naismith, Leonard P Ullman Chair in Psychology at the School of Psychology at the Charles Perkins Institute
* Associate Professor Sue Ogle, Geriatrician, Royal North Shore Hospital
* Dr Maurice Finn, Clinical Psychologist, Royal North Shore Hospital
* Mr Alexander Clough, Masters Student, University of Sydney.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. **‘What is the purpose of the study?’**

The purpose of this study is to investigate whether cholesterol-lowering medications, or statins (e.g. Crestor, Lipitor), affect memory (cognition) in older adults living with dementia. Information from this study will improve the care of older adults, especially those who experience problems with their memory.

1. **‘Why have I been invited to participate in this study?’**

You are eligible to participate in this study because you are 80 years of age or over, have been taking statins for at least 6 months, and have memory problems or dementia.

1. **What if I don’t want to take part in this study, or if I want to withdraw later?’**

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

If you do withdraw your consent during the research project, the study staff will not collect any further personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the study staff up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

1. **‘What does this study involve?’**

As part of this study, you will stop and start your statin medication for 5 weeks at a time, over a 4-month period.

If you agree to participate in this study, you will be asked to sign the Participant Consent Form.

The study will be conducted over 4-months. Your involvement in the study will involve 4 visits at your home (first visit, 5-weeks, 10-weeks, 15-weeks) over 4-months approximately. These visits will consist of a series of assessments and will last for approximately 1-hour. Your carer will also be required to attend these visits. Your GP will also be contacted 2 months after the study has been completed to determine any changes in statin use.

At each visit you will have to complete a memory test, do a short physical test, and will be asked some questions about your overall well-being (see Summary Table 1 for details).

At the beginning of the study you will either continue your regular statin treatment, or be given a placebo instead. At the first visit, and every 5 weeks at each study visit, after the tests have been done, treatment will be provided for the next stage of the study. At the end of the study, you will resume your regular statin treatment.

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| Summary Table 1 | Week 0 – First Visit | Week 5 – Second Visit | Week 10 – Third Visit | Week 15 – Final Visit |
| Alzheimer’s Disease Assessment Score (Memory Test) | **Yes** | **Yes** | **Yes** | **Yes** |
| Short Performance Physical Battery (Physical Test) | **Yes** | **Yes** | **Yes** | **Yes** |
| Quality of Life in Alzheimer’s Disease (Short Questionnaire) | **Yes** | **Yes** | **Yes** | **Yes** |
| Cambridge Behavioural Inventory (Carer Questionnaire) | **Yes** | **Yes** | **Yes** | **Yes** |

1. **‘How is this study being paid for?’**

The study has been funded by the University of Sydney. Dr Gnjidic, Prof Hilmer, Prof Naismith, A/Prof Ogle and Dr Finn will provide their time as part of the research and quality improvement roles within their existing employment through Royal North Shore Hospital and University of Sydney.

1. **‘Are there risks to me in taking part in this study?’**

The risks associated with taking part in this study are minimal. It is possible that the change in short-term statin use may result in an increase in cholesterol levels, however, you may not experience any symptoms immediately. Change in statin use may lead to symptoms including chest pain or shortness of breath which may result in cardiovascular events such as heart disease and stroke. However, this is unlikely due to the short time period in which you will not be taking your regular statin medication.

# ‘What happens if I suffer injury or complications as a result of the study?’

If you suffer any injuries or complications as a result of this study, you should contact the researchers as soon as possible, who will assist you in arranging appropriate medical treatment. If you do not wish to answer a question in the interview you may skip it and go to the next question, or you may stop immediately.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by the drugs or procedures, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

1. **‘Will I benefit from the study?’**

This study aims to further advance medical knowledge and may improve future treatment of older adults, as well as improve patient-specific care of older adults, however it may not benefit you.

1. **‘Will taking part in this study cost me anything, and will I be paid?’**

Participation in this study will not cost you anything, nor will you be paid.

1. **‘How will my confidentiality be protected?’**

Of the people involved in this study, Professor Hilmer, Associate Professor Ogle and Dr Finn may know whether or not you are participating in this study. Your treating doctor will also be made aware that you are taking part in the study.

Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above, and the Human Research Ethics Committee (HREC) for monitoring purposes, will have access to your details and results. These will be held securely at Royal North Shore Hospital, and on a University of Sydney server located at Royal North Shore Hospital.

1. **‘What happens with the results?’**

If you give us your permission by signing the consent document, we plan to discuss/publish the results at scientific and clinical meetings and in peer-reviewed journals. In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you and your GP.

1. **‘What should I do if I want to discuss this study further before I decide?’**

When you have read this information, the researcher, Alexander Clough, will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact him on 0414 161 528, or Dr Danijela Gnjidic on 02 9351 2298.

1. **‘Who should I contact if I have concerns about the conduct of this study?’**

This study has been approved by the Northern Sydney Local Health District HREC. Any person with concerns or complaints about the conduct of this study should contact the Research Office who is nominated to receive complaints from research participants. You should contact them on 02 9926 4590 and quote HREC reference: HREC/16/HAWKE/286

**Thank you for taking the time to consider this study.**

**If you wish to take part in it, please sign the attached consent form.**

**This information is for you to keep.**



Royal North Shore Hospital and the University of Sydney

CONSENT FORM

**INTERVENTIONAL STUDY**

**Determining the effects of statins on cognition in older adults**

1. I,................................................................................................................. of................................................................................................................

agree to participate as a subject in the study described in the Participant Information Sheet attached to this form

1. I acknowledge that I have read the Participant Information Sheet, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.
2. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.
3. I understand that I can withdraw from the study at any time without prejudice to my relationship to the investigators, Royal North Shore Hospital, or the University of Sydney.
4. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.
5. I understand that if I have any questions relating to my participation in this research, I may contact Alexander Clough on 0414 161 528, or Dr Gnjidic on 02 9351 2298 who will be happy to answer them.
6. I acknowledge receipt of a copy of this Consent Form and the Participant Information Sheet.

Complaints may be directed to the Research Office on Level 13, Kolling Building, Royal North Shore Hospital, St Leonards NSW 2065

Phone 02 9926 4590 | email NSLHD-research@health.nsw.gov.au

**Signature of participant Please PRINT name Date**

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**Signature of witness Please PRINT name Date**

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**Signature of investigator Please PRINT name Date**

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**REVOCATION OF CONSENT**

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the investigators or Royal North Shore Hospital or the University of Sydney.

Signature Date

Please PRINT Name

The section for Revocation of Consent should be forwarded to:

Danijela Gnjidic, Fax: 02 9926 4053, email: danijela.gnjidic@sydney.edu.au

Or send to: Level 12, Kolling Building, Reserve Road, St Leonards, NSW 2065