STUDY INTRODUCTION FOR PATIENT AND PUBLIC INVOLVEMENT AND ENGAGEMENT (PPIE) GROUP MEMBERS - AUSTRALIA

Project title	Combining memantine and cholinesterase inhibitors in Lewy body dementia
Role title	Patient and Public Involvement and Engagement (PPIE) group member
Lead Researcher - Australia	Associate Professor Rosie Watson
PPIE Lead - Australia	Dr Jane Thompson

Background

Australian researchers are collaborating on an international research project jointly funded by the United Kingdom's National Institute for Health Research and Australia's National Health Medical Research Council.

People with lived experience of Lewy body dementia, or other types of dementia, have been involved in the planning of the research and the grant submission process. They will also have an important role in the conduct of the research and dissemination of the findings. A Patient and Public Involvement and Engagement group has already been established in the United Kingdom and we will establish an Australian subgroup to work with this group.

The study, entitled "Combining Memantine and Cholinesterase Inhibitors in Lewy body dementia Treatment Trial" (or, "COBALT"), aims to discover whether people with Lewy body dementia who are already taking drugs known as acetylcholinesterase inhibitors (e.g. Donepezil (Aricept), Rivastigmine (Exelon patch)) might benefit from taking the drug memantine (e.g. Ebixa, Memanxa, APO-Memantine) in addition. This is a combination for which there is evidence for benefit, and is therefore recommended, for people with Alzheimer's disease. However, we do not yet have sufficient evidence to recommend the combination for people with Lewy body dementia. Before this practice can be recommended, we need good evidence of costs, benefits and possible risks.

Lewy body dementia includes dementia with Lewy bodies and Parkinson's disease dementia. These related illnesses have a wide range of distressing symptoms. Compared with Alzheimer's disease, people with dementia with Lewy bodies or Parkinson's disease dementia have worse quality of life; more complex symptoms; higher care costs; and, are more sensitive to medications. Acetylcholinesterase inhibitors can help to improve their day-to-day functioning and thinking abilities. We will test if combining acetylcholinesterase inhibitors with memantine has a better outcome than just taking an acetylcholinesterase inhibitor.

To test this, 372 people with mild to moderate dementia with Lewy bodies or Parkinson's disease dementia, who are on a stable dose of an acetylcholinesterase inhibitor, will be recruited from across the United Kingdom and Australia. Participants will randomly receive either memantine or an inactive drug (placebo). After 26 weeks, we will measure whether participants are getting better, staying the same or getting worse. We will also test thinking abilities, look for changes in other symptoms including hallucinations, depression, and movement function, and monitor any side effects of the combined treatment. We will assess any changes in quality of life for participants, their carers and families, and calculate any extra costs or savings from adding memantine. We will monitor participants for 52 weeks and aim to follow them up longer term.

In the first instance, we would like to involve 7 or 8 people with lived experience of Lewy body dementia, or other forms of dementia, (either as a person with a diagnosis or as a carer, or attending together) in our Australian subgroup. The group may expand as the research progresses. This is an exciting opportunity for Australians interested in public involvement in dementia research to learn from our experienced United Kingdom counterparts.

What does the role involve?

Members of the Patient and Public Involvement and Engagement group will contribute in a number of ways including:

- Attending focus groups
- Joining the research project steering group if interested (one person or by rotation)
- Reviewing/designing user-friendly plain English documents for use with participants and support partners including recruitment, letters of invitation, participant information sheets, consent forms, study newsletters
- Helping to develop lay material for websites and plain English summaries of study findings and publications for informing the general public
- Visiting initiation sites (when safe)
- Assisting with recruitment of study participants
- Helping to evaluate study participants' level of satisfaction with their experience
- Co-organising and attending stakeholder 'end-of-study' events

What skills are required?

To carry out the work envisaged will require volunteers with interest and empathy, competence for the tasks, and the possibility of contributing long term.

Essential skills

- Willingness to review documents and provide an opinion via any preferred method e.g. post, phone, online/video conferencing.
- Enthusiasm to contribute towards the successful delivery of the project
- Willingness to engage with the Australian and United Kingdom patient and public involvement and engagement leads/facilitators

Desirable skills

- Able to join video conferencing with support if needed

What is the time commitment?

The study lasts 4 years but we anticipate that members of the group will come and go as circumstances dictate. There is no expectation for anyone to stay for the whole study unless they want to.

The contribution will vary from month to month but is likely to include a meeting online and a task such as a document review every couple of months. There will never be any pressure to respond to any task or attend any particular

meeting. We understand that everyone has different circumstances and skills and no one will need to participate in every activity.

When will the role begin?

Early 2021.

What support and training will be provided?

We will seek the views of the group members about what support they may require to be involved.

A patient and public involvement and engagement facilitator will be available by email (or phone/video link by arrangement) and we will hold information sessions about the project as it progresses.

The training needs for the group members will be partially met by induction and mentoring of new volunteers by those who are more experienced. This will be supported by training from the research team in trial administrative and governance processes.

Will I be paid?

The role is voluntary and is not a paid position. Currently, we may be able to at least reimburse you for some of the associated costs incurred, such as transportation. We may secure some funding to support patient and public involvement in the future. Please contact us if you have any issues which might impact on your involvement.

I am interested, who should I contact?

Associate Professor Rosie Watson: watson.r@wehi.edu.au

Dr Jane Thompson: jantho@bigpond.com