**PARTICIPANT INFORMATION STATEMENT**

|  |  |
| --- | --- |
| **HREC Project Number:** | HRE2021-0763 |
| **Project Title:** | Improving medication management amongst home- dwelling people living with dementia through a community pharmacy- based service: a pilot study. |
| **Chief Investigator:** | Dr Andrew Stafford, Senior Lecturer, Curtin Medical School |
| **Version Number:** | 1.3  |
| **Version Date:** | 20 July 2022  |

**What is the Project About?**

For many people who live with dementia, managing their daily medicines is a complex and difficult task. Whilst medicines are used to improve health, their incorrect use may cause unintended consequences that range from minor symptoms to serious events that require hospitalisation. The role that community pharmacists have in optimising medicine safety is well-recognised, and several generic programs have been developed for pharmacists to help people living in the community use their medicines more safely and easily.

The project has involved the development of a new in-pharmacy service to meet the specific needs of people living with dementia. The service is called a *MedsCheck Plus*. This will involve the pharmacist holding structured meetings with a person living with dementia (and their family carers if appropriate), so that any medicine-related issues can be identified and overcome. In this pilot project, five community pharmacists will be trained in providing a *MedsCheck Plus*, followed by providing the service to twenty people living with. The experiences of the consumers and pharmacists will be studied.

**Who is doing the Research**?

The project is being conducted by Dr Andrew Stafford, Dr Tin Fei Sim and Professor Anne-Marie Hill from Curtin University, and Mr Jason Burton from Dementia360.

This research project is funded by a grant from the Dementia Centre for Research Collaboration, University of New South Wales.

**Why am I being asked to take part and what will I have to do?**

We are looking for community pharmacists who currently provide MedsChecks and/ or Diabetes MedsChecks, and supporting people living with dementia and their family carers with medication management. Pharmacists who agree to participate will complete have one month to complete the training material provided, then will initiate and provide *MedsCheck Plus* for at least four (4) people living with dementia, with planned follow-ups over the subsequent four months.

As part of the *MedsCheck Plus*, the participating pharmacist will have access to appropriate facilities within their pharmacies to undertake MedsChecks and at least four (4) eligible consumers who can participate in the pilot. The eligibility criteria will be based on the criteria outlined in the *MedsCheck Plus* guidelines developed as part of this project. As part of the service, you will conduct a follow-up consultation (1-3 months from initial consultation). Any participants identified as needing an additional follow-up consultation, will be conducted 1-2 months from previous consultation, in order to be completed in the 4 months timeframe from initial consultation. Upon completion of the service, you will share your experiences in a focus group with other participating pharmacists, along with the completion of a short survey.

There will be no cost to you for taking part in this research. You will be reimbursed with a $100 gift card for the initial MedsCheck Plus consultation, followed by a $50 gift card for the follow-up consultation. You will also be reimbursed with a $50 gift card for completion of a post-trial focus group sharing your experience and input on the pilot. In addition, your pharmacy may be eligible to claim for a *MedsCheck* through the usual means, if the participant meets the required criteria.

**Are there any benefits to being in the research project?**

There may be no direct benefit to you from participating in this research, but you may appreciate the opportunity to share your experiences and opinions.

We hope that the results of this research may benefit people living with dementia and their family carers in the future, through the development of a program in pharmacies that helps people to use their medicines more safely.

**Are there any risks, side-effects, discomforts or inconveniences from being in the research project?**

There is little risk in participating in this research project. If participating within this pilot causes any concern or upsets you, we can refer you to a counsellor.

Apart from giving up your time, we do not expect that there will be any other risks or inconveniences associated with taking part in this study.

**Who will have access to my information?**

The information collected in this research will be re-identifiable (coded). This means that we will collect data that can identify you, but will then remove identifying information on any data or sample and replace it with a code when we analyse the data. Only the research team have access to the code to match your name if it is necessary to do so. Any information we collect will be treated as confidential and used only in this project unless otherwise specified. The following people will have access to the information we collect in this research: the research team and, in the event of an audit or investigation, staff from the Curtin University Office of Research and Development.

All care will be taken to maintain privacy and confidentiality of any information shared during the consultation.

Electronic data will be password-protected and hard copy data (including video or audio tapes) will be in locked storage. The information we collect in this study will be kept under secure conditions at Curtin University for 7 years after the research is published and then it will be destroyed.

The results of this research may be presented at conferences or published in professional journals. You will not be identified in any results that are published or presented.

**Will you tell me the results of the research?**

A summary of the project’s overall results will be provided to you late-2022. Results will not be individual but based on all the information we collect and review as part of the research.

We plan to present the results of the research at conferences and in journal articles.

**Do I have to take part in the research project?**

Taking part in a research project is voluntary. It is your choice to take part or not. You do not have to agree if you do not want to. If you decide to take part and then change your mind, that is okay, you can withdraw from the project. If you choose not to take part or start and then stop the study, it will not affect your relationship with the University, staff or colleagues.

With your permission, if you chose to leave the study we will use any information collected unless you tell us not to.

**What happens next and who can I contact about the research?**

If you have any questions or would like more information, please contact Holly Radford at Curtin Medical School (phone 08 9266 2531 or email [holly.radford@curtin.edu.au](file:///%5C%5Cstaff.ad.curtin.edu.au%5Cdmp%5CA-J%5CDementia_MedsChecks-STAFFA-HS10110%5CEthics%5CFinal%5Cholly.radford%40curtin.edu.au)).

If you decide to take part in this research we will ask you to sign the consent form. By signing it, you are telling us that you understand what you have read and what has been discussed. Signing the consent indicates that you agree to be in the research project and have your information used as described. Please take your time and ask any questions you have before you decide what to do. You will be given a copy of this information and the consent form to keep.

Curtin University Human Research Ethics Committee (HREC) has approved this study (HREC number HRE2021-0763). Should you wish to discuss the study with someone not directly involved, in particular, any matters concerning the conduct of the study or your rights as a participant, or you wish to make a confidential complaint, you may contact the Ethics Officer on (08) 9266 9223 or the Manager, Research Integrity on (08) 9266 7093 or email hrec@curtin.edu.au.