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Establishing Mental Health Friendly Pharmacies to Assist in The Early Identification and Support of Older Adults at Risk of Depression

EMPATHISE Pilot Study

PHARMACIST PARTICIPANT INFORMATION STATEMENT

(1) What is the study about?

You are invited to participate in a research study entitled '*Establishing Mental Health Friendly Pharmacies to Assist in the Early Identification and Support of Older Adults at risk of Depression – EMPATHISE Pilot Study*' being conducted by The University of Sydney, the UNSW Sydney and the Pharmaceutical Society of Australia (PSA). This study aims to pilot a pharmacist-delivered screening and referral model in community pharmacy for older adults at risk of depression.

You have been invited to participate in this study because you are a community pharmacist who is working in Australia. This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the research. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about. Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:

- ✓ Understand what you have read.
- ✓ Agree to take part in the research study as outlined below.
- ✓ Agree to the use of your personal information as described.

You will be given a copy of this Participant Information Statement to keep.

(2) Who is carrying out the study?

The study is being carried out by the following researchers:

- Dr Claire O'Reilly, Senior Lecturer, The University of Sydney
- Dr Natasa Gisev, Senior Research Fellow, UNSW Sydney
- Dr Sarira El-Den, Senior Lecturer, The University of Sydney
- Dr Dan Malone, Senior Lecturer and Deputy Director of Pharmacy Education, Monash University
- Simone Diamandis, NSW State Manager, Pharmaceutical Society of Australia
- Kevin Ou, Training & Delivery Lead, Pharmaceutical Society of Australia
- Dr Lisa Kouladjian O'Donnell, Research Fellow, The University of Sydney
- Duha Nur Gide, MPhil candidate, The University of Sydney

This study is being funded by:

- UNSW Sydney/University of Sydney seed funding scheme: Mental Health and Wellbeing – Early Intervention and Prevention (Older People)

(3) What does the study involve?

Your pharmacy owner/manager has indicated your pharmacy is participating in the EMPATHISE study. Your participation in this project will involve the following three parts:

1. Your pharmacy manager/owner will nominate at least 2 pharmacists to participate in a training program including Blended Mental Health First Aid training and a specialised depression screening module. The pharmacists will be provided training and materials to support the service delivery.
2. Pharmacists will be invited to complete online surveys on their knowledge, attitudes and intended behaviour towards older people at risk of depression to evaluate the training modules. These surveys will be at 3 timepoints: i) pre-training, ii) immediately post-training and iii) post-intervention delivery (at approximately 3 months post training). The post-intervention survey also contains feedback questions to evaluate the training. Consent to participate in this study is assumed upon completion of these surveys.
3. Establishing a pharmacist-led depression screening and referral pilot program within your pharmacy. Pharmacists will be required to screen 10 older adults per pharmacy, and refer/follow-up as appropriate.

(4) How much time will the study take?

The pilot program will span over 6-12 months. Pharmacists will be required to recruit and screen 10 older adults per pharmacy. The screening may take up to 30 minutes per consumer, and pharmacists will be required to follow-up urgent cases in 1 week (follow-up phone call approximately 20 minutes).

Pharmacist training will include:

- 6-8 hours self-directed online component of Blended-Mental Health First Aid training
- Instructor-led component of Blended-Mental Health First Aid training (4 hours face-to-face or 5 hours online)
- 3-hour (face-to-face or online) specialised training in the identification and management of depression in older adults

The online surveys will take approximately 10-15 minutes each to complete (total 30-45 minutes).

(5) Who can take part in the study?

This study is open to community pharmacists who are currently registered and practising in NSW, Australia.

(6) Do I have to be in the study? Can I withdraw from the study once I've started?

Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at The University of Sydney, UNSW Sydney or PSA. If you decide to take part in the study and then change your mind later, you are free to withdraw at any time. However, please note that you will not be able to withdraw any responses from online surveys or any data collected about consumers after entering them into the online data collection sheet as they will be non-identifiable at this point. You are free to stop participating in the pilot program at any time.

(7) Are there any risks or costs associated with being in the study?

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study. However, if any topics raised during the pilot program cause any distress, please contact the Pharmacists' Support Service 1300244910 or Lifeline 131114 to ensure adequate help and support is provided. In addition, you can call the Chief Investigator Dr Claire O'Reilly if you have further concerns.

(8) Are there any benefits associated with being in the study?

Blended Mental Health First Aid training provides pharmacists with 12 hours of Group 2 CPD (or 24 CPD credits) and the depression screening module provides an additional 3 hours of Group 2 CPD (or 6 CPD credits) suitable for inclusion in an individual pharmacist's CPD plan. In addition, the data you provide and collect will be used to develop a pharmacy depression screening service for community pharmacy which may indirectly benefit you in the future.

Participating pharmacies will also be reimbursed with a standard service fee for each service provided, based on current rates for providing MedsCheck services.

(9) What will happen to information about me that is collected during the study?

By providing your consent, you are agreeing to us collecting personal information about you and your pharmacy for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise. All aspects of the study, including results, will be strictly confidential and only the researchers will have access to the de-identified data. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

(10) Can I tell other people about the study?

Yes, you are welcome to tell other people about the study.

(11) What if I require further information about the study or my involvement in it?

When you have read this information, Dr Claire O'Reilly can discuss with you further if you need more information and to answer any questions you may have. If you would like to know more at any stage during the study, please feel free to contact Dr Claire O'Reilly on 02 9351 2729 or claire.oreilly@sydney.edu.au.

(12) Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. The results of this study may be published in journal articles or presented at conferences. You will be provided with the option at the end of the pilot program to request feedback on results of the study. Feedback will be provided upon request via email upon the completion of the study.

(13) What if I have a complaint or any concerns?

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney [2020/603]. As part of this process, we have agreed to carry out the study according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect people who agree to take part in research studies. If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:

- **Telephone:** +61 2 8627 8176
- **Email:** ro.humanethics@sydney.edu.au
- **Fax:** +61 2 8627 8177 (Facsimile)

This information sheet is for you to keep