|  |  |  |  |
| --- | --- | --- | --- |
| Study site:  … Medical Centre  Palmerston North,  New Zealand |  | Ethics committee ref.:  New Zealand Health and Disability Ethics Committee |  |
| Lead/Coordinating Investigator:  Lisheng (Li) Liu |  | Contact phone number:  027 270 1871 |  |

You are invited to take part in a study to test a new method to reduce unsafe overuse of medicines. Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason, and it won’t affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you’d like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 8 pages long. Please make sure you have read and understood all the pages.

## Voluntary participation and withdrawal from this study

Participation is voluntary. You have the right to decline to participate, or if you participate, you can withdraw at any time without requiring a reason, without experiencing any disadvantage.

## What is the purpose of the study?

Older adults often take more medication. This can increase the risk of unsafe medication use leading to bad outcomes such as side effects and hospitalization.

Clinical pharmacists are medication experts who work with your doctor, nurse and other healthcare professionals to ensure the medications you are taking are safe and appropriate.

A new service has been developed which uses clinical pharmacists to support GPs and Nurse Practitioners to reduce unsafe overuse of medication in older adults.

The purpose of this research is to test the suitability of carrying out this method for patients in general practice.

## How is the study designed and what will my participation involve?

We anticipate up to 10 participants will take part in this study over 8 weeks. For participants, the clinical pharmacist will arrange a date and time to meet with you at … Medical Centre and provide a consultation lasting approximately 30-minutes to review the effectiveness and safety of your medications with your GP/Nurse Practitioner.

Afterwards, 30-minutes will be allocated for you and the researcher to discuss how you felt the consultation went, and for you to complete a questionnaire to understand how you feel about your health and medications.

After 8 weeks, participants meet with the researcher again at … Medical Centre to complete a follow up 30-minute discussion and questionnaire about your health/medicine use. The discussion/questionnaire does not contain questions that may be sensitive or cause embarrassment. The discussions between participants and the researcher will be audio recorded. Participants will be provided opportunities within two weeks after the discussion to review and edit their own recordings and transcripts by contacting the Coordinating Investigator.

The study will collect information on the number and types of medication you are taking using medical records, to review if the medicines you are taking is safe and appropriate. The questionnaire and discussions will help the researcher to review your health/medication use and the suitability of implementing this service into general practice.

At the end of the study, your GP/Nurse Practitioner will complete an anonymous 5-minute questionnaire to review the services provided by the clinical pharmacist.

The expected finish date of the study is 01/08/2021.

**Who can take part in the study?**

As you are 65 years old or over, currently enrolled at … Medical Centre, and taking eleven or more unique medications every day, we would like to invite you to participate in this research.

There are no medication/lifestyle restrictions participants will be asked to follow during the study.

## What are the possible benefits/risks of this study?

**Benefits**

* Participants will receive a free consultation from the clinical pharmacist to help identify, prevent and resolve any medication related problems they may experience.
* Participants can benefit from safer, more effective medication prescribing, and less risk of harm caused by medications.
* Participants will be helping other people to better manage their medicines.
* GPs/Nurse Practitioners can improve the quality of their medicine prescribing.

**Risks**

The research has been designed to minimize risks, side effects and discomfort to participant/family members. In the unlikely event of an adverse consequence, physical/psychological risk or incidental finding from this research, the Coordinating Investigator will seek immediate assistance from the participant’s GP/Nurse Practitioner, and report to the project Supervisor and The Health and Disability Ethics Committee.

You will be made aware of new information about study risks/adverse effects which may affect your health, that becomes available during the research.

The extent of the researcher’s responsibility to ensure that care is provided in the study does not extend beyond the pharmacist consultations.

Incidental Findings

Research occasionally may discover unexpected/unrelated findings. If an unexpected finding is discovered such as a medical condition, the clinical pharmacist will advise the you within his expertise and will request assistance from your GP/Nurse Practitioner.

Your privacy and confidentiality would be protected if an unexpected finding is discovered. However, if your life is at risk, there may be a legal obligation to breach confidentiality to protect your health. You should not participate if you do not wish to be informed of such a finding.

**What are the alternatives to taking part?**

People not a part of the study will receive their usual care by their GP/Nurse Practitioner.

## Will any costs be reimbursed?

There are no costs or reimbursement associated with participating in the study.

## What if something goes wrong?

## If you were injured in this study, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

## If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.

## What will happen to my information?

During this study the Coordinating Investigator will record information about you and your participation. This includes results from the pharmacist consultations, post-consult audio recording of discussions and questionnaire, and the medicines you take. You cannot take part in this study if you do not consent to the collection of this information.

## Identifiable information

This is any data that could identify you (e.g. your name, date of birth). The following groups may have access:

* Study researchers and your usual GP/Nurse Practitioner.
* Rarely, it may be necessary for the researcher to share your information with other people – for example, if there is a serious threat to public health/safety, or to the life/health of you/another person, or if the information is required in certain legal situations.

## De-identified (coded) information

To make sure your personal information is kept confidential, any written or audio information that identifies you will not be included in any report generated by the researcher. Instead, you will be identified by a code. The researcher will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

The following groups may have access to your coded information:

* The University of Auckland & Medway School of Pharmacy – originator of the study questionnaire.
* Regulatory/other governmental agencies such as MidCentral District Health Board/THINK Hauora Primary Health Organisation.

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Privacy, Anonymity and Confidentiality

This study is not anonymous as participants will meet with a clinical pharmacist. However, your confidentiality will be protected throughout this study. Written and audio information collected from you will be private and confidential between you and researchers to the extent allowed by law\*.

Your own audio recordings of the post consultation/follow up discussions will be private between the individual participant and the researcher. No other individual or groups will be given access.

\*(Where information is provided to the researcher with the possibility of a serious risk to a person’s health/life, moral/legal obligations require the researcher to report that risk to appropriate persons).

Future research using your information

Your identifiable or coded information will not be used for future research.

Security and storage of your information

Your identifiable information is held at … Medical Centre during the study. After the study, identifiable information including written and audio recordings will be transferred to a secure archiving site and stored for at least 10 years, then destroyed. Your coded information will be entered into electronic case report forms and sent through a secure server to the Supervisor. Coded study information will be kept by the sponsor in secure, cloud-based storage indefinitely. All storage and destruction of information will comply with local and/or international data security guidelines.

## Risks

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information is currently very small, but may increase in the future as people find new ways of tracing information.

This research includes basic information such as your geographic region and age. It is possible that this research could one day help people in the same groups as you. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as you.

## Rights to access your information and results

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected. You may access other study-specific information before the study is over, but this could result in you being withdrawn from the study to protect the study’s scientific integrity. If you have any questions about the collection and use of information about you, you should ask the Coordinating Investigator

## What happens after the study or if I change my mind? (Rights to withdraw your information)

After the study, this pharmacist service will be provided free of charge, without conditions to people enrolled at clinics with MidCentral District Health Board Primary Care Support Pharmacist support, including … Medical Centre.

Outcomes of this study will be used for a Master in Clinical Pharmacy project at The University of Auckland, and subsequent journal/conference presentations. Reports from this study will not include any quotations from the audio recordings.

You may withdraw your consent for the collection and use of your information at any time, by informing the Coordinating Investigator. If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you. Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

**Can I find out the results of the study?**

You can request a summary letter telling you about the study results in plain English. The letter will be sent to you once the final study report is available (available by 08/2022). The study will be submitted into the Australian New Zealand Clinical Trials Registry (ANZCTR). You can access this trial using the link <https://www.anzctr.org.au/TrialSearch.aspx> and searching for the study title.

**Who is funding the study?**

The study is funded independently by the Coordinating Investigator. The study is supported by The University of Auckland and MidCentral District Health Board.

**Who has approved the study?**

This research is approved by an independent group called the Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The HDEC has approved this study on 12 January, 2021 Reference Number 20/STH/238

## Who do I contact for more information or if I have concerns?

If you have any questions, concerns/complaints about the study at any stage, you can contact:

Coordinating Investigator/Master of Clinical Pharmacy student at The University of Auckland/Primary Care Support Pharmacist, MidCentral District Health Board: Lisheng (Li) Liu

Telephone: 027 270 1871 Email: [lliu377@aucklanduni.ac.nz](mailto:lliu377@aucklanduni.ac.nz)

Co-Investigator/Supervisor/Head of School of Pharmacy, The University of Auckland:

Associate Professor Dr. Jeff Harrison

Telephone: 09 923 2144 Email: [jeff.harrison@auckland.ac.nz](mailto:jeff.harrison@auckland.ac.nz)

If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate:

Phone: 0800 555 050  
Fax: 0800 2 SUPPORT (0800 2787 7678)  
Email: [advocacy@advocacy.org.nz](mailto:advocacy@advocacy.org.nz)

Website: https://www.advocacy.org.nz/

For Maori Heath support, please contact:

Best Care Whakapai Hauora Charitable Trust: manawhenua health arm of Tanenuiarangi Manawatū Incorporated, the Iwi Authority for Rangitāne o Manawatū Primary Care Support Pharmacist, MidCentral District Health Board: Bernadette Brokenshire

Telephone: 027 270 7340 Email: [Bernie.Brokenshire@midcentraldhb.govt.nz](mailto:Bernie.Brokenshire@midcentraldhb.govt.nz)

You can also contact the health and disability ethics committee (HDEC) that approved this study:

Phone: 0800 4 ETHIC

Email: [hdecs@health.govt.nz](mailto:hdecs@health.govt.nz)