Participant Information Statement - General Practitioner (GP)

COMFORT STUDY

Clinical observation, management, and function of low back pain relief therapies

Dr. Christina Abdel Shaheed
Institute for Musculoskeletal Health. Level 10, North King George V Building, Royal Prince Alfred Hospital (C39)
Phone: +61 2 8627 6236 | Email: christina.abdelshaheed@sydney.edu.au

1. What is this study about?

Our study compares two ways of prescribing an opioid medicine for people with back pain. The first is the traditional way GPs carefully prescribe this medicine, and the second offers patients other pain relief options in addition to the opioid. We are not sure which way works best for the patient.

You have been invited to participate in this study as a general practitioner who treats people in the community presenting with back pain. This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

Taking part in this study is voluntary, so it is up to you whether you want to participate or not.

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

(i) Understand what you have read.
(ii) Agree to take part in the research study as outlined below.
(iii) Agree to the use of your personal information as described.

You will be given a copy of this Participant Information Statement and the Participant Consent Form to keep.

2. Who is running the study?

The study is being carried out by the following researchers:

Researcher	Affiliation
Dr Christina Abdel Shaheed, Professor Chris Maher, Professor Andrew McLachlan, Professor Fiona Blyth, Associate Professor Patrick Kelly, Associate Professor Fiona Stanaway, Dr Rachel Thompson, Philip Clare	The University of Sydney
Professor Louisa Degenhardt, Dr Thomas Lung	The University of New South Wales
A/Professor Rowena Ivers	University of Wollongong

The study is funded by the National Health and Medical Research Council (NHMRC), Australia and is sponsored by The University of Sydney. There are no conflicts of interest or financial benefits to the researchers, sponsors, or institutions from this research.

3. Who can take part in the study?

We are engaging with over 40 General Practice sites to participate in this study, and through these sites, we are seeking to recruit 410 patients in total to this study. Participating sites must be eligible to prescribe an opioid analgesic (including schedule 8 opioid analgesics), and not have received an education visit or training on judicious opioid prescribing within the last 12 months. You are asked to screen and enrol between 11-15 eligible participants aged 18 years or older who have presented to you with low back pain of any duration and where you consider it appropriate to prescribe an opioid medicine for pain relief.

The patient cannot:

- Have contra-indications to opioid medicines.
- Be less than 18 years of age.
- Be engaged in an opioid tapering regimen at the time of enrolment into the study. i.e., have already begun to reduce their opioid medicine within the past month.
- Be actively treated for cancer or receiving palliative treatment.

The patient must be a holder of an Australian Medicare card and must be able to read and understand study information (or translations available).

4. What will the study involve for me?

If you decide to take part in this study, you will be asked to sign the Participant Consent Form.

As part of the study, you may be allocated to one of the following interventions:

- Deliver usual care to patients.
- Receive training (e.g. short training video) on judicious prescribing of opioid analgesics, treatment options for low back pain (e.g. non-opioid medicines, advice, patient education) and discuss these treatment options with eligible study patients.

You will be asked to enrol and obtain consent from eligible and interested patients (including those with low English proficiency that require translations), notify study researchers once you enrol each patient briefly discuss the study and outcomes collected, and assist with queries from patients regarding the Consumer Medicines Information (CMI) leaflet for medications prescribed at the study visit. To help facilitate recruitment of patients into the trial, the study team may also be involved in the consenting process. We will be collecting information on the patient's hospital presentations and admissions, as well on their prescribed and dispensed medicines. Data for this study will be collected from administrative datasets held by the NSW Ministry of Health, SafeScript, as well as the Pharmaceutical Benefits Scheme/Repatriation Pharmaceutical Benefits Scheme (PBS/RPBS) and Medicare Benefits Schedule (MBS) data.

You may also be required to provide patients with an immediate supply of heat wraps that will be provided by the study team at no cost to the patient. The study team will provide heat wraps to patients for those that were screened and enrolled using Telehealth.

Patients will be provided instructions on how to use the heat wraps and can keep any unused heat wraps provided to them.

You may also be invited to an audio recorded interview to discuss your experiences on the trial, which will be carried out face to face or via an online platform e.g., zoom.

You will also be asked to sign a separate consent form (using the Services Australia form) to allow for the provider/prescriber number to be matched to the medicines dispensed under the PBS/MBS scheme.

Further, the study team may also schedule monthly follow-ups (e.g. over the phone) and/or three-monthly site visits (including, where appropriate, refresher training every 6 months and follow-up questionnaires) to discuss trial progress and provide ongoing support for study sites.

5. Can I withdraw 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, partners on this study or anyone else at The University of Sydney.

If you decide to take part in the study and then change your mind later, you are free to withdraw at any time and can do this by informing the study researcher. The study researcher will then discuss options on suitable pathways for the management of study participants and may include engaging with health professionals in the same practice that are trained in the study, to assist with the care of study participants. If you decide to withdraw from the study, we will not collect any more information from you following the date that the study team has been notified. Any information that we have already collected, however, will be kept and included in the study results.

6. Are there any risks or costs?

We do not expect there to be any risks or costs associated with taking part in this study.

7. Are there any benefits?

Benefits can include receiving training in clinical trial participation, continual professional development (CPD) points, or an opportunity to provide alternative strategies for pain reliefs such as heat wraps, which will be provided by the study. The study will use Flexeze heat patches, a Therapeutic Goods Administration-registered product (Australian Register of Therapeutic Goods (ARTG) #209075) with an excellent safety history. The device is contained in a pouch and does not have direct contact with the skin, therefore is unlikely to cause any skin discomfort, irritation or burning. If the patient reports any skin irritation to you, please encourage them to advise the study researchers, however mild.

Also, in recognition of your time, you will be reimbursed $100 for each eligible patient you recruit to the study and/or $30 for up to 30 ineligible patients, and $100 if you are invited to participate in the audio recorded interview. Further, you may also be reimbursed an additional $50 if you are allocated to the enhanced recruitment of participants with low English proficiency that require translation.

8. What will happen to information that is collected?

Your trial records will be safely secured including being password protected. Electronic files will be stored in an electronic database, paper records will be archived in secure storages provided by the University of Sydney. De-identified individual data will be made available in accordance with NHMRC open access policy. All data will be handled in accordance with section 95A of the Privacy Act 1988. All data will be retained for a minimum of 15 years, after which it will be shredded, deleted, and disposed of securely. Study findings may be published, presented at professional conferences and/or released to the general public, but you will not be personally identified. We may also use the data for future projects, and we will seek ethical approval prior to using this information.

What does it mean to provide consent to using my information?

By providing your consent, you agree for the study to collect personal prescribing information about patients consented into the research study, such as medications and/or referral to other services, from administrative databases and/or the practice software.

Data Linkage

By supporting this research study, you are agreeing to the use of **prescribing information** held in administrative databases and/or from your practice. Any prescribing information used from these data sources are managed completely confidentially and are used only for the purpose of this research study.

How do I know my information is kept confidential?

As the linkage process requires personal details (such as provider details), there may be a small risk to your privacy. The risk will be minimised by separating the process of record linkage and data analysis, where personal details will be removed, and only personal identification numbers and health information will be provided.

9. Will I be told the results of the study?

You can receive results of the study by ticking the relevant box on the consent form and will be provided after the study has finished.

10. What if I would like further information?

If you would like further information, the COMFORT study team can be contacted on [INSERT NUMBER] or email comfort.trial@sydney.edu.au.

11. What if I have a complaint or any concerns?

The ethical aspects of this study have been approved by the Human Research Ethics Committee (HREC) of The University of Sydney [2022/511] according to the *National Statement on Ethical Conduct in Human Research (2007).*

If you are concerned about the way this study is being conducted or wish to make a complaint to someone independent from the study, please contact the University:

Human Ethics Manager: human.ethics@sydney.edu.au
or +61 2 8627 8176.

This information sheet is for you to keep.