Participant Information Sheet

Study Title:

Experiences of prescription and over-the-counter opioid dependence

Locality: Auckland, New Zealand

Ethics committee ref.:16/NTA/211

Lead investigator: Professor Janie Sheridan

Contact phone number: 09 923 5247

You are invited to take part in a study looking at the experiences of people who have developed an addiction to opioid-based painkillers prescribed by a doctor or bought over-the-counter at a pharmacy or similar. Taking part is your choice. If you choose not to take part, you don't have to give a reason and it won't affect your healthcare. If you do want to take part now, but change your mind later, you can withdraw from the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It explains why we are doing the study, what your participation would involve, possible benefits and risks and what happens 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. 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, we will ask you 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 six pages long including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

In New Zealand, it is possible that there are an increasing number of people who are developing addiction to painkillers. If this is the case, it would mirror what has happened in other countries like the United States, United Kingdom and Australia.

The purpose of this study is to better understand the experiences of people who get treatment in specialist addiction services for their addiction to prescription or over-the-counter painkillers and the experiences of those who don't get treatment. We are planning to speak to people who are receiving treatment as well as people who are not receiving treatment, and will be comparing their experiences. It is our aim that the information we collect will help services see what changes they may need to make and what they can do differently to respond to the needs of people with addiction to prescription or over-the-counter painkillers.

This study is funded by the University of Auckland. **The study will be conducted by Carina Walters, who is studying towards a PhD.** Carina will be supervised by three very experienced researchers who are University of Auckland staff.

The study will comply with the New Zealand National Ethics Committee 'Ethical guidelines for observational studies'.

(Study Status: ethical approval received, approval number 16/NTA/211)

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

The study will consist of **three** face-to-face interviews with the researcher:

1. *one when you enter the study,*
2. *one three months later and*
3. *a final one three months after that* (a total of three interviews over 6 months).

The interviews will take around an hour at a place you are comfortable with (e.g. an office at the university, at Community Alcohol and Drug Services or somewhere else). The interviews will be audio recorded for later transcription as the researcher will have difficulty writing down what you say at the same time as listening to you. At the end of the interviews you will be asked to complete three or four short questionnaires, which should not take more than 10 minutes in total.
The questions we will ask will help build a picture of your experience of having problems with painkillers. We will ask about your health and wellbeing and about your use of any other substances. We recognise this is a sensitive area and can be difficult to talk about.

In between the interviews (approx. once in two months) the researcher will phone or text you to see how you are getting on if you are happy for them to do so.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

The benefits of the study are that you get the opportunity to tell your story about your use of painkillers. The information we get from the stories of the participants will help doctors and other health professionals treating people with opioid painkiller addiction to understand how these problems develop, the problems that some people face when trying to get help, and what works best for people in treatment. It will also help people working at government level as they make decisions about how addiction services are provided.

A possible risk of taking part is that you might become distressed or experience a decline in your mental health. If the researcher identifies this is happening she will be able to advise you where to get help if you want it. If you are becoming distressed and want to stop taking part in the study, you can do that at any time.

WHO PAYS FOR THE STUDY?

The study is being paid for by the University of Auckland. There will be no cost to you apart from your time and travel to the interview. In recognition of your time spent with the researcher and possible travel costs, the researcher will give you an MTA or Westfield voucher valued at $40 each time you are interviewed.

WHAT IF SOMETHING GOES WRONG?

If you were injured during the course of taking part in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You will have to lodge a claim with ACC and 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 ARE MY RIGHTS?

Participation in this study is completely voluntary. You are free to decide not to participate in it at any time. Taking part or not will not affect any treatment you are receiving or will receive in the future.

You have the right to access any information collected about you as part of the study, and will be informed if at any time the study reveals any information which could have a positive or negative impact on your health.

You have the right to privacy and confidentiality. The information you provide to the researcher will be treated confidentially. The data collected will not contain any information which can identify you and we will be particularly careful not to disclose any information that could identify you in any reports or presentations that result from the study.

Confidentiality might be broken if the researcher becomes aware of immediate threats regarding the safety of yourself or others. If this were to occur, the researcher would contact the relevant organisation and no-one else.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

All of the interview recordings and written notes will be stored either in locked cabinets or password protected files on the researcher's password protected university computer drive. There will be no information which can identify you stored together with the interview records. The data will be stored securely for 10 years after which time it will be destroyed.

At the end of the study (around the beginning of 2018) we will send you a letter telling you what we have found out about people's experiences with painkiller addiction.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

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

Professor Janie Sheridan, School of Pharmacy, The University of Auckland
Phone: 09 923 5247
Email: j.sheridan@auckland.ac.nz

Carina Walters, PhD Candidate, School of Pharmacy, The University of Auckland
Phone: 09 923 9129
Email: cj.walters@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 on:

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

For Maori health support please contact :

Dr Anneka Anderson
Phone: 09 923 3373
Email: a.anderson@auckland.ac.nz

Or alternatively

Te Atea Marino, Maori Community Alcohol & Drug Service, Auckland
Phone: 845 1818
Email: teatea@waitematadhb.govt.nz

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

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

Consent Form

If you need an INTERPRETER, please tell us.
If you are unable to provide interpreters for the study, please clearly state this in the Participant Information Sheet

Please indicate you consent to the following:

- I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.
- I have been given sufficient time to consider whether or not to participate in this study.
- I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.
- I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.
- I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.
- I consent to the research staff collecting and processing my information, including information about my health.
- If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw, may continue to be processed.
- I consent to the research staff contacting me by text or phone-call to remind me of appointments, or to check in with me once every two months until the end of the study (or until I withdraw from the study).
- If the researcher is unable to contact me, I consent to the researcher contacting my nominated alternative contact person so that they can make contact with me.
- I consent to the research staff audio recording my interview, and understand that the recording will not be used for any other purposes and will be stored securely.
- I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.
- I understand that the researcher has an obligation to report any imminent threats disclosed to them regarding the safety of myself or others to the appropriate organisations.
- I understand the compensation provisions in case of injury during the study.
- I know who to contact if I have any questions about the study in general

- I understand my responsibilities as a study participant.
- I wish to receive a summary of the results from the study. Yes ☐ No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____