INFORMATION SHEET FOR PARTICIPANTS



REC Reference Number: PNM/14/15-110

Version: 2 - 20 April 2015

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of study

Understanding codeine use: exploring the experiences and characteristics of codeine users

Invitation Paragraph

You are being invited to take part in a research study. Before you decide we would like to explain why the research is being done and what it involves. Please take time to read the following information. Ask us if there is anything that is not clear or if you have any other questions. Take time to decide if you want to take part or not.

What is the purpose of the study?

This interview study is being conducted by King's College London as part of an EU funded project about codeine misuse, related health harms, characteristics of users, and dependence. There is limited evidence available on the factors associated with and outcomes of use. The aim of the interview study is to collect qualitative data to explore codeine users' choices and decision-making when using codeine (prescribed or otherwise), codeine use patterns, favoured route of administration, recreational use and tampering with codeine pharmaceuticals, adverse health consequences (including codeine related problems and dependence), characteristics of dependent and non-dependent codeine users, sourcing of codeine, use of other drugs and medication, opinions around medical prescribing, and pharmacy dispensing and internet based retail.

During the interview you will be asked questions about which codeine products you use, how and why. You will be asked about from where you get your codeine and any problems you have experienced as a result of using codeine. We will also ask if you have used any other drugs or any other medicines. We will ask how you first got introduced to

using codeine. This will help to increase the evidence base, which will be of potential benefit to people who decide to use codeine and in the development of public health responses.

If you would like to read more about our research about codeine use, then go to: www.codemisused.org

Do I have to take part?

No. It is up to you to decide whether or not you want to take part. If you do we will ask that you give your consent to take part. You are still free to withdraw up until the point of publication of results without giving a reason. If you wish to do so you must inform the researcher in writing. A decision to withdraw will not affect your rights to any health care you receive.

What will happen to me if I take part?

If you decide to take part we will ask you to take part in an interview that will last about 1 hour and that will be audio recorded. In this interview we will ask you questions about your use of codeine, what products you use, and your experiences with any problems you may have encountered. When taking part in an interview you will receive a £20 gift voucher in reward of your time.

What are the possible risks of taking part?

We understand that answering questions about substance use and dependence can be stressful. We know from experience that talking about these issues as part of an interview can sometimes make participants feel worse. Should you become distressed during the interview, the interview will terminate immediately. We will advice you to seek help from GP.

Will my taking part be kept confidential?

Yes. All the information that we collect will be kept strictly confidential. Any identifying information about you will not be disclosed to anyone outside the research team. You do not have to give us your full name or date of birth.

Once the audio recording of your interview has been transcribed, the audio recording is deleted. Any details that might be used to identify who you are will be erased from the transcription of your interview. All transcriptions are safely stored at King's College London to make sure that no one other than the research team can look at it. We do this by storing it on a computer that can only be accessed with a password.

Researchers work under the same rules of confidentiality as doctors and nurses, which can only be broken, without your consent, in very exceptional circumstances. **Usually** this is if the researcher sees or is told something which raises serious concern for your personal safety.

How is the project being funded?

The research is funded by the European Commission — 7th Framework Programme (reference number: FP7-PEOPLE-2013-IAPP-611736) and is sponsored by King's College London.

What will happen to the results of the study?

The results of the study will be published in reports, articles and conference presentations.

Who should I contact for further information?

Ask us if there is anything that is not clear or if you would like more information. Please contact the researcher using the following contact details:

Dr Andreas Kimergård, Addictions Department, King's College London, T: 020 7848 0446, @: Andreas.Kimergard@kcl.ac.uk

What if I have further questions, or if something goes wrong?

If this study has harmed you in any way or if you wish to make a complaint about the conduct of the study you can contact King's College London using the details below for further advice and information: The Chair, PNM Research Ethics Subcommittee (RESC), rec@kcl.ac.uk

What else do I need to know?

You must be 18 years or older to take part in this study. If you are interested in receiving the final results of this study please get in contact with Andreas Kimergård. However, remember that data from studies such as these often take many months to prepare for publication.

Thank you for reading this information sheet and for considering taking part in this research.

REC ref.: 15/LO/0107

Short Title: Codeine Interview Study

Document name: Annex D: Consent form A

Version: 2 **Date:** 24/02/15

Consent form

Codeine interview study: benefits of codeine use, side effects and use of treatment services

Researcher: Andreas Kimergård, King's College London

Email: Andreas.Kimergard@kcl.ac.uk

Please tick box

☐ I confirm that I have read and understand the information provided for this study. I have had the opportunity to consider the information and ask questions.

☐ I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical care being affected.

☐ I understand that personal information collected during the study will be anonymised and remain confidential.

☐ I understand that I can choose not to answer questions which I feel uncomfortable about answering.

	I agree to the digital recording of this interview.
	I agree that quotes from my interview may be reported in published documents but that this will be anonymous and no-one will be able to identify me from this.
	I agree to take part in the study.
Name of participant:	
Date:	
Signature:	
Name of researcher:	
Date:	
Signature:	
Note	e: This form must be completed in 2 copies, one for the participant and

one for the researcher.