Q-PROMPPT: Qualitative study to design the PROMPPT intervention

The Q-PROMPPT research blog

PARTICIPANT INFORMATION

How can I help?

If you are living with long-term pain or caring for someone who does and have experience of using opioid pain medicines, either now or in the past we need your help. Your experiences and views about living with and taking opioid medication for long-term pain are important to us and will be really valuable in helping us understand the best way for clinical pharmacists to improve care for patients with long-term pain.

By taking part in this research you will help us to develop a new way for clinical pharmacists to review patients taking opioids for long-term pain that is attractive, relevant and useful to patients. We will test the new clinical pharmacist review in future studies and if it is successful, it may become part of routine care in future.

We want to understand the experience and views of as many different people as we can, and we know that many people are not able to take part in face-to-face interviews for research, or do not want to. This is why, as part of the Q-PROMPPT study, we have set up the Q-PROMPPT blog so that people can take part in the research via the internet when and how they want to. We will combine what people tell us through the Q-PROMPPT blog with what patients, clinical pharmacists and GPs tell us in face-to-face interviews so that we have as many views as possible.

What is the Q-PROMPPT blog?

The Q-PROMPPT blog is an online (internet-based) discussion forum which has been created by the research team at Keele University for the purpose of carrying out this study. The Q-PROMPPT blog and website are hosted on a secure Keele University server.

Posters and online advertisements will tell people about the Q-PROMPPT blog and will display the website address, so they can find out more. The Q-PROMPPT blog will be open ('live') for at least 8 weeks and up to 12 weeks and will be a place on the internet where people with experience of long-term pain and pain medicines, who have agreed to take part, can share their views and take part in a discussion with others. After a maximum of 12 weeks the Q-PROMPPT blog will close and those taking part will be informed one week before it closes.

Do I have to take part?

You are free to decide whether you wish to take part or not. If you decide to take part, you will be guided through the process to register on the Q-PROMPPT website and asked to give your permission for the study team to collect your anonymous comments by completing an online consent form.

If you decide not to take part then you can simply leave the website at any stage and no personally identifiable information will be kept about you. If you register and then change your mind, you can withdraw at any time during the study, without giving a reason. Your

decision as to whether or not to take part in the Q-PROMPPT blog will not affect any future care you receive.

What is the purpose of this study?

Almost half of all adults in the UK live with long-term pain. Most are managed by their family doctor (GP), often using medicines. The use of morphine-like painkillers (opioids) has increased dramatically in recent years, and around 2.5 million people are now prescribed opioids (for example: codeine, tramadol, oxycodone, morphine, patches) for long-term pain.

For many people opioids do not seem to help in the long-term, and they may cause other problems. Studies show that people who take regular opioids for long-term pain tend to have worse quality of life than people with long-term pain who do not take these medicines. Also, they are more likely to suffer bone fractures, addiction and overdose, especially with high doses.

Guidelines say that people taking opioids long-term should be reviewed regularly, to make sure that their medicines are helping rather than harming them, but often this does not happen, mainly because GPs are too busy.

A recent report recommends that clinical pharmacists should be more involved in looking after patients with long-term health problems. Clinical pharmacists are qualified pharmacists who have trained to become specialists in medicines and have done extra training in patient care. In future, more clinical pharmacists will be working as part of the team of health professionals in GP surgeries, and will be able to prescribe in the same way as doctors do.

The Q-PROMPPT study aims to find out how clinical pharmacists, working in GP surgeries, can help improve care for patients who take regular opioids for long-term pain and what extra training these clinical pharmacists will need.

What will happen if I take part?

If you decide to take part you will need to register (as explained below) and you will be given a username, which will be your identity (screen name) on the discussion forum. This way any comments you or others make are anonymous and do not reveal anyone's real name or any other personal information.

During the time that the Q-PROMPPT blog is live, the study team will add a new topic for discussion approximately weekly. These topics will all be related in some way to living with long-term pain, using pain medication, and experiences of consulting healthcare professionals (such as doctors, nurses and pharmacists) about pain and pain medication. You will be able to watch a short video explaining the topic and there will also be a written summary available for you to read. We will ask some questions to get the discussion going.

You can share your experiences and views by posting written comments and by replying to other peoples' comments. Your comments and replies (called 'posts') will appear on the blog so other people can see them and comment if they want to. The study team will also comment and ask questions from time to time to keep the discussion going. The study team will also review and moderate all posts, in line with the forum's community guidelines, with any abusive or unsuitable ones being removed. You choose how much to get involved in the discussions, how many times you comment and how much time you spend on the forum.

Only people who have registered to take part are able to post comments and contribute to the discussion. Example screenshots of the Q-PROMPPT blog will be publicly available to

view online during the study. We have done this so that people who are not sure whether or not they want to take part can see what happens to help them decide.

After a maximum of 12 weeks the study will end and the Q-PROMPPT blog will close. All registered users (participants in the study) will receive an email one week before to let them know the date it will close and another email thanking them for their contribution when the blog has closed. The study team will collect all the anonymous comments and contributions when the blog closes. After that, the discussions will no longer be available for anyone to see on the internet.

If I would like to take part, what do I have to do?

In order to take part you will need access to the internet and a valid email address. First, you will be asked to the PROMPPT website and read this information about the study. Then, if you decide to take part, you will need to click the register button on the Q-PROMPPT blog information webpage. You will then be guided through the process to register by following instructions on the website.

You will be asked to provide a valid email address and will be given a username. Your username (but not your email address) will appear above any comments you make on the online discussion forum. You do not need to provide your real name or any other personal information, only a valid email address. You will also be asked to choose a password with 8 characters or more.

Next, you will see a screen to inform you an email has been sent to your email address, asking you to confirm that you wish to register. The email will include a link to confirm your registration. Clicking on this link will take you to the Q-PROMPPT website and will activate your account. You will not need to repeat these steps, unless asked to do so by the website administrator. Once registration is confirmed, you will be invited to log in to the Q-PROMPPT blog with your username (or email address) and password. After logging in, you will be able to take part in the discussion forum. A link on the log-in page will allow you to reset a forgotten password.

You are free to withdraw at any time during the study without giving a reason. You can do this by sending a private message to the study team via the Q-PROMPPT website. If you withdraw from the study, no personal identifiable information about you will be kept.

What are the benefits and disadvantages of taking part?

We hope that what we learn from the study will help us to design a new way for clinical pharmacists (working in GP practices) to review patients taking opioids regularly for long-term pain. If the review is developed using the views of people like you, with experience of long-term pain and pain medicines, then it is more likely to be attractive, acceptable and relevant to patients. In this way the findings from the interviews may have future benefit to you and other people with long-term pain.

One possible disadvantage is the time taken for you to contribute to the discussion forum. We think it will take no more than 5 minutes to listen to and read each discussion topic. The time spent taking part in the discussion is entirely your choice.

It is possible that a discussion topic may bring back unhappy memories or distressing thoughts. If this does happen, you are free to stop taking any further part in that discussion If these feelings or thoughts persist and you feel you would like to talk to someone about

this you are encouraged to contact your family doctor (GP) or local healthcare provider or if you prefer to speak anonymously then telephone numbers for support networks are provided on FAQ page of the website.

If the study team moderating the blog become concerned about your safety or welfare, they will send a private message to you via the website, and may pass this message to the website administrator who can send it to you via email. In the event your contributions to the discussion forum include content that may cause harm to others taking part, this will be removed by the moderators and a private message sent to you explaining the reasons for this and if appropriate advising on how and where to seek help.

What will happen to the information collected about me during the study?

Keele University is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study.

This means that we are responsible for looking after your information and using it properly. Keele University will only keep identifiable data, including email addresses and usernames during the period that the blog is open, after which it will be confidentially destroyed.

If you withdraw from the study, any information you have given us (your contributions on the Q-PROMPPT blog) before withdrawing from the study will be kept. We will not keep any personally identifiable information.

You can find out more about how we use your information at:
https://www.keele.ac.uk/privacynotices/privacynotice-researchparticipants/
Or by contacting Keele University's Data Protection Officer at: dpo@keele.ac.uk

We are committed to protecting the privacy and security of the personal information of all participants in our research.

Authorised individuals from Keele University and regulatory organisations may look at your research records to check the accuracy of the research study. The only people in Keele University who will have access to information that identifies you (i.e. email addresses), during the period that the blog is open, will be the website administrator and people who audit the data collection process.

The people who analyse the data that you provide will not be able to identify you and will not be able to find out your name and contact details (i.e. email address).

We will not keep any usernames, email addresses or any other personal information about you or anyone else who takes part after the Q-PROMPPT blog closes.

Before the study team analyse the blog posts and comments, each person who takes part in the study will be given a unique number (instead of their username) so any comments

made by you on the Q-PROMPPT blog will not allow you to be identified and will not be associated with your personal details. The data published from this study will not contain any of your identifiable information and so cannot be traced back to you. This means that the data is anonymous and on this basis may be used in other research studies. We may use direct quotations from your contributions on the discussion forum in future publications, but these will always be anonymous and will not identify you. Anonymous study data (i.e. blog posts and comments) will be kept for 10 years after the study has finished.

Our procedures for handling, processing, storage of and destruction of data are in line with relevant regulatory requirements. To ensure electronic data are stored securely, it will be held on networks approved by a government backed cyber security scheme.

Who is funding and organising the research?

The Q-PROMPPT study is funded by the National Institute for Health Research (NIHR). This study is part of a bigger programme of work funded by NIHR, which is being conducted by the Research Institute for Primary Care and Health Sciences, and managed by Keele Clinical Trials Unit at Keele University.

Who has approved this study?

To protect your interests, this research has been looked at by an independent group of people, called a Research Ethics Committee who are part of the Health Research Authority (HRA).The East of England- Cambridge East Research Ethics Committee has reviewed and approved this study (REC Number: 19/EE/0151).

The scientific quality of the study has also undergone independent peer review as part of the NIHR Programmes Grant for Applied Research Scheme application process.

Will I get to find out what the results are?

We will publicise the main results on the PROMPPT research programme website (www.promppt.co.uk) and on the Keele University Research Institute for Primary Care & Health Sciences website (https://www.keele.ac.uk/pchs/). We will also expect to publish the results in academic journals and at national and international medical meetings and conferences.

What if I have any questions or there is a problem?

If you want to ask any questions about the study, or have any problems using the website, you can send a private message to the study team via the administrator on the website. You will receive a response by email. Answers to frequently asked questions (FAQs) will also be available on the website and will be updated as needed.

If you have any questions or concerns about taking part in this research study you can also contact the study sponsor, Dr Tracy Nevatte, Head of Project Assurance at Keele University on Tel: 01782 734714, email: research.governance@keele.ac.uk.

Contact for further information

If you have any further questions or concerns about the study you can contact the Q-PROMPPT Study Manager on 01782 732950 or email sch-tr.studypromppt@nhs.net.

Thank you for taking the time to read this information leaflet and for considering taking part in this study.