School of Medicine
University of Dundee

Picture
Chronic Pain IdentifiCation Through Using electRonic rEcords

Participant Information Sheet – Survey

Chronic Pain Identification Through Using Electronic Records (C-PICTURE)

Study title: Chronic Pain Identification Through Using Electronic Records (C-PICTURE). Development and validation of an algorithm to identify people with chronic pain through primary care-based records (C-PICTURE)

Sponsor: The University of Dundee; established by Royal Charter dated 20 July 1967 and a registered Scottish Charity (charity number SC015096) and having its principal office at 149 Nethergate, Dundee DD1 4HN.

Chief Investigator: Professor Lesley Colvin, Professor of Pain Medicine, University of Dundee.

Who is conducting the research?

The research is being conducted within the Division of Population Health and Genomics, University of Dundee. Professor Lesley Colvin is the Chief Investigator who is responsible for the study. Dr Nouf Abutheraa is the Researcher who is responsible for the day to day management of the study.

Who is funding the research?

The research study is funded by the Chief Scientist Office of the Scottish Government.

What is the purpose of the research?

Chronic pain is pain that has persisted for three months or more. There is a lack of accurate information on the number of people living with chronic pain in Scotland. An accurate figure is essential to ensure that the NHS can allocate sufficient resources and provide effective healthcare services for patients living with this condition. It also increases what chronic pain research we can do to better understand the problem and how to improve. There is no robust method for identifying people living with chronic pain, as the previous use of prescribing records excludes people who use other pain management strategies such as physiotherapy, chiropractic treatment or exercise.

The C-PICTURE study aims to develop a chronic pain case identification algorithm; a set of coding rules that will identify people living with chronic pain. The required data will be collected, tested, refined and validated. Through this process, the research team will ensure that the most accurate version of the algorithm is developed before it is used in research and clinical settings.

Since the majority of patients who seek treatment for chronic pain do so in the primary care setting (i.e. not in hospital), we are working with GPs to recruit participants for this study. We want to learn more from people with chronic pain by giving them an opportunity to describe their pain experiences by completing the enclosed questionnaires.

The aim of this survey phase is to gather some understanding of the characteristics of pain, and its management. This includes the need to understand treatment provided and the impact of treatments on pain. We also want to understand the impact of pain in everyday life. This data will be used to refine an algorithm that has been developed by the C-PICTURE team to identify people with chronic pain in Scotland.

How will the study be achieved?

Initially, six GP practices will run the first iteration of the algorithm in their system and provide us with an indication of who does and does not have chronic pain. We will then collect data from some of the patients registered with these GP practices – this will include case note reviews of 1200 records, invitations to 6200 individuals to complete the enclosed questionnaires and from these we will be inviting up to 32 individuals with chronic pain, 16 healthcare professionals to participate in one-to-one interviews with the study researcher and similar numbers to participate in group discussions. These data will be used to assess the accuracy of the initial algorithm. Finally, these data will be used to adjust the algorithm to increase its accuracy at detecting the presence of chronic pain.

You will be given an opportunity to take part in future research about chronic pain. You'll also be invited to attend feedback sessions and join study newsletters (either online or in paper form)

Why have I been invited to take part?

You have been invited to take part because you are registered with one of the six participating GP practices. Whilst this study concerns chronic pain, you do not need to have chronic pain to participate in the survey phase.

Do I have to take part?

No; participation in this study is optional. Choosing to take part in this study, or not, will not affect you or your medical care. Your GP will be informed if you decide to participate; however, your GP will not receive any of the data that you provide to the research team. If you do not complete the included questionnaires, this will be understood as non-participation. Should you wish to opt out of the study formally, you may complete and return the study opt-out form.

What will happen if I take part in the survey phase?

If you decide to participate in the survey phase of the study, it will involve completing the questionnaires about chronic pain. If you do not have pain and choose to participate, you need to complete only one question entitled, 'C-PICTURE: Question 1'. It is estimated that completion of all the questions will take a maximum of **10 minutes**. You may complete the paper copy and return it in the enclosed Freepost envelope ' No Stamp Required' or you may complete it online using the following link [https://redcap.link/c-picture], or you can scan the following barcode with your mobile phone camera:

Additionally, if you would like the study researcher to complete the questions on your behalf – or if you would like further information or support in order to participate – you may contact the Telephone Support number and arrange to do this at a time that is convenient to you. If you prefer to have the study researcher call you, you may return the Telephone Support Request Form in the Freepost envelope provided. If you decide to participate your completion of the questionnaires will be understood as 'consenting to participate'. Non-response will be understood as declining to consent to participate. One reminder will be sent to those that have not yet completed the questionnaires or returned the study opt-out form. If you do not wish to participate in the survey phase, please ignore the reminder.

You will be given an opportunity to express your interest to participate in the C-PICTURE interview and/or group discussions or future research about Chronic Pain. Also, some feedback

sessions will be provided and an opportunity to receive the C-PICTURE newsletter. If you want to be part of any of these please ensure you indicate this on the survey questions.

Are there any risks in taking part?

There are no known risks associated with participating in the present study except the time you take from your day to complete the questionnaire and post it back.

What are the possible benefits of taking part?

The present study does not aim to test interventions; therefore, you will not be offered treatment for health conditions. Whether you do or don't have pain, your participation in this study will benefit the future care of people living with chronic pain.

If you wish, we can give you information about third sector organisations that provide education and support for people living with chronic pain. You can request this form of support by contacting the Telephone Support number or access online resources at Chronic Pain | NHS inform.

Will my taking part in this project be kept confidential?

The University operates a number of Standard Operating Procedures (SOPs) to ensure the confidentiality and security of all study data. Furthermore, staff members who work directly with data are required to be certified in accordance with Good Clinical Practice (GCP). Additionally, all of the information that you provide will be pseudonymised. This means that your personal details, such as your name and address, will be held separately from any health-related or other information that you provide in the questionnaires.

If you would like further information concerning data security protocols in operation at the University of Dundee, you may email the Information Governance Team (dataprotection@dundee.ac.uk).

What will happen to the information I provide?

Paper and online questionnaire data will be retained by the Health Informatics Centre (HIC), University of Dundee for the duration of the study (24 months). HIC provides a Trusted

Research Environment (TRE) and operates a Scottish Government-certified Safe Haven, which is a secure virtual environment that prioritises data security.

HIC will pseudonymise all data (i.e. remove personally identifiable data and hold the key separate from health-related and other data). During this phase, only trained and approved HIC personnel will have access to personal information. Access to the pseudonymised data will be given to a named researcher(s) for the purpose of analysis and writing, they will have no access to any identifiable data.

At the end of the 24-month study period, HIC will transfer all data to the Chief Investigator of the study. Again, the data will be held in a pseudonymised form, with identifiable data (such as name and address) held separately from health-related and other data. The data will then be held on a secure University of Dundee electronic system during the 10-year retention period. The purpose of the retention period is to facilitate further data analysis and also to facilitate further data collection with those who have consented to further contact for participation in future extensions to this study. During this phase, all data will be held by the Chief Investigator and accessed only by approved members of her research team.

At the end of the 24-month study period, HIC will also host the pseudonymised data on the Alleviate Pain Hub within HIC at the University of Dundee (https://alleviate.ac.uk/). The purpose of the Pain Hub is the enlightenment of the scientific community. Scientists may submit queries to HIC concerning the data contained within the Pain Hub. Responses to queries will only ever provide anonymised, aggregate-level data, and no individual-level data will ever be provided to any individual or organisation. During this phase, only trained and approved HIC personnel will have access to personal information.

Data dissemination

Data will be disseminated in aggregate-level forms only; therefore, it will be impossible for any individual study participant to be identified. An end of study report will be provided to the funder (Chief Scientist Office), and findings will be disseminated through scientific conferences and academic journals. Study participants may access copies of all published materials by visiting the Discovery portal, the University of Dundee's research repository. All published materials will be listed in the Chief Investigator's personal profile (https://discovery.dundee.ac.uk/en/persons/lesley-colvin).

Data destruction

At the end of the 10-year retention period, all data will be destroyed securely in accordance with University of Dundee data destruction protocols.

Data Protection

How will we use information about you?

We will need to use information from you for this research project. This information will include your CHI number (NHS unique identifier), name, contact details and any information that you provide. We will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. Your data will be held securely by the University of Dundee if you agree to future contact about research activities relating to this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information at:

- www.hra.nhs.uk/information-about-patients/
- http://www.ahspartnership.org.uk/tasc/for-the-public/how-we-use-your-information
- https://www.dundee.ac.uk/information-governance/dataprotection/
- http://www.nhstayside.scot.nhs.uk/YourRights/PROD_298457/index.htm

Or by contacting Research Governance, Tayside Medical Science Centre (TASC). Tel: 01382383900. Email: tascgovernance@dundee.ac.uk

The University asserts that it is lawful for it to process your personal data in this project as the processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.

The University asserts that it is lawful for it to process special categories of your personal data in this project as the processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) of the General Data Protection Regulation.

The University of Dundee is the data controller for the personal and/or special categories of personal data processed in this project.

You can find more information about the ways that personal data is used at the University at: https://www.dundee.ac.uk/information-governance/dataprotection/.

Is there someone I can complain to?

If you wish to complain about the use of your information, please contact the University's Data Protection Officer in the first instance (email: dataprotection@dundee.ac.uk). You may also wish to contact the Information Commissioner's Office (https://ico.org.uk/).

Alternative formats

If you are experiencing difficulties in accessing the information contained within any of the documents included in this pack, please contact the Telephone Support number [details on the last page] or return the Telephone Support Request Form in the Freepost envelope provided.

Insurance

The University of Dundee holds Clinical Trials indemnity cover which covers the University's legal liability for harm caused to patients/participants.

Other Scottish Health Boards are participating as participant identification centres, and they are also members of the Clinical Negligence and Other Risks Indemnity Scheme. This will cover their liability for carrying out the trial.

Who has reviewed this trial?

This study has been reviewed and awarded a favourable opinion by London - Surrey Research Ethics Committee reference number: 23/LO/0398, and its study Integrated Research Approval System (IRAS) reference number is 323651, which will be used in all documents.

The study engaged with People with Lived Experience (PWLE), GPs, healthcare professionals and academic researchers in all stages of the research cycle.

Contact Details for Further Information

Dr Nouf Abutheraa, Postdoctoral Research Assistant, School of Medicine, University of Dundee.

Tel: +44 (0)1382 383898

Email: c-picture@dundee.ac.uk

Study website: https://www.dundee.ac.uk/projects/c-picture