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Developing and testing a way to correctly identify people with chronic pain from their primary care records

Submission date
14/02/2024

Recruitment status
Recruiting

Registration date
27/02/2024

Overall study status
Ongoing

Last Edited
04/03/2024

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
We believe 2 in 5 people living in the UK could be living with pain severe enough to limit their daily activities. In Scotland, about 6% of adults have severe chronic pain. But these numbers are based on research estimates and cannot show the true number of people who live with chronic pain. Without knowing how widespread chronic pain is in Scotland, it is difficult to plan for health and social care services. We need to better understand the challenges people with chronic pain face to remain in work or take part in meaningful social activities.

Nearly everyone in Scotland has a unique NHS number attached to their health records. We have developed a computer programme, called an algorithm, that can automatically search GP records to identify people with chronic pain. We would like to test it and make sure we are not missing anyone who may have unmet need due to their chronic pain. To do this, we will use information from medical records, patient surveys, and in-depth interviews to see how well the algorithm matches with the other information. With patient partners, we will work to further improve it, so it better identifies people living with chronic pain.

Our enhanced algorithm will revolutionise how we identify, treat, manage, and research chronic pain in Scotland. We will finally be able to have more precise local and national numbers. This information can be used by policy makers and researchers, to quickly identify who needs services and where they are needed.

Who can participate?
A person over the age of 18 years who is a patient in a participating GP practice.

What does the study involve?
The study has 4 defined phases (A-D)
A. We will use medical records to manually look at how chronic pain is impacting the population by reviewing who has chronic pain; how this is found and dealt with, and who does not have chronic pain.
B. Postal and online questionnaires to assess chronic pain and it’s impact. We will ask questions

regarding how people use over the counter medicine and alternative therapies. From this we will offer people the choice to participate in future feedback sessions.
C. Future feedback sessions and interviews. These will help us to have a better understanding of how chronic pain impacts a person. We will also hold focus group sessions with people participating and we will interview some GPs involved in the study.
D. Create a report using the algorithm and use it to understand the conditions and prescribing data that is linked to people with chronic pain.

What are the possible benefits and risks of participating?
The benefit of future research, for example understanding the impact of COVID-19 on chronic pain and healthcare.
To improve pain management and outcomes for people with chronic pain, for example developing precision medicine approaches to pain management.
To influence policy and service planning, for example reducing harmful prescribing by looking at treatment methods.

Where is the study run from?
University of Dundee, School of Medicine (UK)

When is the study starting and how long is it expected to run for?
June 2023 to September 2025

Who is funding the study?
Chief Scientist Office, Scottish Government Health and Social Care Directorate (UK)

Who is the main contact?
Chief Investigator, Professor Lesley Colvin, l.a.colvin@dundee.ac.uk

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

Contact information

Type(s)
Principal Investigator

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
323651

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
IRAS 323651, CPMS 56178

Study information

Scientific Title
Development and validation of an algorithm to identify people with chronic pain through primary care based records

Acronym
C-PICTURE

Study objectives
The use of routinely coded data, (such as diagnostic Clinical Read Codes, prescribing data and secondary care referral) to construct an algorithm, should have the potential to identify people with chronic pain in the community.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/06/2023, Study Research Ethics Committee (2 Redman Place, London, E20 1JQ, United Kingdom; +44 207 1048 088; surrey.rec@hra.nhs.uk), ref: 23/LO/0398

Study design
The study consists of 4 phases using mixed quantitative and qualitative methodology.
Phase A: a medical note review (observational mixed-method cohort study)
Phase B: survey (cross sectional study)
Phase C: interview and focus group (qualitative study)
Phase D: data export of diagnostic and prescribing read codes from the GP system (quantitative study)

Primary study design
Observational

Secondary study design
4 phases using mixed quantitative and qualitative methodology

Study setting(s)
Community, GP practice

Study type(s)
Diagnostic, Quality of life, Screening

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Chronic pain

Interventions
Phase B (survey): If the participant decides to take part in the survey phase, it will involve completing questionnaires (online or paper). If they do not have pain and choose to participate, they only need to complete one question. It is estimated that completion of these questionnaires will not take more than 10 minutes. A reminder letter will be sent 2 weeks after the participant receives the initial invite, and no further communication will be done after that unless the participant has requested to have a telephone call.

Phase C (Qualitative studies): If the participant decides to take part in an interview or focus group (online or in-person). This will not take more than 90 minutes, it will be recorded, and verbatim transcribed and all identifiers will be removed from the transcribed documents (name, GP Practice, address, location, personal details).

Intervention Type
Other

Primary outcome measure
1. Reviewing patient notes at baseline only
Combinations of read codes and free text will be screened to find chronic pain patients and to measure their percentage from the screened medical notes.
2. C-Picture Pain questionnaires at baseline only
Patient-reported outcome of chronic pain and the way they use to control their pain (if any)
3. Level of Expressed Need Questionnaire at baseline only
It measures the need for pain medication.
4. Douleur Neuropathique EN 4 (DN4) Questionnaire at baseline only
It measures the characteristics and symptoms of pain.
5. Brief Pain Inventory (Short Form) at baseline only
The location of pain, the intensity of pain at different time points measured on a scale from 0-10, the pharmaceutical treatment and its impact, and the impact of pain in the patient's lifestyle including work and sleep.
6. Patient interviews at baseline only
Knowledge, attitude and behaviour of chronic pain and its management.
7. Patient focus group at baseline only
Knowledge, attitude and behaviour of chronic pain and its management.
8. SPIRE report data at baseline only
A list of patients with chronic pain using medical conditions and/or prescribing data.
9. Re-run the SPIRE report (i.e. PCIS) with a different algorithm at the end of the study only.
A modified algorithm to provide a list of patients with chronic pain using medical conditions and /or prescribing data.

Secondary outcome measures
Measured using an interview and fcus group, during the 3rd phase of the study and before the modified algorithm can be re-tested again:
1. Patient attitudes towards pain management measured using qualitative interviews and/or focus group.
2. Patient knowledge towards pain management measured using qualitative interviews and/or focus group.
3. Patient behaviours towards pain management measured using qualitative interviews and/or

focus group.
4. Healthcare providers' attitudes towards pain management measured using qualitative interviews.
5. Healthcare providers' knowledge towards pain management measured using qualitative interviews.
6. Healthcare providers' behaviours towards pain management measured using qualitative interviews.

Thematic analysis will be used to analyse the qualitative studies.

Overall study start date
22/06/2023

Completion date
30/09/2025

Eligibility

Key inclusion criteria
Phase A. Selection of medical records for review from SPIRE participants
1. 18 years of age or over
2. Electronic medical record held by SPIRE-enabled GP practice

Phase B. Invited to complete pain questionnaires
1. 18 years of age or over
2. Capable of providing informed consent
3. Able to communicate in English
4. Person registered with participating GP practice

Phase C. Invitation to a semi-structured interview or focus group discussion(s)
1. 18 years of age or over
2. Capable of providing informed consent
3. Able to communicate in English
4. Patient of a participating GP practice (and who has returned a survey with consent for contact) or practice staff responsible for coding

Phase D: SIRE Report
1. 18 years of age or over
2. Registered with one of the 6 GP practices involved in the study.
3. Patient has not opted out of SPIRE

Participant type(s)
Patient, Health professional, Population

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
Phase A: 1200 patients. Phase B: 2000 patients . Phase C: a maximum of 64 participants. Phase D: no target number

Key exclusion criteria
Phase A. Selection of medical records for review
1. Under 18 years of age
2. Patient has opted out of SPIRE

Phase B. Invited to complete pain questionnaires
1. Under 18 years of age
2. Not capable of providing informed consent
3. Unable to communicate in English
4. GP does not deem patient suitable for inclusion
5. Patient has opted out of SPIRE

Phase C. Invitation to a semi-structured interview or focus group discussion
1. Under 18 years of age
2. Not capable of providing informed consent
3. Unable to communicate in English
4. GP does not deem patient suitable for inclusion
5. Patient has opted out of SPIRE
6. Not patient of a participating GP practice or not a member of staff in a GP practice

Phase D:
1. Under 18 years of age
2. Patient has opted out of SPIRE

Date of first enrolment
15/02/2024

Date of final enrolment
15/08/2025

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Aultbea & Gairloch Medical Practice
Birchburn
Aultbea

Achnasheen
United Kingdom
IV22 2HZ

Study participating centre
Dalhousie Medical Practice
The Health Centre
109-111 High Street
Bonnyrigg
United Kingdom
EH19 2ET

Study participating centre
Kirriemuir Medical Practice
Tannage Brae
Kirriemuir
United Kingdom
DD8 4ES

Study participating centre
Craigmillar Medical Group
Craigmillar Medical Centre
106 Niddrie Mains Road
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EH16 4DT

Study participating centre
Edzell Health Centre
High Street
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DD9 7TA

Study participating centre
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Sponsor type
University/education

Website
http://www.dundee.ac.uk/tasc

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office, Scottish Government Health and Social Care Directorate

Alternative Name(s)
Chief Scientist Office, Scottish Government Health Directorate CSO, Chief Scientist Office, Scottish Government Health Directorates, Chief Scientist Office of the Scottish Government Health Directorates, Scottish Government Health and Social Care Directorate of the Chief Scientist Office, Scottish Government Health Directorate Chief Scientist Office, The Chief Scientist Office, CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a relevant peer-reviewed journal.

Intention to publish date
15/07/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (links will be provided later).

IPD sharing plan summary
Stored in publicly available repository, Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 0.2	25/01/2024	20/02/2024	No	Yes
Statistical Analysis Plan		07/02/2024	20/02/2024	No	No