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# Developing and testing approaches to support primary care practices to reduce harmful opioid prescribing (Opioid SMART)

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| **Submission date**<br>16/06/2025 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[X] Protocol |
| **Registration date**<br>08/10/2025 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>16/10/2026 | **Condition category**<br>Other | [_] Individual participant data<br>[X] Record updated in last year |

## Plain English summary of protocol

Background and study aims
Opioids are morphine-based medicines that can result in addiction and increased risks of falls and death. A previous programme, the Campaign to Reduce Opioid Prescribing (CROP), was delivered to primary care practices in West Yorkshire to reduce harmful opioid prescribing. The programme involved providing comparative feedback reports to practices, which prompted clinicians to 'think twice' before initiating opioids for chronic pain and actively review repeat prescribing. After 1 year, the feedback resulted in 15,000 fewer patients being given opioids. Yet some practices were not able to reduce their prescribing, and some took longer to improve. 'Feedback facilitation' involves bringing in a trained facilitator to deliver a support session to practices struggling to change practice. Previous research suggests facilitation works but it costs time and money. It is important to know whether and when such facilitation might help most. We plan to use a Sequential Multiple-Assignment Randomised Trial (SMART) design to answer this question, which changes what support practices get based upon how well they are doing at different times. First, we will aim to adapt the intervention packages and test the feasibility of delivering these packages to primary care practices.

Who can participate?
For the feasibility study, we will recruit eight primary care practices in Yorkshire. We will also recruit several staff at each practice to take part in a one-to-one interview to explore their thoughts on the intervention received.

What does the study involve?
We will test both interventions with eight general practices to check that it is feasible and acceptable. We will randomly allocate half of the recruited practices to receive audit intervention only, and half to receive the audit intervention with feedback facilitation.

What are the possible benefits and risks of participating?
The potential benefits of taking part are that the intervention package practices receive will help to reduce opioid prescribing at their practice. The findings from this study will also aid in the development of a larger randomised trial, which we hope will reduce opioid prescribing in

general practices. This work will also count as quality improvement work for Care Quality Commission (CQC) reviews and for NHS appraisals and revalidation. The risks of the study are expected to be low. A disadvantage to taking part is that practices will have to give up a small portion of their time to take part in the feedback facilitation sessions.

Where is the study run from?
We will deliver the intervention in the feasibility study to eight primary care practices in South Yorkshire.

When is the study starting and how long is it expected to run for?
July 2023 to October 2026

Who is funding the study?
National Institute for Health and Care Research (grant code: NIHR303215) (UK)

Who is the main contact?
opioidsmart@leeds.ac.uk

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## Additional identifiers

### Integrated Research Application System (IRAS)
332047

### Central Portfolio Management System (CPMS)
66665

### National Institute for Health and Care Research (NIHR)
303215

## Study information

### Scientific Title
Adapting and evaluating a complex adaptable intervention to reduce opioid prescribing in primary care (Opioid SMART) – WP1&2

### Acronym
Opioid SMART

### Study objectives
To evaluate the feasibility and acceptability of delivering the two interventions (1. audit and feedback; 2. feedback facilitation in addition to audit and feedback) in general practices.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 03/09/2024, University of Leeds School of Medicine Research Ethics Committee (School of Medicine, Worsley Building, University of Leeds, Woodhouse, Leeds, LS2 9JT, UK; Tel: not provided; FMHUniEthics@leeds.ac.uk), ref: MREC 23-079

## Primary study design
Interventional

## Study design
Randomized; Both; Design type: Process of Care, Complex Intervention, Management of Care, Qualitative

## Study type(s)
Other

## Health condition(s) or problem(s) studied
Opioid prescribing in primary care

## Interventions
We will conduct a randomised feasibility study with a nested qualitative study, with cluster randomisation at the practice-level. We have already shown that it is feasible and acceptable to recruit primary care practices and deliver audit and feedback (A&F) reports on opioid prescribing using routinely collected electronic health record data in the study area (The Campaign to Reduce Opioid Prescribing [CROP]). Therefore, this study will assess the feasibility and acceptability of the feedback facilitation components in addition to A&F, as well as assess the feasibility and acceptability of our updated A&F reports.

Eight practices will be identified from Yorkshire and Humber who have previously received an audit and feedback intervention (i.e., CROP) and are not within the West Yorkshire Integrated Care Board (ICB). We will randomly allocate practices (1:1) to receive bimonthly audit and feedback only, or to receive bimonthly audit and feedback with feedback facilitation and bimonthly follow up telephone calls. All practices will receive their intervention for 6 months.

A copy of the audit and feedback will be emailed to the practice along with a QR code to access their online depository for feedback reports. For practices allocated the feedback facilitation, the support session will be delivered by the research team and is expected to last between 90 to 120 minutes. The session will take place at a time and place (e.g., in-person or online) convenient for the practice. We will ask a range of practice staff to take part in these sessions, including a minimum of one to two prescribers, lead GP, and practice manager or quality improvement lead. The session will involve educational components, local barrier identification and action planning to improve clinical performance.

Quantitative data will include routinely collected data, aggregated at practice-level, from the electronic health record data. Data items will relate to the audits from WP1 for inclusion in feedback reports and to assess any changes in opioid prescribing, number of appointments for consultations regarding pain (where an opioid may reasonably be expected to be prescribed)

and repeat prescription of opioid medication reviews, duration of consultations, staff member involved, method of consultation (face-to-face, telephone, etc.), other related healthcare use (referrals to manage pain) and any changes in opioid medications or other painkillers.

After practices have completed the intervention, we will interview a proportion of practice staff to explore their experiences of their allocated intervention. Qualitative data will be obtained through one-to-one, semi-structured interviews with practice staff (3-5 staff members per practice, total 25-30) exploring intervention acceptability and feasibility.

## Intervention Type
Other

## Primary outcome(s)
1. Time to process electronic health record (EHR) data (in hours) to identify responders and non-responders, measured at the beginning of the study and every 2 months
2. Time to delivery of facilitation event to practices, including proportion of facilitation events delivered within 4 months of delivery of first feedback report, measured between months 1 and 4
3. Duration of facilitation events and follow up calls, measured between months 1 and 4 for event and between months 3 and 7 for follow-up calls
4. Number of follow up facilitation calls delivered, measured between months 3 and 7
5. Time to delivery of facilitation calls following each feedback report delivery, measured between months 3 and 7
6. Number and roles of staff attending facilitation event, measured between months 1 and 4
7. Identification of priorities from data completed at facilitation event, measured between months 1 and 4
8. Identification of barriers at facilitation event, measured between months 1 and 4
9. Completion of an agreed action plan at facilitation event, measured between months 1 and 4
10. Evidence of discussions regarding progress made with action plan at facilitation follow-ups, measured between months 3 and 7
11. Email delivery receipts for feedback reports, measured at month one and every 2 months
12. Behaviour Change Techniques (BCTs) delivered at facilitation event and follow-up calls, measured between months 1 and 4

## Key secondary outcome(s)
1. A&F data obtained for inclusion in feedback reports, including proportion of practices providing data at 6 months on proportion of patients prescribed opioids (per 1000 patients), collected at month 1, every 2 months, and at 6 months
2. Time taken to write report, measured at month 1 and every 2 months
3. Time to obtain routinely collected data from EHRs, measured at month 1 and every 2 months
4. Number of accesses to feedback report online repository, measured at month 1 and every 2 months
5. Time taken by practice to collect additional outcome and process data (information regarding consultations delivered), measured at month 7
6. Number of staff and roles who agree to be interviewed, measured at month 7
7. Number, length and method of consultation (face-to-face, telephone etc) and role of healthcare professionals delivering long-term opioid medication reviews, measured at month 7
8. Number of appointments for consultations regarding chronic non-cancer pain (CNCP) (where an opioid may reasonably be expected to be prescribed), measured at month 7
9. Number of referrals to musculoskeletal, orthopaedics, and pain teams following a consultation for CNCP, measured at month 7

10. Number of attendances at emergency departments or admissions to hospital with an opioid-related condition for patients taking opioid medication, measured at month 7
11. Number of patient complaints as a significant event, measured at month 7
12. Description of patient complaints as a significant event, measured at month 7
13. Fidelity of facilitation delivery from audio recordings and facilitator field notes, including behavioural change techniques delivered as intended, measured between months 1 and 4
14. Qualitative interviews with practice staff at month 7

### Completion date
31/10/2026

# Eligibility

### Key inclusion criteria
Current key inclusion criteria as of 16/10/2026:
WP1 - workshops:
1. Consents to take part in 'World café' stakeholder workshops and/or individual testing rounds
2. Prescribes opioid medication in primary care (clinicians), or is involved in quality improvement in primary care, or commissions services, including medicines optimisation, for primary care, or has expertise in delivering A&F and/or FF, or is a member of the Opioid SMART PPIE group

WP2 – feasibility trial:
1. Practice within Yorkshire and Humber that has previously received the CROP intervention and is not located within West Yorkshire-ICB
2. Able to identify a lead clinician or quality improvement lead for the study
3. Willing to take part in a feedback facilitation event

WP2 – staff interviews:
1. Healthcare staff with a prescribing or quality improvement role within the practice
2. Employed or role within the practice during the intervention delivery period

Previous key inclusion criteria:
WP1 - workshops:
1. Consents to take part in 'World café' stakeholder workshops and/or individual testing rounds
2. Prescribes opioid medication in primary care (clinicians), or is involved in quality improvement in primary care, or commissions services, including medicines optimisation, for primary care, or has expertise in delivering A&F and/or FF, or is a member of the Opioid SMART PPIE group

WP2 – feasibility trial:
1. Practice within Yorkshire and Humber that has previously received the CROP intervention and is not located within WY-ICB
2. Not currently in receipt of other interventions that aim to reduce prescribing of opioid medication
3. Able to identify a lead clinician or quality improvement lead for the study
4. Willing to take part in a feedback facilitation event

WP2 – staff interviews:
1. Healthcare staff with a prescribing or quality improvement role within the practice
2. Employed or role within the practice during the intervention delivery period

### Participant type(s)

Health professional

## Healthy volunteers allowed
No

## Age group
Mixed

## Lower age limit
18 Years

## Upper age limit
100 Years

## Sex
All

## Total final enrolment
0

## Key exclusion criteria
Current key exclusion criteria as of 16/10/2026:
WP1 - workshops:
1. Unable to speak or read English
2. Unable to attend workshops or an in-person or online testing round

WP2 – feasibility trial:
1. Practices located in West Yorkshire.

WP2 – staff interviews:
1. Unable to provide written consent
2. Unable to meet in person or online for an interview

Previous key exclusion criteria:
WP1 - workshops:
1. Unable to speak or read English
2. Unable to attend workshops or an in-person or online testing round

WP2 – feasibility trial:
1. Practice providing enhanced services for drug dependency
2. Practice in lowest ICB decile for opioid prescribing

WP2 – staff interviews:
1. Unable to provide written consent
2. Unable to meet in person or online for an interview

## Date of first enrolment
01/04/2025

## Date of final enrolment
31/10/2026

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**NHS South Yorkshire Integrated Care Board**
-
-
England
-

# Sponsor information

**Organisation**
University of Leeds

**ROR**
https://ror.org/024mrxd33

# Funder(s)

**Funder type**
Government

**Funder Name**
National Institute for Health and Care Research

**Alternative Name(s)**
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**

United Kingdom

# Results and Publications

### Individual participant data (IPD) sharing plan

The quantitative datasets generated during the current study are not expected to be made publicly available due to the data being generated from the NHS Electronic Health Records. The qualitative datasets generated during the current study will be available upon request from Dr Kelly Lloyd (k.e.lloyd@leeds.ac.uk). Only the anonymised qualitative transcripts will be shared to other qualified researchers on application for future research projects, as consented by the participants.

### IPD sharing plan summary

Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet version 5 | 11/11/2025 | 11/11/2025 | No | Yes |
| Protocol file | | 05/05/2026 | 14/10/2026 | No | No |