



BMJ Open Feasibility study of a Behavioural Intervention for Opioid Reduction (BIOR) for patients with chronic non-cancer pain in primary care: a protocol

Helen M Poole ^{1,2}, Bernhard Frank,^{2,3} Emma Begley,⁴ Aimee Woods,¹ Andreia Ramos-Silva,¹ Mike Merriman,⁵ Roisin McCulough,⁵ Catharine Montgomery ¹

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¹School of Psychology, Liverpool John Moores University, Liverpool, UK

²Pain Research Institute, Liverpool, UK

³The Walton Centre NHS Foundation Trust, Liverpool, UK

⁴Aston University, Birmingham, UK

⁵Knowsley Primary Care Trust, Prescot, UK

Correspondence to
Professor Helen M Poole;
h.m.poole@liverpool.ac.uk

ABSTRACT

Introduction Around 30%–50% of adults suffer moderate to severe chronic pain not caused by cancer. Significant numbers are treated with opioids which over time may cease to be effective and produce side effects (eg, nausea, drowsiness and constipation). Stopping taking opioids abruptly can cause unpleasant withdrawal effects. Tapering in small steps is recommended, though some patients might struggle and need support, particularly if they have limited access to pain management alternatives. Awareness of the potential risks as well as benefits of tapering should be explored with patients.

Methods and analysis A randomised controlled pilot feasibility study to investigate the effectiveness and feasibility of reducing high doses of opioids through a tapering protocol, education and support in primary care. Working with NHS Knowsley Place, we will identify patients taking 50 mg or above morphine equivalent dose of opioids per day to be randomly allocated to either the tapering group or tapering with support group. At an initial joint appointment with a pain consultant and General Practitioner (GP) GP tapering will be discussed and negotiated. Both groups will have their opioid reduced by 10% per week. The taper with support group will have access to additional support, including motivational counselling, realistic goal setting and a toolkit of resources to promote self-management. Some patients will successfully reduce their dose each week. For others, this may be more difficult, and the tapering reduction will be adjusted to 10% per fortnight. We assess opioid use, pain and quality of life in both groups at the start and end of the study to determine which intervention works best to support people with chronic pain who wish to stop taking opioids.

Ethics and dissemination The Behavioural Intervention for Opioid Reduction feasibility study has been granted full approval by Liverpool Central Research Ethics Committee on 7 April 2022 (22/NW/0047). The current protocol version is V.1.1, date 6 July 2022. Results will be published in peer-reviewed journals and disseminated to patient stakeholders in a lay summary report available on the project website and in participating GP surgeries.

Trial registration number ISRCTN 30201337.

INTRODUCTION

The prevalence of chronic non-cancer pain (CNCP) is estimated at between 30% and 50%

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Robust intervention development using the Behavioural Change Wheel, incorporating views of patients and professionals in iterative design.
- ⇒ Addresses problem in primary care, capitalising on existing resources and patient collaboration with idea of reducing opioids.
- ⇒ The process is manualised and incorporates training for GPs and Allied Health Professionals who afterwards will have the skills/knowledge to continue to manage opioid reduction.
- ⇒ Feasibility study providing data for a definitive trial.
- ⇒ The relatively small sample size and trial duration limit the extent to which sustained reductions in opioid use and any potentially rare but devastating harms can be assessed.

in UK adults, with 10.4%–14.3% reporting severe, life-limiting pain.¹ Alongside, significant increases in opioid prescribing have been observed,^{2–4} particularly prescriptions for strong opioids.^{4 5} In 2018, there were 5.6 million adults living in England prescribed at least one opioid,⁶ and 540 000 had received an opioid continuously from 2015 to 2018 for CNCP.⁷ Codeine is the most commonly prescribed opioid in the UK.^{2 7} Opioid prescribing has increased, despite a lack of convincing evidence for their effectiveness in CNCP.^{8–11} Adverse consequences such as sedation, depression and impaired cognition are reported,¹² with evidence of medium to long-term opioid prescribing causing ongoing side effects such as constipation, or drowsiness, particularly in combination with other drugs like gabapentinoids or tricyclic antidepressants.¹¹ More potent opioids, higher dosing and heightened risk of harm are associated with increased risk of hyperalgesia,¹³ overdose and death,^{14 15} psychosocial factors (eg, low quality of life, loss of employment) and

poor physical and mental health.¹⁶ There is also evidence to suggest that opioids do not improve, and perhaps worsen functionality and levels of pain in patients with CNCP.^{17 18} A recent UK cohort study reported increased risks in long-term opioid prescribing, heightened in those on daily doses above 50 mg morphine equivalent dose (MED).¹⁹

Lack of alternative treatment for CNCP and the perception of infrequent adverse events have contributed to the continuing opioid crisis.^{11 20} Moreover, prescribers may be reluctant to deprescribe, particularly if there is limited access to effective pain management treatments.^{21 22} This is further confounded by the actions of physicians (eg, lack of knowledge), patients (eg, prioritisation of pain relief over Quality of Life [QoL]) and society (eg, attitudes towards opioid therapy for CNCP).^{18 21} Awareness of potential risks of tapering is essential. It is suggested that medication reviews, focusing on side effects, adverse events and level of pain should be instituted in primary care to explore with patients when the risks of opioid treatment outweigh the benefits.²³ During tapering, patients are at higher risk for potential overdose and relapse.²⁴ Withdrawal symptoms, commonly manifest as anxiety, hypertension, tachycardia, nausea and/or cramps, can occur even with slow tapering and when doses are appropriate.^{25–29} It is important that tapering is completed at a safe rate to ensure minimal suffering associated with withdrawal.³⁰ In addition, a structured management programme that is consistent and supportive can maintain morale, reduce negative experiences with the healthcare system and avoid decreased interest or engagement with care.^{31 32} For most patients, the improved function and increased sense of well-being at lower doses outweighs the temporary increase in pain.^{33 34}

Despite the limited benefits of opioids, negative cognitions around tapering exist with 63% of patients fearing increased pain. Patients who are taking high doses for long periods demonstrate high psychological distress and low self-efficacy,^{33 34} highlighting the importance of working with the patient for behaviour change and pain acceptance. Opioid tapering has found improvements in pain response and pain tolerance, without a decline in function or quality of life,²⁰ while a recent systematic review showed high patient interest in support for tapering.³² GP supervised tapering and Multidisciplinary Team (MDT) group therapeutic sessions are advocated to reduce long-term opioid use.^{35–37}

The National Institute for Health and Care Excellence (NICE) guidelines for CNCP, with an emphasis on support for self-management, reinforce the idea of tapering³⁸ and there is evidence to show that pain-self management programmes can have a moderate effect on reduced opioid dose and pain intensity.³⁹ Similarly, experience from treating patients with substance dependence tells us that interventions offering education and psychosocial assistance can help.^{40–44} However, there is a lack of guidance on supporting patients with CNCP in primary care to reduce or stop high-dose opioids.¹⁰

The most recent Cochrane review⁴⁵ concludes that lack of evidence prevents recommendations for interventions to assist opioid reduction where appropriate. A trial of a self-management intervention (Improving the Wellbeing of people with Opioid Treated CHronic Pain - IWOTCH) has not yet reported the results.⁴⁶ Furthermore, a scoping review of 19 outpatient interventions to support opioid reduction in multidisciplinary specialist services and primary care⁴⁷ identified only one primary care study, which demonstrated a statistically significant reduction in opioids in the intervention group compared with a control group. Alongside, while Sud *et al's* systematic realist review⁴⁸ highlighted that interventions which included components of behaviour change, pain relief and medication management were more likely to be successful than those that did not include them, any gains were short lived and the rates of subsequent reuptake of opioids by patients at 12 months later raised concerns about any long-term effectiveness. In combination, these studies highlight the importance of additional research into the effectiveness of interventions to support opioid reduction in patients with CNCP.

Specifically, feasibility trials of interventions that incorporate patient support and acceptance in CNCP are warranted. We have aligned with Medical Research Council (MRC) guidance on developing and evaluating complex interventions,⁴⁹ which combines four stages, intervention development, feasibility, evaluation and implementation, to develop a Behavioural Intervention for Opioid Reduction (BIOR). We have followed MRC guidance by incorporating theory, findings from our preliminary studies with key stakeholders and clinical experience into the development of the intervention content (stage 1). The current protocol outlines a test of its feasibility, which incorporates a process evaluation (stage 2).

Using a randomised controlled trial design, this pilot feasibility study aims to investigate the effectiveness and feasibility of reducing opioid use in CNCP patients via a tapering protocol, education and support in primary care. The results obtained will inform the development and sample size for a future definitive randomised controlled trial.

METHODS AND ANALYSIS

Study design and setting

The study will take place in primary care across six GP practices in NHS Knowsley Place, Kirkby. Primary care is usually a patient's first point of access for their healthcare needs and where most opioid prescribing is issued and repeated. GP surgeries are also embedded into the community with the advantage of making their services more accessible to patients. This makes it the ideal place to pilot the BIOR intervention as patients can be easily identified and supported in an environment where they currently receive healthcare, thus minimising disruption of their care. Recruitment started in May 2022, and the predicted end date is May 2023. A mixed qualitative and

Table 1 Outcome measures at timepoints across BIOR study

| Measure | Time point (months) | | | | | | |
|---|---------------------|---|---|---|---|---|---|
| | Baseline | 1 | 2 | 3 | 4 | 5 | 6 |
| Pain Stages of Change Questionnaire (PSOCQ) | X | | | X | | | X |
| Pain Self-Efficacy Questionnaire (PSEQ) | X | | | X | | | X |
| Brief Pain Inventory (BPI) | X | X | X | X | X | X | X |
| Subjective Opioid Withdrawal Scale (SOWS) | X | X | X | X | X | X | X |
| Pain Catastrophising Scale (PCS) | X | | | X | | | X |
| Pain Coping Questionnaire | X | | | X | | | X |
| Current MED (prescribed; from GP)* | X | X | X | X | X | X | X |
| Current MED (used; self-report) | X | X | X | X | X | X | X |

*Gp = General Practitioner

BIOR, Behavioural Intervention for Opioid Reduction; MED, morphine equivalent dose.

quantitative randomised study design incorporating a process evaluation will be implemented. The between groups' independent variable will be treatment group (two levels: taper vs taper with BIOR). The within groups' independent variable will be time point (with a maximum of seven levels: baseline and 1, 2, 3, 4, 5 and 6 months poststudy entry). The dependent variables will be subjective measures of pain, withdrawal, current MED and pain-related questionnaires (table 1). The process evaluation will run at all stages of the BIOR protocol (see figure 1) and will be comprised of semistructured interviews assessing the patients' and Allied Health Professionals' (AHPs') experiences of BIOR. The quantitative data will be analysed using mixed Analysis of Variance (ANOVA) in SPSS V.28.0.1.1 (IBM Corp, New York).

Participant identification and recruitment

Participant recruitment will use a two-stage cluster sampling technique, whereby a selection of patients from a GP practice who meet the inclusion criteria will be invited to participate. A lead prescribing pharmacist with access to the Egton Medical Information Systems (EMIS) system will identify patients who meet the inclusion criteria using electronic patient records. Patients are eligible to take part if they:

- ▶ Have CNCP.
- ▶ Are currently prescribed opioids totalling above 50 mg/day MED.

Patients are not eligible to take part if they:

- ▶ Have a major psychiatric comorbidity, for example, schizophrenia, bipolar disorder.
- ▶ Have a major physical illness, for example, rheumatoid arthritis, cancer.
- ▶ Have had pain clinic contact in the preceding 3 years.

To calculate the MED for potential participants, AW used dosing instructions, available information in the British National Formulary, published literature⁵⁰ and a conversion table (table 2) compiled and used by a Consultant in Pain Medicine (BF) in clinical practice to calculate a defined daily dose (DDD) for each prescription. The

DDD was then used to calculate potential patients' MED. Calculations for MEDs varied depending on the type of opioid prescribed and were advised by BF where there were uncertainties.

A sample size of 100 patients and 6 AHPs will be identified and recruited from Knowsley CCG. For pilot studies which may lead to a Randomised Control Trial (RCT), Julious suggests using 12 participants per group⁵¹; Teare *et al*⁵² recommend 70 participants in total. The current pilot aims to recruit 100 participants allowing for 30% attrition.

Materials and procedure

Recruitment and informed consent

Participants who have been identified as eligible to take part will be contacted by their GP/pharmacist and asked if they would be willing to have a consultation regarding their current opioid medication with their GP and a consultant in pain medicine (BF). If willing, they will have an individual appointment with the pain consultant (BF) and their GP in primary care to discuss their chronic pain treatment including effectiveness, discuss reducing their opioids, outline the potential risks to opioid reduction including worsening pain, withdrawal symptoms, decreased tolerance and associated increased risk of overdose and overdose death from both prescribed and over the counter medication when used inappropriately, provide information on the BIOR and assess their suitability for the current study. Patients on more than 50 mg MED per day, who agree at the end of the consultation to be weaned off opioids, and have no significant risks or barriers to weaning identified in the consultation, will begin tapering. The pain consultant will be responsible for the individualised opioid tapering regimens negotiated with each patient and will review this with the responsible pharmacist as necessary. Patients who have significant physical or mental health comorbidities or who are deemed to have complex needs (multimorbidity) after clinical assessment will be referred to a specialist pain service if they are willing to engage in opioid reduction. If

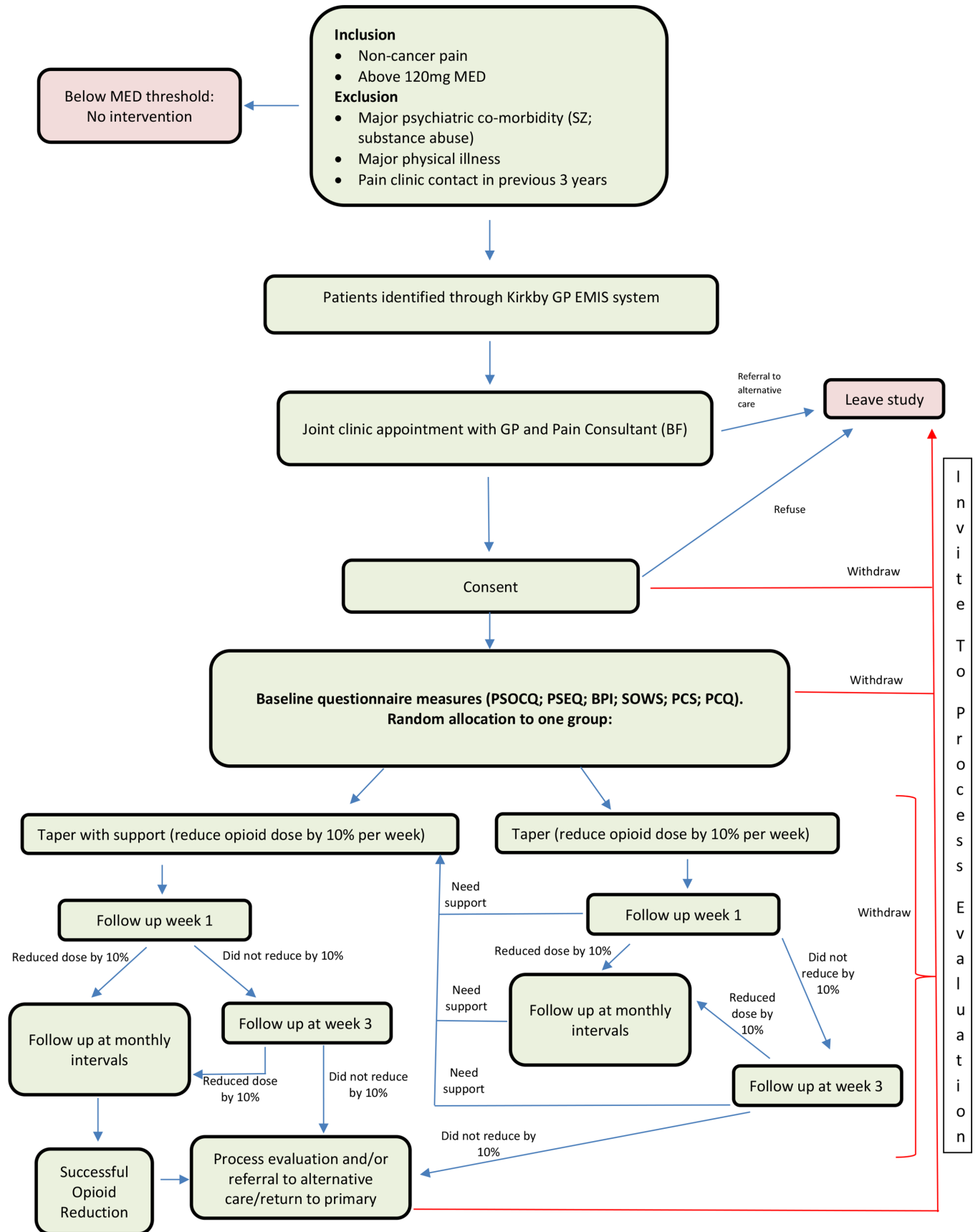


Figure 1 Behavioural Intervention for Opioid Reduction (BIOR) protocol flow diagram. BPI, Brief Pain Inventory; MED, morphine equivalent dose; PCS, Pain Catastrophising Scale; PSEQ, Pain Self-Efficacy Questionnaire; PSOCQ, Pain Stages of Change Questionnaire; SOWS, Subjective Opioid Withdrawal Scale; GP, General Practitioner; EMIS, Egton Medical Information Systems.

Table 2 Equivalence tables used in calculation of DDD and MED

| | Morphine mg/24 hours | | | | | |
|----------------------------|----------------------|--------|---------|----------|------|-----|
| | 10 | 30 | 60 | 120 | 180 | 240 |
| Oxycodone mg/24 hours | – | 20* | 40 | 80 | 120 | 160 |
| Hydromorphone mg/24 hours | – | 4 | 8 | 16 | 24 | 32 |
| Methadone mg/24 hours | – | 10 | 20 | 40 | 60 | 80 |
| Fentanyl ug/hour | – | – | 12 | 25 | – | 50 |
| Buprenorphine ug/hour | – | 10 | 20 | 40 | 52.2 | 70 |
| Codeine mg/24 hours | 100 | 240 | – | – | – | – |
| Dihydrocodeine mg/24 hours | 100 | 240 | – | – | – | – |
| Tramadol mg/24 hours | 67 | 200 | 400 | – | – | – |
| Tapentadol mg/24 hours | 25–50 | 75–150 | 150–300 | 300–600† | – | – |

*Conversion used in USA, Canada and Australia.

†The maximum recommended daily dose of Tapentadol prolonged release is 500mg.

DDD, defined daily dose; MED, morphine equivalent dose.

patients do not engage in opioid reduction, take unsafe doses of opioids or show signs of inappropriate opioid use, they will be referred to a specialist service for addiction medicine. Patients without inappropriate opioid use, but unwilling to engage in opioid reduction after the initial consultation, will continue with treatment as usual but will be allowed to re-enter the assessment stage if they later decide to engage in opioid reduction.

Following the initial consultation and assessment, participants who express an interest in taking part in BIOR will meet with a member of the research team who will provide a participant information sheet and consent form. The consent form and participant information sheet will also confirm that participants understand the purpose of the research and what it involves, what it means if they do not take part and how their interests will be protected. Participants will also be given the opportunity to think it over before making a decision to take part. If patients agree to participate, they will be randomly allocated to either taper or taper with BIOR. Following informed written consent, participants will complete baseline measures comprising: the Pain Stages of Change Questionnaire (PSOCQ),⁵³ the Pain Self-Efficacy Questionnaire (PSEQ),⁵⁴ the Brief Pain Inventory (BPI),⁵⁵ Subjective Opioid Withdrawal Scale (SOWS),⁵⁶ Pain Catastrophising Scale (PCS)⁵⁷ and Pain Coping Questionnaire (PCQ)⁵⁸ and will be given a tapering protocol to reduce their opioids by 10% per week in the first instance. The rate of taper per week is supported from Centers for Disease Control and Prevention (CDC) clinical guidelines,²⁶ suggesting 10% to be appropriate and better tolerated than faster rates, especially with long-term opioid use. By utilising a slow taper, symptoms of opioid withdrawal (eg, vomiting, diarrhoea, craving) can be minimised and better controlled should they arise. Throughout the intervention, the pain consultant will monitor both groups and respond to any queries regarding individual patients from pharmacists, GPs or research staff.

BIOR intervention

Training of AHPs involved in delivering BIOR

Pharmacists in Knowsley already have the necessary skills for delivering the intervention from long term condition management experience. The BIOR team (BF, CM, HMP) will also deliver online and face-to-face training for AHPs delivering the intervention. The online content, delivered live, was recorded for future AHPs and hosted on the BIOR website comprises four elements:

- ▶ Introducing the BIOR project and principles of behaviour change.
- ▶ Opioid management in chronic non-malignant pain.
- ▶ The development of the BIOR study using behaviour change techniques.
- ▶ Useful techniques for delivering behaviour change interventions.

These training materials also include information and education about alternatives to starting opioids for CNCP patients to effect changes in culture at practice level. The face-to-face training sessions (minimum four) are manualised, supported by recorded materials and provide AHPs with training and roleplay in using behaviour change techniques and motivational change talk to effect behaviour change when supporting opioid tapering. Specific roleplay scenarios require AHPs to practice the skills they have learnt to challenge negative cognitions related to opioid tapering, support changes in lifestyle and provide patients with action plans as a contingency for pain management. The sessions also have time for reflection to allow AHPs to assess what worked and what did not work in their delivery of the roleplay sessions.

Collation of behavioural intervention and resources

The intervention is designed to support patients with CNCP to taper and reduce their opioid use, promoting increased self-management of pain. The goal is harm reduction where cessation is not possible, and the pilot will be aimed at reducing opioid use to within safe levels.

Harm reduction refers to general opioid use and potential harms for participating in the study. The intervention is underpinned by psychological theory^{59–61} and delivered using validated behaviour change techniques.⁶² The intervention will be delivered by trained specialists (pharmacists/nurse prescribers) during an appointment and comprises a structured dose reduction prescribing protocol for opioids, education about harms, including worsening pain, withdrawal symptoms, decreased tolerance and risk of overdose and overdose death from both prescribed and over the counter medications if used inappropriately, alongside brief advice supported by written and online materials. During the face-to-face sessions, AHPs will offer emotional, informational and instrumental support to help patients self-manage their pain without opioids. The materials will be available on a range of media, with participants having access to video-based online media throughout the study. The study will also capitalise on and promote existing social prescribing mechanisms that are in place within Knowsley Place to further support patients' self-management. A dedicated website has been set up (hosted by LJMU), which collates existing widely and freely available online resources for pain education and management.

Control condition (taper)

The taper group will be given a tapering schedule and will have access to the resources collated on the BIOR website. If participants are successful in tapering by 10% at week 1, the target of 10% per week will continue until participants are either successfully weaned off opioid medication or they feel that they are unable to taper any further. If participants do not successfully taper by 10% in week 1, they will be asked to taper by 10% over the following 2 weeks and followed up at week 3. If they are still unsuccessful, following consultation, they will be moved to the taper with support group (see [figure 1](#) for study protocol and referral pathways).

Taper with BIOR

The taper with BIOR group will follow the same tapering schedule as the taper group and will also have access to up to six brief (10–20 min) sessions of behavioural support from the AHPs in the practice. These sessions will incorporate a range of techniques, and participants will have access to the online resources to support effective self-management. Details of the six sessions of BIOR are briefly outlined below. Session delivery is informed by the spirit/ethos of motivational interviewing and incorporates a non-judgemental, non-directive, collaborative approach using open questions, active listening, reflections and affirmations.

Session 1: establish rapport with patient, review current progress and plan next steps. Set parameters for meeting and what patient can expect in terms of length and content; review initial session with GP and BF, explore specific questions about this; query their concerns around pain and weaning (identify any perceived barriers) and

explore and discuss. Collaboratively discuss goals—these should be realistic and achievable goals (Specific, Measurable, Achievable, Relevant, Time-Bound - SMART goals).

Session 2: review pain diary and discuss pain triggers/reactions to any increases in pain; identify any discrepancies between current and desired behaviour and encourage conversation around patient's ambivalence (pros and cons/discrepancy); explore importance of goals, support needed to achieve goals, likelihood of achieving based on current behaviour; discuss what pain is and what pain is not to move away from cause/effect model to a biopsychosocial model; ensure patients know who their social prescribing link worker is; summarise for the patient and collaboratively discuss realistic short-term goals using the SMART framework.

Sessions 3, 4 and 5: the initial focus for these individual sessions will be on pain acceptance and more advanced coping skills. It is likely that in these intermediate sessions, patients will be experiencing more side effects from both the tapering schedule and resurgence of their pain; discuss anxiety surrounding weaning and help them to get them to articulate specific concerns; make more use of the social prescribing links and focus on various aspects of promoting a healthy lifestyle; encourage patients to focus on and develop valued instrumental goals during these sessions (eg, a physical activity goal of a certain number of steps per day; a dietary goal related to healthy eating; a goal to reduce alcohol consumption or smoking). While the aim of these sessions is to promote the opioid tapering, help patients to recognise that there are other benefits to actively participating in these sessions such as better sleep quality, physical activity and improved family relationships.

Session 6: review patient's past progress/explore unresolved or new concerns and barriers; Reflect on patient's strengths and accomplishments (feedback, self-efficacy, affirmation); discuss patient's competence/confidence and motivation to continue performing coping strategies and their knowledge on where to seek future support if needed; final review and summary of individual patients. Discuss where they were 18 weeks ago in terms of opioid dosage, acceptance of pain, physical activity, lifestyle, smoking and how far they have come.

Outcomes

All participants will complete follow-up measures (either online via Qualtrics or via telephone if they are unable to access the internet) at monthly intervals after the start of the study (BPI, SOWS, Current MED (from GP and self-report)) ([table 1](#)), with additional measures in months 3 and 6 (PSOCQ, PSEQ, PCS, PCQ). Questionnaire measures cover potential harms of tapering, exploring if patients experience, for example, cramps, muscle spasms, stomach aches, headaches, increased perspiration and any effects on sleep and mood. In addition, patients and HCPs are invited to take part in a semistructured interview to evaluate their experiences of receiving and delivering the intervention. Primary quantitative outcomes

are the MED that patients are taking at the end of the study, the pain scores at the end of the study and how these dependent variables change over time.

Outcomes for the process evaluation will be themes concerning the accessibility, acceptability and feasibility of BIOR from patient and practitioner perspectives. Outcomes from the qualitative and quantitative data will be used to refine the BIOR training and patient facing materials to proceed to a full funded trial of BIOR in primary care.

Patient and public involvement

Informed by MRC guidance,⁴⁹ for the development of complex interventions, we completed a series of studies that include qualitative research (interviews and focus groups) with key stakeholders (patients, healthcare professionals (HCPs)).^{18 19 34 63} These data, relevant literature and clinical experience informed the content of our intervention, which was developed using the COM-B (Capability, Opportunity, Motivation, Behaviour) model and Behaviour Change Wheel.⁶¹ We received feedback on content and delivery from patients and HCPs and the BIOR protocol evaluates its effects in a pilot study.

Data analysis

Data from the quantitative measures will be entered into SPSS V.27 (IBM Corporation, New York). After preprocessing of data (to check for normality, remove extreme outliers), within and between group analyses will be performed using Mixed ANOVAs. Measures of pain, withdrawal and MED will be compared at different time points to assess the effectiveness of BIOR, and mg MED at treatment exit will be used to assess the overall effectiveness and determine effect sizes. Exploratory correlations will be used to investigate the relationship between indices of pain and MED. For this feasibility study, both intention to treat and per protocol analysis will be conducted. The qualitative data from the semistructured interviews will be transcribed verbatim, entered into NVivo, and subjected to thematic analysis⁶⁴ to assess the accessibility, acceptability and feasibility of the service in primary care. The qualitative analysis will be completed by experienced research staff; HP, AR-S and AW.

ETHICS AND DISSEMINATION

The BIOR feasibility study has been granted ethical approval by Liverpool Research Ethics Committee on 7 April 2022, reference number 22/NW/0047.

Ethical and safety considerations

The potential risks associated with tapering opioids are acknowledged. These include the use of illicit opioids, overdose, overdose deaths and side effects from the reduction programme. To reduce the likelihood of harms occurring, patient-centred individual tapering regimes are produced to minimise the occurrence of side effects or withdrawal symptoms. The intervention itself will be

run by trained AHPs who will incorporate it into usual clinical practice. At the first session, the pain consultant and GP outline and discuss with patients the potential risks associated with tapering opioids (described above). Throughout the study, the AHPs will be checking in with patients at their regular sessions and when discussing tapering reduction, and this will facilitate close monitoring of potential risk of harm

If a participant is randomly allocated to the taper group, and it is deemed that they require more support, they can be moved into the taper with support group. If a participant no longer wants to take part in the tapering protocol, they can leave the study and both the GP and pain consultant will decide if the patient returns to treatment as usual or if a referral to specialist care is necessary. Patients are provided with information during their initial consultation around the risks of not following their tapering plan surrounding overdose and harmful side effects. Once consented to take part in the study, patients are also given access to LJMU BIOR website, containing information and resources on risk, behavioural intervention support and self-management techniques. If a patient discloses a serious intention to harm themselves or someone else during the initial consultation, the intervention sessions or the qualitative interviews, then the relevant safeguarding lead at the Kirkby PCN GP practice will be contacted.

Dissemination plan

The research findings will be published as: an accessible digital summary report documenting key findings and recommendations, to be distributed widely to GP practices and treatment professionals. Results will also be disseminated to a public audience through existing social media presence (eg, LJMU Research Centre for Brain and Behaviour Twitter and YouTube feeds, stakeholder and personal/University Twitter accounts) and conference presentations. These will be written with content and language adapted for the intended target audiences and platforms and subjected to readability analysis. An electronic data set will be deposited in the LJMU open access data repository, and a journal article will be published in a high-quality peer-reviewed journal (eg, PAIN (IF 6.029)). We will also write an online article for 'The Conversation', an online magazine that provides a platform for public discussion of scientific findings, to highlight the implications of the research to a wider public audience.

The Pain Research Institute (PRI) and Knowsley CCG will be acknowledged in any of the publications that come from the study, and collaborators from these organisations (MM, BF) will be coauthors on any reports. Participants will be able to view and access publicly available reports in the platforms mentioned above. A patient tailored resource will also be made available via a dedicated online platform hosting study materials, for example, information sheets and sign posting to social prescribing networks.

Twitter Helen M Poole @ProfHelenPoole, Aimee Woods @Aimeewoods_ and Catharine Montgomery @cathymonty_psy

Contributors HMP (Health Psychologist), CM (Psychopharmacologist) and BF (Consultant in Pain Medicine) contributed equally to the development of the design and protocol. MM and RMC contributed a pragmatic critique of the study implementation. EB developed recommendations for the Behavioural Intervention, refined by Poole & CM. AW is working as a research assistant on the project. AR-S is a PhD student working under the supervision of Poole and CM. AW and AR-S contributed to the development of intervention training materials, data collection tools and the application for ethical approval. They will be responsible for conducting the study and the data analysis and interpretation. All above mentioned collaborators will contribute to manuscript writing and dissemination. All authors have provided critical revisions and approved the final manuscript.

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Competing interests BF received honoraria from Gruenthal for educational session about opioid weaning and management for GPs and pharmacist in the past. The other authors have no conflict of interests to declare.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement The paper outlines a study protocol. No data are available at this time.

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ORCID iDs

Helen M Poole <http://orcid.org/0000-0002-6165-3764>

Catharine Montgomery <http://orcid.org/0000-0003-2805-5807>

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