ISRCTN30201337 https://doi.org/10.1186/ISRCTN30201337

A trial to determine whether a tapering regime to reduce high dose opioids for people with persistent non-cancer pains work better with or without additional behavioural support

Submission date
06/06/2022

Recruitment status
No longer recruiting

Registration date
07/06/2022

Overall study status
Completed

Last Edited
30/07/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Around 30-50% of adults suffer from moderate to severe chronic pain not caused by cancer. Some are treated with opioids (strong painkillers) which over time may cease to be effective and produce unpleasant side effects (e.g., nausea, drowsiness and constipation). Stopping taking opioids abruptly can cause unpleasant withdrawal effects. Tapering the opioid drug in small steps is recommended, though some patients might struggle and need support. Experience from treating patients with substance dependence tells us that interventions offering education and psychosocial support can help. This is a multi-center brief behavioural intervention delivered by health professionals using psychological techniques, interviews, and questionnaires.
This project aims to:
1. Understand if a behaviour change intervention in primary care can support patients with CNCP to reduce/stop long-term opioid use
2. Understand patients' expectations around the behaviour intervention and its implementation
3. Understand health care professionals (HCP) expectations and views of the behaviour intervention and its implementations
4. Assess changes in opioid use and pain over time between trial groups to identify potential effect sizes to calculate sample size for a larger trial.

Who can participate?
To be eligible to participate, you must be aged 18 years and over, take opioid medication totaling a Morphine Equivalent Dose above 50mg per day, have chronic non-cancer pain, and are registered to a GP practice in Kirkby.

What does the study involve?
Following your continued interest, during your one-to-one assessment, your GP and/or pain consultant will ask you for written consent.

1. If you agree to take part in the study, you will be randomised into one of two groups. You will have an equal chance of being in either group:
'Taper Group'- if you are randomised to this group, you will receive your care as usual and continue to taper your opioid medication by a tailored fortnightly 10% reduction. You will also receive some access to online information about pain, opioid reduction, and self-management.

'Taper with Support Group'- in this group, you will be receiving your care as usual and continue to taper your opioid medication by a tailored fortnightly 10% reduction. In addition, you will receive up to 6 one to one support sessions with an Allied Health Professional (pharmacist or nurse prescriber). These sessions may be face to face or online/telephone (approximately 15 minutes each) and will be supported by written and online materials. Your pharmacist or nurse will offer informational, emotional, and instrumental support to help you self-manage your pain and opioid dose reduction. The materials will also be available on a range of media, so you can have access to video-based online media throughout the study. You will also have access to a social prescriber to further support your self-management strategies.

2. Once you have agreed to take part in the study you may also be invited to take part in an interview with one of the researchers. The interview will explore your expectations in relation to the intervention, and how you feel about reducing your opioids. Your views about the intervention content and how you're managing your pain and medication reduction and what, if any impact this is having on your life.

3. When you are enrolled in the study, you will complete some initial questionnaires relating to your pain, your ability to manage your pain, your mood, your current opioid usage, and day-to-day functioning. These will take around 10-15 minutes to complete. To measure changes in your pain and opioid use over the course of the study, some of these questionnaires will be repeated once a month for six months. You will be able to complete these either online via a link that will be sent to you or by telephone with one of the project researchers.

4. After 6 months, the questionnaires data will be complete, and you may be invited to take part in a follow-up interview 12 months after you have enrolled in the study to discuss how your experience of taking part and your current management of pain. Although the data collection may have stopped you will continue to receive the same care from your GP and pharmacist in supporting your chronic pain management.
The interview[s] will take place via telephone or video call and should take approximately 50 minutes. You will be offered regular breaks as necessary. You can also ask to pause or stop the interview at any time. Please remember, you have the right to decline to answer any questions you do not want to. If you opt-in and you are invited for an interview, the audio recording is essential to your participation, and you should be comfortable with the audio recording process. You are free to stop the recording at any time and therefore withdraw your participation. With your consent, recordings taken of you will be transcribed and pseudo anonymised and they may be used in the final report and any further outputs. Once the transcriptions have been checked for accuracy, recordings will be destroyed. Your name will not be attributed to the transcriptions.

What are the possible benefits and risks of participating?
Participating in the research is not anticipated to cause you any disadvantages or discomfort. The potential physical and/or psychological harm or distress will be the same as any experienced in everyday life.

Questionnaires
The questionnaires and interviews we ask you to complete include questions that will ask you about your pain and how you deal with your pain on a daily basis which might be considered

sensitive. Reflecting on your chronic pain and opioid reduction may lead to mild distress in some participants. If this happens please discuss it with us (the research team).

Reducing your medication
Before taking part in this study you will have agreed to a tapering regime with your GP. Agreeing to participate in this research means you will be randomised to either a Taper only group or a Taper with Support group. We understand that being randomised can cause some disappointment. If you are randomised to the 'Taper only group' you will remain in the care of your GP who may be able to provide additional support to manage your pain. If you are in the 'Taper Group' and you are unable to continue reducing after 3 weeks at the same rate you will be offered to enter the 'Taper with Support Group'. If you are already in the 'Taper with Support Group' and you are not able to continue to reduce after 3 weeks at the same dose you will leave the study, return to usual care, and be referred to other services as appropriate.

According to government and NHS guidelines at the time of your recruitment, the study team will ensure that appropriate measures are in place to reduce the risk of COVID-19 infection.

Where is the study run from?
The primary location for the study will be Millbrook Medical Centre, Kirkby, Liverpool (UK)

When is the study starting and how long is it expected to run for?
November 2020 to January 2024

Who is funding the study?
The study is part-funded by the Pain Relief Foundation and Knowsley CCG (UK)

Who is the main contact?
Professor Helen Poole, h.poole@ljmu.ac.uk

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
306772

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 306772

Study information

Scientific Title
A feasibility study of a Behavioural Intervention for Opioid Reduction (BIOR) for chronic non-cancer pain patients in primary care

Acronym
BIOR

Study objectives
This is a feasibility trial. We aim to test the feasibility, acceptability and impact of the BIOR intervention in primary care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/04/2022, North West - Liverpool Central REC (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 207 1048118; liverpoolcentral.rec@hra.nhs.uk), ref: 22/NW/0047

Study design
Interventional randomized controlled trial incorporating a process evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Opioid reduction in chronic non-cancer pain patients

Interventions
Participants are randomised to one of two groups using a random number sequence created using an online tool.

'Taper Group'- care as usual and continue to taper opioid medication by a tailored fortnightly 10% reduction. Also receive some access to online information about pain, opioid reduction, and self-management.

'Taper with Support Group'- care as usual and continue to taper opioid medication by a tailored fortnightly 10% reduction. In addition, receive up to 6 one to one support sessions with an Allied Health Professional (pharmacist or nurse prescriber). These sessions may be face to face or online/telephone (approximately 15 minutes each) and will be supported by written and online materials. A pharmacist or nurse will offer informational, emotional, and instrumental support to help self-manage pain and opioid dose reduction. Access to video-based online media throughout the study. Access to a social prescriber to further support your self-management strategies.

Opioid reduction schedule planned by GP and pain consultant in initial consultation, which includes current morphine equivalent dose minus 10%/week if tolerable, fortnightly if not tolerable.
All participants will complete a questionnaire at baseline, monthly for 6 months and at 12 months follow-up. Questionnaires will be completed either online via Qualtrics or via telephone if participants are unable to access the internet. Questionnaires include subjective measures of pain (Pain Stages of Change Questionnaire (PSOCQ), the Pain Self-Efficacy Questionnaire (PSEQ), the Brief Pain Inventory (BPI), Subjective Opioid Withdrawal Scale (SOWS), Pain Catastrophising Scale (PCS) and Pain Coping Questionnaire (PCQ). We will also monitor MED in mg to determine any changes.
The between-groups independent variable will be treatment group (taper or taper with support) and the within groups independent variable will be time-point (with a maximum of 8 levels: baseline and 1, 2, 3, 4, 5, and 6 months post study entry and at 12 month follow up). The dependent variables will be the subjective measures of pain, withdrawal, current MED and pain related questionnaires.
In addition, 2 semi-structured qualitative interviews will be offered to patients and Health Professionals participating in the study. These interviews are designed to elicit in-depth views on patient and AHPs expectations (at baseline) and their views on acceptability and feasibility of the intervention (follow-up). Participants will be given the option to conduct their interview via telephone or face-to-face dependent on preference and national COVID-19 guidance. Interviews will be recorded with permission and transcribed verbatim. These data will be used to inform the process evaluation.
We will also seek consent from AHPs and patients to record a random sample of BIOR sessions - the purpose of this is to help ascertain the fidelity of the intervention delivery. Recordings will

be listened to by a member of the research team to monitor the content and mode of delivery i. e. which behaviour change techniques were used.

Intervention Type
Behavioural

Primary outcome measure
Morphine equivalent dose (MED) of opioid intake reported by the participants at baseline, monthly for 6 months and at 12 months follow-up

Secondary outcome measures
Self-reported questionnaire data measured at baseline, monthly for 6 months and at 12 months follow-up:
1. Pain (Brief Pain Inventory (BPI))
2. Pain coping (Pain Coping Questionnaire (PCQ))
3. Catastrophizing (Pain Catastrophising Scale (PCS))
4. Stage of change (Pain Stages of Change Questionnaire (PSOCQ))
5. Mood measured using a single item from the BPI
6. Function (Pain Self-Efficacy Questionnaire (PSEQ))
7. Self-reported symptoms of withdrawal (Subjective Opioid Withdrawal Scale (SOWS))

Overall study start date
05/11/2020

Completion date
30/01/2024

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 07/07/2022:
Patients:
1. Aged 18 years old or over
2. Diagnosed with chronic non-cancer pain
3. Taking prescribed high dose opioids (>50 mg daily MED)
4. Taking opioids for more than 3 months
5. Registered at a GP practice in Kirkby.

Allied Health Professionals (AHP):
1. AHPs aged 18 years or older
2. AHP currently delivering BIOR as part of the study

Previous participant inclusion criteria:
Patients:
1. Aged 18 years old or over
2. Diagnosed with chronic non-cancer pain
3. Taking prescribed high dose opioids (>120mg daily MED)
4. Taking opioids for more than 3 months
5. Registered at a GP practice in Kirkby.

Allied Health Professionals (AHP):
1. AHPs aged 18 years or older
2. AHP currently delivering BIOR as part of the study

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
Patients:
1. Major psychiatric co-morbidity (e.g. Schizophrenia; substance abuse) - a major physical illness.
2. Contact with a pain clinic in the past 3 years
3. Aged over 75 years

Allied Health Professionals (AHP):
1. Cannot establish conversation in English.

Date of first enrolment
18/05/2022

Date of final enrolment
18/02/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Millbrook Medical Centre
Southdene Pcrc
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ROR
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Funder(s)

Funder type
Charity

Funder Name
Pain Relief Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name
Liverpool John Moores University

Alternative Name(s)
LJMU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
NHS Knowsley CCG

Results and Publications

Publication and dissemination plan
We are seeking permission to conduct a feasibility trial. It is our intention to publish the protocol of the trial, e.g. in a pain journal or Implementation Science.

Intention to publish date
31/07/2025

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
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 2.0	23/03/2022	07/06/2022	No	Yes
Protocol article		18/01/2023	23/01/2023	Yes	No
HRA research summary			28/06/2023	No	No