PARTICIPANT INFORMATION SHEET for CNCP patients

Research Ethics Committee Reference Number: IRAS 306772

Title of Study: Behavioural Intervention for Opioid Reduction (BIOR) Pilot

You are being invited to take part in a research study. You do not have to take part if you do not want to. Please read this information, which will help you decide.

Meet the research team:
The project is a collaboration between Liverpool John Moores University (Prof Helen Poole, Dr Cathy Montgomery, Dr Emma Begley, Ms Aimee Woods and Ms Andreia Ramos Silva), The Walton Centre (Dr Bernhard Frank) and Kirkby PCN (Dr Mike Merriman, Ms. Roisin McCullagh). Ms Andreia Ramos Silva is a PhD student, and this study will form part of her PhD.

1. What is the purpose of the study?

We have developed a behavioural intervention to support patients with non-cancer pain reduce or discontinue high dose opioid medication. This involves co-producing a plan with your GP and a pain consultant to support you to slowly reduce your daily opioid dose using methods of self-management and social support to help improve this experience. We would like to investigate how acceptable and effective our intervention is (e.g. was it easy for you? Did you stop taking opioids at the end?), and how well it works in primary care.

2. Why have I been invited to participate?

You are being invited to take part in the study because you are taking opioids in a dose higher than 120mg/day for more than 3 months and you have agreed with your GP to initiate a tailored tapering regime to reduce opioids whereby your morphine equivalent dose will be reduced by 10% every two weeks.

You are invited to take part if you:

- Are aged 18 years+
- Take opioids totalling a Morphine Equivalent Dose above 120mg/day.
- Have chronic non-cancer pain.
- Are registered at a GP practice in Kirkby.

Exclusion criteria – you must not participate if:

- You have a major psychiatric diagnosis (e.g. psychosis).
- You have a major physical disability.
- You have had contact with a pain clinic in the past 3 years.
- You are 75 years of age or older

3. Do I have to take part?

No. You can ask questions about the research before deciding whether to take part. If you do not want to take part that is OK. Your participation is completely voluntary, and it is up to you to decide whether you take part or not. We will ask you to sign a consent form and will give you a copy for you to keep. If you do it online, you can sign the consent form and print it for you to keep.

You are free to withdraw at any time without having to provide a reason. A decision to withdraw will not affect your rights or any future treatment or service you receive.

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. You may withdraw from the study by contacting us:

Chief Investigator: Prof Helen Poole; email address: h.poole@ljmu.ac.uk

4. **What will happen to me if I take part?**

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 to 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. For additional information on the behavioural intervention please see end of document (Appendix 1).

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, 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.

5. Will I be audio recorded and how will the recorded media be used?

If you opt-in and you are invited for an interview, the audio recording is essential to your participation, and you should be comfortable about 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 pseudoanonymised 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.

6. Are there any potential risks in taking part?

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 the 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 with us (the research team).

Reducing your medication
Before taking part in this study you will have agreed 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.

7. Are there any benefits in taking part?
There are no direct benefits in taking part in this study. If you are randomised to the 'Taper with Support' group, you will be equipped with skills and knowledge of how to manage your pain through

methods of self-management. You will be provided with additional support via online resources. Also, by taking part in a study like this you are contributing to new developments and knowledge which may improve future healthcare services for people with chronic non-cancer pain.

8. Payments, reimbursements of expenses or any other benefit or incentive for taking part

There will be no payment or any benefit or incentive for taking part in this study. Unfortunately, we cannot reimburse any expenses you may incurred.

9. How will we use information about you?

- We will need to use information from your medical records for this research project. This information will include your contact details and your current opioid dosage. This information will be accessed to check your eligibility for the study. Personal data from your medical records will only be accessed by your healthcare team.
- Your participation in this study will not involve the use of personal data (name, date of birth etc.). We will keep all information about you safe and secure, people who do not need to know who you are will not be able to see any personal details. Your data will be identified by a code number instead.
- If you agree to participate in the interviews, we will collect personal data (contact details).
- Once we have finished the study, we will keep some of the data so we can check the results. We will write out report in a way that no-one can work out that you took part in the study.

10. What are the choices about how your information is used?

- You can stop being part of the study at any time point, without giving a reason, however the information we have collected prior to this will be kept.
- 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.
- All personal data and digital recordings will be destroyed after use, less than 3 months before the study ends. Anonymous research data will be kept securely for up to 5 years and then shredded/erased.
- The investigator will keep confidential anything they learn or observe related to illegal activity, unless related to the abuse of children or vulnerable adults, money laundering or acts of terrorism. If the researcher believes you or others may be at significant risk of harm, the appropriate authority will be informed. This will usually be discussed with you first.

11. 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/
- By asking one of the research team
- By sending an email to a.e.woods@ljmu.ac.uk , or h.poole@ljmu.ac.uk

12. Who is organising and who is funding the study?

This study is organised by Liverpool John Moores University in conjunction with Walton Centre NHS Foundation Trust and Kirby Primary Care Network. It is part funded by the Pain Relief Foundation and Knowsley CCG.

13. Whom do I contact if I have a concern about the study or I wish to complain?

If you have a concern about any aspect of this study, please contact Ms *Andreia Ramos Silva* or *Professor Helen Poole*, and we will do our best to answer your query. You should expect a reply within 10 working days. If you remain unhappy or wish to make a formal complaint, please contact the Chair of

the Research Ethics Committee at Liverpool John Moores University who will seek to resolve the matter as soon as possible:
Chair, Liverpool John Moores University Research Ethics Committee; Email: FullReviewUREC@ljmu.ac.uk; Tel: 0151 231 2121; Research Innovation Services, Liverpool John Moores University, Exchange Station, Liverpool L2 2QP

14. Data Protection

Liverpool John Moores University is the data controller with respect to your personal data. Information about your rights with respect to your personal data is available from:

- https://www.ljmu.ac.uk/legal/privacy-and-cookies/external-stakeholders-privacy-policy/research-participants-privacy-notice
- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the study team or contacting us using the information below

15. Contact details

Principal Investigator: *Professor Helen Poole*
Member of LJMU staff

LJMU Email address: *h.poole@ljmu.ac.uk*
LJMU School/faculty: *Faculty of Health*
LJMU Central telephone number: 0151 231 2121

Thank you for taking the time to read this information sheet.

APPENDICES

Appendix 1

Additional information on the behavioural intervention

Group allocation/BIOR sessions	**Taper group**	**Taper group with support**
Session 1 – around week 2.	Complete questionnaire in own time Medication review and continue tapering programme Access to online resources	Complete questionnaire in own time Medication review and continue tapering programme Access to online resources Attend a 15-20-minute session with the pharmacist receive information and support to help self-manage your pain and opioid dose reduction. This session will include reflection on initial session with pain consultant and GP, explore pain navigator tool questions, discuss goals, review progress with tapering, receive information on pain diary and who the social prescibing link worker is, agree short-term goals and action plan for the next session.
Session 2 – around week 4	Complete questionnaire in own time Medication review and continue tapering programme Access to online resources	Complete questionnaire in own time Medication review and continue tapering programme Access to online resources Attend 15-20-minute session with the pharmacist receive information and support to help self-manage your pain and opioid dose reduction This session will review progress with tapering plan, its impact on pain and any other effects (consult pain diary). You will discuss progress and what helped or prevented you tapering your opioids, receive informtion about online resources and revisit and agree goals.
3 – around week 6	Complete questionnaire in own time Medication review and continue tapering programme Access to online resources	Complete questionnaire in own time Medication review and continue tapering programme Access to online resources Attend 15-20-minute session with the pharmacist Receive information and support to help self-manage your pain and opioid dose reduction Follows same structure as session 2
4 – around week 10	Complete questionnaire in own time	Complete questionnaire in own time

	Medication review and continue tapering programme Access to online resources	Medication review and continue tapering programme Access to online resources 15-20-minute session Receive information and support to help self-manage your pain and opioid dose reduction Follows same structure as session 2
5 – around week 14	Complete questionnaire in own time Medication review and continue tapering programme Access to online resources	Complete questionnaire in own time Medication review and continue tapering programme Access to online resources 15-20-minute session Receive information and support to help self-manage your pain and opioid dose reduction Follows same structure as session 2
6 – around week 18	Complete questionnaire in own time Medication review and continue tapering programme Access to online resources – reminded that they will still have access to all resources for future reference. If opted into interview, a member of the research team will be in contact to arrange this.	Complete questionnaire in own time Review progress, reflect on strengths and accomplishments, discuss confidence and motivation to continue performing coping strategies and knowledge on how to seek future support if needed. Final review and summary of individual patients, looking at opioid dosage changes, acceptance of pain, physical activity, lifestyle, smoking etc. Reminded about access to all online resources and social prescribing link worker, will still have medication review with their GP If opted into interview, a member of the research team will be in contact to arrange this.

Note:

Patients who express difficulty with tapering regime, e.g., cannot reduce by 10% after 2 weeks at same dose are able to remain at the current dose for another 2 weeks before attempting a further reduction. Patients expressing high levels of anxiety or depressive symptoms will be referred back to their GP for appropriate treatment and/or referral.