

## **Pain Relief Foundation Grant – Interim Report March 2023**

**Grant Title:** A feasibility study of a Behavioural intervention for Opioid Reduction (BIOR) in primary care

**Award Holder:** Professor Helen Poole (Liverpool John Moores University)

**Project Aims:** 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.

### **Abstract**

*Introduction:* Around 30-50% of adults suffer from moderate to severe chronic pain not caused by cancer. Some are treated with opioids 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-centre brief behavioural intervention delivered by health professionals using psychological techniques, interviews and questionnaires.

*Methods and Analysis:* This study is a randomised control trial to investigate the effectiveness and feasibility of reducing use of inappropriately high doses of opioids through a tapering protocol, education and support in primary care. Working with NHS Knowsley CCG we will identify patients who are over 18 years old, taking 120mg or above morphine equivalent dose (MED) of opioids per day, to be randomly allocated to either the tapering group or tapering with support group. Both groups will have their opioid reduced by 10% per week. The taper with support group will have access to additional support during the process, 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 what works best to support people with chronic pain who wish to stop taking opioids.

*Dissemination:* The results will be published in peer-reviewed journals and disseminated to patient stakeholders in a lay summary report which will be available on the project website and in participating GP surgeries.

### **Study progress to date:**

We appointed Dr Begley as a Research Assistant in December 2021. She left to take up a post in Bath and was replaced by Ms Aimee Woods in February 2022. Alongside the Research Assistant, Prof Poole and Dr Montgomery were successful in securing funds for a PhD student, Ms Ramos Silva whose research aligns with the BIOR project. Ms Ramos Silva has recently returned from maternity leave (March 2023) and is managing day to day running of the study. Ms Aimee Woods secured another position and is now working part-time on the study on a temporary basis.

We received full HRA ethical approval on the 07<sup>th</sup> April 2022.

*Training and Education:* All training manuals and AHP support documentation have been completed and shared with relevant AHPs who are taking part in the study. Face-face training has commenced for AHPs in Millbrook Medical Centre, delivering educational sessions incorporating education and practice (via role play). Ms. Woods (Research Assistant) has shadowed Dr Frank (Pain consultant) during his pain clinic, to develop an understanding of the approaches that are used to encourage patients to engage with opioid tapering, and the nature of clinician/patient discussions within pain clinics. A website has been developed, providing two sites of educational resources, one for AHPs and another for participants <https://www.ljmu.ac.uk/research/centres-and-institutes/research-centre-in-brain-and-behaviour/current-research-projects/behavioural-intervention-for-opioid-reduction-bior>

Training for AHPs is currently bi-weekly, with training for social prescribers commencing late May/early June. Training currently takes place online to accommodate for GP/Pharmacists schedules. An initial training session takes place, with time for reflection/questions and to explore whether the individual requires more training. This is independent of each practice. All AHPs receive a link to online training resources created by Dr Bernhard Frank and Ms Aimee Woods.

*Identifying participants:* Electronic searches have commenced to identify patients who are on 120mg MED and above, to be invited to take part in the BIOR pilot study. Ms. Woods has an honorary contract at Millbrook Medical Centre and is assisting the practice pharmacist in calculating MED for patients that have been identified as being prescribed multiple opioids. Potential participants identified by this method have been contacted by their GP inviting them into a joint clinic consultation with the GP and pain consultant. Search Criteria as been amended to 50mg MED and above to expedite recruitment. Ms Aimee Woods continued searches with honorary contracts in Macmillan Medical Centre, Wingate and St Laurences. Dr Hassan Argomandkhah completed searches for Massaarani and Partners.

*Recruitment:* The first joint clinic (Dr Frank and Dr Merriman) was held May 2022 and 3 patients were recruited. The study has recruited 31 participants across Millbrook, Macmillan, Wingate, St Laurences & Massaarani Practices. 11 participants randomly allocated to 'taper only' and 20 participants allocated to 'taper with support', **a total of 31 participants** 8 baseline interviews completed (4 CNCP patients and 4 AHPs), 14 participants withdrawn due to varying factors. Recruitment is ongoing.

As part of the BIOR intervention, the Social Prescribing offer remains in place. Mr Chris Duvall (Health and Wellbeing Coach) has taken the lead on supporting patients should their GP/Pharmacist refer the patient to this service.

*Dissemination to date:* BIOR featured virtually in the EFIC conference on the 27<sup>th</sup>-29<sup>th</sup> April. The trial protocol has been registered with ISRCTN and has been published in BMJ Open <https://bmjopen.bmj.com/content/13/1/e065646> The PRF have been acknowledged as funders on all the aforementioned.

### **Future steps for BIOR:**

Consultations with Dr Frank and a Pharmacist/GP are ongoing. At these clinics, potential participants are identified, and sign posted to Ms. Woods and Ms Ramos Silva who explain the BIOR study and obtain consent. Data collection in the form of monthly questionnaires, interviews with patients and AHPs continues. Analysis of interviews can commence following completion of baseline interviews. As Ms Ramos Silva has returned from maternity leave she will continue to contact participants to collect questionnaires data and to conduct interviews. Ms Woods and Ms Ramos Silva will continue to deliver training to new HCP involved in the study. Ms Ramos Silva will analyse process evaluation interviews.

**Timeline:** Due to the change in research assistant and the lead in time for ethical approvals, data collection remains ongoing.

We would like to request a further no-cost extension to the study. As Ms Ramos-Silva has now returned to her PhD studies she will manage ongoing recruitment and data collection and analysis. Hence we are confident we can complete the study as planned, albeit over a slightly longer duration.

### *References*

Poole HM, Montgomery C, Begley E, Ramos-Silva A, Merriman M, McCullugh R, Barton C & Frank B (2022) Behavioural Intervention to Support Opioid Reduction (BIOR) in primary care: A protocol. 12<sup>th</sup> Congress of the European Pain Federation (EFIC), Dublin, Ireland, 28/4/22

Poole HM, Frank B, Begley E, Woods A, Ramos-Silva A, Merriman M & Montgomery C (in submission) A feasibility study of a Behavioural Intervention for Opioid Reduction (BIOR) for chronic pain patients in primary care: A protocol. BMJ Open