PROMPPT Trial: Executive Summary

PROMPPT aims to develop and test a new way to reduce opioid use (where appropriate) in patients living with persistent pain led by **practice pharmacists** working in GP practices.

This executive summary:

- Provides an outline of the PROMPPT research programme, the components of the main trial, the spirit of PROMPPT, an overview of the pain review and highlights the key research processes involved in the PROMPPT trial.
- Has been written to provide an **overview** of the PROMPPT intervention for GPs and other practice staff who may come into contact with patients taking part in the research programme
- Can be used by the practice pharmacist as an **aide memoire** following completion of the training.

1. The PROMPPT Programme

PROMPPT is formed of three linked phases:

1

2019 - PHASE 1

An intervention development study to design an evidence-based pain review for patients using long-term opioids for persistent pain to be delivered in primary care settings.

2

2020 - PHASE 2

A feasibility study to test the pain review in four primary care practices in the East and West Midlands with 80 patients.

3

2022 - PHASE 3

A randomised controlled trial (RCT) with over 800 patients to test whether the pain review leads to a reduction in opioid use, without making pain or pain interference worse, and whether this results in better use of NHS resources compared to usual GP care.

2. The Main Trial

The PROMPPT trial is made up of 3 separate components that will help to test the intervention:

MOPP Questionnaire study

- The patient facing name of this part of the study is MOPP (Management of Opioids & Persistent Pain)
- Invitation to participate in the MOPP questionnaire study sent by the GP practice (SMS & Postal using Docmail) and co-ordinated by Keele Clinical Trials Unit (CTU)

Pain Review

- Invitation letter to attend a pain review with the practice pharmacist and 'Getting ready for your pain review' leaflet sent by Keele CTU on behalf of the GP practice
- Patient will contact the GP practice to schedule the pain review with the practice pharmacist
- Pain review led by the pharmacist working in the GP practice

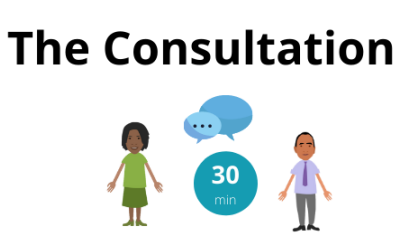
Process evaluation (MOPP-2)

- Each pharmacist will audio-record 3 pain reviews, with prior patient consent
- Patients may be invited to take part in an interview with researchers
- GP lead for PROMPPT and pharmacist will be interviewed after pain reviews have taken place

3. The Spirit of PROMPPT

The spirit of PROMPPT describes four elements that form the **foundation** of the delivery of pain reviews:

4. The Pain Review: An Overview



Pre-consultation

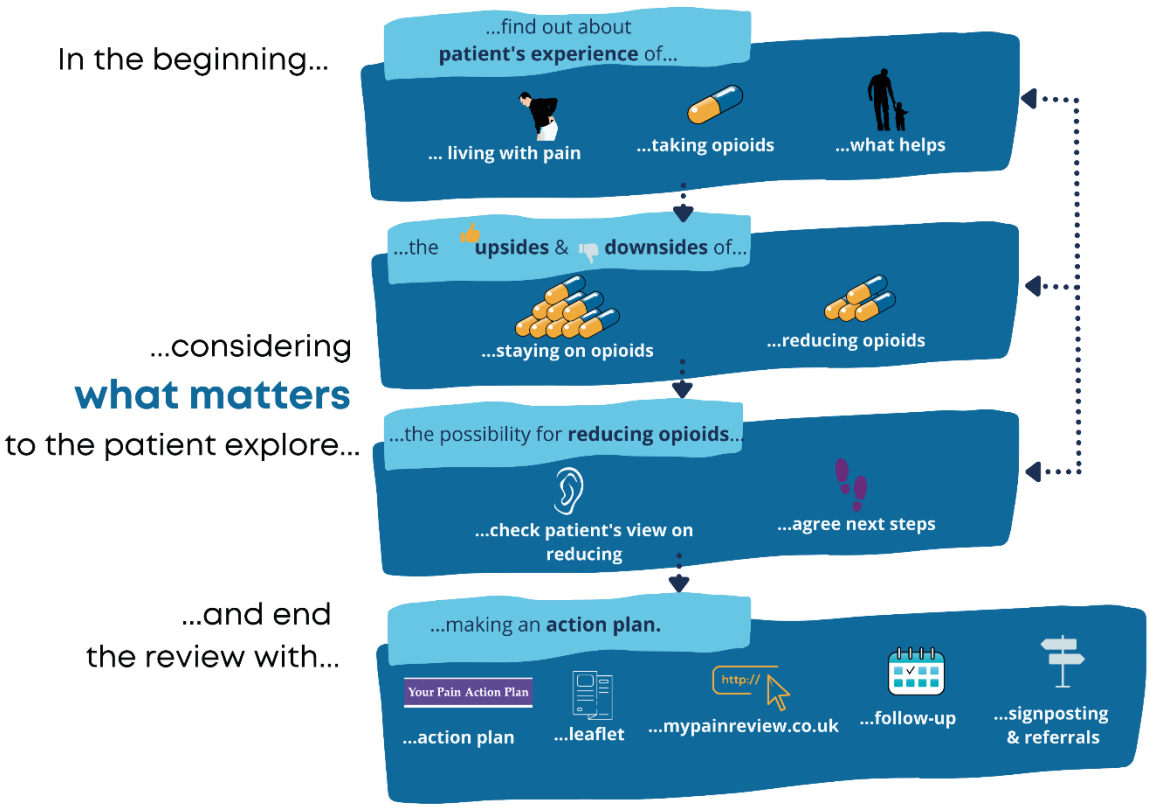
Patients will be sent an invitation letter (on GP headed paper) inviting them to attend a pain review and a Getting ready leaflet which answers FAQs about the consultation.

The Consultation

We suggest that you allocate **30 minutes** for a patient's first pain review.

Pain reviews can be conducted in person or remotely by video or phone. Please consider patient preference.

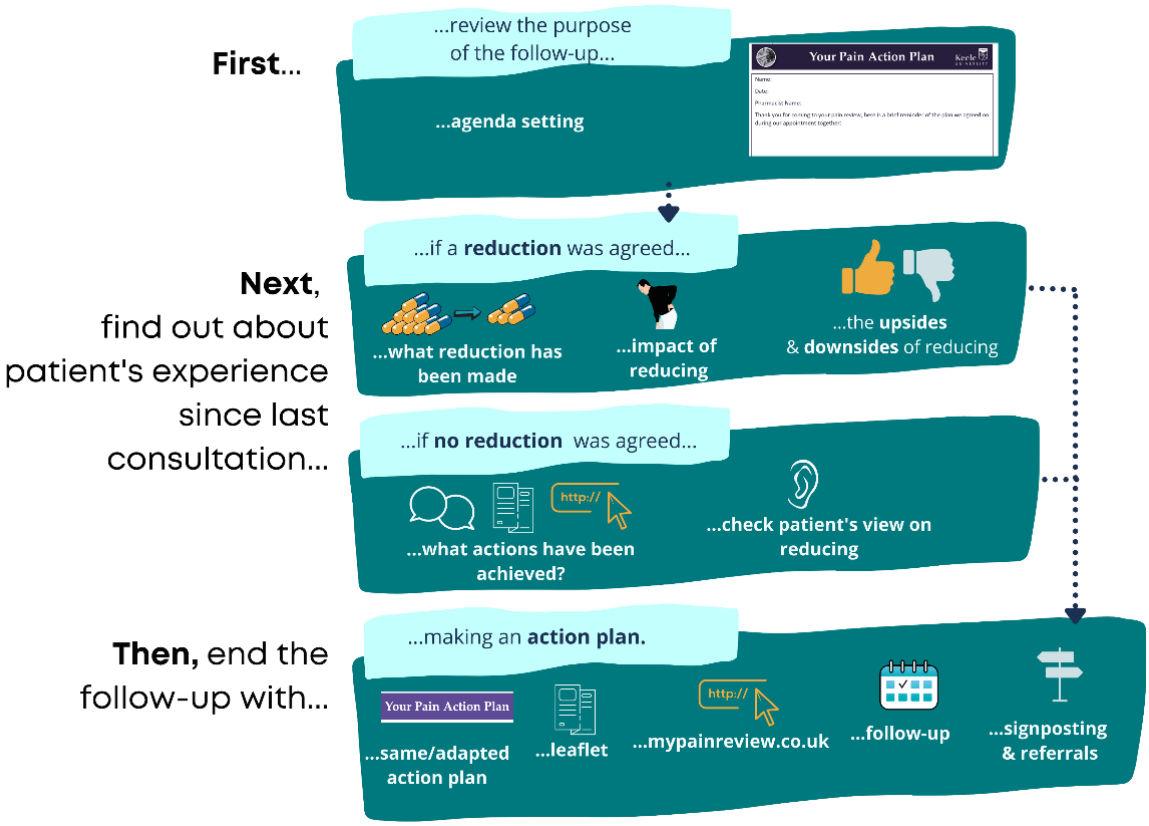
A flexible delivery framework helps to provide some structure for the pain review, which has a beginning, a middle, and an end:



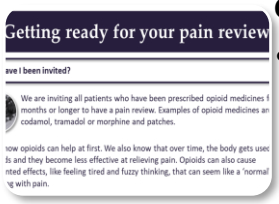
Follow-up

Follow-up appointments are an important part of the pain review. Conducted face-to-face or virtually, follow-ups are likely to last between 10-15minutes.

The follow-up framework:



Patient facing documents for the pain review



Getting Ready Leaflet

- Patients will be sent the 'Getting ready for my pain review' leaflet prior to their first pain review which answers FAQs about the pain review, including; why have I been invited? What is a pain review? Who will my pain review be with? What will happen at my pan review?

Your Pain Action Plan

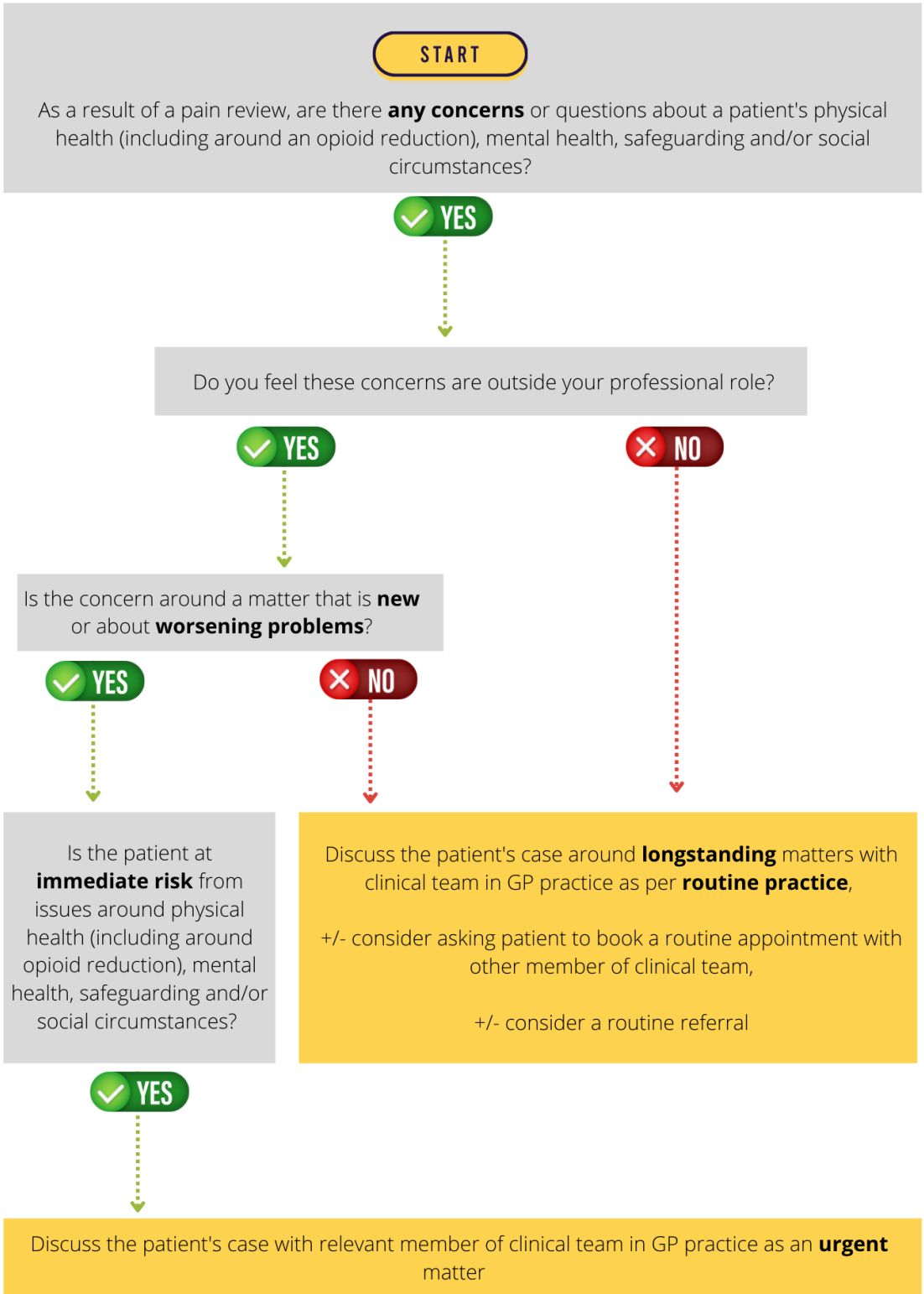
- Pharmacist will complete alongside patient in the initial pain review with a brief statement about the management plan, follow-up arrangements and a link to key information resources.
- A new action plan should be completed at follow-up pain reviews if any adaptations to the original plan are agreed

Positive Changes Leaflet

- Pharmacist will hand out the 'Positive Changes' leaflet with the 'Your Pain Action Plan' at the end of the pain review
- The leaflet aims to support **all** patients to make a change towards reducing opioids.

5. Seeking advice and signposting

We anticipate that pharmacists will be able to manage most of the pain reviews independently, but there may be times when they want to seek advice from a relevant professional, GP and/or the wider healthcare team. Alongside agreed procedures within the GP practice, the figure below will help pharmacists decide on when to seek advice for concerns that seem outside their clinical role.



6. Pain Review Study Documents

To be completed by the practice pharmacist, electronic case report forms (e-CRFs) provide a research record of the pain review.

- Accessed via links to online surveys sent by email
- There are x2 forms:
    1. Initial pain review
    2. First follow-up consultation
- All initial pain reviews and the first follow-up pain review must be recorded on the e-CRF
- The pharmacist will complete the relevant form at the time of, or on the same day of the pain review

7. Safety Reporting

SERIOUS ADVERSE EVENTS

WHAT IS A SERIOUS ADVERSE EVENT?

A Serious Adverse Event (SAE) in the context of the PROMPPT trial would be defined as an untoward occurrence that:

(a) results in death;

(b) is life-threatening;

(c) requires hospitalisation;

(d) results in persistent or significant disability or incapacity;

(e) is otherwise considered medically significant.

We know that reducing opioids can result a transient increase in pain and/or withdrawal symptoms but these events are not considered to be SAEs.

The procedure for safety reporting is as follows: