

# An evaluation of an online pain management programme

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<b>Registration date</b> 16/09/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 26/08/2020	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Chronic (long-term) pain is defined as any pain that has lasted for more than 12 weeks. It is estimated that as many as 20% of adults in Europe experience moderate to severe chronic pain in their lifetime. In the UK, it is recommended that people suffering from chronic pain should be enrolled in pain management programmes (PMP). PMP's are rehabilitation programmes designed to help people to cope with their pain, improving their day-to-day lives. In the past, these programmes are generally given in treatment centres such as hospitals or health centres. It has been found that reasons such as mobility problems, distance from the treatment centre and costs of getting there can mean that some people are unable to receive this treatment. There is growing evidence showing that interactive internet-based applications can help provide effective healthcare solutions for patients at home. The aim of this study is to see whether we can deliver an online PMP guided by clinicians (called My Pain Compass) to patients suffering from chronic pain so that we can then do a larger study in the future to test whether it works.

### Who can participate?

Adults diagnosed with chronic pain, which has existed for a least 6 months.

### What does the study involve?

Participants are guided through the 12 module programme over a period of 12 weeks. They are able to speak to a psychologist or a physiotherapist once a week for 20 minutes via a video call, as well as being asked to complete worksheets and exercises in-between each session as part of the programme, e.g. writing down beliefs about pain, practising relaxation and stretching. Before they start using My Pain Compass and during the programme, participants record their daily pain and physical activity levels. At the start, half way through (6 weeks) and at the end (12 weeks) of the programme, participants also complete questionnaires about their levels of pain, independence, general health and their opinions on My Pain Compass. Additionally, seven of the participants are interviewed over the telephone half way through (6 weeks) and at the end (12 weeks) of the intervention about their experiences using the programme. The healthcare professionals are also asked to complete a questionnaire on their views of My Pain Compass.

### What are the possible benefits and risks of participating?

Benefits of taking part in this study are the possibility of helping participants to manage their

pain more effectively. There are no significant risks of participating, however people may experience some worry when trying this new programme. The programme aims to help build up confidence in managing pain slowly, so this risk is minimal.

Where is the study run from?

Chelsea and Westminster Hospital (UK)

When is the study starting and how long is it expected to run for?

April 2016 to January 2017

Who is funding the study?

My Pain Ltd (UK)

Who is the main contact?

1. Dr Rahul Seewal (Public)

2. Dr Esther Flanagan (Scientific)

## Contact information

### Type(s)

Public

### Contact name

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# Additional identifiers

## Protocol serial number

MyPMP/2015/1

# Study information

## Scientific Title

A single arm study investigating the feasibility of a clinician guided online pain management programme for people with chronic pain conditions

## Study objectives

1. My Pain Compass is feasible to deliver and is acceptable to patients with chronic pain and clinicians
2. Collection of patient-reported outcome measures through My Pain Impact is feasible
3. There is initial evidence that My Pain Compass can alter daily measures of pain and physical activity

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

London - Fulham Research Ethics Committee, 24/03/2016, REC Ref: 16/LO/0272

## Study design

Replicated single-case design feasibility study

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Chronic pain

## Interventions

The PMP (My Pain Compass) is provided online and will be accessed by the patient from an environment of their choosing. The My Pain Compass programme is estimated to take 12 weeks. The content of the modules is mainly delivered via animated videos, with some written text and interactive worksheets. A clinician will not be present when the patient is accessing and learning from the programme but will contact the patient via a 20 minute videoconference call (using software in-built into programme) once a week during the study. There are 12 modules included in the programme as follows:

Introduction to programme (what to expect from the programme)

Module 1: Understanding Pain (understand pain mechanisms, the impact of pain and introducing the CBT model)

Module 2: Understanding the body, healing and chronic pain (understanding injury and healing)

Module 3: Planning change (looking at personal values, setting goals and making plans)

Module 4: Pacing yourself (understanding unhelpful activity cycles and how to pace up activity)  
Module 5: The Pain Compass (exploring connections between thoughts, emotions, behaviour and pain, and learning how to challenge unhelpful thoughts)  
Module 6: Movement and stretching (the importance of movement and stretching and how to introduce them)  
Module 7 - Improving Sleep (impact of pain on sleep, sleep hygiene and other strategies)  
Module 8 - Learning relaxation (learning to let go of tension in the body)  
Module 9 - Introducing mindfulness (learning the basic principles of mindfulness)  
Module 10 - Communication & Pain (learning how pain can impact on communication and how to communicate effectively in different settings)  
Module 11: Flare-ups (understanding and managing flare-ups)  
Module 12: The future (identifying what helped, continuing to use skills, overcoming obstacles)

Within these modules participants will be asked to complete online worksheets, including goal-setting, thought records and a flare-up checklist.

Participants will be guided through the content and asked questions throughout as part of the learning objectives of the programme. Participants will complete one module at a time and will not be able to move onto the next module until they have completed the tasks set in the previous module.

The patient has access to the programme and will progress through treatment themselves. Every two weeks for the duration of the study they will have a 20 minute phone call with a clinician.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

1. Feasibility of delivering My Pain Compass and its acceptability
  - 1.1 How patients use My Pain Compass and their learning outcomes will captured by the computer software
  - 1.2 Patient satisfaction questionnaire (CSQ-8) completed post intervention
  - 1.3 Patient interviews completed mid- and post intervention
  - 1.4 Clinician acceptability questionnaire completed post intervention
2. Feasibility of collecting data via My Pain Impact
  - 2.1 PROMS completion rates are determined at baseline, mid- and post intervention using the Patient Health Questionnaire (PHQ-9), Pain Self-Efficacy Scale (PSEQ), Pain Catastrophising Scale (PCS) and Depression, Anxiety and Positive Outlook Scale (DAPOS)
  - 2.2 Pain score (0-10) reported weekly in video-conference with clinician
3. Initial evaluation of My Pain Compass
  - 3.1 Physical activity (steps, distance) completed daily through baseline and intervention periods
  - 3.2 Daily pain scores completed daily through baseline and intervention periods

## **Key secondary outcome(s)**

N/A

## **Completion date**

30/06/2022

## **Eligibility**

**Key inclusion criteria**

1. Over 18 years of age
2. Diagnosed with a chronic pain condition for at least 6 months
3. If medicated for anxiety or depression, on a stable dose of medication as defined by no change in medication dose for 1 month or more
4. Full capacity to consent
5. Has regular access to the Internet and a smartphone / tablet / computer
6. Prepared and comfortable to regularly interface with a treatment modality primarily delivered through online methods including mobile devices
7. Able to understand the contents and participate in the language of the programme (English only)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. People with an unstable mental health condition as determined by assessing clinician or GP
2. People with severe symptoms of depression >20 on Patient Health Questionnaire (PHQ-9) or suicidal/self-harming thoughts experienced more than half the days in the previous 2 weeks
3. People who already score highly on self-efficacy; 50 or more on the Pain Self Efficacy Scale (PSEQ; see outcomes section)
4. People with chronic headache, autoimmune diseases, malignant cancer pain, and facial pain
5. Participating in any psychological therapy for any condition at the point of recruitment
6. Previously accessed cognitive behavioural pain management

**Date of first enrolment**

01/10/2016

**Date of final enrolment**

31/01/2017

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**  
**Chelsea and Westminster Hospital**  
369 Fulham Road  
London  
United Kingdom  
SW10 9NH

## Sponsor information

**Organisation**  
My Pain Ltd

**Organisation**  
Chelsea and Westminster Hospital NHS Foundation Trust

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
My Pain Ltd

## Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**  
Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			26/07/2023	No	No