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An evaluation of an online pain management programme

Submission date 06/09/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 16/09/2015	**Overall study status** Completed	
Last Edited 26/08/2020	**Condition category** Signs and Symptoms	

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 tol 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Feasibility study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure

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

Secondary outcome measures
N/A

Overall study start date
01/09/2016

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
15

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
England

United Kingdom

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

Sponsor information

Organisation
My Pain Ltd

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Sponsor type
Industry

Website
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Industry

Funder Name
My Pain Ltd

Results and Publications

Publication and dissemination plan
Planned submission to a high impact, peer reviewed journal (for example the BMJ).

Intention to publish date
31/12/2022

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?
HRA research summary			26/07/2023	No	No