

Osteopathy, mindfulness and acceptance for persistent pain

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| Submission date 06/06/2014 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 08/07/2014 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 10/05/2019 | Condition category Signs and Symptoms | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Research has found that people with persistent pain often suffer from anxiety, depression and isolation, which can lead to loss of mobility, loss of independence and unemployment. People with long-term conditions can benefit from multidisciplinary healthcare where health care professionals with different areas of medical expertise work together to make a complete healthcare plan. Self-management programmes can also improve emotional health and result in the patient taking less medication. However, at the moment there are few programmes that offer both physical treatment and psychological support for individual patients living with persistent pain. The British School of Osteopathy (BSO) is developing a new course as part of the OsteoMAP project, to help people to live more flexible and fulfilling lives, despite ongoing pain. The aim of this study is to explore whether providing a healthcare course which includes osteopathic treatment, mindfulness skills and self-care exercises can help people to cope better with long-term pain. We will be collecting feedback from patients and assessing how successful it is in order to improve the course.

Who can participate?

Adult patients that have suffered from persistent musculoskeletal pain for more than 6 months, who are suitable for manual therapy and whose pain is stopping them from doing their usual daily life activities

What does this study involve?

Patients are offered personalised courses that deal with their own needs, which they attend for one hour, once a week for six weeks. Each session includes tailored manual therapy, mindfulness breathing and meditation and mindful movement exercises to improve body awareness. Home practices are also suggested to develop skills to help live better with pain. The patients continue with their usual medical care during the course but are asked not to start new treatments which aim to control pain, unless recommended by the GP. Treatment is provided by teams consisting of a qualified osteopath and up to three student osteopaths. Each patient is asked to complete a set of questionnaires about their pain and general health before the course starts and then six months later. About 5% of participants are also asked for permission for a member of the study team to observe a course session for evaluation purposes, or to take part in a follow-up research interview after six months.

What are the possible risks and benefits of participating?

The course is considered to be low risk as it does not involve invasive treatment and is based on activities that are regularly used in pain management courses in the UK. All patients are screened by the clinic team to check that manual therapy is suitable and their GPs are asked if unsure. Around half of patients may feel minor muscle soreness lasting less than 24 hours after the first treatment but they will be given advice as to how to treat this if it happens. All physical treatment and movement-based activities will be adapted for each patient's personal capabilities and they will not be asked to do anything they are uncomfortable with. The course encourages patients to think about how pain is affecting their life, which they may find emotionally upsetting. Mindfulness and mindful movements have been used successfully on similar pain management programmes and carry little risk of harm as they consist of the movements of normal daily living. There are no guaranteed specific benefits for individual participants but previous research has shown that some people on mindfulness pain management courses report feeling able to cope better with their symptoms. This course may encourage patients to do activities they may have been avoiding because of pain, so potential benefits could include a more active, enjoyable life.

Where is the study run from?

The British School of Osteopathy (UK)

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

September 2014 to May 2015

Who is funding the study?

Department of Health (UK)

Who is the main contact?

Mrs Hilary Abbey

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT02121587

Protocol serial number

16731

Study information

Scientific Title

Developing OsteoMAP: an integrated osteopathy, mindfulness and acceptance-based programme for patients with persistent pain

Study objectives

1. Do patients with persistent musculoskeletal pain report improvements in quality of life, well-being and ability to engage in personally-valued activities six months after participating in an individually delivered pain self-management course, which integrates Mindfulness and Acceptance-based approaches to self-care with Osteopathic manual therapy treatment?
2. Are changes in quality of life, well-being and physical activity associated with increased pain acceptance and/or mindfulness skills.
3. Does this new, integrated approach to promoting more effective self-care strategies appear to be feasible for further evaluations of effectiveness for patients in primary care?

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee London: City Road and Hampstead, 28/05/2014, ref: 14/LO/0828

Study design

Non-randomised; Observational; Design type: Cohort study

Primary study design

Observational

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Topic: Primary Care; Subtopic: Not Assigned; Disease: All Diseases

Interventions

Mindfulness exercises: In each one hour session, participants will be encouraged to develop and practice new mindfulness skills to promote their own self and body awareness, as part of the healthcare approaches of Acceptance and Commitment Therapy (3rd wave CBT). Interventions will include mindfulness breathing meditations and mindful movement practices, as well as acceptance-based activities to promote resilience and encourage re-engagement with personally valued activities and social roles.

Osteopathic treatment, Manual therapy treatment in each one hour session will be pragmatic and personalised for that patient's musculoskeletal condition, physical capabilities and personal life goals. Treatment for long-term pain patients is usually conservative, consisting of massage, stretching, and passive and active joint articulation techniques and home exercises.

Follow Up Length: 6 month(s); Study Entry : Registration only

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

European Quality of Life Questionnaire EQ5D; Timepoint(s): Pre intervention and after 6 months

Key secondary outcome(s)

1. Bournemouth Pain Questionnaire; Timepoint(s): Pre intervention and after 6 months
2. Freiburg Mindfulness Inventory; Timepoint(s): Pre intervention and after 6 months
3. The Activity Avoidance Questionnaire AAQ-II; Timepoint(s): Pre intervention and after 6 months

Completion date

29/05/2015

Eligibility**Key inclusion criteria**

1. Adult patients with persistent musculoskeletal pain for more than 6 months
2. Suitable for manual therapy
3. With pain-related limitations to daily life activities
4. Willing to participate actively in exploring new approaches to self-care
5. Have scope for increasing their physical activity levels

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

208

Key exclusion criteria

1. Aged under 18, unsuitable for osteopathy
2. Uncontrolled alcohol or substance dependency, which would limit ability to participate in mindfulness exercises
3. Active, uncontrolled psychosis for the same reason
4. Unwilling to participate in enhancing their own well-being
5. Speaking insufficient English to participate in their own healthcare consultations without an interpreter

Date of first enrolment

01/09/2014

Date of final enrolment

29/05/2015

Locations

Countries of recruitment

United Kingdom

Study participating centre

The British School of Osteopathy

London

United Kingdom

SE1 1JE

Sponsor information

Organisation

The British School of Osteopathy (UK)

ROR

<https://ror.org/05tnja216>

Funder(s)

Funder type

Government

Funder Name

Department of Health (UK) - Voluntary Sector Investment Programme; Grant Codes: IESD AIMS 2527190

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/06/2017 | 10/05/2019 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |