OSCAR (Osteopathic Single CAse Research) – assessing the effect of standard and biopsychosocial osteopathic management for patients with non-specific low back pain: protocol for a Single Case Experimental Design (SCED)

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Abstract/Summary

Background: Osteopathy has been shown to be effective in the management of chronic low back pain (LBP). Guidelines recommend biopsychosocial care for chronic, complex musculoskeletal conditions, including non-specific LBP.

Objectives: This study has four aims: 1/ to assess how patients with LBP improve after osteopathic treatment, both before and after an osteopath has completed a Biopsychosocial Pain Management course; 2/ to assess if it is feasible and acceptable for osteopaths to receive weekly SCED data and use it to guide patient management; 3/ to assess if it is acceptable for patients to submit daily data and discuss weekly summary with their osteopaths; and 4/ to test feasibility for researchers in collecting, managing and storing large quantities of individual patient data.

Methods: A multiple baseline single case experimental design trial with up to 10 UK osteopaths with more than 15 years in practice and 60 patients will assess how change occurs as a result of osteopathic treatment for patients with non-specific LBP of more than 12 weeks' duration. Statistical analysis will assess the degree and rate of change between baseline, intervention and follow-up periods, and whether differences in effect are observed after the osteopaths have completed the biopsychosocial patient management training course. Primary outcomes will be the Numeric Pain Rating and Patient Specific Function Scales, measured daily at baseline and for 6 weeks during the intervention stage, and weekly or fortnightly during a 12-week follow-up period.

Ethics: This research was approved by the XXX Research Ethics Committee.

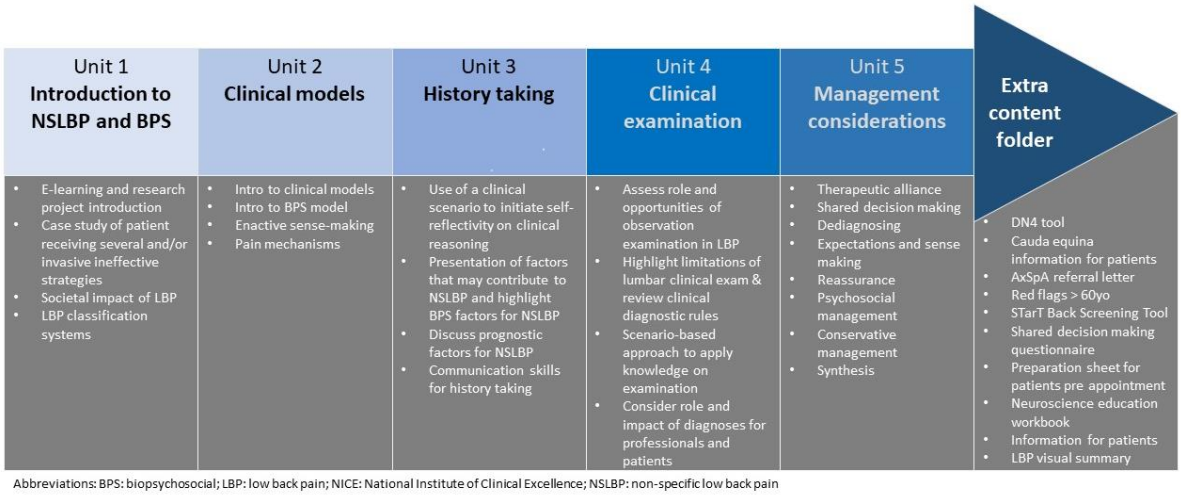
Keywords: Low Back Pain; Models, Biopsychosocial; Manipulation, Osteopathic, single case experimental design; protocol; e-learning

Background

The updated Osteopathic Practice Standards (General Osteopathic Council 2019) state that osteopaths should practice evidence-informed healthcare and collect data to enhance patient care, but challenges have been identified in many healthcare professions in translating research into clinical practice and developing practice-relevant research skills. In the absence of standard research career pathways for osteopaths, few Randomised Controlled Trials (RCTs) have been conducted due to limited funding, knowledge, skills or capacity within the profession.

Osteopathic management has been shown to be effective in the management of chronic low back pain (Franke, Franke et al. 2014, Verhaeghe, Schepers et al. 2018). Guidelines recommend biopsychosocial (BPS) care for chronic, complex musculoskeletal conditions, including non-specific low back pain (NSLBP) (National Institute for Health and Care Excellence 2016) but there is a lack of evidence comparing standard osteopathic care, which has traditionally been based on dated and disputed biomechanical theories of dysfunction, and more contemporary biopsychosocial theories are yet to be fully adopted. Promising results were reported from a mixed methods feasibility study assessing practitioner outcomes from a BPS e-learning programme (Draper-Rodi, Vogel et al. 2021). The original e-learning development is reported elsewhere (Draper-Rodi, Vogel et al. 2018) and was updated in February 2022: the final e-learning course is 8-hour long and was developed using the ADDIE (Analyse, Design, Develop, Implement, and Evaluate) and COM-B (Capability, Opportunity and Motivation – behaviour) models to provide an easy to use for the osteopaths and promote a change of their behavioural with patients. The content of the e-learning is detailed in Figure 1. The rationale for this study is to combine an existing but updated e-learning course that was previously tested for feasibility (Draper-Rodi, Vogel et al. 2021) within a single case experimental design (SCED) trial in order to involve practising osteopaths in research. It aims to generate new insights into potential differences in process and outcomes between standard osteopathic treatment and BPS-informed, patient-centred care. This protocol followed the SPIRIT reporting guidelines.

Figure 1. E-learning content



Abbreviations: BPS: biopsychosocial; LBP: low back pain; NICE: National Institute of Clinical Excellence; NSLBP: non-specific low back pain

Aims

This study has four aims:

- To compare pain and function in patients with low back pain after osteopathic treatment before and after an osteopath has completed a Biopsychosocial Pain Management (BPM) course.
- To assess if it is feasible and acceptable for osteopath participants to receive weekly SCED data and use it to guide patient management.
- To assess if it is acceptable for patient participants to submit daily data about low back pain and discuss weekly summary data with their osteopaths to guide treatment.
- To test the feasibility for the research team to handle frequent data gathering, a complex individual-level randomisation scheme, and a complex longitudinal design (daily, weekly, fortnightly) in SCED trials.

Design

Design: Single Case Experimental Design (SCED) using randomised multiple baselines (registered on clinicaltrials.gov, on 18/10/2021, ID number NCT05120921) during two distinct recruitment periods, before and after osteopaths take the e-learning programme (see Figure 2). Multiple baseline SCEDs (Morley 2017, p.67) require replication in small numbers of patients (Krasny-Pacini and Evans 2018).

Study setting: private osteopathic clinics in the UK

Eligibility criteria: The criteria for osteopaths and patients are detailed in Table 1

Table 1 – Eligibility criteria for the osteopath and patient participants.

Participants	Inclusion criteria	Exclusion criteria
Osteopaths	- be osteopaths practising in the UK - have a minimum of 15 years' practice experience (although trained in subjects such as psychology or sociology within the context of holistic care, they would not have been introduced to the biopsychosocial model in their undergraduate professional education) - agree to take part in the study and provide written consent - not have been involved in osteopathic education in the last ten years: as the biopsychosocial model is taught in Osteopathic Educational Institutions, osteopaths could have encountered the biopsychosocial model while teaching. This is supported by Roots, Niven et al. (2016) - not have taken part in the previous biopsychosocial e-learning feasibility study	- osteopaths with less than 15 years of practice - osteopaths involved in osteopathic undergraduate teaching in the last 10 years
Patients	- 18 or more years old - agree to take part in the study and provide formal online consent after having been assessed as capable of providing informed consent by the osteopath - be fluent enough in English to be able to understand content of consent forms (and participate in osteopathic treatment without an interpreter) - present with non-specific low back pain of a duration of a minimum of 12 weeks) - Numeric Pain Rating Scale score between 5 and 9 on a 11-point scale - Patient Specific Functional Scale score between 2 and 7 at baseline - who can be contacted by email - available for an appointment within two days of their randomisation date	- Under 18 - lack capacity to give consent - present with low back pain with a known or suspected pathological cause (e.g. infection, cancer or fracture) - patients who have received osteopathic treatment in the last 6 months - people for whom osteopathic treatment may be contra-indicated (assessed by osteopaths in initial consultations) or who disclose information during treatment which requires referral for other medical investigations or care - Low back pain of less than 12 weeks - Numeric Pain Rating Scale score below 5 or above 9 - Patient Specific Functional Scale score above below 2 or above 7 - patients providing fewer than 3 data points at baseline

Intervention(s)/method: The interventions in this SCED involve a pragmatic approach to osteopathic manual therapy which does not require adherence to a protocol. Osteopaths will provide treatment in line with standard treatment practices, as outlined by the General Osteopathic Council (General Osteopathic Council 2019), including soft tissue massage and joint articulation and manipulation as appropriate for NSLBP and individual patients' needs. Treatment will be delivered in individual osteopathic practices for approximately 30-60 minutes a week for up to 6 weeks (Ellwood and Carnes 2021). The tested intervention is an e-learning programme on BPS approaches to patient management. After the e-learning course, it is anticipated that osteopaths' normal treatment approaches will incorporate new communication strategies and advice aligned with current best practice guidelines for Biopsychosocial Pain Management (BPM) (Draper-Rodi, Vogel et al. 2018). To reflect real-world clinical practice and minimise risk of harm, patients will be asked to continue with existing healthcare treatment and support as normal. They will be able to withdraw from the study at any time, without giving reasons and without detriment, and can choose to stop or continue osteopathic treatment. Osteopaths will be required to report adverse events to the study team immediately but risks from manual therapy and osteopathy are considered to be low (Carnes et al. 2010) and may be lower in this study due to daily data collection and the increased focus on patients' experiences.

Outcomes Measurement Timeline: A multiple baseline single case experimental design study with daily and weekly collection of quantitative self-report questionnaire data for pain and function. Data will be collected at baseline (randomised duration between 5-14 days), during treatment (4-6 weeks) and at follow-up (12 weeks) and in two stages: before and after osteopaths complete a 6 week/hour BPM e-learning course.

Osteopath participants: A small purposive sample of approximately 10 qualified osteopaths will be recruited. Osteopaths will participate in a one-day online training session which will introduce SCED methodology and methods of using individual patient data to guide care. Each osteopath will be invited to recruit and treat a maximum of 3 patients in their own clinic to take part in a course of osteopathic treatment before the osteopath starts the BPM course, and then to recruit and treat a further maximum of 3 patients after completing the course.

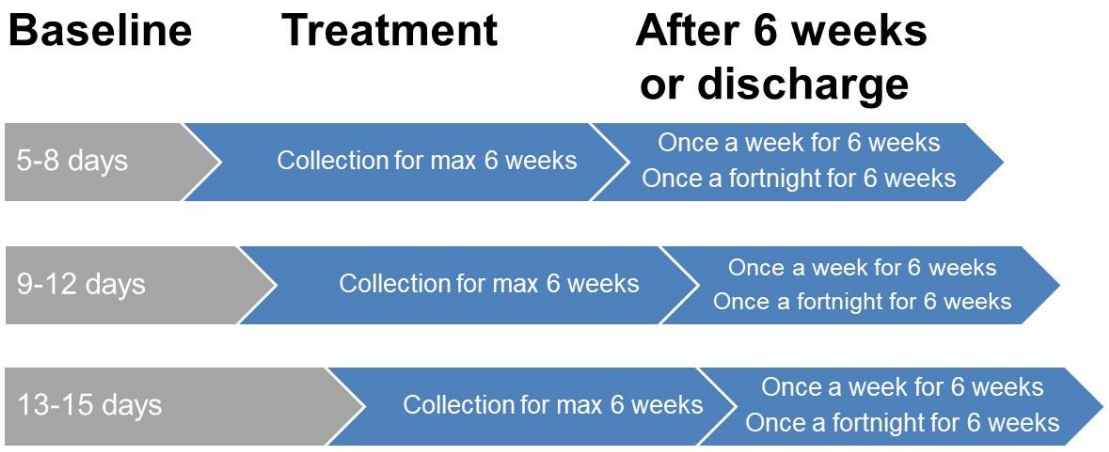
Patient participants: A purposive sample of up to 60 (3 patients per osteopath before, and 3 after the e-learning course) adults with recurrent NSLBP who have not visited an osteopath within the last 6 months. At the recruitment stage, patients must have a Numeric Pain Rating Scale score between 5 and 9 and a Patient Specific Functional Scale score between 2 and 7. This is to minimise the risk of floor effects due to low baseline symptoms

and to minimise the risk of harm due by delaying treatment in the SCED randomisation process by excluding patients with severe self-report symptoms.

Recruitment: Osteopaths will be invited to take part in this research study by email, social media posts and articles in the professional bodies e-newsletters. Patients will be recruited directly from the osteopathic clinics.

Allocation and implementation: Patients will be randomised to early (5-8 days), medium (9-12) or late (13-15) first consultation date (see figure 3). For the second eligible patient recruited, their first consultation date will be randomly selected from the remaining 2 options. The third patient will start on the remaining date. The randomisation is within each group (i.e., either within the group of patients treated before taking the e-learning, or within the group of patients treated after the e-learning) so overall changes in time is similar within each group. The software programme Qualtrics© will be used enrol participants and to randomly assign the early/medium/late consultation dates.

Figure 3 - Randomisation in each group



Blinding: It is not possible to blind the osteopath participants, but patients will be informed that the study aims to assess experiences and outcomes from osteopathic treatment and will be unaware of their stage. Data will not be analysed until all patients have completed the second stage and the statistician will be blinded to stage (pre or post e-learning) by labelling them as X and Y.

Data collection methods and management: Data will be collected from all participants online using Qualtrics©, a secure and GDPR compliant platform. Reminders will be sent to patients if they fail to upload data for more than 1 day. At the end of the study, data will be stored securely at the sponsor institution for a period of 6 years, after which time electronic

data will be deleted. Participating osteopaths will store patient weekly summaries anonymised by code as part of their clinical data.

Primary and secondary endpoint(s):

Primary endpoints

- Numeric Pain Rating Scale (NPRS) (Dworkin, Turk et al. 2005)
- An 11-item unidimensional measure of pain intensity that will not be used on its own as it does not capture the complexity of chronic pain patients' experiences (Hush (Hush, Refshauge et al. 2010), Refshauge et al. 2010). It has high test–retest reliability and good validity (Ferraz, Quaresma et al. 1990). Patients will complete the NPRS daily (approx. 1 min.) being asked "Please rate your pain by indicating the number that best describes your pain on average in the last 24h (0 = 'No pain', and 10 = 'Pain as bad as you can imagine')". The within-group MCID is set at 30% (Gatchel, Mayer et al. 2013) and between-group MCID is set at 20% (Smith, Dworkin et al. 2020). Patient Specific Functional Scale (PSFS) (Horn, Jennings et al. 2012)

Measures functional change in patients with musculoskeletal disorders by listing up to 5 activities that are difficult to perform. Patients will record data for the first chosen activity throughout the study but can add activities if goals change (e.g. improving or worsening symptoms). Patients rate level of difficulty for each activity on an 11-point scale, where 0 = able to perform and 10 = unable to perform at previous level. Mean averages are calculated as total difficulty ratings divided by number of activities. The PSFS is reliable and responsive for chronic low back pain (Horn, Jennings et al. 2012). The Minimum Detectable Change (MDC) is 3 points for 1 activity or 2 points for 2 or more activities.

Secondary endpoints

- Measure Your Medical Outcome Profile 2 (Polus, Kimpton et al. 2011)

MYMOP2 is a self-report questionnaire for one or two symptoms and one activity affected by the patient's condition. The first PSFS activity will automatically be entered for MYMOP2. It is a validated, sensitive and responsive measure (Polus, Kimpton et al. 2011, Hermann, Kraus et al. 2014). Minimum clinically important change (MCIC) is 0.5-1.0, and changes greater than 1.0 are clinically significant.

- The Arthritis Research UK Musculoskeletal Health Questionnaire (Hill, Kang et al. 2016)

MSK-HQ captures generalised health outcomes for a range of musculoskeletal conditions. It has excellent test-retest reliability, and strong convergent validity with reference standards. It includes 14 questions scored on a 0-4 scale (range 0-56, where higher scores represent

better health). A licence has been obtained to use the questionnaire online from Oxford University Innovation Centre for free (only questionnaire requiring a licence in this project).

- The Depression, Anxiety, and Positive Outlook Scale (Pincus, Williams et al. 2004)

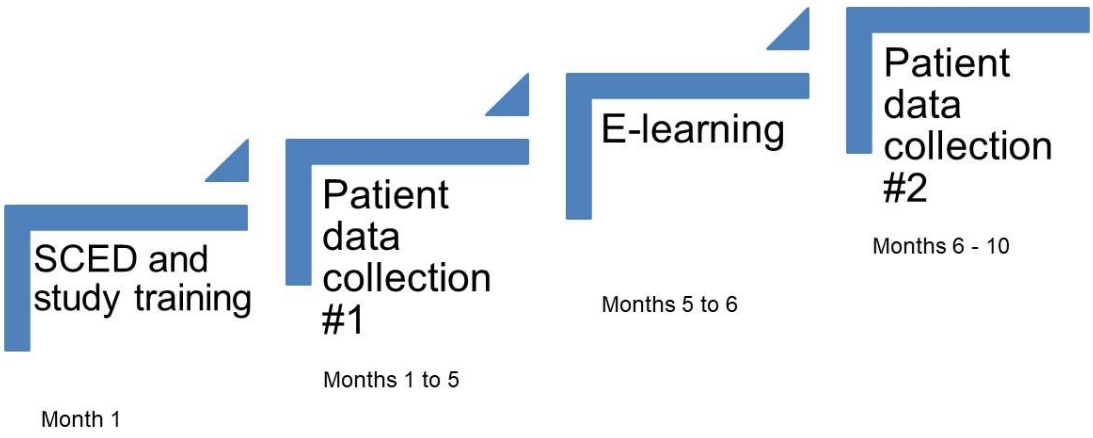
DAPOS measures distress and positive affect in chronic musculoskeletal pain populations. It has 11 items: 5 on depression, 3 on positive affect and 3 on anxiety; answered on 5-point Likert scales ranging from 'almost never' to 'almost all the time'. It has acceptable responsiveness, excellent internal consistency and construct validity in comparison with the SF-36, Pain Catastrophizing Scale and Zung Depression questionnaire (Pincus, Rusu et al. 2008).

- Survey of patients' experiences of osteopathic treatment and participating in the SCED

A questionnaire was adapted from the Patient Enablement Index for Back Pain (Molgaard Nielsen, Hartvigsen et al. 2021), containing 12 questions on patients' perceptions of shared decision-making, treatment outcomes, relevance of measures, and acceptability of data collection processes.

See summary of patient measures in Figure 2.

Figure 2 – study design



- Pain Attitudes and Beliefs Scale (for osteopaths) (Houben, Ostelo et al. 2005)

PABS is a 19-item questionnaire with six-point response scales which assess two LBP treatment orientations: biomedical and behavioural (Ostelo, Stomp-van den Berg et al. 2003). The modified PABS will be used (Houben, Ostelo et al. 2005) and has content and construct validity, internal consistency, reliability and responsiveness (Bishop 2007).

- Prognostic surveys (Brunner, Dankaerts et al. 2018) (*for osteopath participants*)

It was previously used in Brunner *et al.* (2018) to assess physical therapists' ability to estimate a patient's prognostic risk of poor outcome. Osteopaths will complete one survey after patients' initial visit answering three questions:

1. On a scale of 0 to 10, what are your perceptions of the patient's current level of [one subquestion per item: Distress; Depression; Anxiety; Fear of movement]? (0 = none 10 = very high CJ = Cannot judge)
2. What is the risk that this patient will still have persistent functional limitations in 6 weeks' time? (Low / Medium / High)
3. Please list the factors that have influenced your assessment of prognosis and risk (open text)

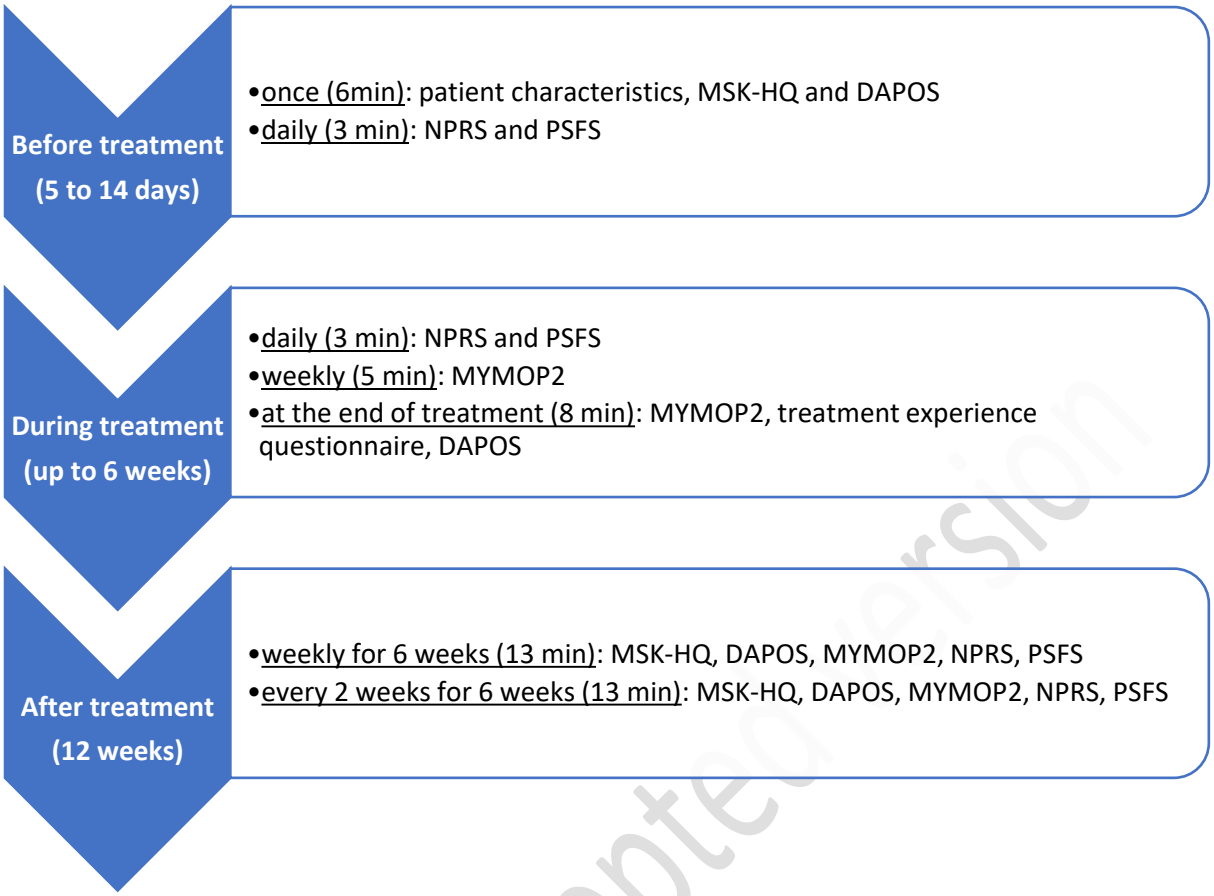
and one survey 6 weeks later, answering three questions:

1. On a scale of 0 to 10, what are your perceptions of the patient's current level of: (0 = none, 10 = very high, CJ = Cannot judge)
    a. Distress 0 1 2 3 4 5 6 7 8 9 10 CJ
    b. Depression 0 1 2 3 4 5 6 7 8 9 10 CJ
    c. Anxiety 0 1 2 3 4 5 6 7 8 9 10 CJ
    d. Fear of movement 0 1 2 3 4 5 6 7 8 9 10 CJ
2. How well has this patient responded compared to your initial expectations? (Better than expected, As expected, Worse than expected)
3. Please list the factors that may have influenced this patient's response to treatment (open text)

- Survey of SCED feasibility, acceptability and impact of e-learning course on patient care (Molgaard Nielsen, Hartvigsen et al. 2021)

Adapted from the Patient Enablement Index, consisting of 12 questions with 11-point Likert scale responses for agreement and satisfaction and 2 open text questions about osteopaths' experiences of SCED processes and outcomes to guide future training and research.

Figure 4 – patient outcome measures



Statistical analysis

Primary analyses

Linear mixed-effects modelling of NPRS and PSFS

Modelling will address treatment effects on NPRS and PSFS scores, and whether outcomes differ after BPS training, having accounted for individual-specific differences in means and linear trends. A mixed-effects linear modelling approach will be used to account for lack of independence due to repeated measurements on all participants.

The following maximal model for the predictors is envisaged:

- Fixed effects:
    - Demographics (age, gender, education level)
    - Phase of study (nominal variable with three levels: pre-treatment, during treatment, post-treatment)
    - BPS training (nominal variable with two levels: pre and post training)
    - Time in days (time at which NPRS and PSFS obtained relative to first data point)
- Interaction effects:
    - Phase of study X time

    - Phase of study X time X BPS training
- Random effects:
    - Osteopaths as random intercepts
    - Participants as random intercepts and slopes

Analyses will be conducted using the R (R Core Team 2020) packages LME4 (Douglas, Maechler et al. 2015) and lmerTest (Kuznetsova, Brockhoff et al. 2017).

See secondary analyses in Appendix 1.

Patient and consumer involvement

A feasibility study was conducted with osteopaths (Draper-Rodi, Vogel et al. 2021), but patients have not been involved in developing this design or the e-learning programme.

Ethical issues

This research was approved by the University College of Osteopathy Research Ethics Committee. All participants (osteopaths and patients) will receive information sheets and have a cooling-off period to decide whether to take part. There will be several cooling off periods for the osteopath participants with a minimum of one week between: before and after the SCED training day; and before each collection data stage from patients. Patient participants will have a minimum 5-day cooling off period between booking and attending their first appointment. All participants will provide written consent (Appendices 2 & 3).

Adverse events will be logged in two processes relating to clinical care and participating in research. Osteopaths will be responsible for logging adverse events related to treatment as part of normal requirements for professional practice, which include case history records and contacting their insurer. For any adverse events that occur, or are thought to have occurred, because of participation in this study, osteopaths will be asked to contact the Principal Investigator within 24 hours and complete the Adverse Event Recording Form (Appendix 4). Patients will be covered by their osteopath's standard liability insurance. Complaints relating to harm caused by taking part in the study will be covered by the sponsor insurance.

Discussion

This work represents the first application of multiple baseline randomised SCED, which the authors are aware of, testing an osteopathic intervention. It is also hoped it will provide some

preliminary results on the effect of an educational intervention, although this effect cannot be regarded as causal. Osteopaths being able to select their patients may lead to a risk of selection bias. To limit this, patients will be recruited prior to attending their first appointment: patients contacting the practice or looking for online information on the practice will have directly access to information to make an informed decision on taking part.

Publication plan and dissemination plan

The results of the SCED trial will be published in a peer-reviewed journal in accordance with (International Committee of Medical Journal Editors 2019) and will follow the SCRIBE guidelines. Secondary analyses may subsequently be separately published. The final deidentified participant-level data will be made available after assessment of written requests sent to the PI for up to 6 years after trial completion.

Time required

The study will be conducted between November 2021 and December 2022 in six stages detailed in appendix 5.

Funding source(s).

The Osteopathic Foundation are funding the project for £20,000 over a 2-year period. The funder has no role in study design; collection, management, analysis, interpretation of data; or writing the report. The Principal Investigator (PI) is required to seek the funder's approval for the target journal before submitting results (with no editing rights from the funder). Osteopaths will receive their normal treatment fees from participating patients.

Trial sponsor: UCO (see authors' details for contact details). Trial auditing process in line with usual institutional ethics processes will be ensured by the Sponsor and will be independent from the funder.

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