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Research report

The effect of osteopathy in the treatment of chronic low back pain – a feasibility study

L. Kirk[a,*], M. Underwood[b], L. Chappell[c], M. Martins-Mendez[d], P. Thomas[e]

[a]*Osteopathy programme, School of Health and Social Care, Oxford Brookes University, Mill Court Clinical Centre, Windmill Road, Oxford OBU 3BX, UK*
[b]*Institute of Community Health Sciences, Barts and The London, Queen Mary University of London, UK*
[c]*Harrow Primary Care Trust, Grace House, Bessborough Road, Harrow, Middlesex HA1 3EX, UK*
[d]*Brent Primary Care Trust, Wembley Centre for Health & Care, 116 Chaplin Road, Wembley HA0 4UZ, UK*
[e]*Thames Valley University, Slough campus, Wellington Street, Slough, Berkshire SL1 1YG, UK*

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Abstract

Introduction: Osteopaths commonly treat back pain. Evidence of effectiveness is limited. We describe a feasibility study for a pragmatic randomised controlled trial of an osteopathic approach for treating patients with chronic low back pain.
Method: We recruited participants with chronic low back pain from one general practice. Those randomised to treatment received up to eight treatments, the control participants received usual care from their general practice. The primary outcome measure was the Roland Morris Disability Questionnaire. Follow up was by postal questionnaire 3 and 6 months after randomisation.
Results: We approached 15 patients; of which nine were recruited to the study. We recruited two participants for each 1000 registered patients at our pilot practice. Participant feedback from those randomised to treatment was positive; all of them reported some benefit from the treatment. Follow up rates were poor (30% at 3 months).
Discussion: Despite some practical difficulties administering the study at a general practice level, we have shown that recruitment adequate to achieve good statistical power for such a trial is feasible. We estimate that 1.7 participants with appropriate inclusion criteria per 1000 registered patients from each general practice could be recruited into the trial. Thus, recruiting from 20–30 general practices should provide 200 recruits for a randomised controlled trial. The intervention was reported as being of benefit.
Conclusion: A randomised controlled trial comparing an osteopathic approach to the management of chronic simple back pain to usual general practice care is feasible with the collaboration of two Primary Care Trusts.

Keywords: Osteopathic medicine; Spinal manipulation; Low back pain; Feasibility study; Controlled clinical trial

1. Introduction

Disability from chronic low back pain (CLBP) has been described as a 21st century epidemic.[1,2] Frymoyer and Cats-Baril[3] estimate a 1000% increase in reported disability from LBP over the last 50 years, currently there is no consensus about how it should be managed. We are not aware of any evidence that the prevalence of CLBP is increasing; it is likely that this apparent epidemic is a response to changing attitudes to back pain. CLBP is commonly defined as an episode of low back pain lasting longer than 3 months.[4] Many patients with *acute* low back pain improve rapidly.[5,6] However, most patients with CLBP have continuing problems. Low back pain, both acute and chronic, is a major cause of disability in the western world, affecting up to 75% of

* Corresponding author.
E-mail address: lkirk@brookes.ac.uk (L. Kirk).

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individuals during their lifetime.[7,8] Deyo and Tsui-Wu[9] estimate a lifetime prevalence for LBP of 14% in the United States. Jenner and Barry[10] record that in 1993 11% of people surveyed in the United Kingdom reported that their activity had been restricted by LBP within the previous four weeks. CLBP has a large economic impact.[11] Between 10–20% of people with acute low back pain will go on to develop chronic low back pain, or suffer recurrent bouts over a period of years.[12] People with CLBP are managed largely in primary care and account for a substantial proportion of general practitioner (GP) time.[11] Some sufferers from CLBP may never fully recover[13] especially if the pain has been established for greater than 1 year.[10,14,15]

CLBP is not a discrete mechanical entity, the progression from acute pain to chronic pain is, for the most part, poorly understood.[16] Psychosocial factors, the so called 'yellow flags' appear to predict development of chronic pain.[15,17] Additionally changes in the processing of pain within the brain can impede recovery from a persistent painful episode.[16,18] The longer a patient has pain, the more resistant it is to treatment.[3,10,13] Longstanding severe pain is likely to affect a person's employment, relationships and emotional stability. When employment problems are encountered as a result of chronic pain and both relationships and emotional stability are affected these psychosocial problems may need managing in their own right. For an individual patient, determining whether psychosocial or physical factors are pre-eminent in their experience of chronic pain in this bio-psychosocial model of spinal disability can be problematic. Chronic low back pain is clearly a more complex entity that acute low back pain and requires an approach to treatment that addresses psychological and social aspects.

Although many GP practices seek to evaluate the impact of bio-psychosocial factors on health, simple time constraints may preclude the effectiveness of their interaction in a multifactorial illness such as CLBP.[19] The time allocated by the participating institution, to the osteopathic treatment, and the continuity of care may allow the practitioners to work more effectively within a bio-psychosocial healthcare model. The primary aim of the present study was to investigate the feasibility of undertaking a randomised controlled trial to establish the value of this approach. Patients were recruited from general practice and the outcomes of osteopathic treatment given by students against 'usual care' were compared. This paper describes this feasibility study.

1.1. Theories about the prevention and treatment of chronic low back pain

Fear avoidance behaviour,[20] negative beliefs about pain, illness behaviour, depression and anxiety[17] may all increase the risk of progression from acute to chronic low back pain. One study found a decrease in compensation claims in a general population when information regarding the effect of negative beliefs and perceptions was provided.[21] This is in broad agreement with an earlier study that demonstrated that patient education pamphlets can alter negative beliefs.[22] Guzman's systematic review of CLBP management concluded that pain was reduced and function improved through intensive multidisciplinary treatment.[23]

Attempts have been made to assess the effect of spinal manipulation and osteopathic treatment on CLBP with mixed success.[24,25,26] There is however, broad agreement that 'manipulation' may be of value.[27] It is likely that there are more similarities in the manipulative approach used by different physical therapy professions than there are differences. This has prompted the UK Medical Research Council (MRC) to fund a randomised controlled trial[28] that has investigated a common package of manipulative therapy delivered by chiropractors, osteopaths, or physiotherapists.[29] However, there is no consensus about how to manage this condition. As a result, 'usual treatment' in general practice commonly consists of advice to abstain from certain activities, prescription of anti-inflammatory medication and referral to out patient physiotherapy services, which are often heavily oversubscribed,[27] with consequent long waiting periods for appointments. Usual practice does not include referral for osteopathic treatment.

2. Method

2.1. The institution's approach to chronic low back pain

Osteopathy as a system of healthcare has a philosophy that emphasises the whole person rather than physical treatment alone.[30] In order to demonstrate consistency with this philosophy, osteopaths at the participating institution (British College of Osteopathic Medicine) are trained to degree level in nutrition and psychology in addition to core osteopathic skills. The institution provides clinical services, commonly delivered by students working under supervision. Patients normally attend as a result of a personal recommendation, a referral, or as a result of the institution's public relations campaign.

This study took a pragmatic approach to the treatment of chronic low back pain, meaning that the practitioner was free to determine the precise type and blend of treatment for the individual patient, in accordance with the holistic paradigm of osteopathy. All commonly used osteopathic physical treatment modalities were available to the patient with the exception of cranial treatment. The physical treatment

modalities included the following generic categories: high velocity low amplitude thrust manipulation techniques (HVT/HVLAT), mobilisation/articulation, soft tissue treatment, functional treatment, muscle energy techniques (MET) and passive stretching.

An individual suffering with chronic low back pain, if suitable for treatment, receives advice on posture, exercise, diet and lifestyle. They are informed about likely causes, diagnosis, and progression. In addition, the patient is encouraged to enter into a therapeutic dialogue with the practitioner to explore their understanding of the condition. The intention is for patients to feel in control of their illnesses and therefore better able to help themselves.

Just as in a typical osteopathic practice there is continuity of care; student practitioners maintain their own personal list of patients. A new patient is allocated 1 h for initial consultation and treatment if appropriate. The patient gives a global subjective rating of the severity of their condition at each treatment session, measured on a visual analogue scale (VAS). They are blinded to their previous VAS score. Follow up visits are allocated 30 min.

We proposed to use these students as practitioners in a pilot study investigating the feasibility of conducting a larger randomised controlled trial. Three local research ethical committees granted approval for the feasibility study.

2.2. Participant recruitment

We tested the feasibility of recruiting study participants from general practices close to the institution by;

(a) Assessing feasibility of recruiting 10 participants from one 'feasibility practice'
(b) Gaining expressions of interest and support from other local practices and local primary care organisations
(c) Testing our follow up procedures

We sought to identify patients who had consulted the feasibility practice with back pain. Initially we attempted to identify patients with chronic back pain by searching the practice computerised record system. It is important to add that no researchers accessed directly any GP records. However, a limitation of current classification was discovered as the diagnostic coding was unreliable and did not adequately identify those with CLBP. With full local ethical committee approval we therefore relied upon general practitioner recall of potential participants and opportunistically identifying participants in the consulting room.

Potential participants received a brief questionnaire assessing eligibility for, and interest in, the study. Those who appeared suitable for the study met the practice nurse for more detailed study entry assessment. If the patient met the entry criteria they were formally entered as participants in the feasibility study utilising a new remote telephone randomisation service, administered by staff from the local primary care research network, West London Research Network (WeLReN), to find out their treatment allocation. The randomisation sequence was decided from a set of random numbers. An uninvolved person sealed an indication of control or intervention in a set of opaque envelopes and the order they were to be opened in was written on the outside of the envelope. The practice nurse telephoned an administrator at the West London Research Network who opened the next envelope and informed the nurse which arm of the study this patient was in.

2.3. Inclusion criteria

- Subjects aged between 18 and 64 years.
- History of low back pain of at least 6 months duration.
- Low back pain on at least 75% of days during the 3 months prior to randomisation.
- No previous osteopathic intervention.

2.4. Exclusion criteria

- On the day of randomisation, less than 18 years of age or older than 64 years (avoiding issues of parental consent in the younger, and the prevalence of degenerative conditions in the older).
- Systemic inflammatory conditions (marked morning stiffness, peripheral joint involvement, family history, skin rashes).
- Signs of nerve root involvement (muscle atrophy or weakness, absent reflexes, pain radiating to the foot).
- Cauda equina symptoms (bladder/bowel symptoms, gait abnormality).
- Signs of serious spinal pathology (unexplained thoracic pain, weight loss, widespread neuropathy).
- Any past history of cancer.

2.5. Assessment

We used a portfolio of previously validated, self-completed, questionnaire instruments. The practice nurse explained these to participants at recruitment. These instruments cover psychological and social changes as well as changes in back pain and disability. The selection made for the UK back pain exercise and manipulation trial (BEAM) trial[28] informed our choice of measures giving the potential to make comparisons between the two trials' results.

Instruments used were:

(1) The Medical Outcomes Study 12-Item Short Form Health Survey (SF12) to measure perceived general health and well being.[31]
(2) The Back Beliefs Questionnaire to assess beliefs about treating back pain.[32]
(3) The Roland Morris Disability Questionnaire to measure disability and pain related to back pain.[6,33]
(4) The Modified Von Korff to assess pain and disability.[33,34]
(5) The Perceived Health Competency Scale to measure a sense of self-control.[35]

Each person randomised to treatment was seen for up to eight treatment sessions over a 3-month period. The questionnaires were administered at baseline by the practice nurse. The student practitioners also kept detailed records of clinical progress to help the research team to consider potential unexpected effects on participants of the full project.

Each participant completed a log detailing their experiences over the duration of treatment and the practitioners asked for a self-rated global assessment of progress on a visual analogue scale (VAS) at each treatment session to obtain a subjective measure of outcome. The participants were blinded to their previous VAS scores.

In order to enhance the sense of collaboration between the institution, the general practice and the patient it was intended that the GP would ask about progress if the patient were seen opportunistically (there was space in the patient log to record this conversation).

2.6. Follow up

The practice nurse posted follow up questionnaires 3 and 6 months after randomisation. There was one reminder notice sent at 3 months.

2.7. Statistical considerations

A difference of 2.5 points in Roland Morris Disability Questionnaire (RMDQ) is commonly used by researchers in the USA and UK to define a clinically important difference in outcome for trials of back pain treatment. In primary care studies the RMDQ commonly has a standard deviation of up to 4.4.[28] To show this difference with 80% power at the 5% significance level requires data from 50 participants in each group. Allowing for 30% loss to follow up, a total of 150 participants are needed. However, there are likely to be individual practice and individual practitioner effects. An allowance for this is needed. Based on data from the UK BEAM trial this is unlikely to be greater than 0.05 for either practices or osteopaths. If each therapist treats 10 participants, seven of whom contribute to the final analysis, the inflation factor is given by $1 + (7 - 1) \times 0.05 = 1.3$.[28] If each participating practice recruits 10 participants the same calculation applies. Thus, for the main trial we estimate that 195 randomised participants are needed. This could be achieved by each of 14 practices recruiting 14 participants. For the pilot practice this translates as 2.25/1000 of their 6000 patients. This is double the rate achieved by UK BEAM practices that identified participants only when they initially presented. We anticipated a higher rate because we were also considering historical consultations. Because this was a single practice feasibility study there is no statistical analysis of the outcome data.

3. Results

3.1. Recruitment

The pilot practice was that of one of the research team (PT). Gaining practice approval required informal lobbying, a meeting with the practice team, a waiting room notice, a practice booklet to explain the project, and training for the nurse. A project grant from the West London Research Network enabled the involvement of the feasibility practice.

Acquiring participants was more problematic than anticipated and took 3 months. We identified 15 participants from in-practice recruitment. Six of these were not interested. Subsequently, five patients were randomised to the intervention arm, and four to the 'usual care' arm of the study. One participant randomised to the intervention appeared to have systemic symptoms on initial osteopathic evaluation and was referred back to the general practice. On further investigation there was no evidence of systemic pathology and the patient was re-entered into the study (see Fig. 1). The randomisation process was also difficult because a new telephone randomisation service had to be established. Staff from the local primary care research network (WeLReN) administered this, but were often not available at times convenient to the surgery.

Participants found it easy to complete the self-administered questionnaires after instruction and were willing to do this. However, the practice staff reported administrative difficulty in sending out the repeat questionnaires on time and were slow to follow up defaulters. This was attributed to unfamiliarity, practice staff illness and limited time due to many other workload commitments (see Fig. 1).

3.2. The therapeutic effect and statistical considerations

According to therapist records, the visual analogue scales, and instruments used, all those who received the

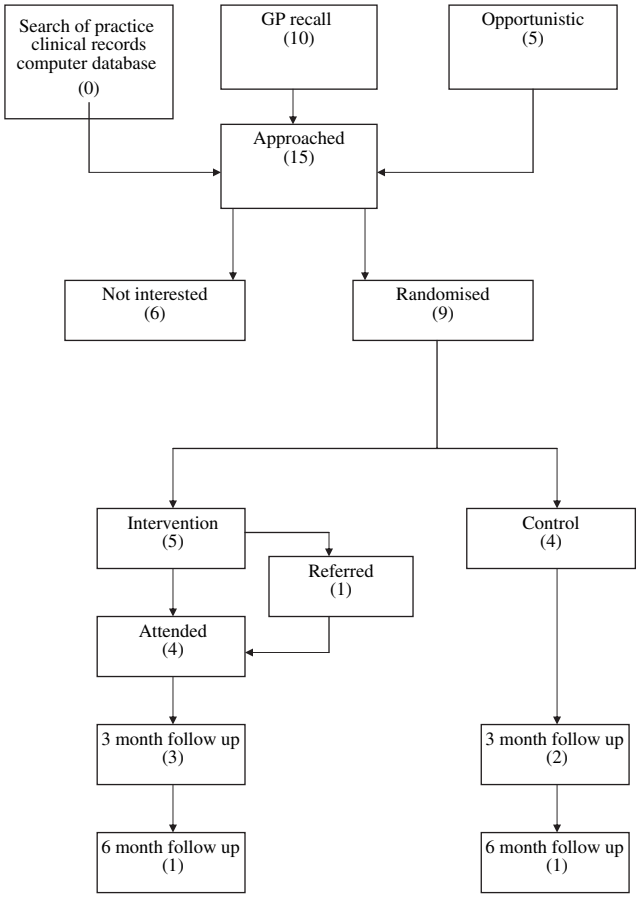

Fig. 1. Participant recruitment and follow up.

intervention benefited. Different subjects benefited in different ways. This ranged from considerable reduction in longstanding pain (Patient E) to decreased anxiety (Patient A). One person (Patient F) had made a partial return to work. Anecdotes from patients suggest that the Learning Logs were poorly understood. One patient found it very helpful to record her thoughts, but there was insufficient exploration of this aspect in this study to gauge their overall value.

4. Discussion

4.1. Recruitment and follow-up

We were able to recruit participants from one feasibility practice. Searching the practice computer system for patients with chronic back pain was impractical and the general practitioners could only identify a few potential participants. Based on this experience we might expect 10 eligible recruits from a practice of 6000 patients (1.7/1000). Our recruitment and follow up procedures were dependent on active participation by the one practice involved. Of the 15 patients approached, nine agreed to participate.

We consider that it would be better to refer all potential recruits, both for intervention and control arms, to a research assistant based at a local treatment centre, after practice team members had introduced the patients to the study locally. This centralisation would help minimise practice overload, maintaining quality control, and ensure that the questionnaires are completed. Additionally, the practice could approach all those patients who have presented with back pain to elicit expressions of interest. We would then be able to search practice computers for those who have consulted with back pain, thereby identifying likely candidates to approach for participation in the study. This approach could result in some dissatisfaction in those allocated to the control arm of the study because they have attended an osteopathy service and not been treated. To avoid this we suggest that the provision of advice and literature about back care, and invitation to a conference to receive feedback at the end of the project might be sufficient to motivate the ongoing participation of the majority of patients in both groups. Feedback of progress to all participating practices might retain their ongoing interest and learning from the project.

Based on our experience, the recruitment target was too optimistic. To recruit 200 participants, based on recruiting at a rate of 1.7 participants/1000 patients would require a minimum population base of 120,000 people, or 20 practices with a mean list size of 6000. Such a study is therefore only likely to be practical in densely populated areas that can refer to an osteopathic institution or very large group practice.

Evaluation of research activity in the West London Primary Care Research Network (WeLReN) shows that with support from the relevant political groups and appropriate incentive, a quarter of practices will become involved in such collaborative research.[36] The average local practice population is closer to 4000 than 6000, therefore requiring a total of 30 actively recruiting practices from a pool of 120 practices might be needed to recruit enough patients. This may require participation from two whole Primary Care Trusts. In view of the multiple calls on scarce resources for research, this amount of support might require the active participation of these Trusts as research partners. With such support and research grant funding it would be feasible to recruit sufficient participants for a study of this nature based at a large institution or osteopathic practice.

Posting follow up questionnaires was not administered efficiently within the practice. A lack of priority for posting questionnaires may have contributed to the poor response rates at follow up (see Fig. 1). For a future study, a central administrator with a more intensive regimen of reminders would better manage these. Our experience of developing our own randomisation service

suggests that an experienced randomisation agency should be used.

4.2. Intervention

Analysis of the pilot case studies suggest that different patients get different benefits from the intervention, affirming the original suspicion that a whole person approach affects different aspects of health. For example, one patient had a dramatic reduction in pain and others benefited more by being able to cope better. The hope is that triangulation of the results from the different evaluation tools will reveal useful insights into the healing process with chronic low back pain. More in depth qualitative work might also provide further insights into the meaning of the apparent benefits received.

The instruments chosen for the study were all administered by the practice nurse who reported very little difficulty in their use. Most of the instruments were brief questionnaires and were acceptable to patients once their purpose had been explained. For this particular study, no language difficulties were encountered, However, in future to ensure reliability it is important that the questionnaires are interpreted accurately in a situation when English is not the first language. We consider that it would be impractical to use additional questionnaires and that the spread of instruments used allows sufficient evaluation of potential treatment effects across a broad range. Of interest is the fact that the practitioners delivering the intervention were novice practitioners working under the guidance of more experienced osteopaths. In spite of this, the patients did derive an apparent therapeutic benefit from treatment. However, it is possible that if a further study were to utilise experienced practitioners then the effect(s) of osteopathic intervention may be more evident.

The improvement in symptoms of these patients strengthens the argument that the an osteopathic intervention might be able to demonstrate a 2.5 point difference in the change from baseline of the Roland Morris Disability Questionnaire after 1 year (the target of several back pain trials in the UK and USA).[28] In addition, the intervention might be able to demonstrate social and psychological advantages.

One aspect that remains to be explored is the value of the patient logs. Evaluation of these could be a research project in its own right nested within the RCT. It could be that the process of a patient reflecting in a structured way on their own illness and giving feedback to the clinicians itself assists both clinical improvement, as well as compliance with the study. This could have transferable implications for the management of other complex clinical conditions as well as a way of including patients as research partners.

5. Conclusion

The clinical approach used by the participating institution for the treatment of CLBP in this feasibility study appeared to be of benefit to subjects with chronic low back pain who were recruited into the trial. The instruments used were acceptable to patients. A larger randomised controlled trial investigating this approach is feasible given appropriate collaboration with local general practices. The results of this feasibility study indicate that to recruit a target sample size of 200 subjects into a RCT would likely require a local population base of at least 120,000. A recruiting rate of 1.7 subjects (meeting inclusion criteria) per 1000 registered patients is achievable. The local population base in the geographic area surrounding the participating institution is of sufficient size to achieve the target sample size. The interventions undertaken in this feasibility study were acceptable to participants.

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PT, LK and LC conceived the original idea through a series of workshops facilitated by the West London Research Network. MMM piloted the materials and gave feedback to the other team members. MU, LK, PT and LC devised the materials and reviewed learning at each stage. All authors commented on and contributed to the manuscript.

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