



A pragmatic multi-centred randomised controlled trial of yoga for chronic low back pain: Trial protocol

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A B S T R A C T

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A systematic review revealed three small randomised controlled trials of yoga for low back pain, all of which showed effects on back pain that favoured the yoga group. To build on these studies a larger trial, with longer term follow-up, and a number of different yoga teachers delivering the intervention is required. This study protocol describes the details of a randomised controlled trial (RCT) to determine the effectiveness and cost-effectiveness of Yoga for chronic Low Back Pain, which is funded by Arthritis Research Campaign (arc) and is being conducted by the University of York. 262 patients will be recruited from GP practices in 5 centres in England. Patients will be randomised to receive usual care or 12 weekly classes of yoga. A yoga programme will be devised that can be delivered by yoga teachers of the two main national yoga organisations in the UK (British Wheel of Yoga and Iyengar Yoga Association (UK)).

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1. Background

Back pain is an extremely common and costly condition and treatments for low back pain (LBP) tend to be unsatisfactory. Exercise treatment, though widely used and recommended, has only a small effect on back pain,¹ and manipulation treatments, delivered either by a physiotherapist, chiropractor or osteopath, are better than exercise alone but are not widely available on the NHS and are more expensive than group exercise sessions.¹ An alternative approach to the treatment of low back pain may be the use of yoga. Yoga offers a combination of physical exercise with mental focus that may make it a suitable therapy for the treatment of low back pain. A randomised controlled trial (RCT) undertaken in the USA has shown that LBP patients allocated to yoga classes had significantly less pain after 12 weeks compared with those allocated to an exercise control group.² The improvement in back pain

at 12 weeks was 3.4 points on the Roland and Morris back pain scale, which was more than twice as much as that noted for manipulation in the recent UK BEAM study¹ among a similar group of patients and at a similar follow-up time.

We have undertaken a systematic review of the Cochrane database and the relevant research registers and at this time found no ongoing RCTs of yoga therapy of low back pain. We did, however, identify a total of three small published RCTs of yoga therapy for low back pain.^{2–4} All three studies showed effects on back pain that favoured the yoga group and this was statistically significant in two of the studies (yoga versus written material $P < 0.001$,² yoga versus exercise $P = 0.034$,² yoga versus educational control $P = 0.003$ ³).

Despite these encouraging results there is still need for another trial. The main limitation with existing trials is that only one yoga teacher delivered the intervention which makes the trial's results unrepresentative of all yoga teachers, therefore it is important that several yoga teachers deliver treatment. In order to develop an intervention with the widest possible applicability, it is also important to gain the agreement of yoga practitioners of the most prominent schools of yoga operating in the UK on a package of movements that all would be willing to deliver to patients with low back pain. An agreed package would allow the results to be generalisable across all yoga practitioners. Existing trials as well as

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being small also have short-term follow-up. It would be useful to see whether the effects of yoga are longer lasting. The potential for yoga to have a longer term influence is more likely than, for example, manipulation, as yoga participants will be encouraged to practise the technique at home between classes, and to continue with home practice after the classes have been completed. It is reasonable therefore to suppose that if participants do continue with home practice, initial yoga training may have long-term benefits on back pain making it important that we should follow-up a cohort of low back pain patients, after having had yoga treatment, for at least a year to ascertain whether or not any long-term benefits are seen.

Because back pain is an excessive burden on society and is associated with high costs, it is important that we should evaluate any treatment that may reduce this problem. Yoga is potentially a very cost-effective treatment as it can be delivered in group sessions, which substantially reduces the cost per treatment for each individual, when compared to a treatment delivered on a one-to-one basis such as physiotherapy.

2. Trial objectives

The primary objectives of this study are to test the effectiveness and cost-effectiveness of yoga for LBP in primary care. This will be achieved by:

1. Producing a package of yoga care agreed by a cross-section of yoga practitioners from different Yoga traditions, including a written manual for yoga teachers and their students.
2. Undertake a large multi-centre RCT of the agreed yoga care package versus usual care on patients with low back pain to evaluate if the yoga intervention is more effective in reducing disability due to back pain.
3. Undertaking a cost-effectiveness analysis of yoga treatment and usual care in relation to usual care alone for LBP.

3. Methods

3.1. Trial design

This study is a multi-centred pragmatic two-arm RCT which will collect patient preference data before all patients are randomised. Randomisation will be at the patient level and patients will be randomly allocated to receive yoga or usual care. We will recruit approximately twenty yoga teachers at five sites (Cornwall, North London, West London, Manchester and York). These yoga teachers will be trained in the agreed package of care.

3.2. Recruitment and participants

We plan to use a 'database' recruitment method as this method has been shown to recruit large numbers of patients in a relatively short space of time. We will recruit GP practices local to each site by mailing out to them an invitation letter and an information sheet detailing the process of the trial and what would be required of the practice if they agreed to participate. GP practices will be compensated for the time taken on the research and all stationary and postage costs will be provided. Participating GP practices will search their databases using Read Codes and mail out a recruitment pack to all patients aged between 18 and 65 who have had a consultation with low back pain in the last 18 months. Patients will be asked to consider taking part in a trial of yoga therapy for LBP. Those patients who agree will be asked to complete an eligibility questionnaire containing the Roland and Morris back

pain scale and to return this to the York Trials Unit at the University of York. The trial co-ordinator will then assess eligibility. Patients who score 4 or more on the measure, and meet other inclusion criteria will be eligible to participate. One back pain trial based in Manchester used the database recruitment method and found 2068 LBP patients from 9 GP practices. Out of these 234 (11.3%) met the inclusion criteria and were randomised.⁵ This trial used the database method of recruitment and recruited its sample size on time. In this study we propose to recruit 20 GP practices in case of differential recruitment rates across the different geographical areas, and we anticipate recruitment will take 6 months.

3.3. Inclusion and exclusion criteria

The inclusion criteria will be: aged 18–65; presented to their GP with low back pain in the previous 18 months; a score of 4 or more on the Roland & Morris Disability Questionnaire (RDQ); must be physically mobile (i.e. able to climb up and down stairs, and able to get off the floor unaided); and, indicated that they are able to attend at least one of the yoga classes on offer.

The exclusion criteria will be: patients over 65 as they are more likely to have serious spinal pathology; clinical indications of serious spinal or neurological pathology as indicated by 'warning signs'⁶; pregnant women; previous spinal surgery, and; history of psychosis or alcohol abuse (due to difficulty in assessing outcomes).

3.4. Randomisation and allocation

Eligible patients will be randomised remotely to either yoga or usual care. In the trial eligibility questionnaire, participants will be asked to specify their availability to attend yoga classes in different regions from a list of dates and times available. Once the total number of participants wanting to attend each yoga class is known, then the randomisation will be undertaken. To ensure that each yoga class does not exceed its maximum capacity, but still ensure balance in the overall number of participants in each trial arm, unequal allocation may be used for some classes. For example, if 24 participants specified their availability as being the yoga class in Manchester on Monday and the maximum capacity for this class was 15, then a allocation ratio of 1:1.7 (9 to the control group and 15 to the yoga group) could be used. Allocation ratios will need to be amended to ensure balance overall and thus it is possible that some classes will not reach their maximum capacity. The randomisation and allocation will be conducted by an independent data manager in the York Trials Unit, University of York, using a computer program. The trial co-ordinator will write to the participants informing them of their treatment allocation.

3.5. Interventions

The yoga intervention will consist of 12 weekly 75-min classes (with a one or two week break at mid-course), plus education and information for home practice. There are a number of recommended yoga practices for people with low back pain, which are delivered by teachers of different yoga traditions. Among the co-applicants are representatives of the two largest yoga associations within the UK: British Wheel of Yoga and Iyengar Yoga Association (UK). Within the first three months of the study, whilst we gain ethics permission and NHS Research and Development approval, we will conduct a series of meetings between experienced yoga practitioners in order to agree on a basic package of yoga that can be delivered by yoga teachers of these two national organisations. Yoga teachers taking part in the study will be trained in this package of care over two intensive training weekends. As part of the study we will also develop a manual for yoga teachers and

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