Homoeopathy for delayed onset muscle soreness: a randomised double blind placebo controlled trial

Andrew J Vickers, Peter Fisher, Claire Smith, Sheena E Wyllie, George T Lewith

Abstract
Objective—To pilot a model for determining whether a homoeopathic medicine is superior to placebo for delayed onset muscle soreness (DOMS).
Design—Randomised double blind placebo controlled trial.
Setting—Physiotherapy department of a homoeopathic hospital.
Subjects—Sixty eight healthy volunteers (average age 30; 41% men) undertook a 10 minute period of bench stepping carrying a small weight and were randomised to a homoeopathic medicine or placebo.
Outcome measures—Mean muscle soreness in the five day period after the exercise test, symptom free days, maximum soreness score, days to no soreness, days on medication.
Results—The difference between group means was 0.17 in favour of placebo with 95% confidence intervals ± 0.50. Similar results were found for other outcome measures.
Conclusion—The study did not find benefit of the homoeopathic remedy in DOMS. Bench stepping may not be an appropriate model to evaluate the effects of a treatment on DOMS because of wide variation between subject soreness scores.

Keywords: homoeopathy; muscle soreness; exercise; randomised controlled trial

Delayed onset muscle soreness (DOMS) is a sensation of pain or discomfort that follows unaccustomed muscular exertion. DOMS is usually first noticed 12 hours after exercise, peaks at 36–48 hours, and lasts for some five to seven days in total. Although the cause of DOMS is not fully understood, reversible damage to muscle fibres is thought to be implicated. Symptoms are believed to be most severe after eccentric exercise, where a muscle lengthens under tension, but are susceptible to a training effect such that the degree of soreness after repeated bouts of specific exercise diminishes over time.

Homoeopathy is a form of therapy based on the principle of “let like be cured with like”. Practitioners prescribe in a low dose whatever drug would cause symptoms similar to those in the patient were that drug to be taken in a high dose. One well known feature of homoeopathy is that many of the medicines used are so dilute that they are unlikely to contain a single molecule of the original drug. Although often described as an “alternative” or “complementary” therapy, homoeopathy is practised by about 1000 doctors in the United Kingdom and is available on the NHS at five homoeopathic hospitals (source: Faculty of Homeopathy, Powis Place, London WC1).

Practitioners of homoeopathy claim to be able to provide symptomatic relief for DOMS. This claim seems worthy of evaluation, especially as homoeopathy is a simple inexpensive intervention that seems to be free from adverse effects. Moreover, there is preliminary evidence that homoeopathy is of benefit for DOMS. Hildebrandt and Eltze undertook a series of experiments comparing a homoeopathic medicine known as Rhus tox with placebo for DOMS induced by an hour’s exercise of the upper arms. Although significant differences between homoeopathy and placebo were reported for some outcomes in some of these trials, problems with the study include lack of randomisation, inadequate details of baseline characteristics, small numbers of subjects, and multiple hypothesis testing. In a double blind trial, Tveiten et al randomised 36 runners to receive homoeopathic arnica or placebo after a marathon. Stiffness scores and blood creatine kinase were lower in the group that received arnica, with differences for soreness approaching statistical significance (P = 0.07) on day 2 and 3. No differences were found in levels of haemoglobin, magnesium or enzymes other than creatine kinase.

The research question posed here is: can a homoeopathic medicine reduce levels of DOMS more than placebo? The first task in answering this question was to pilot a suitable model of DOMS induction and assessment. For this study, we aimed to induce DOMS by a simple bench stepping exercise, randomise a small number of subjects to the homoeopathic medicine or placebo on a double blind basis, and measure outcome using a Likert scale. Our main objectives were to determine the appropriateness of the study model and to produce some estimates on which to base a sample size calculation for a definitive trial.

The choice of test medicine was determined by discussion with a number of homoeopaths. Arnica was chosen as it is the classic remedy for any type of soft tissue trauma, Rhus tox because it is indicated for stiffness that worsens on rest but is relieved by exercise, a feature characteristic of DOMS, and sarcolactic acid as it is...
indicated for sore and aching muscles. The most appropriate homoeopathic dose was thought to be a “30c potency”, where the drugs are prepared by a process of serial dilution and succussion (agitation) to a theoretical dilution of 10^-30.

They are therefore highly unlikely to contain a single molecule of the original medicine.

While developing the protocol for the study, a group of researchers at the Department of Medicine at Southampton University took an interest in our work and agreed to pilot a similar trial. This was completed just as our study started and its results have been reported elsewhere. We intended to undertake an individual patient data meta-analysis of both trials to increase the precision of our results.

Methods
Healthy volunteers aged 18–40 were recruited primarily from staff and visiting health professionals at the Royal London Homoeopathic Hospital. Recruitment took place between April and October 1996. The trial was stopped when a fund to pay volunteers a small fee had been expended.

Subjects were excluded from the trial if they had concurrent musculoskeletal or fatigue disorder, a history of cardiovascular disease, non-steroidal anti-inflammatory treatment in the week preceding the trial, steroids or “constitutional” homoeopathic treatment by mouth in the previous six months or regularly participated in vigorous exercise in the previous six months. Vigorous exercise was defined as playing a sport, such as squash, tennis, or football, or undertaking an activity designed to increase physical fitness, such as jogging, aerobics, step training, or swimming. Regular participation was defined as undertaking the activity three or more times a week for more than three consecutive weeks and for more than 15 minutes at a time. During the trial, subjects were asked to avoid anti-inflammatory drugs, pain relieving ointments or creams, exercise, stretching or massage. Subjects were given an information leaflet that described the trial. They then provided written informed consent.

Baseline data included age, sex, weight, lower leg length, and level of exercise. The latter was assessed using the following two questions: “do you participate regularly in any activity likely to exercise the legs—for example, cycling, dancing—for more than 10 minutes more than twice a week or has there been a period of more than three consecutive weeks in which you have done so in the previous six months?” and “do you participate in any sport or any activity specifically designed to increase fitness or has there been a period of more than three consecutive weeks in which you have done so in the previous six months?” If a subject gave a positive answer to either of these questions, they were categorised as a moderate exerciser.

Subjects were assigned the next code number available from a sequentially numbered list of randomised treatment allocations and given the appropriately coded bottle of medication. They were instructed to take one tablet by mouth three times a day, starting 24 hours before the bench stepping exercise and stopping when they no longer felt sore.

A homoeopathic complex of Arnica 30c, Rhus tox 30c, and sarcolenic acid 30c was produced by Ainsworth’s, a registered homoeopathic manufacturing pharmacy. The medicines were freshly prepared following the guidelines of the Blackie Foundation, a homoeopathic research organisation. Placebos were also prepared that were indistinguishable from the active medication in appearance, taste, or smell. A computer generated randomisation list in permuted blocks of four was given to the manufacturer who dispensed the placebos and active medicine into the coded bottles. The investigator dispensing the medication (SW) was provided with the bottles but had no access to the randomisation list, ensuring that treatment allocation was fully concealed.

The exercise regimen used was that described by Hasson et al. Subjects stepped up on a bench set at 110% of their lower leg length while carrying a load equal to 10% of their body weight. Exercise was continued for 10 minutes at a rate of one step per second. The order of steps was right leg up, left leg up, left leg down, right leg down. This regimen causes greatest soreness in the right thigh and left calf. If the subject failed to complete the exercise test, this was recorded.

After the bench stepping exercise, each subject was given an outcome form, which they were asked to complete at specified times every 12 hours for the next five days. The outcome form consisted of a Likert scale as described by High et al. (see fig 1) and a check box asking whether the subject had stopped taking medication. After the five day period, subjects were asked if they had used any analgesics,

Please tick the sentence below that best describes your level of muscle soreness over the past 12 hours.

1. A complete absence of soreness
2. A light pain felt only when touched—a vague ache
3. A moderate pain felt only when touched—a slight persistent pain
4. A light pain when walking up or down stairs
5. A light pain when walking on a flat surface/painful
6. A moderate pain, stiffness or weakness when walking/very painful
7. A severe pain that limits my ability to move

Figure 1  Likert scale of muscle soreness (taken from High et al’).
Table 1  Baseline characteristics. Results are mean (SE)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Placebo (n=28)</th>
<th>Homoeopathy (n=29)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>30.4 (1.11)</td>
<td>30.9 (1.01)</td>
</tr>
<tr>
<td>Male/female ratio</td>
<td>12:19*</td>
<td>11:18</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>65.1 (2.05)</td>
<td>64.9 (2.52)</td>
</tr>
<tr>
<td>Lower leg measurement (cm)</td>
<td>47.0 (1.18)</td>
<td>47.8 (0.953)</td>
</tr>
<tr>
<td>Estimate of body mass index</td>
<td>25.0 (1.36)</td>
<td>23.5 (1.02)</td>
</tr>
<tr>
<td>Moderate exercisers</td>
<td>10 (35.7%)</td>
<td>10 (34.4%)</td>
</tr>
</tbody>
</table>

* One missing observation.

Table 2  Outcome variables. Results are either mean (SD) or median (interquartile range)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Placebo (n=28)</th>
<th>Homoeopathy (n=29)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean five day muscle soreness</td>
<td>2.21 (0.91)</td>
<td>2.38 (0.97)</td>
</tr>
<tr>
<td>Days with score 1 or less</td>
<td>2 (1-2.75)</td>
<td>2 (1.5-2.5)</td>
</tr>
<tr>
<td>Maximum soreness score</td>
<td>5 (4-5)</td>
<td>5 (3-5)</td>
</tr>
<tr>
<td>Days to score of 1 or less</td>
<td>3.5 (3-4.5)</td>
<td>4 (3-4)</td>
</tr>
<tr>
<td>Days on medication</td>
<td>4.5 (3-5)*</td>
<td>4.75 (3.5-5)</td>
</tr>
</tbody>
</table>

* One missing observation.

Table 3  Muscle soreness by degree of exercise

<table>
<thead>
<tr>
<th></th>
<th>Mean muscle soreness</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>No exercise (n=37)</td>
<td>2.57*</td>
<td>0.79</td>
</tr>
<tr>
<td>Moderate exercise</td>
<td>1.80*</td>
<td>1.00</td>
</tr>
</tbody>
</table>

* P < 0.002 by t test.

Table 4  Results of individual patient data meta-analysis

<table>
<thead>
<tr>
<th></th>
<th>Mean muscle soreness</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Homoeopathy (n=44)</td>
<td>2.13*</td>
<td>1.03</td>
</tr>
<tr>
<td>Placebo (n=38)</td>
<td>2.20*</td>
<td>1.06</td>
</tr>
</tbody>
</table>

* No significant difference between groups.
Homoeopathy for muscle soreness

<table>
<thead>
<tr>
<th>Table 5 Results from meta-analysis by type of outcome variable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>Mean soreness</td>
</tr>
<tr>
<td>Days soreness score ≤ 1</td>
</tr>
<tr>
<td>Days on medication</td>
</tr>
</tbody>
</table>

Given this figure of 300, we believe that bench stepping may not be an appropriate model for testing the effects of homoeopathic medicines on DOMS. We found it difficult to recruit suitable volunteers, something that surprised us because the exercise test was relatively short and the degree of discomfort moderate. It took a considerable amount of time and effort to recruit the 57 evaluable subjects and we do not currently consider it feasible to mount a trial with a sample size five times as great.

The way forward may be to assess the effects of homoeopathy on DOMS in long distance runners. Soreness does not have to be specially induced in this group, and the large numbers of runners regularly taking part in races will make it easy to obtain a sufficient sample size.

Using a more naturalistic model will also make the results of the trial more applicable to the real world. We have recently randomised the first subjects in such a study. It is expected that the results will be reported in 1998.

Although it is wise to avoid using pilot studies to test hypotheses, we believe that it would be worth drawing the following conclusions:
(a) the trial did not provide evidence for an effect of a homoeopathic medicine on DOMS;
(b) we can exclude the possibility that the homoeopathic medicine reduces DOMS by more than 25% compared with placebo;
(c) the great variation in soreness scores after bench stepping suggests that this may not be an appropriate model to evaluate the therapeutic effects of a treatment on DOMS; (d) individuals who undertake moderate exercise experience lower levels of DOMS after a standard exercise test than sedentary subjects.

We would like to thank Ainsworth’s homoeopathic pharmacy for providing the medicines and the Dove Healing Trust for a donation towards covering the costs of the volunteers.

Discussion

We used the data from the meta-analysis to undertake a sample size calculation for a definitive trial. Mean muscle soreness was used as our primary outcome measure. We assumed that the mean soreness score in the placebo group would be as reported in table 4 but that the mean soreness score for the homoeopathy group would be 1.80. This difference between groups is clinically significant and falls within the 95% confidence intervals estimated in the meta-analysis. Standard deviations were held constant. Setting alpha at 5% and power at 90%, we calculated that 144 evaluable subjects per group would be required, a total sample size of about 300.

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