The OMENS trial: opportunistic evaluation of musculo-skeletal physician care among orthopaedic outpatients unlikely to require surgery


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The health technology studied was the use of musculoskeletal medicine (MSM; based on a combination of manual therapy, injections, acupuncture and other pain management techniques) for the treatment of orthopaedic outpatients unlikely to require surgery.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised 18 year-old or older orthopaedic outpatients who were unlikely to require surgery.

Setting
The setting was a hospital and secondary care. The study was carried out in Edinburgh, UK.

Dates to which data relate
The effectiveness data appear to have been collected between December 1993 and February 1996. Resource utilisation data appear to have been collected during the same period as the effectiveness data. The price year was not reported.

Source of effectiveness data
The source of the effectiveness data was a single study.

Link between effectiveness and cost data
Most of the resource quantities appear to have been obtained retrospectively from hospital case notes of the same sample population as that used in the effectiveness analysis. However, costs borne by patients and indirect costs were collected retrospectively from a sub-sample of this sample population, using questionnaires. Moreover, the authors also made some assumptions in order to estimate the costs related to orthotic services.

Study sample
Power calculations were performed in the planning phase of the study: a sample of 1,000 patients was required to detect a difference of three percentage points in the improvement of the physical function SF-36 subscale with approximately 80% power. All patients with orthopaedic referrals who were unlikely to require surgery were considered for the effectiveness analysis. Two sub-samples were considered:
those patients who were not referred to a named clinician and therefore could be randomly assigned to the interventions considered at analysis; and

those who were directly referred for a particular intervention according to the preferences of the referring primary care practitioners and, therefore, were not randomly allocated.

To be included in the study, patients had to return a baseline questionnaire and attend their outpatient appointment. A total of 1,260 patients were randomly allocated to either the MSM or the COSS group. After excluding those who did not return the baseline questionnaire or did not attend the appointment, the final randomly allocated sub-sample comprised 829 patients. 420 of these patients were allocated to the MSM group and 409 were allocated to the COSS group. The final non-randomly-allocated sub-sample comprised 497 patients, of whom 277 were directly referred to the COSS group, and 220 were directly referred to the MSM group. The total number of patients included in the study was 1,326. The authors did not report evidence that the study sample was appropriate for the study question.

**Study design**

Two parallel sub-studies were performed: a randomised controlled trial, which considered the randomly allocated sub-sample, and a prospective cohort study, which considered the non-randomly allocated sub-sample. The study was performed at a single centre. In the randomised controlled trial, patients were allocated using alphabetical alternation of all eligible referrals. Patients were followed-up for 12 months. The authors reported that 63.7% of the randomised patients could be followed-up at 3 months, and 62.6% at 12 months, while 81.1% of the non-randomised patients could be followed-up either at 3 and/or 12 months.

**Analysis of effectiveness**

The basis for the effectiveness analysis was intention-to-treat. The primary health outcomes assessed in the study for randomly allocated MSM and COSS patients were:

- the change in the scores of the SF-36 subscales (i.e. physical function, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health subscales) and the changes in the Europol scores at 3 and 12 months;

- for those randomly allocated MSM and COSS patients with back or knee pain, either the Aberdeen Low Back Pain Scale or the Edinburgh Knee Function Scale, as relevant, were also assessed at 3 and 12 months of follow-up.

The primary health outcomes assessed in the study for non-randomly allocated MSM and COSS patients were the changes in the scores of the SF-36 subscales at 12 months. Effectiveness data were collected by postal questionnaire. Randomly-allocated MSM and COSS patients included in the clinical analysis were shown to be comparable in terms of case mix (i.e. pain condition, which could be either general pain, back pain or knee pain), the gender ratio, and their age, although COSS patients had statistically significant longer waiting times from referral to first appointment when compared to MSM patients. Non-randomly allocated MSM and COSS patients included in the analysis were shown to be similar in terms of age and waiting times, although some differences were found regarding case mix. A higher percentage of MSM patients presented with back pain, while a higher percentage of COSS patients presented with knee pain. It could not be stated whether these differences were statistically significant. Multiple regression analysis was used to adjust for the following confounding variables: age, gender and case mix.

**Effectiveness results**

There were no statistically significant differences in SF-36 subscales, Euroqol or condition specific knee and back pain scales at 3 and 12 months between randomly-allocated MSM and COSS patients, nor in SF-36 subscales at 12 months between non-randomly-allocated MSM and COSS patients. The authors stated that adjustments for confounding factors by multivariate analysis did not alter these findings.

**Clinical conclusions**
The same health gains were found for both sub-samples (randomly and non-randomly allocated groups), irrespective of whether patients consulted a musculoskeletal medicine physician or an orthopaedic surgeon.

**Measure of benefits used in the economic analysis**

No summary measure of health benefit was used in the economic analysis because there was no statistically significant difference in any of the clinical measures used in the effectiveness analysis. The study was therefore categorised as a cost-minimisation analysis.

**Direct costs**

Direct costs were reported only for the groups of patients that were randomly allocated to one of the interventions, but not for those non-randomly allocated patients. Resource quantities were reported separately from the costs, although unit costs were not reported. The direct costs considered in the economic analysis were those of the hospital, and included the costs of outpatients' procedures (such as steroid/anaesthetic injections, epidural injections, manual therapy, acupuncture, and other treatments), costs of inpatient care and costs of other services (such as referrals to physiotherapy, prescribed orthotics, transport provided by the hospital, and referrals to other specialties). Costs borne by patients and relatives were also considered, but they were mistakenly reported as indirect costs. Costs borne by the patients included travel costs for outpatient and other appointments, companions' costs, and child or eldercare costs. The hospital's general practitioner fundholder tariffs and published costs for the Health Service in Scotland were used to estimate marginal costs. A consumer cost questionnaire (obtained from a published study by Henderson et al., see 'Other Publications of Related Interest' section) was used to obtain the costs borne by patients and relatives. Additionally, the authors made some assumptions in order to estimate the costs related to orthotic services. Therefore, the estimation of the costs was based on actual data and some assumptions. Discounting was not performed, but this was, correctly, not relevant since the period over which costs were incurred was shorter than 2 years. The study reported marginal costs per patient. The price year was not reported. The authors stated that some adjustments were performed in order to take account of differences in marginal costs of a medical versus a surgical consultation, which were not reflected in the tariffs used to estimate costs.

**Statistical analysis of costs**

The mean and standard deviation of the resource quantities related to the direct costs were reported. The 95% confidence interval (CI) of the differences in the resource utilisation between randomly allocated MSM and COSS groups was also reported. Additionally, the upper 95% CI for the marginal costs per MSM patient and the lower 95% CI for the marginal costs per COSS patient were reported.

**Indirect Costs**

Indirect costs were reported only for the groups of patients that were randomly allocated to one of the interventions. Resource quantities and costs were not reported separately. The same consumer cost questionnaire used to obtain the costs borne by patients and their relatives was used to obtain patients' time. Data obtained from the Office of National Statistics may have been used to value patients' time, although it was not stated clearly how the authors valued productivity losses. Discounting was not performed, but it was, correctly, not relevant as the period over which costs were incurred was shorter than 2 years. The study reported marginal costs per patient and incremental marginal costs per patient. The price year was not reported.

**Currency**

UK pounds sterling (£).

**Sensitivity analysis**

A sensitivity analysis was performed to assess the robustness of the costs results when the unit cost of physiotherapy was doubled and the unit cost of inpatient procedures was halved. Thus, a two-way sensitivity analysis appears to have been performed. Moreover, an extreme scenario was taken into account by considering the upper 95% CI for the costs.
of the MSM group and the lower 95% CI for the costs of the COSS group. This means that the area of uncertainty considered was variability in data.

Estimated benefits used in the economic analysis
The reader is referred to the ‘Effectiveness Results’ section reported earlier.

Cost results
The marginal direct costs per patient (without including costs borne by patients and their relatives) were 179 per MSM patient versus 287 per COSS patient, and the incremental marginal costs of COSS when compared to MSM were equal to 108 (95% CI: 25 - 191). The marginal costs per patient that included both indirect costs and costs borne by patients and their relatives were 50.10 per MSM patient versus 80.90 for COSS patient. The sensitivity analyses showed that the results were robust and MSM generated costs savings, even considering a extreme scenario that was unfavourable to the MSM intervention.

Synthesis of costs and benefits
Not applicable due to the cost-minimisation analysis undertaken.

Authors' conclusions
The authors concluded that no differences in health gain were detected between patients that were treated by either a musculoskeletal medicine physician or an orthopaedic surgeon-led service, while cost savings were found in the group treated by musculoskeletal medicine.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator chosen, namely that orthopaedic surgeon-led services (alongside musculoskeletal medicine) was the current practice in the authors’ setting. As the user of this database, you should decide whether this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
There were two designs of study used for the effectiveness analysis. The first was a randomised controlled trial, which was appropriate for the study question. The second was a prospective cohort study, which may present more biases since patients were not allocated randomly and the groups considered at analysis were less comparable than those in the randomised controlled trial. The authors did not report any evidence that the study sample was representative of the study population, and this may be unlikely since patients were recruited only from one centre. Multiple regression analysis was used to adjust for confounding variables, although it is not clear whether all the important confounding variables were considered. The fact that the study sample may have been very heterogeneous made controlling for confounding factors more difficult. It is important to highlight that the time and nature of treatments according to the particular interventions were entirely at the discretion of the individual clinician, as the authors stated. Therefore, the health care received by patients within the same group (either MSM or COSS) may not have been the same across individuals within the same comparison group, and it is not clear how this may have affected the results obtained. As the authors stated, they were not able to rule out clinically important effects due to the fact that the sample size was not large enough to detect the pre-specified target differences in health gain.

Validity of estimate of measure of benefit
No summary measure was used in the economic analysis because the study was categorised as a cost-minimisation analysis (see ‘validity of effectiveness’ comments above).

Validity of estimate of costs
The perspective adopted was not stated, although the costs reported corresponded to a societal perspective. All the direct costs that were relevant to the economic analysis may have been reported. The authors reported jointly the costs borne by patients and their relatives as total indirect costs, without specifying the method used to calculate productivity losses. Resource quantities related to the direct costs were reported separately, although the unit costs used to value them were not reported. Resource quantities and costs related to indirect costs or to costs borne by patients and their families were not reported separately. Sensitivity analyses were performed in order to assess the robustness of the costs results obtained, and this may enhance the reliability of the results. Since no price year was reported and not all the resource quantities were reported separately from the costs, it would be difficult to perform reflation exercises to other settings. As the authors stated, the consideration of a longer-term follow-up would enable us to determine the full cost implications that the interventions considered at analysis have in the long-term.

Other issues
The authors made some comparisons of their findings with those obtained from other studies, although the outcomes compared were different. The authors stated that their own results may not be generalisable to other orthopaedic outpatient departments. Some drawbacks of the analysis were discussed.

Implications of the study
The authors reported that this is the only randomised controlled trial of a musculoskeletal medicine service that has ever been undertaken. Since the results may not be generalisable to other settings, the authors recommended the trial be replicated in other places in order to provide a more secure basis before wider introduction. Any replication should try to follow a random allocation of patients at the time of appointment, to reduce possible bias due to withdrawals.

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Other publications of related interest


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