Cost-effectiveness of spa treatment for fibromyalgia: general health improvement is not for free

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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 study assessed an adjuvant spa treatment programme for patients with fibromyalgia syndrome (FM). The spa treatment programme comprised five elements: thalassotherapy, low-impact aerobic exercise, patient education, recreational activities and relaxation. The treatment programme was provided in Tunisia over a period of 2.5 weeks and was compared with usual care (UC). Although a full description of the spa programme was provided, UC was not described.

Type of intervention
Palliative care.

Economic study type
Cost-utility analysis.

Study population
The study population comprised patients with FM. The inclusion criteria included a diagnosis of primary FM made by a rheumatologist, age between 18 and 65 years, and willingness to undergo an inpatient treatment of some weeks.

The exclusion criteria were as follows: a diagnosis of secondary FM; co-morbidity interfering with spa treatment and other serious co-morbidity; dependency on a wheelchair or help from other people; current involvement in a legal procedure concerning disability or employment; recent spa treatment for musculoskeletal disorders; and difficulty in understanding Dutch.

Setting
The study setting was not explicitly reported but it is likely to have been secondary care. The economic analysis was carried out in the Netherlands.

Dates to which data relate
The dates of the effectiveness and resource use data were not reported. The price year was 2000.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the analysis of effectiveness, via monthly questionnaires. Retrospective data linked to the costs were also collected in order to test group differences in costs at baseline.

Study sample
Power calculations were not reported in this paper. The reader should refer to the clinical paper for full details of the
trial (Zijlstra et al. 2005, see ‘Other Publications of Related Interest’ below for bibliographic details). The initial sample comprised 134 patients with primary FM who were randomly allocated to the two groups. There were 58 patients in the combined spa treatment programme and 76 in the UC group. Three patients were reported to have been excluded from each group (4% of the total sample). The reasons for this exclusion were not reported.

**Study design**

This was a pre-randomised controlled trial that was carried out at a single site, a hotel on the Island of Jerba, Tunisia. Randomisation-before-consent was applied, in which control patients only received information concerning their part of the protocol but not the spa treatment; the control group was blinded to the intervention. Blinding was not performed for either the intervention group or for the observers. The length of follow-up was 12 months and 128 (96%) of the 134 patients were followed up for this period.

**Analysis of effectiveness**

The primary health outcome used was a health-related quality of life score. This was assessed in two different ways using the Short Form 6D (SF-6D) and a visual analogue scale (VAS). The SF-6D was calculated by converting the RAND-36 using Brazier’s methods. At baseline, the study groups were comparable in terms of their demographic and clinical factors. Values were obtained at baseline, 1, 3, 6 and 12 months.

**Effectiveness results**

There were statistically significant differences in the SF-6D and in the VAS at 1 and 3 months post treatment as patients reported better quality of life, but this effect was no longer significant after 6 months.

At 6 months post treatment, patients reported a difference of 0.02 in the score of the SF-6D (0.32 in the therapy group compared with 0.30 in the control group, p<0.05) and of 0.04 in the score of the VAS, (p<0.01).

**Clinical conclusions**

There was a temporary improvement in the quality of life of patients with primary FM due to the combined spa treatment. This improvement ceased after 6 months.

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

The measure of health benefit used was the quality-adjusted life-years (QALYs). Utilities were assessed by the SF-6D utility index and a VAS. The SF-6D was calculated by converting the RAND-36 (a validated Dutch version of the SF-36 health survey) using Brazier’s methods.

**Direct costs**

The authors adopted a societal perspective for the economic analysis. Both medical and non-medical direct costs were included. These were assessed and valued in accordance with Dutch guidelines for pharmacoeconomic research. The medical costs comprised spa treatment, visits to the general practitioner, specialist and paramedical professionals, alternative medicine, hospitalisation, and prescription and over-the-counter drugs. The non-medical costs included travel costs for medical care visits and professional domestic care.

Most cost prices were obtained from Dutch standard prices, as described in the Dutch manual for costing. These were converted to the price level for the year 2000 using the price index rate for the Dutch health care sector of 2.6%. The cost of the spa programme was based on the costs of thalassotherapy, travel expenditures, accommodation, and overhead costs including staff expenses. A second calculation was also carried out, taking into account group booking discount and 2007 airfares. The unit cost values were reported for the majority of the cost categories. The costs were reported as the average cost per patient.
Statistical analysis of costs
The costs were treated stochastically and were presented as the arithmetic mean per patient per group. The between-group differences in resource use were analysed per period using the Mann-Whitney U-test. Mean incremental costs per patient and study period were calculated, and 95% confidence intervals (CIs) were estimated using double-sided bootstrapping.

Indirect Costs
Productivity costs were included, with the authors reporting that they may account for up to 70% of total FM-related costs. The unit costs and the resource quantities were presented. Estimated days of sick leave (absenteeism from work) were derived directly from the clinical trial and their costs were obtained from the Dutch manual for costing. As in the analysis of the direct costs, the price year was 2000 and discounting was not relevant.

Currency
Euros (EUR).

Sensitivity analysis
The examination of uncertainty was restricted to the bootstrapping of the incremental cost-effectiveness ratio, estimated using the VAS general health after 1 year of follow-up.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The mean total cost per patient was EUR 3,415 (standard deviation, SD=1,714) for the spa programme group and EUR 2,105 (SD=3,967) for the control group after 6 months' follow-up. Therefore, the mean incremental cost per patient for this follow-up period was EUR 1,311 (95% CI: -369 to 2,439).

After 1 year' follow-up this difference rose to EUR 1,417 (95% CI: -593 to 3,156).

The authors also calculated the cost for the spa treatment based on what they stated as a more realistic cost estimate (i.e. group discount). In this case, the mean incremental cost per patient was EUR 885 (95% CI: -381 to 1,790) after 6 months' follow-up. However, these data were not reported.

Synthesis of costs and benefits
An incremental cost-utility ratio was calculated in order to combine the costs and QALYs of the two strategies.

After 6 months' follow-up, the incremental cost-utility ratio based on the VAS was EUR 32,775 per QALY gained (95% CI: -375,000 to 273,000).

The authors also computed the incremental cost-utility ratio based on the SF-6D after 6 months' follow-up. This proved to be even higher (EUR 65,550, 95% CI: -684,000 to 682,000).

As group differences at 1 year were not statistically significant, the incremental cost-utility ratio was not calculated for this time horizon.

Authors' conclusions
A temporary improvement in quality of life due to an adjuvant treatment course of spa therapy for patients with fibromyalgia syndrome (FM) is associated with limited incremental costs per patient.
CRD COMMENTARY - Selection of comparators
Although no explicit justification was provided for the comparator used, the authors stated that they had compared the combined spa treatment strategy with standard practice. As there was no information on the standard practice, it is not possible to make an objective assessment of its validity. You should decide if the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a pre-randomised controlled trial. Limited details of the clinical trial protocol were provided in this paper. The study sample appears to have been representative of the study population and the patient groups were shown to be comparable at analysis, with details of appropriate statistical comparisons being reported. Given the nature of the treatment, neither the patients nor investigators could be blinded to the intervention. In addition, knowledge of being in either the combined spa treatment group or in the control group might have influenced the results. However, without referring to the clinical paper it is not possible to know if the authors dealt with this threat to internal validity in some manner. The length of the study seems to have been appropriate and the losses to follow-up were minimal.

Validity of estimate of measure of benefit
The summary measure of benefit was overall health as measured by the QALYs. These were estimated using both the SF-6D and a VAS method of estimation. The use of QALYs aids comparisons with the results of other health-related technologies.

Validity of estimate of costs
The analysis of the costs was performed from a societal perspective and in accordance with Dutch guidelines for pharmaco-economic research. All the relevant categories of costs appear to have been included in the analysis. Resource use and cost data were mainly derived prospectively from a survey conducted on the patients involved in the study; some retrospective cost data were also collected and utilised. Appropriate adjustments were made where necessary and reported. Given that the study was undertaken in the Netherlands, following Dutch guidelines, you may wish to consider whether these costs are likely to be representative of the costs in your own health setting.

Other issues
Although this was the first study to have addressed the cost-effectiveness of a combined spa treatment in patients with FM, the authors compared their findings with those from other relevant studies. In this respect, they stated that the mean incremental cost achieved was in agreement with the mean incremental cost from other published results. However, you should be careful in your analysis as different measures of utilities were used in the studies compared; the authors also highlighted this difficulty in making comparisons.

The authors acknowledged variation in the cost of treatment and assessed what they considered to be a "more realistic" calculation for the cost of the spa treatment. This scenario reduced the incremental cost and subsequently the incremental cost-effectiveness ratio. However, they did not fully present these results, nor did they undertake any sensitivity analysis to address any uncertainty. The authors felt that their results were generalisable to the wider population of FM patients. You should refer to the inclusion and exclusion criteria (see the 'Study Population' section) to verify relevance to your patient population. Limitations to the study were reported; these related to the underestimation of productivity costs. However, and in accordance with the authors, it is likely that this had a limited effect on the final results.

Implications of the study
The authors did not suggest any changes in practice, but stated that further research should assess society's willingness to bear the incremental costs of this treatment.

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Other publications of related interest
Because readers are likely to encounter and assess individual publications, NHS EED abstracts reflect the original publication as it is written, as a stand-alone paper. Where NHS EED abstractors are able to identify positively that a publication is significantly linked to or informed by other publications, these will be referenced in the text of the abstract and their bibliographic details recorded here for information.


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Subject indexing assigned by NLM

MeSH
Absenteeism; Adult; Climatotherapy /economics; Cost of Illness; Cost-Benefit Analysis; Female; Fibromyalgia /economics /therapy; Health Care Costs /statistics & numerical data; Health Resorts /economics; Humans; Male; Middle Aged; Netherlands; Quality of Life; Quality-Adjusted Life Years; Tunisia

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