Cognitive-educational treatment of fibromyalgia: a randomized clinical trial. II: Economic evaluation

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
An educational/cognitive intervention (ECO), an educational discussion intervention (EDI) and a waiting list condition (WLC) approach to the treatment of fibromyalgia (FM) were assessed.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
Patients aged 18 to 65 who met the American College of Rheumatology criteria for FM.

Setting
The practice setting was primary care. The economic study was carried out in Maastricht, the Netherlands.

Dates to which data relate
The dates relating to resource use and effectiveness analysis were not reported. Prices relate to 1993.

Source of effectiveness data
The estimate of final outcomes was based on a single study.

Link between effectiveness and cost data
Costing was undertaken on the same patient sample and was, for the most part, prospective.

Study sample
It was not reported whether power calculations were used to determine sample size. In total 131 patients were included in this study: 49 in the ECO group, 39 in the EDI group and 43 in the WCL group.

Study design
A randomized controlled trial was undertaken at a single centre. The duration of follow up was 1 year post termination of treatment for ECO and ECI groups (patients were seen at 2 weeks before the start of treatment, at the start of treatment, after completion of the 6 week treatment programme and 6 and 12 months post treatment). Also, patients in the WLC group were followed for 6 weeks. There was a 29% dropout rate in the ECO group, a 20% rate in the EDI
group and a 10% dropout rate in the WLC group.

**Analysis of effectiveness**
The study was based on intention to treat. The primary health outcomes used were pain control, pain coping, knowledge, tension and relaxation. No statistically significant differences in terms of clinical and sociodemographic characteristics were found. At baseline, no difference in health care utilisation or utilities were found between the groups in the year before the trial.

**Effectiveness results**
Effectiveness results were reported in a separate paper, Vlaeyen et al, 1996. Post-treatment, ECO patients improved their knowledge about FM (p=0.007) and pain coping (p<0.001) compared to the WLC group. EDI patients improved on pain coping (p=0.005) and pain control (p=0.002). Significantly less fear was reported by EDI patients as compared to ECO patients, (p=0.005). At post-treatment and 6 and 12 months follow-up periods no other differential effects occurred between ECO and EDI groups. Taking the reliability of change index for clinical significance, short term success rates were 6.4 and 18.4% for ECO and EDI respectively.

**Clinical conclusions**
Overall, in the sample studied, very little improvement was found. The authors suggested that it was possible that the lack of differential effects between the two treatment interventions was because of the different effects in the EDI and ECO condition. In summary, it seems that an outpatient educational programme using cognitive treatment or not, is not sufficient to meet the needs of the disabled patients within the population.

**Modelling**
Not undertaken.

**Measure of benefits used in the economic analysis**
Quality adjusted life years gained (QALYs) was the outcome measure used in the economic analysis. The basic method of valuation of health states was by direct measurement at interview. The values elicited were those of the patient. They were valued at the start of treatment, after completion of the 6 week treatment programme and at 6 and 12 months after termination of the treatment. The valuation tool used was a quality of life questionnaire involving the rating scale and standard gamble.

**Direct costs**
Costs were not discounted as the study period was one year only. Quantities and costs were analysed separately. Direct health care costs measured included the treatment costs, GP visits, outpatient specialist contacts, physiotherapy, alternative health care, hospitalisations, home help, OTCs and prescribed medications. Direct non-health care costs included paid and unpaid help, transportation costs and out of pocket expenses for pain related activities and purchases. A societal perspective was adopted. The estimation of quantities and costs was based on actual data. The source of quantity data was the institution-s own files. The costs of the drugs were based on Dutch pharmacy prices and the costs of ,alternative health care- were based on the guidelines of the professional associations for alternative medicine. Out of pocket expenses, non-health care direct costs and the days of absence from work and disability for performing daily life activities were obtained from a weekly diary completed by each patient. The dates during which the quantities of resources were measured were not reported. 1993 prices were used.

**Statistical analysis of costs**
Not undertaken.
Indirect Costs
Quantities and costs were reported separately. The value of the loss of potential production during the total absenteeism period was calculated via the human capital approach. The cost boundary adopted was the patient, the relative and the friend. The estimation of quantities was based on actual data collected by the patient in a weekly diary. No date for the quantity of resources used was provided. The average national gross hourly wage was used to estimate costs.

Currency
US dollars ($). The original calculation was carried out in Dutch guilders and these were converted to dollars by using the 1993 Purchasing Power Parities rate of the OECD HealthData File.

Sensitivity analysis
Numerous sensitivity analyses were undertaken to assess the analytic methods and to test the following assumptions: the inclusion of a group discussion component in the EDI programme, cost accounting estimates used instead of charges, inclusion of high cost events, mean costs as opposed to median costs, and finally the human friction approach versus the friction cost method of calculating indirect costs.

Estimated benefits used in the economic analysis
Benefits were estimated using the QALY technique. The EDI treatment produced a gain of 0.027 QALY per patient per year compared to the ECO treatment based on the rating scale results. Using the standard gamble utility measurement approach compared to the ECO treatment.

Cost results
The mean total direct cost per patient per year for ECO was $4,260 (SD $6,510) and for the EDI group it was $2,637 (SD $4,649) which was statistically significant. The total indirect cost per patient per year for the ECO group was $6,379 (SD $15,569) whereas the EDI group reported an amount of $5,817 (SD $14,303), (not statistically significant, p=0.872).

Synthesis of costs and benefits
A synthesis of costs and benefits was not undertaken as no additional improvement in terms of quality of life was found for the EDI versus ECO approaches. Therefore only costs were used in what became a cost-minimisation analysis. EDI resulted in significantly lower health care costs compared to ECO.

Authors’ conclusions
No benefits resulted from the addition of the cognitive component to the educational intervention in the treatment of FM and costs were significantly higher for the ECO compared to the EDI programme.

CRD COMMENTARY - Selection of comparators
reason for choice of comparators is clear.

Validity of estimate of measure of benefit
QALY estimates provided are likely to be internally valid. The authors recommend that RCTs be conducted to investigate the effectiveness of a cognitive treatment that is undertaken as part of a more comprehensive programme, including for example, counselling and spouse involvement. Unfortunately, loss to follow up was high: 56% in the ECO group and 47% in the EDI group at one year.

Validity of estimate of costs
Entities and costs were reported separately and adequate details of quantity and cost estimation were given.

**Other issues**

In general, the authors' conclusions appear to be justified and the economic study is quite comprehensive. Very little economic research has been conducted in the area of FM to date, and in this respect the study is pioneering work.

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**Other publications of related interest**


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