Cost-effectiveness of a graded exercise therapy program for patients with chronic shoulder complaints


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 use of behavioural graded exercise therapy (GET) for the management of patients with chronic shoulder complaints (CSC). GET is a behavioural treatment programme characterised by graded activity and time-contingency and operant conditioning. It was administered by physiotherapists. The programme consisted of a maximum of 18 group sessions of approximately 60 minutes over a 12-week period.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis and cost-utility analysis.

Study population
The study population comprised patients who were at least 18 years old and had been suffering from CSC for at least 3 months. Patients suffering from systemic diseases, referred pain, or severe biomedical or psychiatric disorders were excluded.

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

Dates to which data relate
The patients enrolled to derive effectiveness and resource use data were contacted between January 2002 and July 2003. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was carried out on the same sample of patients as that included in the effectiveness study.

Study sample
Power calculations, if performed, were not reported. An overall sample of 176 patients was enrolled between January 2002 and July 2003. There were 87 patients in the GET group and 89 patients in the UC group. Patient demographics were not reported.
**Study design**
This was a prospective, randomised clinical trial that was carried out in the Province of Limburg in the Netherlands. Several general practitioners and physiotherapists participated in the study in order to recruit eligible patients. Details of the method of randomisation were not provided. The length of follow-up was one year. The outcomes were measured at baseline, directly after the 12-week treatment period, and after 52 weeks of follow-up. Eighteen patients (10%) withdrew from the study during the treatment period, while 11 (6%) withdrawals were observed during the 52-week follow-up period. Blinding was not performed.

**Analysis of effectiveness**
The analysis of the clinical study was conducted on an intention to treat basis. The primary outcome measures to assess the performance of daily activities were the main complaints instrument and the Shoulder Disability Questionnaire (SDQ). In the main complaints instrument, patients selected the three most important daily activities that were affected by their CSC and rated their ability to perform these activities during the past week on a scale at baseline and during follow-up. The SDQ is a functional status measure consisting of 16 statements about pain and limitations to daily activities during the past 24 hours. Generic health-related quality of life was also estimated using the EuroQol-5D. The study groups were comparable at baseline in terms of their clinical and demographic factors. Participants in the study were also comparable to patients who withdrew from the study.

**Effectiveness results**
In the GET group, the score for main complaints was 76.2 (+/- 19.2) at baseline. The improvements were 32.8 (+/- 25.7) after 12 weeks and 41.1 (+/- 26.7) after 52 weeks.

In the UC group, the score for main complaints was 71.9 (+/- 19.6) at baseline. The improvements were 25.3 (+/- 24.5) after 12 weeks and 31.8 (+/- 27.4) after 52 weeks.

The mean difference in improvements between groups was 7.5 (95% confidence interval, CI: 0.0 to 15.0; p=0.49) after 12 weeks and 9.2 (95% CI: 1.2 to 17.3; p=0.025) after 12 weeks.

Differences between the groups in SDQ and quality of life did not reach statistical significance.

**Clinical conclusions**
The effectiveness analysis showed that, compared with UC, GET improved main complaints for patients with CSC.

**Measure of benefits used in the economic analysis**
The summary benefit measures used were scores of main complaints, the SDQ and quality of life. These were estimated directly from the effectiveness analysis.

**Direct costs**
The analysis was conducted from a societal perspective. The direct costs included were intervention costs, health-related costs and non health-related costs. The intervention costs for GET covered visits to physiotherapists during the 12-week treatment period. The intervention costs for UC were for visits to general practitioners, physiotherapists (for UC), or to manual therapists or Cesar/Mensendieck exercise therapists during the 12-week intervention period. Health-related costs included the costs of prescribed medication, hospitalisation, and visits to physicians or alternative therapists during the 12-week treatment period. After the treatment period, these costs included the costs of visits (general practitioners, physiotherapist, manual therapists, Cesar/Mensendieck exercise therapists, physicians, and/or alternative therapists), hospitalisation and prescribed medication during the 52-week follow-up period. Non health-related costs covered professional home care, paid housekeeping, unpaid help from relatives or friends, health-related activities (e.g. fitness training), and other out-of-pocket expenses (e.g. non-prescribed medication).

The average quantities of resources used were reported, but the unit costs were not. The resource use data were derived...
from the sample of patients included in the clinical trial, using cost diaries and a registration form for physiotherapist visits. Only 102 patients (58%) completed the full diaries and no cost data were available for the 15 (9%) withdrawals. Overall, 1,213 out of a total of 1,499 (81%) cost diaries were returned during the 52-week follow-up period. The costs of visits to health care providers, hospitalisation, professional home care, and paid housekeeping were obtained from the Dutch Health Care Insurance Counsel. Other costs came from professional organisations, shadow prices, the Royal Dutch Society for Pharmacy and cost diaries. Discounting was not relevant as the costs were incurred during one year. The price year was not reported.

**Statistical analysis of costs**
Mean cost-differences between groups were analysed using non-parametric Mann-Whitney tests for non-Gaussian distributions. If data were missing, individual mean imputation was applied, while if no cost data were available, unconditional imputation of the group mean was used.

**Indirect Costs**
The indirect costs (i.e. costs of production losses due to sick leave from paid or unpaid work) were included in the analysis as a societal perspective was adopted. These costs were estimated using the human capital approach. The resource use data were obtained from the sample of patients included in the effectiveness analysis. As in the analysis of the direct costs, discounting was not relevant and the price year was not reported.

**Currency**
Euros (EUR).

**Sensitivity analysis**
A sensitivity analysis was carried out to adjust the base case-results (costs and cost-effectiveness ratios) for the one patient who reported extremely high use of unpaid help from relatives or friends.

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

**Cost results**
The total costs in the 12-week treatment period were EUR 332 (+/- 332) in the GET group and EUR 133 (+/- 175) in the UC group (difference EUR 199, 95% CI: 139 to 261; p=0.000).

The total costs in the follow-up period were EUR 198 (+/- 681.6) in the GET group and EUR 244 (+/- 435) in the UC group (difference -46, 95% CI: -217 to 123; p=0.003).

The total costs in the 0- to 52-week period were EUR 530 (+/- 869.2) in the GET group and EUR 377 (+/- 548.4) in the UC group (difference EUR 153, 95% CI: -63 to 369; p=0.001).

After adjustment for the outlier patient, the adjusted total mean costs were EUR 79 higher for patients allocated to GET.

**Synthesis of costs and benefits**
Incremental cost-effectiveness and cost-utility ratios were calculated to combine the costs and benefits of GET over UC by bias-corrected bootstrapping (using 1,000 replications).

The incremental cost-effectiveness ratios after 52 weeks indicated that the incremental costs for GET per unit improvement were EUR 17 (95% CI: -4 to 129) for severity of the main complaints, EUR 74 (95% CI: -2 to 101) for
SDQ, and EUR 5,278 (95% CI: -11.808 to 51.407) for EQ-5D.

The cost-effectiveness ratios were plotted on a cost-effectiveness plane. This showed that most cost-effect pairs (91%) indicated positive effects at higher costs for main complaints. For the SDQ and EQ-5D, more cost-effect pairs indicated smaller clinical effects at higher costs.

After adjustment for the outlier patient, the adjusted incremental cost-effectiveness ratio after 52 weeks was EUR 9 (95% CI: 6 - 16) for severity of the main complaints, EUR 40 (95% CI: -4 to 57) for SDQ, and EUR 2,846 (95% CI: -2.765 to 3.763) for EQ-5D.

Authors’ conclusions
Graded exercise therapy (GET) was more cost-effective than usual care (UC) for patients with chronic shoulder complaints (CSC) in primary care in the Netherlands. GET was more effective in restoring daily activities and it significantly reduced direct health-related and non-health-related costs. However, the intervention costs were higher in comparison with UC.

CRD COMMENTARY - Selection of comparators
The rationale for the selection of the comparator was clear since it reflected the standard care offered to patients with CSC. You should decide whether this is a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence came from a clinical trial. This was appropriate for the study question and usually ensures a high internal validity of the clinical evidence. Some of the strengths of the analysis were the use of intention to treat to deal with the loss to follow-up, the baseline comparability of the study groups, and the use of a randomised design. The length of follow-up appears to have been appropriate. Information on randomisation and sample selection was not reported. It was not stated whether some patients refused to participate or were excluded from the study sample for any reason. No justification for the size of the study groups was provided, and power calculations were not reported. Also, since blinding was not used, some bias could have affected the results of the analysis. The clinical and demographic characteristics of the patients included in the study were not reported. These issues might limit the validity of the analysis.

Validity of estimate of measure of benefit
Both disease-specific and more generalisable benefit measures were used. Health-related quality of life scores are comparable with the benefits of other health care interventions. Since no statistically significant difference in quality of life was observed, the authors noted that improvements in individual daily activities due to GET were presumably too specific to be detected by this generic health-related quality of life measure.

Validity of estimate of costs
The costs included were consistent with the perspective adopted in the study. A detailed breakdown of the costs was provided and the source of the data was reported for all items. The unit costs were not presented, but extensive information on the quantities of resources used per patient was. This allows the analysis to be replicated in other settings. Statistical analyses of the costs took the skewed distribution of the costs into account. Variations in the cost estimates were investigated in the sensitivity analysis. The price year was not reported, which will make reflation exercises in other time periods difficult.

Other issues
The authors did not make extensive comparisons of their findings with those from other studies. However, it was noted that the cost-effectiveness ratios for GET in patients with CSC and for manipulative therapy as an add-on to UC in patients with CSC and concomitant neck problems were comparable. The authors did not explicitly address the issue of
the generalisability of the study results to other settings. Very limited sensitivity analyses were carried out, which limits the external validity of the study. The analysis referred to patients with CSC and this was reflected in the authors’ conclusions.

**Implications of the study**
The authors recommended using GET to restore daily activities in patients with CSC in primary care. They pointed out that "the programme should focus more on work-related goals and work-related activities in patients having paid work, which might improve the social benefits of GET".

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**Other publications of related interest**


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