Cost-effectiveness of evidence-based pharmacotherapy or cognitive behavior therapy compared with community referral for major depression in predominantly low-income minority women


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 pharmacotherapy (paroxetine hydrochloride or bupropion hydrochloride) and cognitive-behavioural therapy (CBT) for women with major depression. The pharmacotherapy protocol consisted of 10 to 50 mg/day paroxetine (adjusted based on response and reported adverse effects) for up to 6 months. Patients unable to continue on paroxetine were switched to bupropion. Patients on CBT received the therapy from experienced psychotherapists supervised by a licensed clinical psychologist. CBT consisted of eight weekly sessions, administered in group or individual sessions, over the course of 8 weeks. It could be extended an additional 8 weeks if the patient still met the criteria for major depressive disorder and wanted additional therapy.

Type of intervention
Treatment.

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

Study population
The study population comprised a cohort of women with major depression, as estimated using the Composite International Diagnostic Interview tool. Women who were bereaved were excluded, as were those who tested positive for current alcohol or other substance abuse, or were currently receiving mental health care. Women who were pregnant or planned to become pregnant, or were currently breastfeeding, were also excluded.

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

Dates to which data relate
The effectiveness and resource use data were derived from a study published in 2003. The price year was 2002.

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

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

Study sample
Power calculations were not reported. There was limited information on the methods used to select the sample since the design and other details of the study had been published elsewhere. Eleven per cent of the women initially evaluated were eligible for inclusion in the study. Overall, 267 women participated. There were 88 women (ethnicity: 55% Latina and 39% African American) in the pharmacoeconomic group, 90 (48% Latina and 46% African American) in the CBT group and 89 (48% Latina and 47% African American) in the community referral group. The mean age of the women was 28.7 (+/- 6.6) years in the pharmacoeconomic group, 29.8 (+/- 7.9) years in the CBT group and 29.5 (+/- 9.1) years in the community referral group.

**Study design**
This was a prospective, randomised clinical trial that was carried out at several family planning clinics in Prince George's and Montgomery counties (MD), and in Arlington and Alexandria (VA). The length of follow-up was 12 months. The patients were assessed at baseline and at 1, 2, 3, 4, 5, 6, 8, 10 and 12 months. It was not stated how many patients were lost to follow-up. However, missing values were imputed using a statistical approach.

**Analysis of effectiveness**
The analysis of the clinical study was conducted on an intention to treat basis. The primary outcome measures were depression symptoms, which were assessed using the Hamilton Depression Rating Scale (HDRS), and the Medical Outcomes Study 36-Item Short-Form Health Survey. The latter was a generic health status measure, which was administered at baseline and at 3, 6 and 12 months. It had two summary scores, the mental component summary (MCS) and the physical component summary (PCS). The HDRS was used to assess depression-free days (DFDs) using the following approach:

- If participants reported HDRS scores of 22 or higher, they were considered to have no DFDs;
- If they had HDRS scores of 7 or lower, they were assumed to have a complete DFD; and
- For participants with HDRS scores between 8 and 21, each day was weighted proportionately.

A random intercept and slope repeated-measures analysis of variance was used to compare the mean HDRS, MCS and PCS scores among the three treatment groups for 12 months. At baseline, the study groups were comparable in terms of the demographic and clinical characteristics.

**Effectiveness results**
In terms of the HDRS scores, the pharmacotherapy and CBT groups performed better than the community referral group during the first 4 months of the study. After 4 months, the mean HDRS scores for the pharmacotherapy group increased slightly in comparison with those of the community referral group, whereas the mean scores for the CBT group were not significantly different from those of the community referral group.

During the 12-month follow-up, the number of DFDs was 258 (95% confidence interval, CI: 236 - 280) in the pharmacotherapy group, 251 (95% CI: 230 - 273) in the CBT group and 225 (95% CI: 206 - 244) in the community referral group.

A statistically significantly higher mean number of DFDs was observed in the pharmacotherapy group compared with the community referral group (mean 39.7, 95% CI: 12.9 - 66.5; p=0.005), and in the CBT group compared with the community referral group (mean 25.80, 95% CI: 0.04 - 51.50; p=0.05).

No statistically significant differences in MCS and PCS scores between either of the intervention groups and the community referral group were observed over the 12-month time period, although MCS scores were better in the pharmacoeconomic group than in the community referral group during the first 3 months.

**Clinical conclusions**
The effectiveness analysis showed that the two interventions led to more DFDs in comparison with community referral.
A non significant trend towards improvements in specific dimensions of health was also observed.

**Measure of benefits used in the economic analysis**
The summary benefit measures used were the DFDs and quality-adjusted life-years (QALYs). The DFDs were derived from the clinical trial. The utility weights required for the calculation of QALYs came from a published study and were based on the standard gamble approach. The utility values were 0.30 for severe depression and 0.86 for depression remission. No discount was applied.

**Direct costs**
The cost analysis was performed from the perspective of state Medicaid programmes. The health services included in the economic evaluation were emergency department visits; outpatient psychiatrist, physician and other health care provider visits; medication costs; and study-related pharmacotherapy and CBT services. Such costs were then aggregated to calculate the total outpatient costs. The total medical costs were also calculated with study intervention costs, total outpatient costs, and hospital and inpatient-related physician costs taken into consideration. The study intervention costs also included receipts for taxi and other transportation expenditures, as well as estimated costs for babysitting services associated with participation in medication monitoring or CBT sessions. Other costs associated with hospitalisation were excluded because of the low number of patients hospitalised (12%). The unit costs were not presented separately from the quantities of resources used. Most of the costs were presented as macro-categories. The resource use data were estimated from the clinical trial that provided the effectiveness data. All inpatient and outpatient medical services were valued using Maryland Medicaid payment rates, while drugs were priced using the lowest wholesale prices. Discounting was not relevant since the costs were estimated over 1 year. The price year was 2002.

**Statistical analysis of costs**
The costs were presented as mean values with standard deviations. Ordinary least-squares regression models were used to compare the total outpatient costs and total medical costs between the three groups. The regression models included demographic variables and baseline HDRS and PCS scores.

**Indirect costs**
The indirect costs were not included in the economic evaluation.

**Currency**
US dollars ($).

**Sensitivity analysis**
Sensitivity analyses were not performed.

**Estimated benefits used in the economic analysis**
The estimated QALYs were not reported. The estimated DFDs have been reported already.

**Cost results**
The total outpatient costs were $1,020.95 (+/- 69.62) in the pharmacotherapy group, $976.18 (+/- 89.65) in the CBT group and $313.65 (+/- 48.32) in the community referral group. The difference between the pharmacotherapy and community referral groups was $677 (95% CI: 484 - 870; p<0.001). The difference between the CBT and community referral groups was $636 (95% CI: 446 - 826; p<0.001).

The total costs were $1,996.83 (+/- 349.97) in the pharmacotherapy group, $1,844.29 (+/- 238.73) in the CBT group and $1,244.98 (+/- 286.30) in the community referral group. However, the differences between the groups did not
reach statistical significance. The mean difference was $772 (95% CI: -7 - 1,551; p=0.05) for pharmacotherapy versus community referral and $530 (95% CI: -241 - 1,300; p=0.18) for CBT versus community referral.

**Synthesis of costs and benefits**

Incremental cost-effectiveness and cost-utility ratios were calculated to combine the costs and benefits of either of the interventions with community referral.

When comparing pharmacotherapy with community referral and using outpatient costs, the incremental cost was $24.65 per DFD (95% CI: 13.89 - 65.66) and $16,068 per QALY (95% CI: 9,052 - 42,794).

The corresponding values when using total costs were $46.06 per DFD (95% CI: 20.89 - 139.48) and $30,023 per QALY (95% CI: 13,617 - 90,911).

When comparing CBT with community referral and using outpatient costs, the incremental cost was $27.04 per DFD (95% CI: 12.85 - 449.22) and $17,624 per QALY (95% CI: 8,375 - 292,794).

The corresponding values when using total costs were $57.64 per DFD (95% CI: 22.38 - 4,351.36) and $37,568 per QALY (95% CI: 14,590 - 2,836,158).

**Authors' conclusions**

The implementation of pharmacotherapy or cognitive-behavioural therapy (CBT) improved clinical outcomes among women with major depression at a cost comparable to that of other accepted health care interventions. Thus, either intervention was cost-effective for the public health care system.

**CRD COMMENTARY - Selection of comparators**

The comparators were selected on the basis of interventions examined in a published clinical trial. Both interventions were compared with standard care, which consisted of community referral. You should decide whether they are valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**

The effectiveness data came from a clinical trial, which was appropriate for the study question. The use of a randomised and multi-centre design ensures a high internal validity. In addition, the study groups were comparable at baseline and some statistical analyses were performed to limit the impact of confounding factors. However, the trial had been published elsewhere and limited information on the design of the study was provided.

**Validity of estimate of measure of benefit**

Two summary benefit measures were used. The use of DFDs was appropriate as a disease-specific measure in the cost-effectiveness analysis. The use of QALYs captures the impact of the interventions on the most important dimensions of health (i.e. survival and quality of life). The utility values came from the literature and the methods used to derive them were explicitly reported. Discounting was not applied.

**Validity of estimate of costs**

The costs included were consistent with the perspective adopted in the study. A breakdown of the cost items was reported, but information on the unit costs and quantities of resources used was not. This limits the possibility of replicating the results of the analysis in other settings. The source of the data was given for all items. The costs were aggregated as total costs and outpatient costs. Statistical analyses of the costs were carried out. The price year was reported, which aids reflation exercises in other settings.
Other issues
The authors reported the results of other published cost-effectiveness analyses of treatments for depression, and stated that similar results were found. The issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were not performed, which might limit the external validity of the study. Some limitations of the analysis were noted. First, most of the clinical outcomes and resource use data were self-reported, which might limit the robustness of such data. Second, a large group of women potentially eligible did not participate in the study. Third, contacts were not the same in the three groups. In general, a limitation of the analysis appears to have been the lack of an analysis of uncertainty, which could have been relevant given the large CIs found around the mean cost-effectiveness ratios.

Implications of the study
The study results suggested that expenditures for improved interventions for depression in low-income minority women represent a good investment when compared with a range of other generally acceptable medical treatments.

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Other publications of related interest


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MeSH
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