The London Depression Intervention Trial: randomised controlled trial of antidepressants v. couple therapy in the treatment and maintenance of people with depression living with a partner - clinical outcome and costs


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
Antidepressant medication was compared with couple therapy for depressed patients living with a partner. The first-line antidepressant was desipramine, and second-line treatments were trazodone and fluvoxamine.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with a major depressive episode were included in the study. Patients were primarily recruited through professional contacts such as GPs, outpatient services and an emergency clinic. Patients were under 65 and had lived with a heterosexual partner for at least one year. Patients with psychotic features, bipolar illness, organic brain syndrome, suicidal tendencies, primary substance abuse or pregnancies were excluded from the study.

Setting
The setting was the community.

Dates to which data relate
The authors did not explicitly report when the underlying clinical and resource estimates were made. Prices were from 1996.

Source of effectiveness data
Effectiveness data were based on a single study.

Link between effectiveness and cost data
A single, prospective, randomised, controlled trial was the source of both cost and effectiveness data.

Study sample
The authors reported that a power calculation with alpha = 0.05 and beta = 0.8 indicated that a sample size of 40 in each group was required. The calculation was based on relapse rates in naturalistic studies. However, the difference between the groups on which the authors based this calculation was not reported. Patients were recruited either through newspaper adverts or through GPs or outpatient clinics. The researchers were in contact with 290 people in total, of
whom 196 satisfied the exclusion criteria. Six people of the remaining 94 refused randomisation. One treatment arm of cognitive therapy was dropped from the study at an early stage because of a high patient dropout rate. Therefore, 77 patients were randomised; 37 to antidepressant therapy and 40 to couple therapy. It is unclear whether this population sample was appropriate for the study population in question.

Study design
This was a single-centre, randomised, controlled trial. Drug treatment and couple therapy was provided for one year, with an additional two years' follow-up. 21 patients who were randomised to antidepressant therapy never received the allocated treatment, whereas 6 patients who were randomised to couple therapy never received therapy. A total of 18 patients were lost to follow-up in the antidepressant group, and 9 in the couple therapy group. The number of patients followed up at two years was therefore 25 in the antidepressant group and 29 in the couple therapy group. Although clinicians and patients were not blinded, the assessment of subjects was carried out by researchers who were blind to treatment allocation.

Analysis of effectiveness
The health outcome measurements in this study were the Hamilton Rating Scale for Depression (HRSD) and the Beck Depression Inventory (BDI). The analysis was based on all available data for treatment completers only. For example, a total of 16 patients received antidepressants as allocated, whereas 21 patients did not receive the allocated antidepressant. Only the 16 patients receiving treatment were followed up at one year. At two years a total of 25 patients in the antidepressant group were included in the analysis of effectiveness. The higher proportion of follow-up at two years was due to a small financial inducement that persuaded a number of dropouts to return for assessment. The authors attempted to control for potential confounding through exploring the impact of value of BDI, age, gender and history of depression. These variables were not statistically significant. From the table presented in the paper the patients in the treatment arms seem to be comparable, apart from the fact that the depressed patients in the antidepressant group were less likely to be men: 17/23 male in couple therapy group against 10/27 in antidepressant group.

Effectiveness results
From the initial assessment to the one-year follow-up, the BDI scores in the couple therapy fell to an average of 6.4 (95% CI: 1.62 - 11.54) lower than the corresponding mean in the medication group. This difference was maintained until the 2-year follow-up.

A significant improvement for both groups was recorded with the HRSD scores, and there was no significant advantage for couple therapy over medication. The absolute BDI scores (including mean and standard deviation) were only reported graphically.

Clinical conclusions
The authors commented that couple therapy was superior to drug treatment when outcomes were assessed with BDI, whereas the HRSD did not discriminate between the two.

Measure of benefits used in the economic analysis
No summary measure of benefits was used, thus making this a cost- consequences analysis.

Direct costs
Resource use data were collected prospectively using a version of the Client Service Receipt Inventory, which covered health and social services such as inpatient, outpatient and day hospital services, day care, GP visits, psychiatric nurse, counsellor and social worker. In additional costs of treatment were calculated based on drug acquisition costs and blood tests in the antidepressant group and the cost of time with the therapist in the couple therapy group. Unit costs were drawn from published national cost estimates that represent real costs from 1996. Discounting costs was not relevant.
Statistical analysis of costs
The collection of costs started after the trial had been initiated and resource use data were therefore missing for 27 cases. Further drop-outs and losses to follow-up reduced the sample further. The analysis of cost difference between the two groups was based on average costs and was conducted using a non-parametric bootstrap procedure to estimate 95% confidence intervals.

Indirect Costs
Indirect costs were not included in this analysis.

Currency
UK pounds sterling (£).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
See under "effectiveness results" earlier.

Cost results
Costs were presented aggregated into three components: treatment, hospital services, and community services. The mean cost difference of the intervention was 58 (range: 45 - 72) more per month for couple therapy during the treatment period versus antidepressant use. The mean cost difference was 20 less (range: -87 to 20) for hospital services per month and 32 less (range: -91 to 1.4) for community services per month when comparing couple therapy to antidepressant use. During the follow-up period the mean cost difference for hospital services was 26 (range: -88 to 19) less in the couple therapy group and the mean cost difference was 2 (range: -9 to 20) more in the couple therapy group per month.

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
The authors stated that "for this group, couple therapy is much more acceptable than antidepressant drugs and is at least as efficacious, if not more so, both in the treatment and maintenance phases. It is no more expensive overall".

CRD COMMENTARY - Selection of comparators
Antidepressant treatment was compared with couple therapy and this comparison was adequately justified by the authors. It appears appropriate to compare couple therapy with first-line treatment with a tricyclic antidepressant. The selective serotonin reuptake inhibitors are increasingly used as first line treatment in the UK and these could have been used as an alternative comparator to couple therapy.

Validity of estimate of measure of effectiveness
Depression was rated by two validated disease-specific tools, the BDI and the HRSD scales. The sample size was based on power- calculations. The analysis of reduction in severity-score was appropriately controlled for the fact that the
couples therapy group had a lower score at the outset of the study. The main problem with the analysis was the large loss to follow-up, which was nearly 50%, although the authors did take steps to maximise follow-up and included dropped-out patients in the analysis.

Validity of estimate of measure of benefit
Not applicable.

Validity of estimate of costs
Costs were collected across a comprehensive range of relevant items and through the use of a standardised instrument. Furthermore, the cost data were appropriately analysed by the use of non-parametric bootstrap analysis, which took account of the skewed nature of the data. The main issue with the analysis was the fact that costs were not recorded for many patients, so that the sample supplying data for the analysis was 24 patients in the couple therapy group and 14 patients in the drug therapy group at 1-year follow-up. From the outset, the study was not powered to detect differences in resource use and the small sample further limits the power of the study to detect significant differences.

Other issues
The authors explicitly discussed the results of the study in the context of other studies and stated that, although comparison is not straightforward, other studies have failed to show a significant benefit of counselling over control treatment in alleviating depression. The authors discussed the generalisability of the study and commented that these results could not be extrapolated beyond those patients living with a heterosexual partner.

Implications of the study
The authors commented that their "findings constitute a strong argument for training primary care personnel in the skills of couple therapy", but also stated that further trials should be undertaken.

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None given.

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