A randomized controlled trial and economic evaluation of counselling in primary care

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
Using generic counselling or usual general practitioner (GP) care in the primary care of patients with mental health problems.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients, aged 16 years and over, with emotional or relationship problems, and with no well-defined phobic conditions or frank psychoses.

Setting
Primary care. The economic study was carried out in Cardiff and Swansea, UK.

Dates to which data relate
The effectiveness and resource use data were collected during 1993 and 1994. Prices were those prevailing in the years 1992-1994.

Source of effectiveness data
Effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were reported, and gave 100 and 50 as the number of patients needed in the intervention and comparator, respectively (using a 2-to-1 randomization ratio), in order to detect a difference of 0.5 SD between treatment arms with an 80% power at the 5% level of significance (2-tailed). The total number of patients in the intervention group (counselling) was 111, whilst the number in the comparator (usual GP care) was 51, giving a total of 162 patients included in the study.

Study design
The study was a randomized controlled trial conducted in nine centres, five in Cardiff and four in Swansea. The duration of follow-up was four months. Overall, 25% of patients were lost to follow-up; 26% from the comparator group and 24% from the intervention group.

**Analysis of effectiveness**

The analysis of clinical outcomes was based on intention to treat. The primary health outcomes used in the analysis were improvements in mental health status and social function. These were measured by the corresponding differences between baseline and four-month follow-up patient responses on the following scales:

- Hospital Anxiety and Depression (HAD) scale;
- the Dartmouth COOP/WONCA Functional Health Assessment Charts, and
- the delighted-terrible faces scale for overall quality of life.

The groups were shown to be comparable in terms of age, sex, social class, marital status, history of mental health referral, presenting problem, current use of psychotropic drugs, Duke Functional Social Support scale, the delighted-terrible faces scale, and on all dimensions of the COOP/WONCA scale. However, the baseline median scores on the HAD scale were higher in the comparator group. Regression analysis was utilized to investigate the statistical significance of centre effects (Swansea and Cardiff) on health outcomes after controlling for potential confounding factors.

**Effectiveness results**

The difference between groups (intervention minus comparator) in terms of mean improvement scores between baseline and follow-up were as follows:

- COOP/WONCA Overall health, 0.2 (95% CI: -0.2 - 0.6; p=0.38);
- delighted-terrible faces, -0.1 (95% CI: -0.5 - 0.4; p=0.81);
- HAD scale anxiety, -0.6 (95% CI: -2.2 - 1.1; p=0.49);
- HAD scale depression, -0.7 (95% CI: -2.6 - 1.1; p=0.43).

The only additional result from the regression analysis was the finding of a greater mean improvement in all patients in Cardiff compared to all those in Swansea for the overall health and anxiety outcome measures.

**Clinical conclusions**

No differences in clinical outcomes were evident between treatment groups.

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

Since the effectiveness analysis showed no difference in clinical benefit between the intervention and the comparator, the economic analysis was based on the difference in costs only.

**Direct costs**

The quantities of resource use were reported separately from costs except for medications. The costs consisted of prescribed medications, practice staff and counsellor time, and referrals to other agencies. The analysis was based on actual data from the clinical trial. The perspective adopted in the cost analysis was not explicitly specified. The unit costs for referrals were based on the "current" mean prices set by NHS trusts in Avon. The prices used in the final calculation were those prevailing in the years 1992-94.
Indirect Costs
Not considered.

Currency
UK pounds Sterling (£).

Sensitivity analysis
A sensitivity analysis on the referral costs was performed presenting three different scenarios according to the number of appointments attended per referral and unit costs applied to them (either private or NHS costs). The effects of alteration in cost of counsellor time were also assessed.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The scenarios explored in the sensitivity analysis yielded upper and lower bounds on the mean cost per patient for each treatment group. When all referrals were included, the range for the intervention group was 71.21 - 81.23, whereas the corresponding figure for the comparator was 89.67 - 109.51. When only mental health referrals were included, the corresponding figures were 74.43 - 68.15 and 83.91 - 67.32, respectively.

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
The study results provide no evidence that counselling is more effective than usual GP care in treating a wide range of mental health problems. There was no clear cost advantage associated with either intervention. These findings provide important evidence to inform future purchasing policy.

CRD COMMENTARY - Selection of comparators
The reason for the choice of comparator was clear.

Validity of estimate of measure of benefit
The results are likely to be internally valid, given the study design, and the control of differences between groups in terms of patients characteristics and known confounding variables. The sample size however, did not allow for patient subgroup comparisons to be carried out in order to identify possible patient-profiles for those likely to benefit from the intervention.

Validity of estimate of costs
Most of the quantities of resource use were reported separately from the prices, and adequate methods of cost estimation were provided. All relevant costs were included in the analysis with the possible exception of those associated with overhead resources.

Other issues
The conclusions reached by the authors were justified given the uncertainties in the data. The authors considered the results as generalisable to other general practice settings, given the spectrum of mental health problems included in the
study, with the most common main complaint in the study (anxiety) being in accordance with previous reports. With respect to the general population, however, the generalisability is uncertain since, according to the authors, the proportion of potentially eligible patients entered into the clinical trial was unknown.

**Implications of the study**
While clear implications can be derived from the present study for the whole spectrum of emotional problems for patients 16 years of age and over, further studies are required to investigate that subgroup of patients who are likely to benefit from the intervention.

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