A randomised controlled trial of self-help interventions in patients with a primary care diagnosis of irritable bowel syndrome


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
Two self-help interventions for patients with irritable bowel syndrome (IBS) were examined.

The first intervention consisted of a comprehensive self-help guidebook produced following a series of focus group meetings with other IBS patients who described the information they required to help them cope with their symptoms better. Specifically, the guidebook contained information about lifestyle, diet, and pharmacological and alternative therapies.

The second intervention consisted of the above-mentioned guidebook in combination with a one-off self-help group meeting (8 - 12 patients) during which patients shared their experiences of living with their functional bowel symptoms and described approaches that helped them manage their illness.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised adult patients attending their primary care physician with functional gastrointestinal symptoms diagnosed as IBS by either the general practitioner (GP) or specialist (if they had been referred before), but not necessarily fulfilling Rome II criteria.

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

Dates to which data relate
The period during which the effectiveness and resource use data were gathered was not reported. The price year was not given, but some unit costs were taken from sources published in 2002 and 2003.

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

Link between effectiveness and cost data
The costing was performed prospectively on the same sample of patients as that used in the effectiveness analysis.
Study sample
Power calculations were not performed, but all eligible patients who consulted for functional bowel symptoms over a period of 22 months were offered the opportunity to participate in the trial. Only patients able to read and understand English were considered. Of the 458 patients initially identified at 54 GP practices and invited to participate in the trial, 34 declined and a further 4 agreed to participate but missed the recruitment deadline. As a result, 420 patients were randomised. The mean age of the participants was 40 (±14.4) years and 89% were female. The patients had suffered bowel symptoms for an average of 6 (±7.2) years and 38% satisfied Rome II criteria. There were 141 patients in the guidebook group, 139 patients in the guidebook plus self-help group, and 140 patients in the control group.

Study design
This was a prospective, randomised clinical trial that was carried out at 54 centres throughout UK. The patients were randomised using a central telephone randomisation system based on minimisation. The groups were stratified according to duration of illness, frequency of primary care visits, age and gender. The length of follow-up was 1 year. At the end of the follow-up period, data for 56 patients (13%) were missing. In particular, 16 patients were lost to follow-up in the guidebook group, 17 in the guidebook plus self-help group, and 23 in the control group. These data were imputed using logistic regression. However, GP records were reviewed for 139 of 141 patients in the guidebook group, 131 of 140 in the guidebook plus self-help group, and 134 of 140 in the control group. Blinding was not performed.

Analysis of effectiveness
The analysis of the clinical study was conducted on an intention to treat basis. The primary outcome measure was the number of primary care consultations recorded from the primary care records, and the patients' clinical global impression scores. The global impression scale requires patients to rate two items, the severity of their IBS symptoms and the improvement in symptoms. These were both rated on a 7-point scale (from unbearable to no symptoms for 'severity', and from very much worse to very much improved for 'improvement'). The secondary outcome measures were hospital consultation rates, symptom severity, quality of life scores, and health status (using the GHQ-28 and the SF-36). The patients rated their symptoms using four visual analogue scales representing severity of abdominal pain, abdominal distension, constipation and diarrhoea. Additional questions allowed the authors to identify whether the Rome II criteria for IBS had been fulfilled. Patients completed the IBS-QOL, a disease-specific instrument for measuring quality of life. As for health status, the GHQ-28 is a 28-item measure of general psychological well-being, while the SF-36 has eight sub-scales rating physical function, physical role limitation, mental health, emotional role limitation, social function, energy and vitality, bodily pain and health perceptions.

The baseline comparability of the study groups was not explicitly discussed, but the methods used for randomisation should have ensured comparability among patient groups. A multiple regression analysis was performed using primary and secondary outcomes and patient characteristics as the covariates. Patient characteristics included gender, age, marital status, education, time with condition, family history of IBS, use of information sources, Eysenck neuroticism, extroversion, and psychoticism scores.

Effectiveness results
Over the 1-year time period, there was a reduction of 1.56 primary care visits per patient (95% confidence interval, CI: 1.15 to 1.98; p<0.001) in the guidebook group in comparison with conventional care. This represented a 60% reduction in visits. The guidebook plus self-help group did not add any benefit.

Improvements in the global impression scores were comparable between groups.

Hospital visits were significantly lower for patients in the guidebook group compared with those in the control group. The mean difference was 0.22 visits (95% CI: 0.01 to 0.42) after controlling for baseline levels (40% reduction). The hospital visits in the guidebook plus self-help group were similar to those of the guidebook alone group.

Symptoms and quality of life scores were comparable among the three groups.
In terms of self-care activities, there was evidence that the use of dietary treatments (0.19, 95% CI: 0.01 to 0.37; p=0.035) and relaxation therapy (0.23, 95% CI: 0.06 to 0.41; p=0.011) was higher for the guidebook groups, but no differences were observed with the use of exercise, alternative products, or complementary therapies.

Differences in the GHQ scores did not reach statistical significance.

Most dimensions of the SF-36 were comparable between groups, except for scores for health perceptions and scores on the physical role limitation scale. Scores for health perceptions were significantly higher for patients who received the guidebook (5.11, 95% CI: 0.55 to 9.68; p=0.029), while scores on the physical role limitation scale were significantly improved for those assigned to the self-help group (6.80, 95% CI: 0.85, to 12.75; p=0.026).

Clinical conclusions
The effectiveness analysis showed that, compared with conventional care, the guidebook intervention significantly reduced consultation visits and hospital visits for patients with IBS. The guidebook plus self-help intervention did not confer any additional benefit. The interventions had no significant impact on quality of life and symptoms.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was carried out.

Direct costs
The analysis of the costs was carried out from the perspective of the NHS. It included the costs of GP visits, hospital visits and prescribed drugs. Unit costs were presented for most items, but little information on resource consumption was provided. Resource use was estimated from the actual consumption of resources incurred by the sample of patients in the clinical trial. The costs of GP visits were estimated from the national average cost of a surgery consultation. The cost of a hospital visit reflected the national average cost of a gastroenterology outpatient follow-up attendance with no investigation or procedure. The drug costs were estimated using the British National Formulary. Average dosages were used. Discounting was not relevant as the costs were incurred during 1 year. The price year was not reported, but the unit costs were taken from sources published in 2002 and 2003.

Statistical analysis of costs
The costs were treated deterministically.

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

Currency
UK pounds sterling ( £ ).

Sensitivity analysis
Sensitivity analyses were not performed.

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

Cost results
Over the 1-year study period, the guidebook reduced total resource costs (GP and hospital visits plus prescribed drugs) by approximately 73 per patient (95% CI: 43 to 103; p<0.001) in comparison with the control group (a cost-saving of approximately 40%). In particular, there was a reduction of 31.30 in primary care visits (95% CI: 22.99 to 39.60; p<0.001), a reduction of 15.85 in hospital visits (95% CI: 0.88 to 30.82; p=0.038) and a reduction of 24.23 in prescription drugs (95% CI: 2.33 to 46.12; p=0.031).

Treatment with the guidebook plus self-help intervention had no effect on any aspect of NHS resource consumption. The reduction in costs versus the control group was similar to that found for the guidebook alone group.

**Synthesis of costs and benefits**
A synthesis of the costs and benefits was not relevant as a cost-consequences analysis was carried out.

**Authors’ conclusions**
Compared with conventional care, the introduction of a self-help guidebook significantly reduced consultations and hospital visits and total National Health Service (NHS) costs for patients with irritable bowel syndrome (IBS), although there was only a minimal effect on quality of life and symptom improvement.

**CRD COMMENTARY - Selection of comparators**
The authors justified their choice of the interventions, which were extensively described and were appropriate for the study question. The rationale for the choice of the comparator was clear since it reflected conventional care. You should decide whether they are valid interventions in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness evidence came from a clinical trial, which was appropriate for the study question. The methods of randomisation and stratification of patients were described, and should have reduced the impact of selection bias. The approach used to select the sample of participating patients was reported, as were details of the sample selection process. For example, the number of patients who refused to participate or were excluded from the initial study sample was reported. Strengths of the analysis were the high follow-up rate and the use of regression analysis to assess the potential impact of baseline factors on the clinical estimates. It was unclear whether the study groups were well balanced at baseline. Since the trial was open-label, owing to the nature of the interventions, assessment bias might have affected the results of the study to some extent. Further, the sample size was not justified, which might explain the lack of statistically significant differences between groups in all outcome measures. These issues could limit the internal validity of the analysis.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted. Please refer to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

**Validity of estimate of costs**
The analysis of the costs was consistent with the perspective adopted in the study. Some information on the unit costs was provided, but it could be difficult to replicate the study in other settings since limited data on resource consumption were reported. The sources of the costs were appropriate given the perspective of the NHS. The authors did not investigate the issue of variability in the cost estimates and statistical analyses of the costs were not performed. The authors did not report the price year, which will hinder reflation exercises in other settings.

**Other issues**
The authors did not compare their findings with those from other studies. They also did not explicitly address the issue of the generalisability of the study results to other settings. Sensitivity analyses were not carried out, which might limit
the external validity of the analysis. The authors noted that the impact of the intervention on patients for whom English was not their first language could not be assessed. Further, since recruitment took place in a primary care setting, patients with more severe disease might have been under-represented.

Implications of the study
The study results support the use of a self-help guidebook as first-line treatment for patients with IBS. Future studies should assess the long-term effects of the guidebook since consultation rates might increase again with time.

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