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INFLAMMATORY BOWEL DISEASE

A randomised controlled trial to assess the effectiveness and cost of a patient orientated self management approach to chronic inflammatory bowel disease

A P Kennedy, E Nelson, D Reeves, G Richardson, C Roberts, A Robinson, A E Rogers, M Sculpher, D G Thompson, the North-West Regional Gastrointestinal Research Group


Over the past six years, we have developed a self management package designed to bridge the gap between the clinicians requirement for continuity of clinical care and patients' requirements for more involvement in disease management. The components of the system have developed are outlined in box 1. The aim of our study was to determine whether this approach could lead to a more appropriate use of health service resources and improve symptoms. The study was designed to expand greatly upon our previously published early report. It was on a far larger scale (700 patients recruited), patient information was more developed, and it was more pragmatic, being administered in a number of randomly selected hospitals throughout a region rather than one enthusiastic unit.

We used inflammatory bowel disease (IBD) as a suitable example of a chronic disease to test our approach. IBD (Crohn’s disease and ulcerative colitis) affects approximately 175 000 people in the UK (symptoms include bloody diarrhoea, abdominal pain, and weight loss, and follow a relapsing course with periods of remission). The aetiology is unknown and medical treatment is ameliorative rather than curative; many patients need maintenance treatment with drugs whose dose varies according to disease severity. Although recently developed national management guidelines state...
that patients with IBD should be provided with information about treatment options. Recent surveys reveal that patients still feel insufficiently informed and want greater involvement in their treatment.

**METHODS**

The study design was a multicentre trial with randomisation by treatment centre (cluster randomisation). This method was chosen to avoid the risks of contamination within centres, as staff training, an essential part of the intervention, could only be delivered to entire clinical teams. All 24 district hospitals in the North West of England (population 6.7 million; UK census data 2002) with gastroenterology departments were approached and 19 agreed to participate (of the other five sites, including one teaching hospital, three failed to reply and two were already engaged in IBD research and declined to participate). The 19 hospitals (seven teaching hospitals and 12 non-teaching hospitals) were then randomly allocated either to continue to provide treatment as usual (10 sites) or to deliver the self management programme to eligible patients attending the outpatient clinics (nine sites). At the time of recruitment, 15 centres had a policy of following up all patients with IBD on a long term basis (six randomised to intervention), two sites discharged patients when their symptoms had been quiescent for more than one year (both randomised to intervention), and at two sites there was no consistent follow up policy (one randomised to intervention).

The project was presented to and approved by the North West region multicentre research ethics committee (MREC 98/8/23).

**Patients**

Eligible patients had established ulcerative colitis or Crohn’s disease, were over the age of 16 years, were able to write English, and were attending a follow up clinic. Patients were recruited during a 13 month period (July 1999–August 2000) and followed for 12 months. The trial ended 12 months after the last patient entered the study.

**The intervention**

Clinicians in the intervention group of hospitals received a two hour training session in “patient centred consultations in gastroenterology”. Training took place after site randomisation and before recruitment of patients and aimed to fully

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**Box 1 Components of the intervention**

- (a) Provision of a patient guidebook containing a combination of lay and traditional evidence based knowledge (guidebooks for ulcerative colitis and Crohn’s disease were developed with patients prior to the study). The full colour pocket sized guidebooks contained information about investigation, treatment, and self management of IBD and indicated areas where patient choice might influence treatment decisions. A section was included for patients to record personal details and the negotiated self management plan was placed in the guidebook for easy reference.

- (b) Guided self management—a written self management plan to which patients can refer when making decisions about treatment and the need for service contact.

- (c) A patient centred approach to care provided by trained clinicians.

- (d) Direct access to services, enabling patients to self refer based on their own evaluation of need.

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**Data collection**

Demographic data and details of illness duration and severity were collected from all patients. The inflammatory bowel disease questionnaire (IBDQ) was used at the start and end of the trial to measure disease specific quality of life. Anxiety and depression was scored using the hospital anxiety and depression scale (HADS). Patient enablement was measured after the initial consultation using the patient enablement instrument (PEI). Satisfaction was measured using the consultation satisfaction questionnaire after the initial consultation. Patients provided an estimate of the number of general practitioner visits on the entrance and exit questionnaires. Medical records were examined to record both IBD and IBD related outpatient visits during the study year and preceding year; drug treatments, number of investigations, and number of hospitalisations during the study were also noted.

**Healthcare resource use**

Health service resource use was determined using both patient diary data (for general practitioner and hospital visits) and hospital records data for each patient. Details of how costs were estimated and analysed are available from other sources.

**Sample size and recruitment**

Analysis was performed on an intention to treat basis. The power calculation was based on the IBDQ which is made up of 32 items each recorded on a seven point scale, with higher scores representing improved quality of life. A 1 point improvement on a quarter of items would increase the IBDQ score by 8 points. With an estimated within treatment arm standard deviation of 25 and an intraclass correlation coefficient (ICC) of 0.02 (the upper 95% confidence limit of the ICC from an unpublished study by one of the authors, AR), a trial with eight treatment centres in each arm (16 sites) and 40 patients per treatment centre (640) would have a power of 81% to detect such a difference at a 0.05 significance level.
365 completed entrance questionnaire: 391 had data extracted from hospital notes
6 hospital notes not available
89 did not return exit questionnaire
308 completed exit questionnaire (includes 8 who did not return entrance questionnaire)

19 hospitals sites randomised
10 control sites
24 potential hospital sites

2 declined to participate
3 failed to reply
9 intervention sites

389 eligible patients identified
116 not entered: 84 declined to give consent
32 withdrawn by consultant before consent
37 did not return questionnaire

519 eligible patients identified
403 entered into study
6 withdrew from study during the year

365 completed entrance questionnaire: 391 had data extracted from hospital notes
6 hospital notes not available
89 did not return exit questionnaire
308 completed exit questionnaire (includes 8 who did not return entrance questionnaire)

369 not entered: 50 did not return questionnaire
16 withdrawn by consultant
11 did not return questionnaire

270 completed entrance questionnaire: 292 had data extracted from hospital notes
4 hospital notes not available
53 did not return exit questionnaire
243 completed exit questionnaire (includes 8 who did not return entrance questionnaire)

The main analyses were conducted using the Survey procedures in STATA version 7. These procedures are based on theoretical assumptions specific to clustered survey data. Hospital was designated as the cluster variable and robust estimates of variance adopted. Continuous and count variables were analysed by linear regression and binary variables by logistic regression. One variable, general practitioner visits, was in ordered categories of unequal range (no visits, 1, 2, 3–5, 6–10, 11 visits or more) and was analysed by ordered logistic regression. To adjust for missing exit questionnaires, logistic regression was used to estimate the probability of questionnaire return on the basis of hospital and patient characteristics. The inverse of these probabilities was then assigned to individual cases as weights in the main analysis. Where data were skewed, bootstrapping (using 10 000 repetitions and percentile confidence intervals (CI)) was used to confirm the statistical significance of the result.

Qualitative interviews were undertaken to obtain an in-depth understanding of both patients’ and consultants’ experience of the intervention and to focus on the processes underlying the outcomes of the trial. All consultants at the intervention sites were interviewed and 28 patients were purposefully selected on the basis of responses in the exit questionnaires to represent success (n = 17) or failure (n = 11) of the intervention.
RESULTS

Figure 1 shows the recruitment profile. A total of 908 patients (519 control v 389 intervention) met the eligibility criteria for the study; 700 (403 (78%) v 297 (76%)) consented to enter the study, of whom 635 (365 (70% of those eligible) v 270 (69%)) provided baseline questionnaire data. These values show that recruitment and baseline questionnaire return rates were very similar for both groups, and were reasonably high. The mean number of eligible patients per site was larger during the trial than before, but not significantly so (Mann-Whitney U test comparing eligibility rates for intervention v control sites; p = 0.19). Table 1 shows the patient characteristics which were very similar for both groups, but there was a difference in the national prevalence pattern, with 63% having ulcerative colitis, reflecting the national distribution of IBD.

Table 2 shows that neither IBDQ scores (difference 1.94 (95% CI −3.27 to 7.15); p = 0.45) nor HADS scores (difference −0.35 (95% CI −1.21 to 0.51); p = 0.40) differed appreciably between the two groups at the end of the trial (even after adjustment for baseline score). Immediately after the initial consultation, the two groups were not significantly different with respect to satisfaction with the consultation but after the patient centred session, the intervention group reported a higher enablement score (difference 0.90 (95% CI 0.12–1.68); p = 0.026).

The number of self-reported disease relapses during the year differed between groups (difference −0.36 (95% CI −0.63 to −0.09); p = 0.013), with the intervention group reporting on average 16% fewer relapses.

More patients at intervention centres self referred for at least one appointment (43% compared with 22% in control centres) (p<0.001). No difference was found (p = 0.47) between the groups with regard to general practitioner appointments during the trial, after controlling for frequency prior to the trial, along with other factors: 78% of the control group reported fewer than three general practitioner visits for IBD compared with 82% of the intervention group.

Data obtained from the medical records showed no difference between the two groups in the percentage of patients receiving corticosteroid treatment (48.6% in the control group and 52.5% in the intervention group).

After completion of the trial, 74% of patients in the intervention arm stated a preference to continue self management.

Outcome measures

Hospital appointments

The number of kept appointments reduced by approximately one third in the intervention group compared with the control group (difference −1.04 (95% CI −1.43 to −0.65); p<0.001) (Figure 1), from 3.0 to 1.9 for the intervention group and from 3.1 to 3.0 for the control group.

The mean number of clinic non-attendances per person during the trial was also lower for the intervention group (difference −0.08 (95% CI −0.15 to −0.01); p = 0.034), even after adjustment for number of non-attendances in the prettrial year. For both groups, non-attendance increased slightly (from a mean of 0.07 to 0.09 for the intervention group and from 0.13 to 0.22 for the controls).

Secondary analysis was undertaken for the group of intervention patients only, to examine relationships between those outcomes that had been found to be significantly (p<0.05) affected by the intervention and a number of

Questionnaire data

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Intervention subgroup analysis

Secondary analysis was undertaken for the group of intervention patients only, to examine relationships between those outcomes that had been found to be significantly (p<0.05) affected by the intervention and a number of
DISCUSSION

IBD is a condition well suited for guided patient self management; it is chronic with unpredictable relapses, therapy is required quickly when relapse occurs, and routine follow up visits rarely coincide with relapse. We have now shown that the great majority of IBD patients are both willing and able to self manage their condition, achieve benefit from so doing, and can reduce their use of health services.

We hypothesised that the initial patient centred consultation would improve patients’ ability to self manage and use the PEI as an indicator of enablement. The PEI has not previously been used in a specialist care setting but enablement has been proposed as an alternative outcome to satisfaction.27 Our findings indicate that the initial patient centred consultation left patients feeling more enabled.

**Table 2** Summary of results

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Control group</th>
<th>Intervention group</th>
<th>Coefficient (SEM) method*</th>
<th>95% CI</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcomes from hospital records</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No of kept appointments during trial</td>
<td>364 (2.55)</td>
<td>274 (1.92)</td>
<td>-1.04 (0.19) R</td>
<td>-1.43 to -0.65 &lt; 0.001</td>
<td></td>
</tr>
<tr>
<td>No of DNAs during trial</td>
<td>364 (0.78)</td>
<td>274 (0.34)</td>
<td>-0.08 (0.03) R</td>
<td>-0.15 to -0.01 0.034</td>
<td></td>
</tr>
<tr>
<td>Percentage of patients who DNA*</td>
<td>364 (12.1%)</td>
<td>274 (8.0%)</td>
<td>0.66 (0.25) L</td>
<td>0.30 to 1.47 0.29</td>
<td></td>
</tr>
<tr>
<td>Outcomes from entrance questionnaire</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enablement (after initial consultation)**</td>
<td>352 (3.9)</td>
<td>260 (4.3)</td>
<td>0.90 (0.37) R</td>
<td>0.12 to 1.68 0.026</td>
<td></td>
</tr>
<tr>
<td>Satisfaction with initial consultation**</td>
<td>335 (12.1)</td>
<td>260 (12.0)</td>
<td>3.47 (1.95) R</td>
<td>-0.62 to 7.56 0.09</td>
<td></td>
</tr>
<tr>
<td>Outcomes from exit questionnaire</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IBDQ†</td>
<td>296 (37.5)</td>
<td>236 (36.6)</td>
<td>1.94 (2.48) R</td>
<td>-3.27 to 7.15 0.45</td>
<td></td>
</tr>
<tr>
<td>HADS†</td>
<td>306 (7.6)</td>
<td>242 (11.7)</td>
<td>-0.35 (0.41) R</td>
<td>-1.21 to 0.51 0.40</td>
<td></td>
</tr>
<tr>
<td>No of reported relapses during trial</td>
<td>246 (2.2)</td>
<td>206 (1.8)</td>
<td>-0.36 (0.13) R</td>
<td>-0.63 to -0.09 0.013</td>
<td></td>
</tr>
<tr>
<td>Frequency of GP visits during trial (%)</td>
<td>288 (78.5%)</td>
<td>232 (81.9%)</td>
<td>1.17 (0.24) O</td>
<td>0.75 to 1.81 0.47</td>
<td></td>
</tr>
<tr>
<td>No of DNAs during trial</td>
<td>246 (2.2)</td>
<td>206 (1.8)</td>
<td>-0.36 (0.13) R</td>
<td>-0.63 to -0.09 0.013</td>
<td></td>
</tr>
<tr>
<td>% patients making appointment for themselves (excluding those with no appointments)**</td>
<td>250 (22.0%)</td>
<td>144 (43.1%)</td>
<td>2.70 (0.65) L</td>
<td>1.63 to 4.46 0.001</td>
<td></td>
</tr>
</tbody>
</table>

DNA. did not attend for clinic appointment; IBDQ, inflammatory bowel disease questionnaire; HADS, hospital anxiety and depression scale; 95% CI, 95% confidence interval.

*Coefficients and standard errors are adjusted for covariates. For linear regressions (R), the coefficient is the adjusted mean difference between control and intervention groups; for logistic and ordered logistic regressions (L and O), the adjusted odds ratio.

†Frequency of general practitioner (GP) visits is presented here for convenience as a percentage but the underlying data entered into the multivariable analysis were on an ordinal scale (no visits, 1, 2, 3–5, 6–10, 11 visits or more).

‡Adjusted for appointments kept in pre-trial year, entrance IBDQ, sex, age, and duration of illness.

§Adjusted for percentage who DNA in the pre-trial year, appointments kept in the previous year, entrance IBDQ, sex, age, and duration of illness.

**Adjusted for appointments kept in the pre-trial year, appointments kept in the previous year, entrance IBDQ, sex, age, and duration of illness.

††Adjusted for entrance IBDQ, sex, age, duration of illness, and diagnosis.

‡‡Adjusted for entrance IBDQ, sex, age, duration of illness, and diagnosis.

### Qualitative analysis

The in-depth interviews gave an insight into the different components of our approach and helped to indicate which parts of the intervention were of most use. In particular, we found that the guidebooks were well received by both patients and clinicians while the intervention itself was stated to have clarified responsibilities and to have provided confidence in symptom management. The analysis does suggest that the approach may not be suitable for those with multiple social problems.
Because enablement was only measured at the initial consultation, we cannot say anything about longer term effects on enablement but the information obtained at the qualitative interviews indicated that while in general all patients enjoyed a good doctor-patient relationship, negotiation of a self management plan further clarified treatment options and enhanced confidence in recognising and treating disease relapse for the entire one year trial period. Using data on relapses obtained from patient diaries (kept by all patients in the trial), we suspect that the reduction in reported relapses by the intervention group is due to patients changing their definition of a relapse following discussion with consultants.

Findings from the subgroup analysis of intervention patients included: lack of a significant influence of education level on any outcome; that those reporting being given open access had fewer total appointments and made more appointments for themselves; and outcomes were no different for patients who reported a self management plan compared with those who did not. A caveat to the finding on the lack of effect of self management plans is that the variable may reflect patients’ understanding and memory of what information they were given as much as the actual possession of written plans.

**Limitations of the trial**

There were minor pre-trial differences in discharge policies between the centres; in particular, the two sites where there was a policy to discharge patients with quiescent disease were both randomised to the intervention group. This however would have biased the trial outcome in favour of “no effect” because if patients in remission are discharged, there will be more patients with active disease at the clinics, and it was expected that those with quiescent disease would be most likely to benefit from the intervention. It is of interest to note, however, that despite these discharge policy differences, we found no centre differences in patient characteristics at the beginning of the trial.

Our study found that uptake of self management was dependent on the hospital centre delivering the intervention. As this was a pragmatic trial of a complex intervention delivered through a diverse group of hospital specialists in different centres, it is perhaps not surprising that not all eligible patients received the full intervention. The most likely explanation for this variation in compliance between centres is variation in degree of engagement by consultants in the principles of patient centred self management. In post study interviews we conducted, some consultants expressed strong ideas about who was suitable for the intervention and were reluctant to give patients more control. However, while we recognise that there are a small number for whom this approach is unsuitable, it seems equally true that most patients have a right to decide how much they want to take responsibility for self management at different times during their illness.

The initial time burden of patient education was also reported by some clinicians to be the limiting factor in whether or not the intervention was delivered in clinic. Overall however, our study has demonstrated that the greater time taken to introduce patients to self management is more than offset by a reduction in the number of outpatient follow up visits, a benefit which would be expected to steadily increase with time.

**Strengths of the trial**

A key factor in the success of self management is known to be provision of relevant written information. However, in IBD, most available information has been shown to be of limited utility in supporting shared decision making, being predominantly biomedical, rather than patient, focused. Indeed, a recent study found that some IBD related information actually worsened quality of life, the information was irrelevant to patients’ needs and impossible to understand without reinforcement by health professionals. Our information, in contrast, was designed in close collaboration with patients and contained lay experiences of living with chronic disease, has been found to be both relevant and supportive.

Patients also reported that self referral to clinics improved their ability to self manage and the post-study interviews with clinicians revealed evidence that patient self referrals were appropriate. Some however were concerned that patients might avoid contacting the hospital and thereby put themselves at risk. While we found no evidence for this, such concern could be addressed by greater clarification of criteria for self referral by clinicians.

A further important finding was that self management reduced patient cost, a benefit primarily driven by reduction in both outpatient and inpatient hospital contacts. Although the absolute cost reduction per patient per year was relatively small (£148), given the prevalence of IBD (200 per 100 000), savings for an entire healthcare system would be enormous, probably in the region of £20 million a year in the UK. If more chronic diseases were managed in the same way, savings would be considerably greater.

In conclusion, adoption of guided self management was generally popular both with patients and clinicians, reduced use of hospital services without burden to primary care, and increased quality of care without an adverse effect on disease control at the same time as reducing cost. More widespread adoption of this programme for patients with IBD and other chronic medical disorders, particularly those with relapsing remitting patterns, now seems indicated.

**ACKNOWLEDGEMENTS**

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**APPENDIX**

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