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

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Objectives: We developed a patient centred approach to chronic disease self management by providing information designed to promote patient choice. We then conducted a randomised controlled trial of the approach in inflammatory bowel disease (IBD) to assess whether it could alter clinical outcome and affect health service use.

Design: A multicentre cluster randomised controlled trial.

Setting: The trial was conducted in the outpatient departments of 19 hospitals with randomisation by treatment centre, 10 control sites, and nine intervention sites. For patients at intervention sites, an individual self management plan was negotiated and written information provided.

Participants: A total of 700 patients with established inflammatory bowel disease were recruited.

Main outcome measures: Main outcome measures recorded at one year were: quality of life, health service resource use, and patient satisfaction. Secondary outcomes included measures of enablement—confidence to cope with the condition.

Results: One year following the intervention, self managing patients had made fewer hospital visits (difference −1.04 (95% confidence interval [CI] −1.43 to −0.65); p<0.001) without increase in the number of primary care visits, and quality of life was maintained without evidence of anxiety about the programme. The two groups were similar with respect to satisfaction with consultations. Immediately after the initial consultation, those who had undergone self management training reported greater confidence in being able to cope with their condition (difference 0.90 (95% CI 0.12–1.68); p<0.03).

Conclusions: Adoption of this approach for the management of chronic disease such as IBD in the NHS and other managed health care organisations would considerably reduce health provision costs and benefit disease control.

Chronic diseases are disruptive for patients and place considerable demands on health service costs and manpower. In the UK, most patients with such disorders rely on hospital-based services for treatment which have traditionally tended to provide little or no patient involvement and only limited support for disease related problems between hospital visits. As most chronic diseases follow an unpredictable clinical course, fixed appointment systems rarely provide coincidence of attendance and disease relapse, which results in both high non-attendance rates (approximately 12% across all specialties1) and inadequate access for those in need of urgent attention. An additional dilemma in the management of chronic diseases is that on the one hand, patients are increasingly demanding greater autonomy while on the other, health professionals are anxious about losing control of patients in their care. In response, there has been increasing recognition that self management constitutes an important aspect of coping with long term illness.2 In some instances, self care approaches have been incorporated into disease management through schemes which involve a development of shared guidelines designed to treat episodes of disease activity and to alleviate symptoms.3,4 Self management plans provide patients with a framework within which to understand their disease and a basis for discussion of therapeutic options. Self management is based on the premise that provision of good quality patient information empowers patients to be more involved in their care,5 and evidence is accumulating to show that patient education improves disease control in chronic illness.6

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.6 The components of the system we 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.4 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 UK7 (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 guidelines8,9,10 state...
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.

that patients with IBD should be provided with information on 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 engage the specialists in the trial and to provide them with the basic skills needed to carry out the intervention. Training encompassed the principles of patient centred medicine advocated by Stewart and colleagues which were adapted and applied to self management of IBD. An expert in postgraduate medical education led the sessions using role play and video feedback.

After commencement of the study, the first 38 eligible patients who gave informed written consent were recruited from each of the 19 sites (mean recruitment period per site 8 months (range 3–13)). When the target number of 38 patients was reached, recruitment was stopped in that centre. Patients at control sites continued to receive the management process deemed appropriate by the hospital specialist. Those at intervention sites went on to participate in a patient centred consultation conducted by a clinician during which a self management plan was negotiated and written into the guidebook. Patients were instructed to telephone a specified number if they felt an unscheduled appointment was necessary, according to the circumstances listed in the guidebook. Patients were not given access to on demand colonoscopies.

As can be seen from box 1, there were four components to the intervention which were delivered as deemed appropriate to the individual’s condition by the consultants at the intervention sites. It was recognised that giving the full intervention might not be possible for all patients: in particular, those with active uncontrolled disease at recruitment for whom an effective treatment regimen had yet to be established might not be given a written self management plan straight away and might still require fixed appointments as well as being given open access for self referral.

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
The results of the multivariate analyses of the outcomes are summarised in table 2. For each outcome, a set of covariates to be controlled for was chosen on theoretical grounds prior to any analysis. The covariates used in each analysis are listed in table 2.

Three outcome measures were constructed from medical records: number of appointments kept during the trial year; number of made appointments not attended; and percentage of patients who failed to attend at least once. The records also allowed comparative figures to be derived for the pre-trial year. When computing these outcome measures, the recruitment appointment was excluded, as it would be inappropriate to class this as either a pre-trial or in-trial appointment. The pre-trial period is therefore taken as the 364 days prior to the recruitment date and the in-trial period as the 364 days following recruitment.

Significance level. In the event, 19 sites signed up to the study and therefore it was decided to aim for 38 patients per site (722 in total), which gives 80% power even after allowing for 20% withdrawals or missing data.

Outcomes derive from each patient’s hospital medical record, the entrance questionnaire (completed following recruitment), and the exit questionnaire. Sample sizes for these outcomes vary depending on the data source and as a consequence of missing values.

**Statistical methods**

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 for control than for test sites (51.9 v 43.2) but not significantly so (Mann-Whitney U test comparing eligibility numbers at intervention v test sites; p = 0.19). Table 1 shows the patient characteristics which were very similar for both groups: 63% had ulcerative colitis, reflecting the national prevalence pattern,9 and 25% had active disease at entry to the study, defined pragmatically by the patient. Medical records showed that 31% were on systemic glucocorticosteroids and 17% were on immunosuppressants at baseline.

It was noted that some consultants withdrew patients from the trial before their consent was obtained. At one year, completed exit questionnaires were available for 551 patients. Questionnaire data 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 −0.14 (95% CI −0.43 to −0.65); p<0.001 (table 2), 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 pre-trial 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).

Table 1 Demographic characteristics of the 635 patients at baseline

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Control</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Range</td>
<td>17–86</td>
<td>18–81</td>
</tr>
<tr>
<td>Sex (n (%))</td>
<td>Male</td>
<td>157 (43)</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>208 (57)</td>
</tr>
<tr>
<td>Work status (n (%))</td>
<td>In work</td>
<td>211 (57.8)</td>
</tr>
<tr>
<td></td>
<td>Retired</td>
<td>81 (22.2)</td>
</tr>
<tr>
<td></td>
<td>Long term sickness</td>
<td>9 (2.5)</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>64 (17.6)</td>
</tr>
<tr>
<td>Marital status (n (%))</td>
<td>Married/cohabiting</td>
<td>222 (60.8)</td>
</tr>
<tr>
<td>Education (n (%))</td>
<td>Continued after 16 y</td>
<td>165 (45.2)</td>
</tr>
<tr>
<td></td>
<td>Degree or professional qualification</td>
<td>99 (27.1)</td>
</tr>
<tr>
<td>Disease type (n (%))</td>
<td>Ulcerative colitis</td>
<td>226 (61.9)</td>
</tr>
<tr>
<td></td>
<td>Crohn’s disease</td>
<td>139 (38.1)</td>
</tr>
<tr>
<td></td>
<td>Missing</td>
<td>—</td>
</tr>
<tr>
<td>Activity at baseline (n (%))</td>
<td>Active</td>
<td>85 (23.3)</td>
</tr>
<tr>
<td></td>
<td>Relapse in past 18 months</td>
<td>196 (53.7)</td>
</tr>
<tr>
<td></td>
<td>In remission—no flare ups in past 18 months</td>
<td>58 (15.9)</td>
</tr>
<tr>
<td></td>
<td>Missing</td>
<td>26 (7.1)</td>
</tr>
<tr>
<td>Duration of illness (n (%))</td>
<td>0–2 y</td>
<td>86 (23.6)</td>
</tr>
<tr>
<td></td>
<td>3–9 y</td>
<td>141 (38.7)</td>
</tr>
<tr>
<td></td>
<td>10 y or longer</td>
<td>137 (37.7)</td>
</tr>
<tr>
<td>Baseline health status measures (n (%))</td>
<td>Disease specific quality of life value (mean (SD))</td>
<td>165.4 (37.4)*</td>
</tr>
<tr>
<td></td>
<td>Anxiety and depression score (mean (SD))</td>
<td>12.2 (7.5)‡</td>
</tr>
</tbody>
</table>

*n = 358; †n = 262; ‡n = 364; §n = 265.
patient characteristics: IBDQ scores at baseline; disease duration; diagnosis (ulcerative colitis or Crohn’s disease); sex; age; and level of education (left education at 16 years; stayed beyond 16 years; gained degree or professional qualification). Two further variables were included as indicators of the extent patients reported (at the end of the trial) their consultant had engaged them in the intervention: whether or not the patient said they were given open access to appointments; and whether or not they said they were provided with a self management plan (the percentage of patients per centre saying they had a plan ranged from 14% to 61% (mean 43%)). For each outcome, a backwards stepwise linear (or logistic regression) regression was run using this set of predictors while controlling for the values of the outcome at baseline.

This analysis found that the number of appointments kept by intervention patients during the trial was unaffected by any of the patient characteristics (p > 0.05 in all cases) but was reduced by an average of 0.44 consultations for patients who reported being given open access compared with those who did not (p = 0.033). The extent to which patients made appointments for themselves was also—not surprisingly—related to being given open access (p = 0.023). Younger patients more frequently made appointments for themselves (p = 0.002), even though younger patients were no more likely to be given open access (logistic regression; p = 0.08). The only factor found to be related to “did not attend for clinic appointment (DNAs)” was IBDQ score, such that patients with higher quality of life scores at baseline were slightly less likely to DNA (p = 0.036). The frequency of relapses was also lower for patients with higher initial quality of life scores (p = 0.010). Feelings of enablement after the initial consultation demonstrated a wider range of associations, with reported enablement being higher for women (p = 0.005), for older people (p = 0.006), for more recently diagnosed patients (p = 0.045), and for those with higher initial IBDQ scores (p = 0.026).

Hospital centre effect before trial
To examine the extent to which hospitals varied initially in terms of patient outcome measures, ICCs were computed to indicate how strongly patient outcomes were clustered within centres during the year prior to the trial. The results revealed low ICCs with respect to IBDQ (0.033) and HADS (0.030) scores, DNAs (0.047), and relapses (0.054). There was some variation between centres with respect to numbers of hospital appointments, where the ICC was 0.109.

Qualitative analysis
The indepth 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.

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.21 Our findings indicate that the initial patient centred consultation left patients feeling more enabled.
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\textsuperscript{18}), we suspect that the reduction in reported relapses is due to patients changing their definition of a relapse following discussion with colleagues. 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.\textsuperscript{22} However, in IBD, most available information has been shown to be of limited utility in supporting shared decision making, being predominantly biomedically, rather than patient, focused.\textsuperscript{23} Indeed, a recent study found that some IBD related information actually worsened quality of life,\textsuperscript{24} 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.\textsuperscript{25}

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),\textsuperscript{26} given the prevalence of IBD (200 per 100 000), savings for an entire healthcare system would be enormous, probably in the range 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.

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APPENDIX

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