

A randomised controlled trial to assess the impact of a package comprising a patient-orientated, evidence-based self-help guidebook and patient-centred consultations on disease management and satisfaction in inflammatory bowel disease

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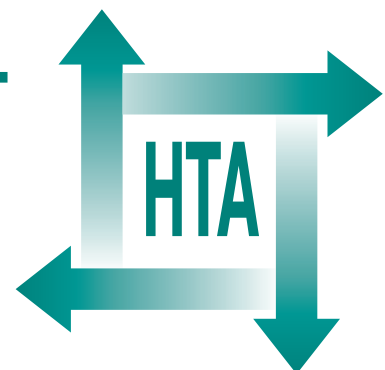


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Declared competing interests of authors: none

Published October 2003

This report should be referenced as follows:

Kennedy A, Nelson E, Reeves D, Richardson G, Roberts C, Robinson A, et al. A randomised controlled trial to assess the impact of a package comprising a patient-orientated, evidence-based self-help guidebook and patient-centred consultations on disease management and satisfaction in inflammatory bowel disease. *Health Technol Assess* 2003;7(28).

Health Technology Assessment is indexed in *Index Medicus/MEDLINE* and *Excerpta Medica/EMBASE*.

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The research reported in this monograph was funded as project number 96/11/02.

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ISSN 1366-5278

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Published by Gray Publishing, Tunbridge Wells, Kent, on behalf of NCCHTA.
Printed on acid-free paper in the UK by St Edmundsbury Press Ltd, Bury St Edmunds, Suffolk.



Abstract

A randomised controlled trial to assess the impact of a package comprising a patient-orientated, evidence-based self-help guidebook and patient-centred consultations on disease management and satisfaction in inflammatory bowel disease

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Objectives: To determine if a whole systems approach to self-management improves clinical outcomes and leads to cost-effective use of NHS services.

Design: Nineteen hospitals were randomised to 10 control sites and nine intervention sites. Consultants from intervention sites received training in patient-centred care before recruitment and introduced the intervention to eligible patients. Patients at the control sites were recruited and went on to have an ordinary consultation. Qualitative interviews were undertaken to obtain an in-depth understanding of patients' and consultants' experience of the intervention.

Setting: Follow-up outpatient clinics at 19 hospitals in the north-west of England.

Participants: Seven hundred patients (297 at intervention sites and 403 at control sites) with established ulcerative colitis or Crohn's disease, aged 16 years and over, and able to write in English.

Interventions: Consultants were trained to provide a patient-centred approach to care. Guidebooks on ulcerative colitis and Crohn's disease were developed with patients prior to the study. Patients prepared a written self-management plan and self-referred to services based on a self-evaluation of their need for advice.

Main outcome measures: Rates of hospital outpatient consultation, quality of life (QoL) and acceptability to patients. Health service resource use and assessed cost effectiveness using the EQ-5D.

Results: After 1 year, the intervention resulted in fewer hospital visits, without change in the number of primary care visits. Patients felt more able to cope with their condition. The intervention produced no reduction in QoL and did not raise anxiety. The intervention group reported fewer symptom relapses; 74% of patients in the intervention group indicated a preference to continue the system. Qualitative results showed the guidebook was effective but organisational limitations constrained patient-centred aspects of the intervention for some. Cost-effectiveness analyses favoured self-management over standard care.

Conclusions: Further use of this method in chronic disease management seems likely to improve overall patient satisfaction and reduce health expenditure without evidence of adverse effect on disease control. Further attention needs to be given to self-referral and access arrangements and a re-distribution of control to patients through increased adherence to patient-centred norms on the part of consultants. Future research is recommended to evaluate the operating systems within secondary and primary care that would allow self-managers to self-refer and to keep them informed of new treatments, also to explore models for training health professionals in self-care methods, to study long-term effects of self-management in chronic disease and to transfer this approach to other chronic conditions.



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List of abbreviations

ANOVA	analysis of variance	MRC	Medical Research Council
BNF	British National Formulary	MREC	Multi-centre Research Ethics Committee
CCA	complete case-analysis	NACC	National Association for Colitis and Crohn's disease
CD	Crohn's disease	NeLH	National Electronic Library for Health
CEAC	cost-effectiveness acceptability curve	NMB	net monetary benefit
CHIQ	Centre for Health Information Quality	NS	not satisfied
CI	confidence interval	NUD*IST	non-numerical unstructured data with indexing, searching and theorising (qualitative data analysis)
CONSORT	Consolidated Standards of Reporting Trials	PEI	Patient Enablement Instrument
CSQ	Consultation Satisfaction Questionnaire	QALY	quality-adjusted life-year
df	degrees of freedom	QoL	quality of life
DNA	did not attend	S	satisfied
EQ-5D	an instrument to value health from the EuroQol group	SD	standard deviation
HADS	The Hospital Anxiety and Depression Scale	SE	standard error
IBD	inflammatory bowel disease	SF-36	Short Form with 36 Item
IBDQ	Inflammatory Bowel Disease Questionnaire	SMP	self-management plan
ICC	intraclass correlation coefficient	SPSS	Statistical Package for the Social Sciences
ICER	incremental cost-effectiveness ratio	Stata	statistical analysis package
MAR	missing at random	UC	ulcerative colitis
		VS	very satisfied

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.



Executive summary

Objectives

The aim of this study was to determine if a whole systems approach to self-management using a guidebook developed with patients combined with physicians trained in patient-centred care improves clinical outcomes and leads to cost-effective use of NHS services.

Design

The design was a pragmatic cluster trial with randomisation by treatment centre. Nineteen hospitals were randomised to 10 control sites and nine intervention sites. Consultants from intervention sites received training in patient-centred care before recruitment and introduced the intervention to eligible patients. Patients at the control sites were recruited and went on to have an ordinary consultation. Qualitative interviews were undertaken to obtain an in-depth understanding of patients' and consultants' experience of the intervention.

Setting

The study was conducted in follow-up outpatient clinics at 19 hospitals in the north-west of England.

Subjects

A total of 700 patients (297 at intervention sites and 403 at control sites) were recruited who had established ulcerative colitis or Crohn's disease, were aged 16 years and over and able to write in English.

Interventions

The intervention included the following components:

- training consultants to provide a patient-centred approach to care
- provision to patients of an information guidebook; guidebooks on ulcerative colitis and

Crohn's disease were developed with patients prior to the study

- negotiation of a written self-management plan
- improving access to services – patients to self-refer to services based on a self-evaluation of their need for advice.

Main outcome measures

The main outcomes measured were the rates of hospital outpatient consultation, quality of life and acceptability to patients. Other clinical outcomes included anxiety and depression, patient enablement, patient satisfaction, relapse duration and the interval between relapse and treatment. The economic evaluation looked at health service resource use and assessed cost effectiveness using the EQ-5D. Data were obtained at baseline through face-to-face interviews and at 12 months from patient diaries, postal questionnaires and hospital medical records. Processes underlying outcomes were the focus of the qualitative interviews.

Results

After 1 year, the intervention resulted in fewer hospital visits: 1.9 versus 3.0 per year ($p < 0.001$) without change in the number of primary care visits. Patients felt more able to cope with their condition ($p < 0.05$). The intervention produced no reduction in quality of life and did not raise anxiety. The intervention group reported fewer symptom relapses: 1.8 versus 2.2 ($p < 0.01$); 74% of patients in the intervention group indicated a preference to continue the system. Qualitative results showed the guidebook was effective but organisational limitations constrained patient-centred aspects of the intervention for some. Cost-effectiveness analyses favoured self-management over standard care.

Conclusions and implications

More widespread use of this method in chronic disease management seems likely to improve overall patient satisfaction and reduce health expenditure without evidence of adverse effect on

disease control. However, the qualitative data also suggest that further attention needs to be given to self-referral and access arrangements and a re-distribution of control to patients through increased adherence to patient-centred norms on the part of consultants.

Recommendations for future research

Recommendations are to evaluate the effectiveness and efficiency of operating systems within

secondary and primary care which would allow self-managers to self-refer and to keep them informed of new treatments, explore models for training health professionals in methods to promote and support self-care, study long-term effects of self-management in chronic disease, transfer our approach to other chronic conditions and perform a tightly controlled study of whether faster treatment reduces the duration of relapses in inflammatory bowel disease.

Chapter I

Background

Introduction

Long-term medical conditions are disabling and disruptive to daily life for patients and place considerable demands on the health service in terms of costs and use of personnel resources. In the NHS, patients with chronic diseases such as diabetes, arthritis and bowel conditions have traditionally been managed via attendance at specialist outpatient clinics where hospital specialists decide appropriate treatment regimens. Information about chronic conditions in routinely provided care has tended to be prescriptive with little patient input in deciding on treatment or management. However, outside of the hospital environment patients are responsible for managing day-to-day disease-related problems such as fitting in treatment with work, education and family life and coping with the symptoms of the condition, and there is increasing recognition that self-care constitutes an important aspect of the management of long-term illness.¹

It is acknowledged that much of the patient information currently available is of poor quality and fails to support patient choice and participation in the formulation of treatment plans. Moreover, although it is recognised that there is absence of patient access to information that is evidence-based and relevant to their needs, there is evidence that high-quality information increases knowledge and patient satisfaction and there are good guidelines for how to produce quality information.²⁻⁵

There are a variety of guided self-management schemes where patients and healthcare professionals work together to formulate a self-treatment plan that the patient can consult when the disease flares up or for ongoing prevention.⁶⁻⁹

The NHS Plan proposed changes in the roles and responsibilities of both health professionals and patients as a means of supporting self-care initiatives.¹⁰ There is a focus on the need for health professionals to improve communication with patients, provide better information and offer more choice and control over treatment and access to services. Through the Expert Patients Programme,¹¹ which was developed by the government during the

course of this study, it is envisaged that patients will have a greater role to play in their own treatment and will be given opportunities to influence the way in which the NHS works. Support for the introduction of expert patient programmes in the NHS¹² comes from an acknowledgement of the shortcomings of a purely technical, biomedical approach to healthcare (orientated by disease and drug treatment), the need to take account of patients' social circumstances and the value of experiential knowledge in lay health action.

One of the underlying assumptions of arguments for greater patient involvement in chronic disease management is that personal control over aspects of disease management can lead to improved outcomes in terms of quality of life (QoL), reduction in symptomatology and less reliance on formally provided services.¹³ For guided self-management to be successful, a positive patient-physician relationship has been shown to be a key factor.¹⁴⁻¹⁶ Building on the existing established relationships between patients and professionals working within the NHS may be one way of doing this. The paternalistic approach to long-term care where a health professional makes all the decisions about treatment and closely monitors the patient's progress is considered inappropriate for modern healthcare. A different model is one that incorporates the development of increasing partnership working between patients and clinicians. The latter is viewed as more conducive to shared clinical decision-making and disease management because patients with chronic conditions have been shown to find such a relationship more supportive¹⁷ and patients do want to be directly involved in decision-making.¹⁴

In this study, we adopted an approach to guided self-management that provides patients with information in a way which we considered would promote shared decision-making and increase the ability to self-manage. The method also required physicians to modify their approach to patient care by actively developing partnerships for long-term disease management. Key changes in practice included:

1. Provision of high-quality information developed with patients.

2. Easier access to advice and services when necessary.
3. Self-management plans.
4. Patient-centred consultations.

We have termed this a ‘whole systems approach’¹⁸ and have tested the effects of these key changes in practice using inflammatory bowel disease (Crohn’s disease and ulcerative colitis) as an exemplar. We do not know how shared care between patients and practitioners can be best delivered and what the cost implications may be.

Inflammatory bowel disease

The inflammatory bowel diseases (IBDs) include Crohn’s disease and ulcerative colitis; the cause is unknown and current medical treatment is not curative, although surgical removal of the colon and rectum effectively cures ulcerative colitis. Ulcerative colitis is a mucosal inflammation and can involve the colon and rectum. It is characterised by inflammation and ulceration of the bowel wall, which result in the symptoms of bloody diarrhoea, abdominal pain, weight loss, malaise and fever. Crohn’s disease is a transmural inflammation and it can affect any part of the gut from the mouth to the anus, but it is mainly localised to the terminal ileum and colon. It is characterised by diarrhoea, anorexia, weight loss, fever, nausea and pain. Clinical features of Crohn’s disease may include narrowing and obstruction of the bowel and abscess and fistula formation.

IBD follows a course of relapses (flare-ups) of symptoms and periods of remission. The severity of symptoms depends partly on the amount of inflammation present and the extent and region of the bowel affected. IBD may also lead to extra-intestinal complications of eyes, joints, skin and the liver. The cause of IBD is unknown but predisposing factors are thought to include genetic susceptibility, environmental pathogens and possibly diet.¹⁹ Nearly all patients need continuous medication (maintenance treatment), which has to be adjusted if there is a relapse. Patients have an increased risk of needing abdominal surgery.

There are about 175,000 people in the UK with IBD²⁰ and the overall cost to the NHS of treating IBD is estimated to be £75–85 million per year (see Appendix 1).

The study presented here has been informed by literature on the proposed changes to practice:

self-care, guided self-management, patient information, access to services and the likely impact on patients and doctors. Research in the field of self-care in chronic illness has identified ways to change and optimise self-care behaviours. The more intensive self-care programmes have involved patient education and instruction and have been designed to actively support the development of self-care potential. Establishing safe and effective self-care (while there are many definitions of self-care, this study has principally been concerned with self-care related to illness management²¹) has considerable potential for the management of chronic conditions^{1,22,23} and for managing demand in modern healthcare systems.²⁴

Although, from a medical perspective, concerns have been expressed that too much reliance on self-care carries risks and that people will ignore dangerous symptoms or self-medicate with inappropriate medicines, research has shown that there is little validity in such claims. A literature review²⁵ found that self-care is in widespread safe use and that self-care education is generally effective. Elliot-Binns²⁶ studied the effect of lay advice in 500 subjects and found only one case where there was unnecessary delay before seeing a doctor.

Reducing the need for professional input may increase the cost-effectiveness and efficiency of care, reduce ‘inappropriate’ demand and allow clinicians to focus on patients with more severe and complex problems.²⁷ Research suggests that greater involvement in care and increasing feelings of control over illness management have considerable health benefits.^{28–30}

Theories and studies of self-care leading to behavioural change

The current study has been informed by a number of theories and studies about self-care relating to behavioural change. The health belief model^{31,32} suggests that two key factors – personal susceptibility and belief in the benefits of action – influence the likelihood of changing personal health action. A person must feel **personally susceptible** to a disease with serious or severe consequences and **believe** that the benefits of taking a particular course of action outweigh the perceived costs and barriers. The notion of self-efficacy³³ is predicated on people’s belief in their skills and abilities to perform a specific task or adopt a certain behaviour that will lead to a desired outcome. The transtheoretical model of behaviour change³⁴ posits that people change

behaviour through stages: precontemplation, contemplation, preparation, action and maintenance. Consequently, self-care interventions (particularly those founded on computer-based interactive packages) can be designed to move an individual from one stage to the next.

Leventhal and colleagues³⁵ have proposed a self-regulation model that addresses the impact of emotion, the time course of the disease and changes in the perception of threat over time on disease management. The patient is viewed as a problem solver able to assess the risk of the disease and identify what actions to take whilst account is taken of personal factors and the individual's socio-cultural context.

Technologies of self-care

A number of technologies and procedures have been used in the study of illness-related self-care interventions. There is evidence on the effectiveness of professionally produced information packages, such as books or leaflets containing information about the condition or treatment advice on management and dealing with crises,³⁶⁻⁴³ or specific therapeutic techniques (such as problem-solving);⁴⁴ written self-care plans (instructions written by or with a health professional);⁴⁵⁻⁴⁷ credit card instructions (very simplified self-care plan in easy-to-carry format);⁴⁸ audiotape or videotape containing information or instructions about condition or treatment;⁴⁹⁻⁵¹ electronic information sources such as computer-based programs or the Internet;⁵²⁻⁵⁴ patient or professional-mediated support group;⁵⁵⁻⁶⁵ and telephone support.⁶⁶⁻⁶⁹ Additionally, the NHS has recently set up a 24-hour telephone advice line, NHS Direct; one of the aims of this service is to provide advice to support self-care.⁷⁰

Difficulties in overcoming the initial barriers to participation have characterised a number of failures in self-care programmes.⁷¹ Placing self-care at the interface with services was thought to help overcome initial uptake problems by making a connection with the management context with which the patients were familiar.

Guided self-management

There is evidence that healthcare professionals can enable and support patients with chronic diseases to monitor their disease, adjust their treatment in response to changes and identify situations where

medical intervention is advisable.^{30,72,73} Guided self-management involves the provision of a shared set of guidelines containing action plans designed to prevent disease activity and/or to alleviate symptoms. The guidelines are developed by patients and doctors in collaboration and recognise preferences and agreed treatments. The patient decides whether or not to follow any or all of the instructions in response to perceived or measured changes in their health. The benefits are reported to go beyond simple disease control. By providing the patient with a clear set of goals, guided self-management plans also give patients a basis for discussion and negotiation with the health provider and a framework within which to understand their disease.⁴⁶ Structured schemes offering patients a way of participating in the management of chronic conditions have been developed in the fields of diabetes,⁷⁴ asthma,⁷⁵ ulcerative colitis⁷⁶ and arthritis.^{55,64} Such schemes have demonstrated improved outcomes and are cost-effective.

Chronic disease requires long-term ongoing management that involves continuity of care and contact. There is some evidence that people have improved health outcomes when they participate in self-management programmes.^{28,29,76}

The successful implementation of guided self-management requires a mutual acceptance by patient and health professionals of the value of the advocated approach to care,^{72,77} time to explain the practical aspects involved,^{78,79} a willingness to share information freely,⁸⁰ and understanding of the social, psychological and behavioural factors which influence patient concordance.^{17,81} These include patients' knowledge, lifestyle, practical self-management skills, desired goals, interpretation of standards achieved, perceived benefits, severity of disease, locus of control, role of important others and general emotional adjustment.⁸²

Patient information needs and shared decision-making

A frequently unmet patient need identified in studies is for better information about their condition.⁸³⁻⁸⁷ Research suggests that most patient information is of poor quality and of limited utility in supporting shared decision-making and biomedically rather than patient focused.^{88,89} There is a wealth of information available on the World Wide Web and the Internet is an easily accessible source of information for patients, but is

variable in terms of its quality and appropriateness, as follows. It is complicated for both patients and doctors to extract relevant facts.⁹⁰ Three previous studies evaluating the quality of information on vascular surgery,⁹¹ paediatric diarrhoea⁹² and menorrhagia⁵⁴ concluded that the Internet is a poor source of patient-centred information and is characterised by voluminous misinformation. Of particular concern is the challenge for a user without medical knowledge to determine which pages are credible and usable and which should be ignored.⁹² Others report that medical information directed towards patients is at a much higher reading level than the majority of the population. Patients with chronic diseases, particularly those whose symptoms are not well controlled, may be vulnerable to false claims of help or cure.

Evidence-based guidelines have been developed to help in the production and evaluation of high quality information.^{2-4,93-95} The UK-based organisation Centre for Health Information Quality (CHIQ) considers that good-quality patient information comprises three key elements: it should be clearly communicated, evidence-based and involve patients throughout development.⁵ Instruments such as DISCERN⁹⁴ and MICE⁹⁶ have been developed to measure the quality of patient information.

It is apparent that there is a considerable imbalance in the type and quality of information available to professionals and that provided to patients (there is an increasing number of excellent sources of evidence-based information and guidelines for practice for health professionals, for example Cochrane, NICE and Bandolier; <http://www.jr2.ox.ac.uk/bandolier/index.html>). Initiatives in the UK such as the NeLH (National Electronic Library for Health; <http://www.nelh.nhs.uk/>) and NHS Direct have been set up to help address this imbalance. Although from a traditional medical viewpoint, provision of the 'best available' medical information is seen as a counterbalance to the biased and inaccurate information available through other channels and a contribution to self-management decisions, there are areas of uncertainty in medical knowledge and competing sources of knowledge about causation and amelioration. Amongst some patients the views and approaches of alternative practitioners who tend to adopt holistic models of illness are more or equally acceptable to a traditional biomedical approach^{97,98} (studies have shown that those who use alternative medicine are more educated, have

a poor health status and are not dissatisfied with conventional medicine, but want to regain a feeling of 'wellness'). There is also evidence that patients draw on a wide range of 'official' and alternative information sources in managing health problems including information based on the personal experience of managing illness.²⁴ Patients value the views and experiences of others and find such information therapeutic.⁷⁹

Although studies of chronic disease management acknowledge the importance of good information, many show that information alone does not change behaviour or result in increased patient empowerment. Behaviourally orientated patient education has been found to be significantly better than didactic programmes in promoting self-care, for example in diabetes.^{56,58,99,100} A recent review of randomised controlled trials of self-management training in diabetes⁹ found evidence that self-management training was effective in the short-term and that educational interventions that involved patient collaboration were more effective in improving health outcomes than didactic interventions.

Information for people with inflammatory bowel disease

Currently patients get information about their condition from their consultant during regular visits to the outpatient clinic.¹⁰¹ Information sources are *ad hoc* and fragmented and there is a need to be systematic about giving information to patients. Most patients have access to the information booklets and videos produced by drug companies but these fall short of the standards recommended by agencies such as CHIQ.⁵ Patients who join NACC (National Association for Colitis and Crohn's disease, which has 30,000 members) have access to more detailed information. However, not all patients want to join a support group (for which they must pay); a recent study found that 25% of patients attending medical outpatient clinics were members of NACC.¹⁰² At present, available resources are not orientated towards helping individuals make decisions about their treatment.

Over a decade ago, Scholmerich and colleagues¹⁰³ highlighted deficiencies in the provision of information to patients with IBD and subsequent studies have reported that patients are insufficiently informed about their disease^{83,102} and wanted further information, particularly in relation to treatment choice.¹⁰⁴ Guidelines for the management of IBD have been produced by the British Society of Gastroenterology.¹⁰⁵ These state

TABLE 1 Currently available written patient information

Name of producing organisation	Title of leaflets	Number of pages	Clarity of language ensured	Treatment choices explained	Patient involvement		
NACC – Patient support group. Leaflets available on payment to join NACC	Ulcerative colitis	20	Not specified	Yes	NACC members		
	Living with IBD	16					
	Drugs used in IBD						
	The role of diet						
	Medical terms used in IBD						
Astra Pharmaceuticals	Communicating ulcerative colitis	12	Not specified	No	Written by sufferer None specified		
	Ulcerative colitis patient information pack	10 + 5 sheets					
Ferring Pharmaceuticals	Ibd club – The not so rough guide to ibd	Folder with 25 leaflets (2–6 pages) + 20-page record book	Not specified	Yes	None specified		
Pharmacia Limited	Living with ulcerative colitis	20	Not specified	No	None specified		
SmithKline Beecham pharmaceutical company	20 questions about UC	16	Not specified	No	None specified None specified None specified None specified None specified		
	20 questions about proctitis and distal colitis	12					
	Diet Crohn's disease and colitis	12					
	Pregnancy in ulcerative colitis and Crohn's disease	12					
	Surgery in ulcerative colitis and Crohn's disease	12					
Stafford-Miller pharmaceutical company	Ulcerative colitis – about your condition – treatment available – its impact on you – surgical options	2-sided folded pages	Not specified	No No No Yes	None specified		
Digestive Disorders Foundation charitable organisation	Ulcerative colitis and Crohn's disease	16		Not specified		Yes	None specified

that providers should demonstrate responsiveness to the needs of patients, including the provision of written information on treatment options, choice and informed consent.

Most information provided is in the form of leaflets. Apart from the guidebooks we have developed, none provide evidence of significant user involvement in their development (see *Table 1*).

Impact on patients and professionals

Given the extensive use and reliance on formal healthcare by patients, maximising the opportunities presented by user involvement and self-management in practice also requires a recognition of the way in which lay people view and use the NHS, the value they place on contact

with health professionals and information and the limitations of current access arrangements to the health services.²⁴

Self-care has been viewed as an opportunity to take more control over illness, but may also, amongst some people, create anxieties about taking on 'new' responsibilities. If self-management is viewed (correctly or not) as 'the cheap option' and an attempt to offload costs or to reduce access to health professionals,¹⁰⁶ patients may feel that responsibility for care is being dumped on them without consideration of their needs.¹⁰⁷

There have been studies of the attitudes of professional groups towards self-help organisations and materials which suggest that professional resistance to self-care is widespread.^{108,109} Even positive attitudes can conceal professional expectancies of power and control over disease management (e.g. the suggestion that professionals should act as the group leaders during education or training sessions). Concerns among health professionals about the validity of treatments offered, accountability and monitoring and issues of responsibility and litigation differ according to the type of self-care being advocated. Shuval and colleagues found that doctors' views were more favourable concerning specific self-management behaviours (e.g. self-monitoring of blood pressure) than the more general issue of increasing patient independence and questioning of medical authority.¹¹⁰ There may be differences between nurses and doctors in attitudes to provision of social support^{111,112} and who should care for those with chronic illness.¹¹³ Current policy is to increase the responsibilities of nurses, who may be the most appropriate professionals to provide support and advice with self-care to patients.^{18,114}

Patient-centred care

There are a number of reasons why the professional consultation is an appropriate context for developing self-management skills. In recent years there has been a key shift in the medical consultation from being 'doctor-centred' to 'patient-centred'.¹¹⁵ Although the exact definition of patient-centredness varies, it includes consideration of psychological issues, understanding the patient as an individual, sharing control over decision-making and developing a long-term therapeutic relationship between patient and professional.¹¹⁶ Some of the skills required to increase patient involvement and

patient-centredness have already been identified, and include broad professional attitudes (e.g. self-awareness) and specific consultation behaviours (e.g. use of open questions, expressions of empathy). Rather than trying to change the behaviour of patients, Clark and colleagues⁷² studied the impact of training designed to change the way in which physicians educated their asthmatic patients, their rationale being that the practitioner needs to be taught how to form effective partnerships with patients.¹⁵

Increasing patient participation in disease management presupposes a way of informing the patients about their illness. There is growing acceptance of the view that patients need evidence-based information in order to engage and participate in the management of their illness. A willingness to disclose information to patients constitutes an integral component of shared care and management of chronic disease.^{14,80} **Shared care** refers to a disease management partnership between the patient and the doctor and **shared decision-making** refers to "decisions that are shared by doctor and patient and informed by best evidence, not only about risks and benefits but also patient specific characteristics and values".¹¹⁷

A recent study where general practitioners and nurses were trained in patient-centred consulting and use of education materials for people with diabetes^{78,118} found that patients attained better communication with their doctors and greater treatment satisfaction but that clinical outcomes and changes to lifestyle were not significant.

Open access to outpatient clinics

The current system of routine follow-up appointments is centred on hospital and consultant routines. Reasons given by hospital doctors for long-term follow-up in outpatient departments include a perceived need for review of symptoms, medications and blood tests, unwillingness to discharge to primary-care management and a belief that patients expect hospital treatment.¹¹⁹ However, a number of limitations are evident about these current organisational arrangements and a system of fixed appointments is unlikely to coincide with patient attendance during a relapse of the condition. Current practice results in many DNAs (did not attend) at clinics, which also preclude providing urgent appointment slots when patients need them. The most recently available Department of Health statistics show a DNA rate of approximately 12% across all specialities for

follow-up appointments (http://www.doh.gov.uk/hospitalactivity/statistics/2001-02/outpatient_attendances/q2/y00.htm). Graduated access to service (predicated on different levels of response to need) allows patients to access services based on expressed need and reduces the rate of routine fixed appointments when patients are managing their condition adequately themselves;⁷³ this has the potential to reduce NHS resource use.

Telephone advice might provide a needed response to reinforce self-management and may reduce demand for higher level services.¹²⁰ (NHS Direct is a way for patients to access services, which performs a triage function, advice given being graded from advising on self-care actions, or seeking advice from a GP to recommending immediate treatment at the nearest Accident and Emergency centre⁷⁰). Open access to follow-up clinics for IBD has been shown to be effective in two UK studies.^{73,121} In the study reported by Williams and colleagues,¹²¹ responsibility for patient care was transferred back to the GP and rapid access to specialist care was guaranteed when necessary either through the GP or by patients contacting the hospital directly. They found that patients randomised to open access had fewer outpatient appointments, that patients preferred open access and that GPs supported the approach.¹²² Robinson and colleagues⁷³ transferred responsibility of care to patients (guided self-management), who were given instructions as to when they should telephone to make a hospital appointment. Intervention patients were found to make fewer visits to their hospital doctors or their GPs and patients preferred the open access system.

The research design

The use of a complex intervention which involved the interaction effects of several components meant that it was not possible to specify definitively which of the strategies had the greatest or least effect on outcomes.¹²³ At a quantitative level the aim was to measure the combined interactive effect of the components. However, the qualitative aspect of the research design was aimed at complementing the quantitative findings through illuminating the way in which each of the components had worked in practice and how they were perceived by a sub-sample of patients and consultants who had taken part in the trial.

The intervention

We adopted a phased approach to the development of the intervention (see *Box 1*).¹²³

BOX 1

Strategy	Method
Improve information	Provision of a patient guidebook containing information that is relevant, accessible and uses a combination of lay and traditional evidence-based knowledge. Two guidebooks were developed prior to the study, one for patients with ulcerative colitis and one for those with Crohn's disease
Guided self-management	A written self-management plan to be negotiated
Change professional response	Promote flexibility in professional response through a patient-centred approach
Improve access to services	Change access arrangements to health services and use patient-professional contacts as a means of impacting on future utilisation

The strategies used were based on evidence from a number of research projects previously undertaken by the research team. The evidence of the wide range of information sources used by patients to manage health problems ('official', alternative and personal experience²⁴) led us to consider a need for an information source and approach to self-management that is negotiated between patients and health professionals. Given the imbalance in power relationships between patient and professional, we adopted a patient-centred approach that would acknowledge the value to the patient of alternative and lay as well as traditional 'evidence-based' information. Work on establishing whether guided self-management was feasible for people with chronic bowel conditions was funded by the MRC (Medical Research Council).⁷³ A parallel study on the development of effective information for people with IBD was funded by the King's Fund 'Promoting Patient Choice' project and the North West Region NHS Development and Implementation fund.^{79,124}

Intervention strategies

Development of the information

The development of the guidebooks has been reported fully elsewhere.¹²⁴ The content was determined by patients who shared their experiences of living with IBD and identified their information requirements at a series of meetings.¹²⁵ Patients attending these focus groups were recruited from outpatient clinics and through the North-West Regional branches of NACC and

represented the spectrum of age, disease severity and length of illness. Medical information about IBD was obtained by searching MEDLINE and CINAHL to establish evidence-based areas of treatment. Review articles were hand searched for references to original work, and grey literature, including that produced by patient support groups, drug companies and individual clinicians, was reviewed for content and presentational style. All drafts were reviewed by patients and later drafts of the books were reviewed by gastroenterologists, pharmacists and dieticians with an interest in IBD to check for professional acceptability. The end results were two full-colour guidebooks containing six to seven sections with a series of pages highlighting areas of patient choice, and including a separate section for writing down personal details and a guided self-management plan.^{126–128}

Each guidebook contains sections which give details of the areas where patients have a choice in their treatment, and these were pointed out during the initial consultation. The guidebook has two main sections:

1. An information section with an introduction to the disease, details of tests and treatments, information on surgery, facts on pregnancy and contraception and details about surveillance for cancer. In this section areas have been identified in which patient choice is relevant or where knowledge might inform or alter self-management:
 - (a) topical (in the form of suppositories or enemas) versus oral drugs
 - (b) concordance with taking glucocorticosteroids – long-term use of glucocorticosteroids is something which worries this group of patients
 - (c) nutritional therapy (a form of therapy available for treatment of Crohn's disease)
 - (d) timing of surgery and choice of operation
 - (e) whether or not to undergo surveillance for cancer.
2. A record book which contains the following: a section on how their disease was diagnosed; a record of test results; a symptom diary; a food diary; a self-management plan; and instructions on when and how to contact the hospital for an appointment.

Guided self-management

The guidebook can be used as a tool to enable the patient and health professional to work together to develop an individualised plan for safe self-management. A written self-management plan acts

as an *aide-mémoire* to which patients can refer when making decisions about treatment and the need for service contact without consulting a health professional. We have shown in a pilot trial that this approach does not increase morbidity, leads to greater satisfaction as patients prefer self-management and self-referral to conventional follow-up and reduces the number of GP and clinic visits that patients make.⁷³

Changing professional response: a patient-centred approach

The evaluation of the patient guidebook that we developed found that most users place high value on their relationship with professionals and regard them as the most important source of information.⁷⁹ Thus the utility and impact of patient information were thought to be enhanced if professionals were involved in the dissemination of and use of the guidebook jointly with patients.

Patient-centred medicine emphasises a holistic philosophy in interacting with patients and is designed to expand and strengthen physician relationships with patients. We considered that giving a patient-centred consultation would work in a way that emphasised to patients that they were working in a partnership with their doctor.¹⁶

Improved access to services

Allowing and enabling patients to self-refer to services based on a self-evaluation of their need for advice is one of the tenets of self-management. Open access and self-referral are an important aspect of our approach. They allow patients to access services based on expressed need and reduce the rate of routine fixed appointments when patients are managing their condition adequately themselves. We have found that past experience of the use of services impacts on future use and illness management strategies; also, people self-ration and are influenced by perceptions on rationing in the NHS and internalise the norms of organisational arrangements.¹²⁰

Study aims

We have developed evidence-based, patient-orientated guidebooks that inform patients about different treatment options and hypothesise that when used in collaboration with consultants trained both in their use and in patient-centred consultation the following benefits may be achieved:

1. For patients:
 - (a) improved communication with their doctor
 - (b) greater control over their illness and more involvement in decisions about treatment
 - (c) reduced anxiety
 - (d) increased satisfaction with their care
 - (e) improved QoL
 - (f) greater willingness to undertake self-treatment
 - (g) more appropriate use of health services
 - (h) improvement in symptoms.
2. For doctors:
 - (a) better communication with informed patients
 - (b) better care for patients because of improved concordance with shared treatment decisions.
3. For the NHS:
 - (a) more efficient clinics
 - (b) reduced use of services
 - (c) lower treatment costs
 - (d) greater patient satisfaction.

Chapter 2

Methods

Planned study population

The entry criteria for patients were that they should have established ulcerative colitis or Crohn's disease, be over the age of 16 years, be able to write English and be attending follow-up clinics in hospitals in the north-west of England with gastroenterology departments. All hospitals which were able to meet the entrance criteria were approached (apart from six hospitals where a site-controlled trial evaluating the effectiveness of the guidebook had already been undertaken) and consultants were asked to opt into the study before site randomisation took place. Before the study could start, we had to recruit consultants who were willing to participate in the study and be trained in giving patient-centred consultations. A letter was sent to the consultants giving a brief description of the study and asking them if they would like to be involved (see Appendix 2).

The two experimental groups consisted of hospitals randomised to a treatment-as-usual group (control) and hospitals randomised to an experimental group (intervention). Patients in the control group were recruited into the study and received usual care. Consultant teams in the intervention group received training in 'patient-centred consultations' with patients and instructions on how to use the guidebook. Patients in the intervention group were given a copy of the appropriate guidebook by their consultant on entrance to the trial. The consultants instructed patients in how to use the guidebook and worked with them to draw up a self-management plan which was written in the guidebook. Patients in the intervention group were not given routine follow-up appointments but were told they could make an appointment whenever necessary through telephoning a specified number at the hospital.

Ethical approval

The project protocol was given ethical approval by the North West MREC (Multi-centre Research Ethics Committee).

Professional training – changing professional response

The training of consultants in gastroenterology to

consult in a patient-centred style formed the initial stage of the trial. The aims of the training session were twofold: to recruit fully the specialists to the trial and to provide them with the basic skills that they would need to carry out the intervention. The learning techniques of role-play and video-feedback are established methods of developing consultation skills.¹²⁹ Training encompassed the components of patient-centred medicine advocated by Stewart and colleagues¹¹⁵ and related them to self-management of IBD.

1. Exploring the disease and illness experience
 - (a) What are they worried or unhappy about, for example cancer, pregnancy, surgery?
 - (b) Personal and psychological impact of IBD.
 - (c) How to recognise and treat relapses immediately.
 - (d) Recognise situations when help is needed.
2. The whole person – understanding their role and position in life
 - (a) How do treatment regimes fit in with working and personal life?
 - (b) Can they work during a relapse?
 - (c) Any problems in self-treatment?
3. Finding common ground for management
 - (a) What decisions (shared decision-making) have to be made about:
 - life-style
 - drug treatment
 - living with side-effects
 - surgery
 - surveillance for cancer
 - quality of disease management versus medical efficacy.
 - (b) Explore guidebook together and write in:
 - test results
 - everyday maintenance treatment
 - how to recognise symptoms of relapses
 - treatment regime for self-management of relapse.
4. Prevention and health promotion
 - (a) Starting treatment fast.
 - (b) Removing unnecessary stresses from life.
 - (c) Importance of routine medication.
 - (d) How to access others, for example, dietitian.
5. Enhancing patient–professional relationship
 - (a) Acknowledge areas of uncertainties.
 - (b) Allow patients to take on responsibility for self-management.

- (c) Write down personal treatment plan.
 - (d) Make follow-up appointments on request.
 - (e) Recognise legitimacy of patient's non-medical approaches to care.
6. Being realistic, ensure understanding
 - (a) Making sure patient understands and is happy with joint management and decisions.
 - (b) Not dumping all uncertainties on patient.

All members of the consultants' team for each site were invited to the training sessions which were led by an experienced expert in consultant training. The training sessions lasted for 2 hours and included:

1. Use of a product champion¹³⁰ (a respected professor of gastroenterology) to introduce the research and training team and 'sell' the importance and relevance of the project.
2. Description of the background to the research including the results of the successful pilot project.
3. Description of the research and interventions.
4. Description of the skills necessary for working in a patient-centred style.
5. Demonstration video.¹³¹
6. Role-play and video-feedback training.
7. Discussion.

Skills necessary to work in a patient-centred style

The two major components of a patient-centred consultation for IBD were taken to be:

1. Addressing the impact of the disease on the patient.
2. Establishing with the patient what treatment works.

The skills consultants were instructed to use included:

- open-ended questions
- picking up cues from patients
- clarification
- summarising
- checking out
- collaborative approach to treatment.

These skills were demonstrated to the participants using a previously recorded video of a model consultation. The video gives an example of an entire consultation between a patient with ulcerative colitis and a gastroenterologist. The consultation is patient-centred and it demonstrates how self-management can be introduced and

treatment options explored by using the guidebook.

The participants were then asked to pair off and take part in a role-play, using a patient-centred consultation to introduce changes in management including introduction of the guidebook, making a written management plan and enabling self-referral to the clinic. One pair's role-play was recorded on a video and used to aid discussion.

Participants were able to discuss their concerns about the trial and, where possible or necessary, adjustments were made to the protocol. *Table 2* shows the views of the participants as recorded at the end of each training session. The sessions were viewed positively and showed slightly less enthusiasm for the role-play than for the other aspects of the training session. Participants felt that the most important things they gained from the session were:

- opportunity to discuss practicalities of the trial
- greater understanding of patient-centredness
- discussion with peers about current consultation practice
- potential impact of study on clinics
- many participants thought the training session needed to be longer.

Timing of interventions

The consultant training took place after site randomisation and before recruitment of patients. Consultants were given a one-page outline containing bullet points on how to conduct the recruitment consultation (see Appendix 3). The guidebook was given to patients at the intervention sites during this recruitment consultation and the self-management plan was written into the record book.

Open access

All patients in the intervention group were given a telephone number that was written into their copy of the guidebook by the consultant during the recruitment consultation. They were told they could phone for an appointment when they thought it was necessary, or under the circumstances listed in the record book (see Appendix 4).

Patient recruitment

Patients were recruited from gastrointestinal outpatient clinics. Researchers identified eligible patients from the medical records held in the clinic. In control sites, all suitable patients were

TABLE 2 Opinions of participants at the patient-centred training sessions

	Not at all 0	1	2	3	Very much 4
1. Did you enjoy the training?	0	0	4	11	9
2. Did you like the structure?	0	0	4	13	7
3. Did you find the research background interesting?	0	0	1	13	10
4. Did you find the research instructions useful?	0	2	2	10	9
5. Did you find the video useful?	0	2	4	10	7
6. Did you find the role play helpful?	0	5	5	7	7
7. Did you find the video review interesting?	0	1	6	12	5
8. Was the discussion at the end of benefit?	0	0	1	11	12
9. How actively involved were you during the evening?	1	0	7	11	5
Total	1	10	34	98	71
% of total replies	0.5	5	16	46	33

approached as they arrived in clinic and given information about the study. If they agreed to participate, they were interviewed, asked to fill in a questionnaire and instructed in how to use the diary. They then went on to have a normal consultation with their doctor.

At intervention sites, three patients were randomly selected from the list of eligible patients as owing to time constraints, three patient-centred consultations were the maximum that consultants could take on per clinic session. These patients were approached as they arrived in clinic and given information about the study. If they agreed to participate, they were interviewed, asked to fill in a questionnaire and instructed in how to use the diary. They then went on to have a patient-centred consultation with their doctor who gave them a copy of the guidebook and told them how to use it.

Baseline and follow-up assessments

Entrance questionnaire

During the initial interview of consenting patients, the following procedure was followed.

1. The project was explained to patients. Both groups (control and intervention) were given instructions on how to use the patient diaries and the intervention group were told that their consultant would give them a copy of the guidebook. Those in the control group were told that they would be sent a copy of the guidebook at the end of the study.
2. Demographic data on age, gender, education, occupation and duration and severity of illness were collected from all patients (see Appendix 5).

3. Patients were asked to self-complete the following validated questionnaires:
 - (a) EuroQol EQ-5D,¹³² a short, three-page questionnaire. EQ-5D is a measure of health status developed for use in evaluating health and healthcare. It provides a simple descriptive profile and an overall numeric estimate of health-related QoL that can be used for both clinical and economic evaluations and is designed for use alongside disease-specific or other generic measures of QoL. The EQ-5D is classified in terms of five dimensions: mobility, self-care, usual activity, pain/discomfort and anxiety/depression. Each dimension is divided into three levels: (1) no problem, (2) some problem, and (3) extreme problem. The patient is classified into one of 243 possible health states. In the UK, the relative importance of each level/dimension (in terms of health state values or 'utilities') has been estimated from the results of a national survey of the general population commissioned by the Department of Health in 1993. The EQ-5D also includes a patient rating of their own overall health status using a thermometer-like scale, marked 0–100 (visual analogue scale) and a minimal background information page on the patient. It therefore provides three types of data for each patient: a profile, indicating the extent of problems across the five dimensions; a weighted health index, based on population values obtained from the 1993 survey; and a score on the self-rated scale, indicating the patients' own assessment of their health state.
 - (b) Anxiety and Depression: The Hospital Anxiety and Depression Scale (HADS).¹³³

- This is a generic scale, designed to measure the presence and severity of mild degrees of mood disorder in non-psychiatric hospital outpatients. It has been shown to be sensitive to changes both during the course of diseases and in response to psychotherapeutic and psychopharmacological intervention.¹³⁴ There are 14 questions, seven relating to depression and seven to anxiety. Each item provides four response categories in terms of frequency or severity. The wording of response categories is positive (i.e. 0–3) for six items and negative for eight items (i.e. 3–0). Responses relate to feelings during the last week. Item scores for each sub-scale are summed and indicate non-cases (≤ 7), doubtful cases/borderline (8–10) and definite cases (≥ 11). It has been used in a wide range of settings including clinics for IBD.¹³⁵
- (c) SF-36: medical outcomes survey, Short Form with 36 Items. The SF-36 is a general health status questionnaire developed for the Rand Corporation.¹³⁶ It is a generic measure which can be applied to different populations and conditions. Health-related QoL is classified by eight dimensions: physical functioning, social functioning, role limitations due to physical problems, role limitations due to emotional problems, mental health, pain, vitality and general health perception.
- (d) Inflammatory Bowel Disease Questionnaire (IBDQ).¹³⁷ The IBDQ is a disease-specific measure of QoL. It consists of 32 questions dealing with four sub-scales: gastrointestinal symptoms, symptoms not directly related to the disturbance (systemic symptoms), symptoms of emotional dysfunction and social dysfunction. All questions employ seven response categories, with 7 representing ‘best function’ and 1 representing ‘worst function’. Scores on individual items are summed to produce a score for each of the four sub-scales. Items for inclusion were selected on the basis of literature reviews, consultation with professionals and interviews with patients suffering from IBD. It has been extensively tested for reliability, validity and responsiveness to change. It is designed to be administered by an interviewer, with completion time 15–25 minutes at first administration, then 10–20 minutes on subsequent administrations. It represents small numbers limited testing with respect to Crohn’s disease patients.
- (e) Patient Enablement: The Patient Enablement Instrument (PEI).¹³⁸ The PEI consists of six questions designed to draw out patients’ feelings of confidence, ability and coping after a consultation. The PEI has been shown to be related to but is different from general satisfaction. The developers link the PEI to patient-centredness and empowerment.¹³⁹ However, the PEI was developed for use in primary care and its use has not been reported in specialist secondary care settings. The PEI is very quick to complete. The scoring system ranges from a score of 2 for ‘much better’ or ‘much more’, a score of 1 for ‘better’ or ‘more’ and a score of 0 for ‘same or less’ (range 0–12). The scoring does not allow measurement of those who feel less enabled after a consultation.
- (f) The Consultation Satisfaction Questionnaire (CSQ).¹⁴⁰ This questionnaire was designed to be self-administered as a consultation-specific measure. It was designed and tested in the setting of British general practice. It has 18 questions relating to four sub-scales: general satisfaction, professional care, depth of relationship and perceived length of consultation. Responses are expressed as agreement/disagreement on a five-point scale. It is relatively quick to complete: 10–15 minutes. One criticism of the scale has been the repetitive nature of the questions due to the presence of reversed items (improved validity).¹⁴¹ The CSQ has been used in other settings, e.g. with community nurses.¹⁴²

Note that the PEI and the CSQ were completed following the initial recruitment consultation.

During the 12 months of the study, all patients were asked to fill out the CSQ (to be found in the diary) after every consultation with a doctor in outpatient clinics.

Patient diary

All patients were asked to keep a diary for the entire year of the study (see Appendix 6). Patients were requested to return the diary at the end of the year. The diary contained details of:

1. Relapses
 - (a) Symptoms – patients were asked to write down the symptoms of the relapse.
 - (b) Duration – patients were asked to note the start and end dates of the relapse.

- (c) When treatment started and other actions taken – patients were asked to note how soon (in hours or days) they started treatment and whether they contacted their GP or hospital before starting treatment.
 - (d) Treatment started.
 - (e) Time off work/education.
2. Visits to the doctor
 - (a) Who they saw – GP, hospital specialist or doctor at Accident and Emergency department.
 - (b) Costs of journey and mode of transport.
 - (c) Time taken off work.
 3. Treatment
 - (a) Prescribed drugs.
 - (b) Over-the-counter drugs plus costs.
 - (c) Other treatment (e.g. acupuncture) plus costs.
 - (d) Surgery – the type of operation and dates of hospitalisation.

Exit questionnaire

At the end of 1 year in the study, all patients were asked to complete an exit questionnaire that contained questions on information seeking during the year, details of number of relapses, hospital and GP visits and their views on the study. The retrospective data on relapses and doctor visits was collected to validate data obtained from the diaries; although these data were less detailed than the diary data, a higher response rate was expected. Patients in the intervention group were asked about the intervention, the care they received and their use of the guidebook (see Appendix 5). The questionnaire booklet also contained the following scales: EQ-5D, HADS, SF-36, IBDQ and the PEI.

Hospital medical records

Medical records (see Appendix 7) for all patients were examined to obtain:

- details of IBD and IBD-related outpatient visits over the course of the year of the study and the year preceding the study
- records of medical treatment and investigations for IBD occurring during the study
- records of surgery for IBD and length of stay as inpatients
- details of drugs prescribed for IBD.

Qualitative interviews

- A purposeful sample of 30 patients from the intervention sites were interviewed at the end of the study (these were selected on the basis of responses to the quantitative outcome measures, in addition to socio-demographic criteria).

- Consultants from the intervention sites were interviewed as soon as possible after all patients had been recruited from their site.
- A group interview was conducted with consultants from the intervention sites when all follow-up data had been collected.

Primary and secondary outcome measures

The primary outcome measure was the IBDQ.

Other outcome measures included the following:

1. Study of consultations
 - (a) Number of visits to clinic over 1 year. Data were obtained from the medical records for each patient and the patient diaries.
 - (b) Patient satisfaction with the consultation. After each consultation, patients were asked to fill in a satisfaction questionnaire – this was included in the initial questionnaire and in the patient diary.
2. Treatment for IBD
 - (a) Initiation of self-care treatment. Data were obtained from the patient diaries on the time taken between recognition of symptoms of a relapse and start of treatment.
 - (b) Medical and surgical treatment in hospital. Details of drugs prescribed, medical investigations and surgical treatment were obtained from the medical records for each patient.
3. Record of symptoms
 - (a) Number and duration of relapses during the course of the year. Data were obtained from the patient diaries and the exit questionnaire.
 - (b) Details of symptoms. Data were obtained from the patient diaries on the reasons why treatment was started (in order to determine if the symptoms were that of a medically recognisable relapse).
4. Economic costs
 - (a) Time off work or education. Data were obtained from the patient diaries.
 - (b) Visits to the hospital or GP. Data were obtained on number of visits, transport costs and time taken off work from the patient diaries and the medical records for each patient.
 - (c) Patients' out-of-pocket drug costs. Data were obtained from the patient diaries.
 - (d) In-patient stays and hospital investigations. Data were obtained from the medical records for each patient.

5. Qualitative information

- (a) This was aimed at illuminating the mechanisms and processes underlying changes in self-management and help-seeking behaviour. Data were obtained through in-depth qualitative interviews with selected patients at the end of the 1-year study period. Themes explored in the data were the personal and social context of managing illness and coping strategies prior to the intervention and perceptions about patient experience of each component of the intervention (guidebook, patient consultation and access arrangements) and overall impact on self-management and health behaviour (methods of analysis are described in Chapter 5).
- (b) Medical views on the intervention. Data on the consultants' experience of initiating the intervention with patients were collected through qualitative interviews. Themes focused on the training, the effectiveness and acceptability of the guidebook, the patient-centred intervention and the process of introducing the intervention into normal practice.

6. Intervention strategies

As this was a pragmatic trial of a complex intervention, we were aware that not all patients were likely to have received the full intervention. It was decided that the presence or absence of a self-management plan was the most appropriate indication of whether or not patients had received the intervention. This was measured on the exit questionnaire by asking intervention-site patients if their consultant gave them a self-management plan (see Appendix 5). There are limitations to this as it is dependent on patient recall of a past event.

Analysis methods

This section relates to measures of effectiveness estimated in the trial. Details of the methods used for the economic evaluation are reported in Chapter 6. Analysis was performed on an intention-to-treat basis. The study design is a cluster trial with randomisation by treatment centre. The trial design was justified as the staff training, an essential part of the intervention, could only be delivered to groups of staff to avoid risks of contamination.

Sample size estimation

The sample size was calculated from the primary outcome measure of disease-related QoL. The

power calculation was based on the Guyatt IBDQ, which is made up of 32 items each recorded on a seven-point scale with higher scores representing improved perception of QoL. An average of a one-point improvement on a quarter of all items would lead to an increase in the IBDQ of eight points. With an estimated within-treatment arm standard deviation of 25, a trial with eight treatment centres in each arm and 40 patients per treatment centre was estimated as having a power of 81% at a 0.05 significance level.

Descriptive statistics

Most of the purely descriptive statistics in this report (i.e. where inference testing was not undertaken) were produced using the Statistical Package for the Social Sciences (SPSS) version 10.1.¹⁴³ These statistics are based on pooling the patient samples across the centres; they are unadjusted for response rates or the clustering of patients within centres.

Multivariate analysis

Multivariate analysis was used to undertake inference testing with respect to the impact of the intervention on the various outcome measures. The analyses were conducted using the Survey procedures in Stata (statistical analysis package) version 7.¹⁴⁴ *Svyreg* was used to analyse continuous outcomes *Svylogit* for binary outcomes and *Svyologit* for ordered interval outcomes. These procedures allowed Centre to be designated as a cluster variable (in the study patients were clustered within centres), probability weights to be specified as described below and robust estimates of variance to be implemented. The Stata Survey procedures are based on theoretical assumptions specifically relevant to clustered survey data (StataCorp,¹⁴⁵ pp. 331–2).

The diary data included details of each patient's hospital and GP visits and relapses over the course of the trial, with the numbers of visits/relapses varying from patient to patient. In effect this constitutes multistage clustering, with visits/relapses clustered within patients, who are themselves clustered within centres. The Stata Survey commands are suitable for use with multistage samples; they produce variance estimates that are approximately unbiased or biased towards being conservative. Other methods exist (although not in Stata) that explicitly account for secondary sampling. However, these require more assumptions than the Survey methods, and as such the variance estimates can be less robust (StataCorp,¹⁴⁵ p. 324).

Prior to the analysis the distributional properties of the data were examined and the question of what to do about missing values was addressed.

Distributions

All variables were examined for the presence of extreme outliers. Action was deemed appropriate in only one instance; with regard to patient reports of the number of relapses during the trial, where four outliers were identified (values of 20, 30, 50 and 100 where all other patients reported 12 or fewer). It was not desirable to 'lose' these four cases, and to recode all data points into a smaller number of interval categories would entail considerable information loss. Therefore, the outliers were all recoded to values of 12 and the Stata bootstrapping procedure used to validate the results of the subsequent analysis.

Outcome variables were examined for non-normal distributions. Lack of normality is generally not a serious issue with samples of this size, but where high skew was in evidence (e.g. with respect to the numbers of missed appointments), the results of the analysis were validated using bootstrapping.

Missing values

Missing values on the independent variables used in the analyses were estimated using the Stata Impute command. There were varying numbers of missing values on several variables. Many of these were a consequence of 16 patients lacking an entrance questionnaire. Imputation under Stata is based on a regression method, and the following variables were included in the equation (except where they represent the variable being estimated): gender, age, diagnosis, length of illness, number of appointments in pre-trial year, entrance IBDQ score, entrance HADS score and Centre (as a dummy variable). Missing values on the educational level and smoking behaviour variables were assigned to a dummy category. The largest numbers of missing values imputed were for the entrance IBDQ score (31 values) and the entrance HADS score (22 values); for most other variables, fewer than 10 values were imputed. Data on the number of visits to a GP in the pre-trial year were missing for 201 patients and on frequency of relapses for 55. It was decided that these numbers were too large for imputation to be warranted.

Response weights

One hundred of the 651 patients recruited to the study and who completed the entrance questionnaire failed to complete an exit questionnaire at the end of the trial. These patients were unevenly distributed across centres,

ranging from none at one centre to a third of all patients at another. This pattern of incomplete cases has the potential to bias the statistical analysis should the patients who failed to return an exit questionnaire be in some ways different to those who did. Response weights were therefore derived so as to adjust for incomplete cases in the analysis of outcomes from the exit questionnaire. Logistic regression was used to build a model to predict missing exit questionnaires on the basis of centre and patient characteristics (age, gender, entrance IBDQ, HADS and enablement scores, kept appointments in previous year, missed appointments in previous year, length of illness, diagnosis, smoking behaviour and educational level). After stepwise removal of non-significant factors, the final model consisted of centre and educational level (10% of those with qualifications failed to return the exit questionnaire compared with 18% of the unqualified who left school at 16 years old and 17% of unqualified who continued beyond 16 years old). The model was next used to generate predicted response rates (i.e. probability of return of the exit questionnaire) for each combination of centre and educational level. The inverse of these probabilities was then assigned to the individual cases for use as weights in the main analysis (educational level was missing for 16 cases, and in these instances the mean weight for the centre from which each case came was used). The weights can be thought of as a way of adjusting the final sample to make the results more representative of all cases initially entered into the trial. The ratio of the largest weight to the smallest was 1.72:1.0.

A large proportion of patients failed to complete the patient diary. After elimination of missing, incomplete and spoiled diaries, a total of 320 were deemed to be of good or usable quality. The volume of missing diaries was so much larger than the number of missing exit questionnaires that a separate set of response weights was required for the analyses of these data. Logistic regression was undertaken to model the presence of diary data. The analysis found that women were significantly more likely to have provided usable diary data (men 46%, women 51%; $p < 0.05$), as were those who DNA less frequently ($p < 0.01$) and those with lower HADS scores on entrance ($p < 0.01$). There were also significant differences between centres, with the proportion of patients who provided usable diaries ranging from 18% to 72%. This model was then used to derive probability weights for use in subsequent analyses. However, when Centre was included in derivation of the weights, the ratio between the largest and smallest

weight was very large (22.7), so Centre was removed from the equation (resulting in a ratio of 5.4) to avoid the risk of over-correction.

Only a small number of outcome data were missing from either the entrance questionnaire or the hospital records. Therefore, it was deemed unnecessary to apply response weights to these analyses.

Control variables

Each multivariate analysis included a number of control variables. The purpose of this was to adjust for any group differences in these factors prior to the significance test of the intervention itself. For each outcome variable two of the research team (A.K. and D.R.) selected the baseline variables most expected to bear a relationship with the outcome, working from the available evidence base (age and gender were always included, as is the convention in trials). For example, where the outcome was end-of-trial IBDQ scores, the control variables were gender, age, IBDQ scores at entrance, length of illness and diagnosis (Crohn's disease or ulcerative colitis). The specific combination of variables adjusted for in each case appears in the analysis reports (Chapter 4).

Main analysis

The purpose of the main multivariate analyses was to perform inference tests regarding the impact of the intervention on the various outcome measures. All these analyses were conducted on an 'intention-to-treat' basis, that is, all patients in each arm of the trial were maintained in the sample for that arm, regardless of the extent to which they (or their centre) complied with the protocol for that arm.

Secondary analyses

Secondary analyses were conducted following the main analyses. The main set of secondary analyses involved testing the outcome measures for significant effects related to compliance with the intervention. Compliance analysis requires specialised methods: it is not appropriate simply to compare patients who complied with treatment with patients who did not, or with the control

group, as the reasons for compliance (or non-compliance) may be associated with the outcomes and act as confounders. Accordingly, we utilised a method proposed by Nagelkerke and colleagues¹⁴⁶ that adjusts for such confounders. Effectively, the method estimates a comparison between compliers in the intervention arm with patients in the control arm who would have complied had they received the intervention. The method involves an assumption that all non-compliers receive treatment that is equivalent to control patients. This assumption is most likely violated in the present study: the only measure of compliance available to us (self-management plans) is an approximate one, and all the 'non-compliers' received at least part of the intervention (the guidebook at the very least). However, since these factors will operate to reduce differences between the complier and non-complier groups, the impact will be to reduce the likelihood of finding a significant effect.

Other secondary analyses examine a small number of hypothesised interactions between the intervention and baseline variables with respect to specific outcomes (e.g. the impact of the interaction between the intervention and diagnosis on IBDQ scores). A secondary analysis was also conducted to identify determinants of patient preference for the intervention, as compared with the traditional system of disease management.

Unit of randomisation

Cluster randomisation by hospital site was applied.

Data entry

Data were entered using the SPSS data entry program and data from the entrance and exit questionnaires were verified by double entry. The reliability of data entry from the medical records was assessed by randomly selecting 30 questionnaires that were checked separately by two researchers for accuracy of coding and data entry. The reliability calculation was based on the ratio $[\text{no. of agreements}/(\text{no. of agreements} + \text{no. of disagreements})] \times 100$.

The mean reliability was 98% (range 78–100%).

Chapter 3

Recruitment results

Centre and patient recruitment details

Figure 1 shows the site recruitment profile. Twenty-four sites were approached; two sites did not want to take part in the study because they already had too many research commitments, two sites did not reply despite several approaches and one site did not commit to the study in time for inclusion. The 19 remaining hospital sites were then randomly ordered from 1 to 19 (by a statistician not associated with the study using a prepared sequence of random numbers), and these numbers were randomly drawn out of a hat allocating each hospital either to the treatment-as-usual group (10 sites) or the intervention group (nine sites).

The original target figure for recruitment was 40 patients from 16 sites (640 in total). As consultants from 19 sites signed up to the study, it was decided to aim for 38 patients per site (722 in total). Eligible patients at control group sites were recruited as they came to clinic. It was agreed with consultants at the intervention sites that it was only possible for them to recruit a maximum of

three patients per clinic as it was anticipated that the intervention would take longer than a normal follow-up consultation of 10 minutes. A strategy was put in place to ensure the recruitment procedure was standardised. This is outlined in Appendix 8. The patient information sheet and consent forms are shown in Appendix 9. Letters were sent out to all patients every 3 months to thank them for being in the study and to remind them to fill in their diaries.

Masking

It was not possible to blind participants in this study.

Recruitment details for patients are outlined in Figure 2. Out of a total of 980 patients meeting the entrance criteria for the study, 700 (77%) were entered into the study as available for follow-up. This figure includes patients who gave their consent but were withdrawn by the consultant and those who did not respond to requests to return their entrance questionnaire. Baseline data is available for the 635 patients who returned their entrance questionnaire (see Table 3).

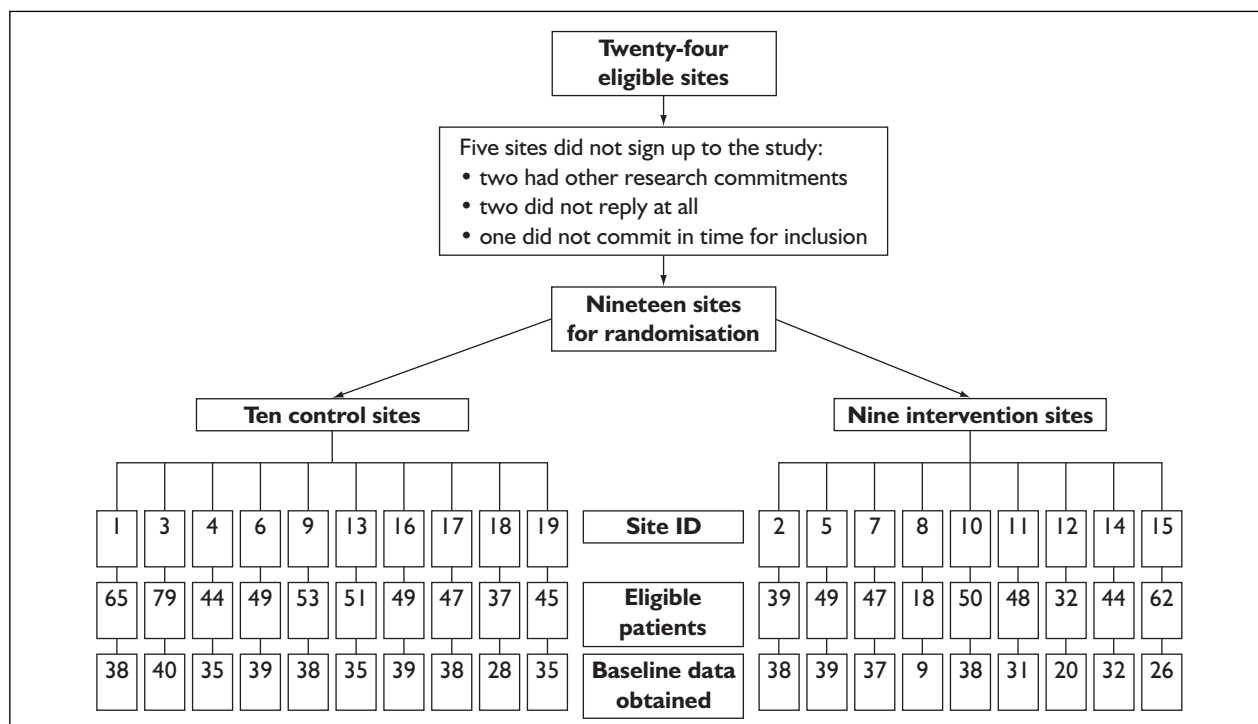


FIGURE 1 Site recruitment

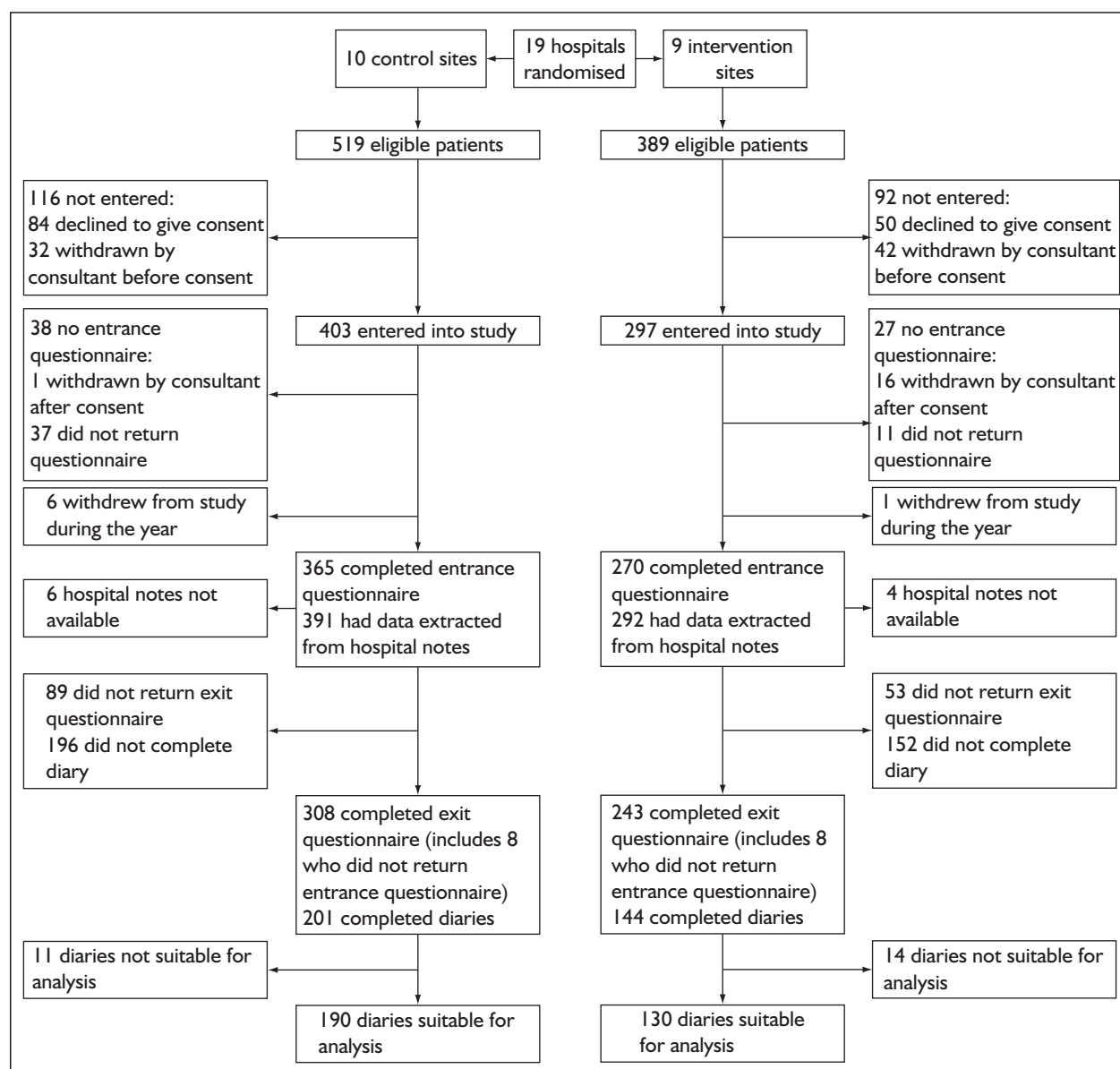


FIGURE 2 Trial profile

TABLE 3 Recruitment and questionnaire return

	Control (10 sites)	Intervention (9 sites)	Totals (19 sites)
Entered into study (% of eligible patients)	403 (78)	297 (76)	700 (77)
Returned entrance questionnaire	365	270	635
Returned exit questionnaire	308	243	551
Returned exit and entrance questionnaire	300	235	535
Returned entrance only	65	35	100
Returned exit only	8	8	16

A number of patients met the entry criteria for the research but were withdrawn by the consultant, 74 before they were asked to give consent to the study and 17 after they gave consent (Figure 2). Most

(47; 33 intervention and 14 control) were considered unsuitable for the project because their current condition was making them too ill. Twenty (nine intervention and 11 control) were judged to

TABLE 4 Reasons given by consultants/nurses for not admitting patients to study

Reason given	Control	Intervention	Total
Not suitable – poorly or unstable disease	14	33	47
Mental health problems	11	9	20
Other medical or health reasons	5	5	10
Other	3	11	14
Total	33	58	91

have mental health problems such as depression or dementia. The other 24 (16 intervention and eight control) were withdrawn because of other medical or health-related problems (see *Table 4*).

As can be seen from *Figure 1*, it was not possible to recruit 38 patients from each of the sites. This was due to:

- Diminishing cooperation/enthusiasm from some consultants, intervention site consultants had to give a great deal of personal commitment to the study and there were concerns that this was impinging on the rest of the clinic.
- A decreasing pool of patients from which to recruit.

Some sites were easier to recruit from than others. The numbers recruited for which entrance questionnaire data are available ranged from nine (site 8) to 40 (site 3) and the percentage of eligible patients recruited ranged from 42% (site 15) to 97% (site 2) with a mean of 70%.

Recruitment commenced in July 1999 and ended in August 2000. Clinic types differed. At 12 centres, IBD patients were seen at clinics run for general gastrointestinal problems, three centres saw IBD patients at general medical clinics, three centres ran special IBD only clinics and one centre saw IBD patients at a general medical and surgical clinic. It took longer to recruit patients from the intervention sites (a mean of 9.3 months, range 6–12 months) than from control sites (mean 7.9 months, range 3–13 months). This is not a source of bias;¹⁴⁷ randomisation took place prior to recruitment and *Table 3* shows that the percentage of eligible patients entered into the study was similar for each arm of the trial. Data from the medical records of 683 (98%) of the 700 patients were included in the trial's analysis.

Baseline characteristics of patients

Entrance questionnaires from 635 patients were returned and the baseline characteristics described in the following section are based on these patients with details shown in *Table 5*. Examination of the mean values shows that both control and intervention groups were very similar for all characteristics, so mean values for the whole group will be described. The mean age was 45.5 years and there were more females (57.6%) than males. Most were in work (57.4%) and 21.1% were retired; 62.1% were married or living with a partner and less than half (43.6%) had continued with an education after the age of 16 years. Coding for social class (*Table 5*) was based on the reply to the question, 'What is your occupation?'; this was coded with reference to the new occupational scale, The National Statistics Socio-economic Classification, developed to replace the former Registrar General's Social Class Scale for all government statistics in 2001. The figures in *Table 5* are based on the responses of the 551 patients who sent back exit questionnaires. The majority of patients (13.1%) are in group 2 (lower managerial and professional).

Details about patients' IBD are outlined in *Table 6*. There were more patients with ulcerative colitis admitted to the study (63.5%); this reflects the pattern in the general population as there are about 100,000 people with ulcerative colitis in the UK compared with 50,000 with Crohn's disease, i.e. one-third of the population of all those with inflammatory bowel disease have Crohn's disease. Most people in the study had a pattern of relapses followed by periods where they had no symptoms (52.4%). Nearly a quarter of patients were in an active phase of their disease when they were entered into the study; this would indicate that up to 75% of patients attending clinics had no current disease problems. The mean duration of illness was just under 9.1 years with a range of 0–53 years.

Other findings of interest from the baseline data include that on smoking. There is a theory that nicotine may protect against ulcerative colitis and the baseline data show that there are fewer people with ulcerative colitis who are smokers (see *Table 6*).

We were interested in whether patients had used the Internet to obtain information on IBD. We aimed to determine current Internet usage and to evaluate the types of information available. Of 635 patients, 162 (25.5%) used the Internet and of

TABLE 5 Demographic characteristics of 635 patients at baseline

Characteristic	Control	Intervention	Total		
Age (years)					
Mean (SD)	46.34 (15.1)	44.37 (14.9)	45.5 (15.04)		
Range	17–86	18–81	17–86		
Gender	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)		
Male	157 (43)	112 (41.5)	269 (42.4)		
Female	208 (57)	158 (58.5)	366 (57.6)		
Work status					
Full-time	165 (45.2)	109 (40.4)	274 (43.1)		
Part-time	46 (12.6)	45 (16.7)	91 (14.3)		
Retired	81 (22.2)	53 (19.6)	134 (21.1)		
Housework	30 (8.2)	19 (7)	49 (7.7)		
Student	9 (2.5)	8 (3)	17 (2.7)		
Seeking work	9 (2.5)	6 (2.2)	15 (2.4)		
Long-term sickness	9 (2.5)	15 (5.6)	24 (3.8)		
Other	16 (4.4)	9 (3.3)	25 (3.9)		
Missing		6 (2.2)	6 (0.9)		
Occupation ^a					
1. Higher managerial and professional	1 (0.3)	0	1 (0.2)		
1.1 Employers and managers in larger organisations	3 (1.0)	3 (1.2)	6 (1.1)		
1.2 Higher professionals	34 (11.0)	31 (12.8)	65 (11.8)		
2. Lower managerial and professional	41 (13.3)	31 (12.8)	72 (13.1)		
3. Intermediate	23 (7.5)	22 (9.1)	45 (8.2)		
4. Small employers and own account workers	9 (2.9)	8 (3.3)	17 (3.1)		
5. Lower supervisory, craft and related	25 (8.1)	11 (4.5)	36 (6.5)		
6. Semi-routine	13 (4.2)	16 (6.6)	29 (5.3)		
7. Routine	23 (7.5)	14 (5.8)	37 (6.7)		
8. Long-term unemployed, never had paid work	35 (11.4)	24 (9.9)	59 (10.7)		
Retired	64 (20.8)	51 (21.0)	115 (20.9)		
Student	8 (2.6)	5 (2.1)	13 (2.4)		
Missing	29 (9.4)	27 (11.1)	56 (10.2)		
Marital status					
Single	74 (20.3)	53 (19.6)	127 (20)		
Married/cohabiting	222 (60.8)	172 (63.7)	394 (62.1)		
Widowed	19 (5.2)	11 (4.1)	30 (4.7)		
Divorced	35 (9.6)	19 (7)	54 (8.5)		
Missing	15 (4.1)	15 (5.6)	30 (4.7)		
Education					
Continued after 16	165 (45.2)	112 (41.5)	277 (43.6)		
Degree or professional qualifications	99 (27.1)	67 (24.8)	166 (26.1)		
Baseline outcome measures	<i>n</i>	Mean SD	<i>n</i>	Mean SD	<i>p</i>-Value
IBDQ	358	165.4 37.4	262	168.1 36.2	0.378
HADS	364	12.2 7.5	265	11.6 7.1	0.277
SF-36					<i>n</i> Mean SD
Physical function (PF)	359	76.5 26.6	265	77.7 25.7	624 77.0 26.2
Role limitation due to physical problems (RP)	346	57.3 43.3	259	57.1 43.8	605 57.2 43.5
Role limitation due to emotional problems (RE)	344	67.8 41.3	257	67.7 41.2	601 67.7 41.2
Social functioning (SF)	363	70.2 29.0	266	70.6 28.3	629 70.4 28.7
Mental health (MH)	362	67.5 20.1	266	70.9 19.4	628 69.0 19.9
Energy/vitality (EV)	362	48.0 25.1	266	50.1 23.1	628 48.9 24.3
Pain (P)	363	66.1 27.4	266	67.5 26.5	629 66.7 27.0
General health perception (GHP)	355	51.4 24.0	265	54.1 23.9	620 52.6 23.0
^a Occupation based on The National Statistics Socio-economic Classifications (NS-SEC) out of 551 who returned exit questionnaires.					
SD, standard deviation.					

TABLE 6 Disease characteristics

Characteristic	Control: n (%)	Intervention: n (%)	Total: n (%)				
Disease type							
Ulcerative colitis	226 (61.9)	177 (65.6)	403 (63.5)				
Crohn's disease	139 (38.1)	92 (34.1)	231 (36.4)				
Missing		1 (0.4)	1 (0.2)				
Activity at baseline							
Active	85 (23.3)	69 (29.6)	154 (24.3)				
Flare-up in past 18 months	196 (53.7)	137 (50.7)	333 (52.4)				
In remission – no flare-ups in past 18 months	58 (15.9)	47 (17.4)	105 (16.5)				
Missing	26 (7.1)	17 (6.3)	43 (6.8)				
Duration of illness (years)							
Mean (SD)	9.13 (8.45)	9.09 (9.57)	9.11 (8.93)				
Range	0–48	0–53	0–53				
Smoking	n	UC (%)	CD (%)	n	UC (%)	CD (%)	n (%)
Smoker	74	10.2	37.0	53	11.2	37.8	127 (20.4)
Ex-smoker	123	39.1	25.4	89	42.0	18.9	212 (34.0)
Non-smoker	166	50.7	37.7	118	46.7	43.3	284 (45.6)

UC, ulcerative colitis; CD, Crohn's disease.

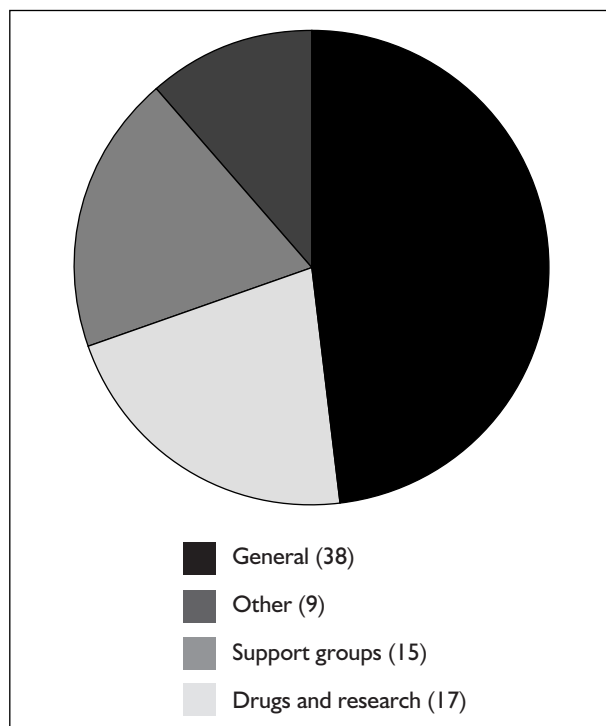


FIGURE 3 Searches done by 79 patients who looked for information about IBD

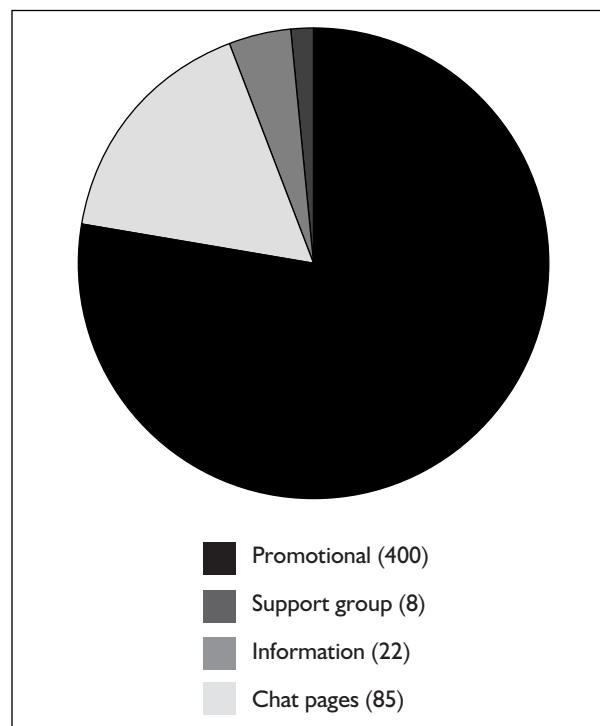


FIGURE 4 Breakdown of content of 623 IBD websites available (date of search 3 October 2000)

these 79 (12%) used it to find information about IBD. Most searches were for general information about IBD (38/79), information about drugs or research (17/79) or to find details of patient support groups (15/79) (see *Figure 3*). Websites with IBD information were identified using the

search terms ‘ulcerative colitis’, ‘Crohn’s’ and ‘inflammatory bowel disease’ in each of five popular search engines (Excite, Yahoo, Lycos, HotBot and AltaVista). The top 100 hits for each of the three search terms in these engines produced 1500 sites for review, although many of

TABLE 7 Quality coding for flare-ups recorded in diaries

	Control	Intervention	Total
Medically defined flare-ups	222 (68%)	155 (76%)	377 (71%)
Patient-defined flare-ups	103 (32%)	48 (24%)	151 (29%)
Total flare-ups recorded	325 (100%)	203 (100%)	528 (100%)

these were duplicated. Sites were categorised into four main groupings: patient support groups, information providers, chat pages and promotional sites. There were 623 different websites after duplicates were excluded. The most frequent site found was the Crohn's and Colitis Foundation of America; 8/623 sites were patient organisations, 22/623 provided 'pure' information, 85/623 were chat pages and over 400 were promotional (products or services) (see *Figure 4*). Many of the promotional sites contain patient information in the context of their own products or services.

Patient follow-up rates

All patients who returned their entrance questionnaires were sent a 1-year follow-up (exit) questionnaire, except for the seven patients who withdrew their consent during the year of the study. Appendix 8 outlines the follow-up strategy used. In addition, exit questionnaires were sent to the 17 patients who were withdrawn by the consultant after they had given consent and the 48 patients who consented to take part but did not return their entrance questionnaire. This was to determine if there was anything different about this group and so that baseline data could be imputed for them.

This strategy resulted in a response rate of 85% return of exit questionnaires sent to the 628 patients who returned their entrance questionnaire (*Table 3*). Response rates for the control and intervention groups were similar but the response rate for the different sites varied from 68% (site 15) to 100% (site 2). The additional 65 questionnaires sent out had a 25% response rate ($n = 16$ exit questionnaires returned). This gives an overall response rate of 80%.

The response rate for diary return was not so good; overall, diary data were available for 347 patients (55% of patients who returned the entrance questionnaire; see *Figure 2*). This includes patients who did not return the diary because they had no relapses or hospital visits during the year of the study (data obtained from the medical records and information given on the exit questionnaire). There were similar response rates for control and intervention groups but the response rates from the individual sites ranged from 32% (site 15) to 74% (site 4). Of those patients who gave reasons for non-return of diary, 32 said they had lost the diary and 44 forgot to fill it in. The main reason for missing diaries was non-return of exit questionnaires ($n = 93$), but five patients returned diaries without an accompanying exit questionnaire. Nearly a quarter of diaries ($n = 65$, 23%) were not returned because the patients said they had not used them because they had no relapses or hospital visits during the year of the study. This accords with the 21.5% of patients who were recorded as having no hospital appointments in the medical records. There is also a significant correlation (Pearson coefficient 0.725) between patients' reporting of hospital visits in the diary and that reported in the exit questionnaire, so we can be confident that most patients were making accurate reports.

The diaries were scored for quality to aid analysis. The criteria applied are outlined in Appendix 10. As analysis of the qualitative data showed some discrepancy between what patients viewed as being a relapse and the medical definition of a relapse; the relapses recorded in the diaries were also coded using medically determined criteria for symptoms and duration (see *Table 7*). All recruited patients were given a diary quality code and 320 were judged to be of good or useful quality and included in the analysis.

Chapter 4

Clinical outcome results

Intraclass correlation coefficients

Intraclass correlation coefficients (ICCs) were computed to provide an indication of how strongly patients were clustered within their centres at the start of the study, with respect to the important outcome measures. The results (*Table 8*) reveal very low ICCs with respect to the main measures of disease severity at entrance, that is, IBDQ and HADS scores, and relapses during the year prior to the trial. The percentages of patients who had missed an appointment also demonstrated a low ICC. Slightly greater but not undue variation between centres was in evidence with respect to numbers of hospital appointments, where the ICC was 0.109.

Main analysis of outcomes

The main analysis is concerned with the impact of the intervention on the various outcome measures used in the study. The outcomes derive from four different data sources: the entrance questionnaire completed by each patient at the start of the study after their initial consultation; the exit

questionnaire completed at the study's end; the hospital record for each patient; and the diary each patient kept during the course of the study.

The study had one primary outcome and a number of secondary outcomes. Results for the primary outcome are presented first.

Primary outcome: quality of life (IBDQ) scores at end of study

Table 9 summarises the analysis of IBDQ scores. The table indicates that after adjustment for covariates (including IBDQ scores at entrance), the difference between the mean IBDQ scores for the control and intervention groups at exit was 1.94 points [95% confidence interval (CI): -3.27 to 7.15]. This difference was not statistically significant ($p = 0.45$). A relatively large number (31) of entrance IBDQ scores had been imputed for the purpose of analysis. Stata uses a regression imputation method, which tends to result in conservative p -values, and therefore the analysis was re-run excluding the imputed cases. The effect of the intervention remained non-significant ($p = 0.34$).

Although not significant, the intervention group had the more favourable mean score, even after adjustment for covariates.

Secondary outcomes

Table 10 summarises the results for the secondary outcomes. Sample sizes vary from one outcome to another depending upon the data source and (to a lesser degree) as a consequence of

TABLE 8 Intraclass correlation coefficients at entrance

Variable	ICC
Entrance IBDQ	0.033
Entrance HADS	0.030
Hospital appointments in pre-trial year (hospital records data)	0.109
% of patients missing an appointment in the pre-trial year (hospital records data)	0.047
Flare-ups in pre-trial year (questionnaire data)	0.054

TABLE 9 Summary of results for the primary outcome

	Control group		Intervention group		Coefficient ^a (standard error)	95% CI	p-Value
	N	Mean (SD)	N	Mean (SD)			
IBDQ	296	167.7 (37.5)	236	172.3 (36.6)	1.94 (2.48)	-3.27 to 7.15	0.45

^a The coefficient represents the mean difference between control and intervention groups after adjustment for covariates (IBDQ score at entrance, gender, age, length of illness, diagnosis).

TABLE 10 Summary of results for secondary outcomes

	Control group		Intervention group		Coefficient ^a (standard error) method ^b	95% CI	p-Value
	N	Mean (SD)	N	Mean (SD)			
Outcomes from entrance questionnaire							
Enablement (after initial consultation)	352	3.0 (3.9)	260	4.0 (3.9)	0.90 (0.37) R	0.12 to 1.68	0.026
Satisfaction with initial consultation	358	62.1 (12.3)	260	65.4 (12.0)	3.47 (1.95) R	-0.62 to 7.56	0.09
Outcomes from exit questionnaire							
SF-36 – Physical functioning	303	75.8 (26.6)	237	78.1 (25.3)	1.27 ^g (0.97) R	-0.77 to 3.32	0.21
SF-36 – Role limitations, physical	290	60.3 (43.2)	232	61.4 (44.1)	0.33 ^g (2.80) R	-5.56 to 6.22	0.91
SF-36 – Role limitations, emotional	292	72.3 (39.6)	229	72.2 (41.0)	1.27 ^g (3.39) R	-5.85 to 8.39	0.71
SF-36 – Social functioning	306	72.2 (29.5)	243	74.8 (31.2)	2.43 ^g (1.53) R	-0.79 to 5.65	0.13
SF-36 – Mental health	303	67.8 (21.3)	243	70.3 (20.9)	1.04 ^g (1.21) R	-1.51 to 3.59	0.40
SF-36 – Energy/vitality	301	48.2 (25.4)	243	51.8 (24.5)	2.37 ^g (1.31) R	-0.39 to 5.13	0.09
SF-36 – Pain	307	67.1 (23.6)	243	69.5 (27.6)	1.78 ^g (1.42) R	-1.19 to 4.76	0.22
SF-36 – General health perception	300	49.4 (1.8)	241	53.2 (25.1)	2.02 ^g (1.25) R	-0.61 to 4.66	0.12
HADS	306	12.3 (7.6)	242	11.7 (7.9)	-0.35 ^h (0.41) R	-1.21 to 0.51	0.40
No. of relapses during trial year	246	2.2 (2.5)	206	1.8 (2.2)	-0.36 ⁱ (0.13) R	-0.63 to -0.09	0.013
% patients making at least one appointment for themselves	250	22.0%	144	43.1%	2.70 ^j (0.65) L	1.63 to 4.46	0.001
Frequency of GP visits during trial year (% making more than 2 visits) ^c	288	21.5%	232	18.1%	0.16 ^k (0.21) O	-0.28 to 0.59	0.47
Outcomes from hospital records							
No. of kept hospital appointments	364	3.0 (2.5)	274	1.9 (2.2)	-1.04 ^l (0.19) R	-1.43 to -0.65	<0.001
No. of DNAs ^d	364	0.22 (0.78)	274	0.09 (0.34)	-0.08 ^m (0.03) R	-0.15 to -0.01	0.034
% of patients who DNA	364	12.1%	274	8.0%	0.66 ⁿ (0.25) L	0.30 to 1.47	0.29
Outcomes from patient diaries							
Satisfaction with hospital visits ^e	397; 132	53.6 (9.1)	187; 64	54.6 (8.5)	1.22 (2.31) R	-3.67 to 6.03	0.62
No. of relapses	190	1.7 (1.8)	130	1.6 (1.6)	-0.15 ^o (0.16) R	-0.49 to 0.18	0.35

continued

TABLE 10 Summary of results for secondary outcomes (cont'd)

	Control group		Intervention group		Coefficient ^a (standard error) method ^b	95% CI	p-Value
	N	Mean (SD)	N	Mean (SD)			
No. of medically-defined relapses	190	1.2 (1.5)	130	1.2 (1.5)	0.02 ^b (0.16) R	-0.32 to 0.36	0.90
Average relapse duration (days) ^e	237; 100	18.4 (36.0)	153; 72	25.8 (47.9)	7.89 (5.72) R	-4.13 to 19.90	0.19
Delay before starting treatment (% starting within 1 day) ^{e,f}	235; 109	50.6%	181; 81	49.7%	-0.02 (0.24) O	-0.52 to 0.49	0.95

^a Coefficients and standard errors are adjusted for covariates. For linear regressions the coefficient is the adjusted mean difference between control and intervention groups; for logistic regressions the adjusted odds ratio; for ordered logistic regressions the beta coefficient. Unless stated otherwise below, the covariates were IBDQ score at entrance, gender, age, length of illness and diagnosis.

^b R = linear regression; L = logistic regression; O = ordered logistic regression.

^c Frequency of GP visits is presented here for convenience as a percentage, but the underlying data (as entered into the multivariate analysis) were on an ordinal scale: no visits, 1, 2, 3-5, 6-10, 11 visits or more.

^d DNA = did not attend outpatient clinic appointment.

^e Sample size refers to total number of visits/relapses across all patients. The number of patients for whom data were available appears after the semi-colon.

^f Delay is presented here for convenience as a percentage, but the underlying data (as entered into the multivariate analysis) was on an ordinal scale: no change to treatment, started within 1 day, 1-2 days, 2-7 days, over 1 week.

^g Adjusted for SF-36 dimension score at entrance, gender, age, length of illness, diagnosis.

^h Adjusted for entrance HADS, gender, age, length of illness, diagnosis.

ⁱ Adjusted for relapses in pre-trial year, entrance IBDQ, gender, age, length of illness, diagnosis.

^j Adjusted for entrance IBDQ, gender, age, length of illness, diagnosis, education.

^k Adjusted for GP visits in pre-trial year, entrance IBDQ, gender, age, length of illness.

^l Adjusted for appointments kept in pre-trial year, entrance IBDQ, gender, age, length of illness.

^m Adjusted for DNAs in pre-trial year, appointments kept previous year, entrance IBDQ, gender, age, length of illness.

ⁿ Adjusted for % who DNA in pre-trial year, appointments kept previous year, entrance IBDQ, gender, age, length of illness.

^o Adjusted for number of relapses in pre-trial year (from entrance questionnaire), entrance IBDQ, gender, age, length of illness, diagnosis.

^p Adjusted for number of relapses in pre-trial year (from entrance questionnaire), entrance IBDQ, gender, age, length of illness, diagnosis.

missing values. For convenience, these outcomes are organised in the discussion according to data source.

Outcomes from the entrance questionnaire

Enablement and satisfaction

The enablement (PEI) and satisfaction (CSQ) scales on the entrance questionnaire were completed by patients immediately after their medical consultation. For patients in the intervention arm, this was the appointment at which the consultant introduced the intervention. These scales have therefore been used as measures of outcome for that initial consultation. The analysis (Table 10) found that the control and intervention groups did not differ significantly with respect to satisfaction with the consultation.

However, the intervention group did have a significantly ($p = 0.026$) higher mean enablement score (up by 0.9 points after adjustment, on a scale of 0-12), suggesting that intervention patients, on the whole, may have experienced an initial boost in their confidence as a result of being in the intervention.

Outcomes from the exit questionnaire

Generic health status (SF-36)

There were no significant differences between the groups on any of the eight dimensions of the SF-36 generic health status questionnaire ($p > 0.05$ in all instances). Given that the disease-specific IBDQ instrument had not detected a difference, it is unsurprising that the generic instrument produced the same result.

Anxiety and depression (HADS)

HADS scores did not differ significantly between the two groups at the exit point ($p = 0.4$). Although not significant, the intervention group had the more favourable mean score, even after adjustment for other factors.

Relapses

The numbers of relapses experienced during the trial year – as reported by patients on the exit questionnaire – differed significantly between groups ($p = 0.013$), with the intervention group reporting on average 16% fewer relapses. However, when responding to this question, patients answered in terms of what they personally regarded a relapse to be, and it is possible that during the trial patients in the intervention group became more knowledgeable about medical criteria for a relapse (as a result of the information to which they were exposed), and adjusted their views accordingly. Hence the apparent reduction in relapses in the intervention group could be due to patients applying more stringent medical criteria when completing the exit questionnaire. This issue is explored in more detail later using the diary data on relapses.

Patients' self-reported disease activity for the year of the study was recorded in the exit questionnaire (see *Table 11*). The results show that disease activity for both groups was very similar, with 18.5% reporting no symptoms during the year of the study, 42.8% had some symptoms always present and 38.7% had an episodic disease course.

Self-made hospital appointments

In order to determine whether patients had been enabled to get open-access to clinics during the course of the study, they were asked to report how many of their hospital appointments had been self-made and how many had been made by the hospital. This serves as an indicator for system compliance. For analysis purposes the information on self-made appointments was dichotomised into two groups: those who had made appointments and those who had not. Considering only those

patients who had an appointment during the trial year, 43% of patients at the test centres made at least one appointment for themselves compared with 22% of patients at control centres. The difference is highly significant ($p < 0.001$).

GP visits

It is possible that the significant reduction in hospital appointments under the intervention (see above) was complemented by an increase in the number of visits to GPs. In other words, that workload was simply shifted from secondary to primary care. To examine this fully would require specific counts of the number of GP appointments (for IBD) made by each patient, both during the trial and for the previous year. These data were not available, but patients did provide an estimate of GP visits made, on both the entrance and exit questionnaires. The figures reported were often approximate or given as a range (e.g. 3–5) or a frequency (e.g. 'every month'). To make this usable the data were recoded as no visits, 1, 2, 3–5, 6–10 and 11 or more, with each category being approximate rather than exact.

Using these data, an ordered logistic regression analysis found no significant difference ($p = 0.47$) between the intervention and control groups with regard to the frequency of GP appointments during the trial, after controlling for frequency prior to the trial, along with other factors. This result was confirmed using bootstrapping. In all, 22% of the control group reported more than two GP visits for IBD compared with 18% of the intervention group.

Hospital record data

Hospital records provided accurate details of outpatient appointments. Three outcome measures have been constructed from this information: the number of appointments kept (i.e. attended) by each patient over the course of the trial year; the number of made appointments that each patient did not attend (DNA); and the

TABLE 11 Summary of disease activity in past year (taken from 551 who returned exit questionnaires)

Symptoms in past year	Control (%)	Intervention (%)	Total (%)
No symptoms at all	54 (18.1)	46 (19.0)	100 (18.5)
Some symptoms always present	124 (41.6)	107 (44.2)	231 (42.8)
Flare-ups followed by symptom free periods	120 (40.3)	89 (36.8)	209 (38.7)
Pearson chi-squared = 0.69, degrees of freedom (df) = 2, $p = 0.71$ not significant.			

percentage of patients who DNA on at least one occasion. The records also allowed comparative figures to be derived for the pre-trial year. One of the features of the intervention is that patients should theoretically be free to make appointments as and when they feel the necessity, rather than be wedded to routine fixed-interval appointments. There is interest, therefore, in whether empowering patients to decide their own appointments changes the frequency of appointments and/or the likelihood that patients will attend once an appointment has been made.

When computing the outcome measures, the appointment at which the patient was recruited to the study 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.

Analysis (*Table 10*) revealed a highly significant reduction in the mean number of kept appointments during the trial for patients in the intervention group, compared with control patients ($p < 0.001$). In view of the highly skewed nature of the distribution of the data, bootstrapping was applied and the significance of this result was confirmed. The mean number of kept appointments went from 3.0 to 1.9 for the intervention group and from 3.1 to 3.0 for the controls. Allowing for the fact that these figures exclude the recruitment appointment, this represents a reduction in the total number of outpatient appointments over a year of around 25%.

The mean number of DNAs during the trial was also significantly lower for the intervention group ($p = 0.034$), even after adjustments for DNA rates in the pre-trial year. Bootstrapping was used to confirm this result. Interpretation of this finding is made complex however, by the fact that the mean number of DNAs (per patient) for both groups increased (from 0.07 to 0.09 for the intervention group and from 0.13 pre-trial to 0.22 for the controls), with the significance of the result being due to the fact that the increase was substantially greater for the control group.

Despite the evidence for fewer DNAs per patient under the intervention, the percentage of patients who DNA at least once did not differ significantly between groups, although it was slightly lower for the intervention group (8% compared with 12%).

Patient diary data

There were no significant differences between groups with respect to any of the five outcomes derived from the patient diaries [satisfaction with hospital visits, number of relapses, number of 'medically defined' relapses, relapse duration and the delay between a relapse starting and the patient beginning treatment (see *Table 10*)].

The failure of the number of relapses to reach significance contradicts the finding based on what patients reported on the exit questionnaire (see above). Part of the reason for this may be that diary data on relapses were only available from little more than half of those who completed the exit questionnaire, resulting in lower power for detecting a difference. Details recorded in the diaries about each relapse allowed the events to be categorised as either 'medically defined' or 'patient defined' flares, with the latter category including all flares that failed to match the medical criteria (see *Table 7* and Appendix 9). It was felt that focusing on medically defined relapses would provide a more reliable test of the possibility that relapse frequency changed under the intervention. Of flares reported in the diaries, 72% matched the medical criteria. No significant difference was found, with the frequency of such flares identical in both the control and intervention groups at an average of 1.2 flares per patient over the trial year.

A total of 528 relapses (medical and patient-defined) were recorded by 218 patients in their diaries; 32% of patients reported no relapses in the course of the year, 25% one relapse and 30% either two or three relapses (see *Table 12*). The maximum number of relapses reported was eight. Of those in remission at baseline (patients who had had no relapses of their condition for 18 months), 53% had no relapses and 33% had one relapse during the year of the study. Those who had active disease at baseline were considerably less likely to have had no relapses (22%) and were more likely to have more than one relapse during the year (54%). *Table 13* shows the number of medically defined relapses reported by patients in each group; 82 patients had one such relapse and eight patients had six relapses.

Doctor visits

Patients were asked to record GP and hospital doctor visits in their diaries. The detailed analysis of hospital visits was based on data from hospital records; diary data gave more detail about the reasons for making the visits, but unfortunately

TABLE 12 Summary of the number of all flare-ups per patient recorded in the diaries

Total no. of all flare-ups	Control (%)	Intervention (%)	Total (%)
0	61 (32.1)	41 (31.5)	102 (31.9)
1	47 (24.7)	34 (26.2)	81 (25.3)
2	29 (15.3)	25 (19.2)	54 (16.9)
3	26 (13.7)	15 (11.5)	41 (12.8)
4	9 (4.7)	5 (3.8)	14 (4.4)
5	6 (3.2)	6 (4.6)	12 (3.8)
6	10 (5.3)	4 (3.1)	14 (4.4)
8	2 (1.1)		2 (0.6)
Total	190 (100)	130 (100)	320 (100)

TABLE 13 The number of medically classified flare-ups per patient recorded in the diaries

Total no. of medical flare-ups	Control (%)	Intervention (%)	Total (%)
1	49 (46.2)	33 (45.8)	82 (46.1)
2	26 (24.5)	16 (22.2)	42 (23.6)
3	18 (17.0)	12 (16.7)	30 (16.9)
4	4 (3.8)	3 (4.2)	7 (3.9)
5	3 (2.8)	6 (8.3)	9 (5.1)
6	6 (5.7)	2 (2.8)	8 (4.5)
Total	106 (100)	72 (100)	178 (100)

TABLE 14 Summary of visits (based on diary replies)

	Control (mean)	Intervention (mean)	Total (mean)
Total outpatient visits	408 (2.14) range 0–10	192 (1.47) range 0–9	600 (1.86)
Total GP visits	114 (0.60) range 0–8	80 (0.61) range 0–12	194 (0.60)
Total A&E visits	9 (0.05) range 0–1	4 (0.03) range 0–2	13 (0.04)

there are insufficient data to allow analysis. Details of doctor visits recorded in the diaries are given in *Table 14*. In total, 29.5% ($n = 95$) of patients recorded 194 visits to the GP; the number of visits made per patient ranged from one to 12. A total of 600 visits to hospital outpatients were made by 60.9% ($n = 196$) of patients; the number of visits ranged from one to 10. Thirteen visits to the accident and emergency department were made by 3.7% ($n = 12$) of patients.

Additional analyses

Interactions between the intervention and other variables

For two of the outcome variables, some specific hypotheses involving interactions between the intervention and certain patient characteristics were subjected to statistical testing. Each hypothesis was tested by repeating the relevant main analysis while including the appropriate interaction term.

Two interactions were hypothesised with respect to IBDQ scores at exit. The first was that the intervention may be more effective (in terms of IBDQ scores) with patients who have higher levels of educational achievement (tested by adding the intervention by education interaction to the model). The result was non-significant. The

second hypothesis was that the intervention may be differentially effective depending upon the status of the patient's disease at the start of the trial (specifically, whether active, intermittent or in remission). This interaction was also non-significant.

Two further interactions were examined, with the aim of exploring further the finding that patients in the intervention arm had significantly fewer hospital appointments during the trial. It was postulated that the extent to which intervention patients controlled their own appointments may be related to their educational level, but the interaction proved to be non-significant. It was also postulated that the amount by which appointments declined may depend upon the patient's diagnosis (Crohn's disease or ulcerative colitis). This interaction was also found to be non-significant.

Compliance analysis

An analysis has been conducted to determine whether any of the trial outcomes were influenced by patient compliance with the intervention. For this purpose patients who received the intervention were subdivided according to information about self-management plans (SMPs). Consultants should have provided each patient with an SMP as part of the protocol for the intervention. Patients in the intervention arm were

TABLE 15 Patients' recall of the parts of the intervention they were given by their consultant (based on patients in the intervention arm of the study)

	Yes	No	Missing
Open access to clinics	158	43	67
A date for the next appointment	138	71	69
An SMP	120	79	79

asked about these plans (see *Table 15*): 120 indicated that they had been provided them with such a plan, 79 said they had not received a plan and 79 did not know or did not answer [the large number here may reflect patient uncertainty as to what the term 'self-management plan' referred to, or doubt as to whether verbally proffered plans (as opposed to written plans) qualified]. It needs to be acknowledged, however, that as a measure of patient compliance the presence/absence of a SMP is only approximate; for example, some patients may have a plan but not follow it; others may have no plan but comply with all other aspects of the intervention.

The compliance analysis requires that patients in the intervention arm are categorised as either compliers or non-compliers (see the section Secondary analyses, p. 18). In this trial these groups are represented by patients with and without SMPs, respectively. The group of 'don't know' patients lie somewhere in-between. Compliance analysis makes the assumption that non-compliers receive the same 'treatment' as control group patients; therefore, in order to meet this assumption best, 'don't know' patients were combined with the complier group.

Considerable variation was observed between test centres with regard to the use of SMPs, with the percentage of patients stating they had received a plan ranging from 14 to 61%. To determine whether any patient characteristics other than centre influenced which patients had received plans, a multinomial logistic regression was performed (with three levels of outcome: plan, no plan, don't know) using the following as predictors: gender, age, length of illness, diagnosis, IBDQ score at entrance, HADS score at entrance, educational level, smoking behaviour, number of appointments in pre-trial year and number of DNAs in pre-trial year. None of these characteristics was found to possess any significant relationship with the presence or absence of an SMP.

A compliance analysis was performed for each outcome variable. The analysis involved

introducing two covariates into each regression analysis in place of the intervention variable: one to represent compliance and a second to account for (unmeasured) factors that determine compliance. All other aspects of the analyses remained the same as in the main analysis, that is, the adjustment factors, the weights and the clusters.

Compliance was found to be statistically significant with respect to five outcomes (*Table 16*): enablement scores subsequent to the initial consultation ($p = 0.025$); number of flare-ups during trial year (as reported on the exit questionnaire; $p = 0.012$); the percentage of patients making appointments for themselves ($p < 0.001$); the number of kept hospital appointments (from hospital records; $p < 0.001$); and the number of DNAs (from hospital records; $p = 0.034$). These findings were a complete duplication of the results of the main analysis (with regard to both non-significant and significant effects), and in all cases compliance with the intervention produced a significantly better outcome. *Table 16* also presents the estimated effect sizes associated with compliance. As an example, the mean number of appointments kept by patients in the intervention arm who complied with the treatment (i.e. those with SMPs and those who were uncertain) was 1.56; the associated effect size of -1.46 means that this is 1.46 points lower than what would be expected had these patients received the control treatment only (i.e. 3.02 appointments).

Management system preference

On the exit questionnaire patients were asked to indicate whether they preferred the traditional management system of fixed hospital appointments, or the intervention system where they receive a personal SMP and can make their own appointments (see *Table 17*). Analysis was undertaken to determine which patient characteristics, if any, predicted patient choice in this respect. The analysis was restricted to patients in the intervention arm, as they were the only ones who had experience of both systems. Overall, 26% of patients in this arm expressed a preference for the traditional system and 74% a preference for the intervention. Logistic regression with stepwise elimination was used to obtain a minimal set of significant predictors.

Two models were produced (*Table 18*). Model I was based on an analysis using patient baseline variables only. In this model patient preference is predicted by length of illness ($p = 0.016$) and

TABLE 16 Summary of compliance analysis

	Coefficient ^a (standard error)	95% CI	p-Value ^b
Outcomes from hospital records			
No. of kept hospital appointments during trial	-1.46 (0.26)	-2.0 to -0.91	0.000
No. of DNAs during trial	-0.11 (0.05)	-0.20 to -0.01	0.034
% of patients who DNA (logistic regression)	0.49 (0.27)	0.16 to 1.54	0.208
Outcomes from entrance questionnaire			
Enablement scores after initial consultation	1.26 (0.52)	0.17 to 2.35	0.025
Satisfaction with initial consultation	4.48 (2.73)	-1.25 to 10.23	0.118
Outcomes from exit questionnaire			
IBDQ	3.11 (3.36)	-3.95 to 10.16	0.367
HADS	-0.52 (0.57)	-1.72 to 0.68	0.373
No. of flares during trial year	-0.51 (0.18)	-0.90 to -0.13	0.012
Frequency of visits to GP during trial year (ordered logistic)	0.18 (0.30)	-0.45 to 0.81	0.555
% of patients making at least one hospital appointment for themselves (logistic regression)	4.28 (1.39)	2.17 to 8.47	0.000
Outcomes from patient diaries			
Satisfaction with hospital visits	1.11 (3.10)	-5.41 to 7.63	0.725
No. of flare-ups	-0.24 (0.21)	-0.69 to 0.21	0.277
No. of medically defined flare-ups	-0.01 (0.21)	-0.46 to 0.44	0.976
Flare-up duration	13.36 (10.95)	-9.65 to 36.37	0.238
Delay before starting treatment (ordered logistic)	-0.08 (0.35)	-0.81 to 0.65	0.828

^a For linear regressions the coefficient is the adjusted mean difference between compliers in the test group and equivalent control patients; for logistic regressions the adjusted odds ratio; for ordered logistic regressions the beta coefficient.

^b The p-values are taken from the regression analysis, using the same adjustment factors as in Table 10.

TABLE 17 To show which system of management patients preferred after taking part in the study

System preference	Control (%)	Intervention (%)	Total (%)
A system where you are given regular fixed appointments	121 (40.6)	59 (25.7)	180 (34.1)
A flexible system with a personal self-management plan and open access	177 (59.4)	171 (74.3)	348 (65.9)
Total	298 (100)	230 (100)	528 (100)

Pearson chi-squared = 12.92, df = 1, p < 0.001.

TABLE 18 Logistic regression modelling of patient preference for the intervention management system

	Significant effects after stepwise elimination	Odds ratio	95% CI	p-Value
Model I (predictor set comprised of patient baseline variables only) ^a	Length of illness	0.96	0.93 to 0.99	0.016
	Diagnosis	1.70	1.01 to 2.85	0.046
Model II (predictor set of patient baseline variables and intervention characteristics) ^b	Aware of self-management plan	3.20	1.29 to 8.00	0.019
	Has made appointments for self	3.43	1.10 to 10.69	0.037
	IBDQ score at entrance	0.99	0.98 to 0.999	0.042
	Length of illness	0.95	0.91 to 0.99	0.022
	No. of hospital appointments in pre-trial year	1.15	1.02 to 1.29	0.028

^a Initial predictor set: entrance IBDQ, entrance HADs, gender, age, length of illness, diagnosis, educational level, appointments in pre-trial year, DNAs in pre-trial year, flare-ups in pre-trial year.

^b Initial predictor set: entrance IBDQ, entrance HADs, gender, age, length of illness, diagnosis, educational level, appointments in pre-trial year, DNAs in pre-trial year, flare-ups in pre-trial year, self-management plan, open access, made appointments for self.

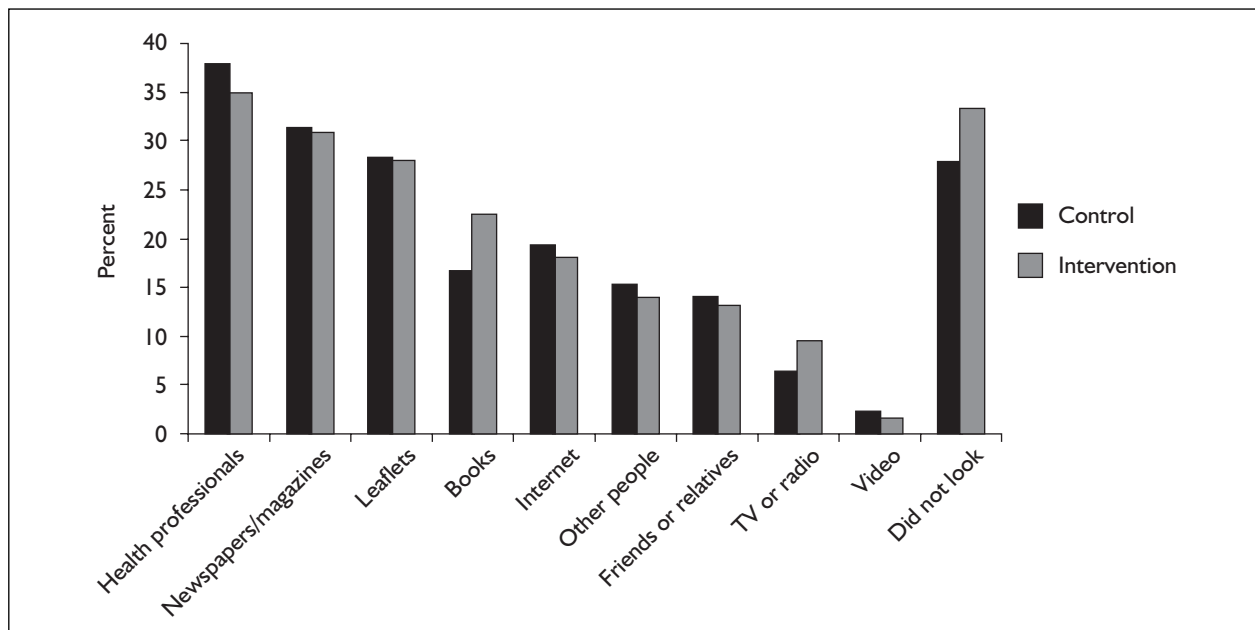


FIGURE 5 Information sources utilised during the year of the study

TABLE 19 To show whether participating in the study has changed patients' views (based on the 535 who returned entrance and exit questionnaires)

Change	Control: <i>n</i> (% who said yes)	Intervention: <i>n</i> (% who said yes)	Total: <i>n</i> (% who said yes)
Changed the way you've thought about your illness	38 (13.2)	57 (25.0)	95 (18.4)
Changed the way you manage your illness	20 (6.9)	45 (20.2)	65 (12.7)
Changed your view of your hospital consultant	35 (12.3)	34 (15.2)	69 (13.6)

diagnosis ($p = 0.046$): patients who had lived with the condition fewer years were more likely to prefer the intervention, as were patients with Crohn's disease.

Model II was derived from an analysis that included factors related to the intervention itself alongside the baseline variables. These were (i) the patient being aware that they had an SMP (compared with not knowing or not having a plan), (ii) the patient being aware they had open access and (iii) the patient making at least one appointment for themselves. All three factors are indicative of compliance with the intervention.

The resulting Model II is rather different from Model I. Of the intervention variables, both SMPs ($p = 0.019$) and self-made appointments ($p = 0.037$) appear as significant terms (preference for the intervention increasing where either of these are present), but open access does not. In addition, the presence of these factors has a marked effect on the baseline variables in the model: length of illness still appears ($p = 0.022$) but diagnosis does not; while lower (i.e. more severe) entrance IBDQ

scores and a higher frequency of pre-trial appointments both join the model as significant predictors of a preference for the intervention ($p = 0.042$ and 0.028 , respectively).

Other data

Other findings from the 551 patients who returned the exit questionnaire related to information seeking. One source of information is a patient support group such as NACC and 95 (17.2%) stated that they were members. Of these, 13 (nine from the control group and four from the intervention group) had joined during the year of the study. Other sources of information are outlined in *Figure 5*. There was no difference between the two groups regarding information seeking during the year of the study; most (36.5%, $n = 201$) got their information from health professionals. There was an increase from baseline figures of those using the Internet to obtain information (12% at baseline compared with 18.7% at exit). Nearly one-third of patients did not seek information during the year of the study.

Changing attitudes

Responses to questions in the exit questionnaire indicate that there were differences between the intervention and control groups (see *Table 19*). Those in the intervention group were more likely to say that being in the study had made them change the way in which they thought about their illness and changed the way in which they

managed their condition. Both groups had similar responses on whether participating in the study had changed their view of their consultant. The qualitative interviews outlined in the next section explore in greater detail which aspects of the study changed the behaviour or thinking of patients and consultants.

Chapter 5

Qualitative results

Interviews with patients

Introduction

The qualitative aspect to the study enabled a more in-depth understanding of the experience of the intervention for individual patients. The qualitative interviews were undertaken to explore the workings of the components of the intervention from the patients' perspective and to illuminate the mechanisms underlying changes identified from the quantitative results (Miles and Huberman,¹⁴⁸ p. 9; Patton,¹⁴⁹ p. 50).

The experience of chronic illnesses is characterised by its uncertainty and longevity and follows a trajectory characterised by alternating periods of stability and crisis, and alterations in life-style and the need for care. There is low probability of improvement and either the possibility or the certainty of a decreased life-span.^{150,151} The ways in which people deal with a chronic illness and subsequent interventions and medical regimes depend on a number of interrelated social and cultural factors, including the patient's own personality and cognitive abilities, family relationships and the external support system.^{152,153}

Attempts to understand how people cope with chronic illness have benefited from theoretical frameworks developed to explain the process of stress and coping. The cognitive theory of stress and coping developed by Lazarus and Folkman¹⁵⁴ (see *Figure 6*) emphasises the ('dynamic, mutually reciprocal, bi-directional') relationship between the person and the environment (Lazarus and Folkman,¹⁵⁴ p. 293). Appendix 11 gives more details of this theory.

The interviews

Informed by a review of qualitative research on self-care,¹⁵⁵ the interviews explored the impact and meaning of the illness to the individual patient, the support available to them and their ways of coping with IBD prior to the intervention. The second focus of the interview was on the way in which the patient had experienced and received the intervention. This included the manner in which the process of self-care was initiated by the doctor and received by the patient, the description and experience of receiving a patient-centred

consultation and the arrangements and use of the 'open-access' contact and appointment system. A further focus was on identifying from accounts possible influences associated with positive or negative outcome and other changes from the patients' perspective that might be attributed to the intervention.

Sample and methods

For the interviews, a purposeful maximum variation sample of patients was selected. This sampling strategy is predicated on the assumption that "Any common patterns that emerge from great variation are of particular interest and value in capturing the core experience and central shared aspects or impact of a programme" (Patton,¹⁴⁹ p. 172). From the exit questionnaires, the first criteria for sample selection were related to the reported symptoms during the year and to the outcome (reported satisfaction) with each aspect of the intervention (guidebook, self-management, access and consultations). From these data, positive and negative responses were evident within each case, and for each of the variables. Thus the sample was selected in stages and the data set was built up to reflect this variability from a range of patients chosen by age, gender, illness characteristics (newly diagnosed

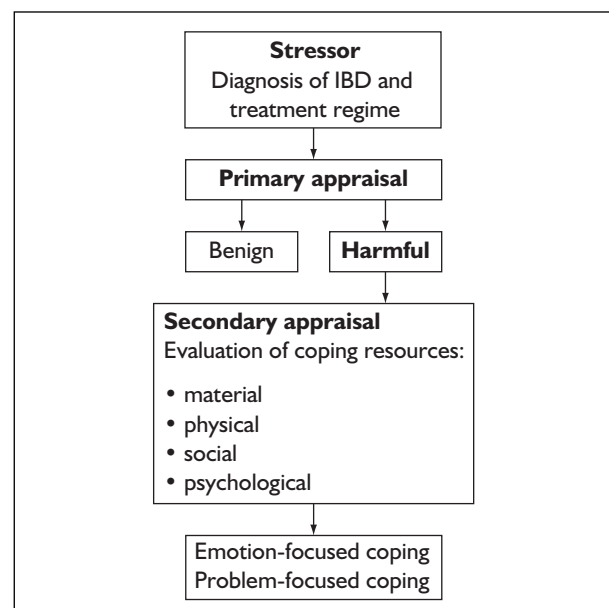


FIGURE 6 The cognitive model of stress and coping¹⁵⁴

and long-term patients) and demographic characteristics (marital and employment status).

Patients were contacted by telephone (E.N.) within 2 months of the return of their exit questionnaires and invited to participate in face-to-face interviews (or telephone interviews if that was the preferred choice) which would be tape recorded for analysis. Patients were fully informed that the purpose of the interview was to obtain a more in-depth understanding of their experiences during the 12 months of the trial and what they remembered about the intervention process.

Reassurance was given as to the confidentiality of the interviews and patients were made aware that they could stop the interview and withdraw at any time. Patients were advised that the interview could take anything from 30 to 60 minutes depending on how much they had to say. From the nine test sites, 38 patients were approached and invited to participate in interviews. Of these, eight patients refused (seven female, one male) because they wanted no more involvement in the study and two female patients were withdrawn because they had not been entered into the trial by the consultant. Of these 10 patients, four had Crohn's disease and six had ulcerative colitis. Of the 28 patients in the sample, nine opted for taped telephone interviews (five males, four females) and 19 were interviewed in their own home. The characteristics of the sample for analysis are shown in *Table 20*. Of those who were employed, 14 worked full time (three were self-employed) and five worked part-time. Of those who were not working, five lived on incapacity benefit, four were retired and two were housewives.

Analysis

Data analysis took place in stages, commencing with full verbatim transcriptions and analysis of initial interviews which informed and helped develop themes in the subsequent collection of qualitative data. Second, the responses from the interviews which formed the bases of emergent themes were entered into NUD*IST (non-numerical unstructured data with indexing, searching and theorising) to build up a filing and retrieval system for later use,¹⁵⁶ and the more objective data (e.g. gender, age and diagnosis) were entered into an SPSS database.¹⁵⁷ Two additional investigators (A.K., A.R.) met with the researcher regularly to read transcripts singularly, share disciplinary insights, debate observations and develop themes.¹⁵⁸ The third step in the analysis was to produce initial reference matrix charts in order to display the variability of the sample and to categorise emerging themes to visualise trends and patterns across cases.^{148,159} The thematic analysis was also informed by the cognitive theory of stress and coping (see Appendix 11).

Prior to the intervention, people had already established ways to self-care and cope with their condition which implicated their domestic, personal and work contexts. However, in the analysis, we are mainly interested in distinguishing any changes in the way people manage their IBD due to the intervention.

Results

It is important to note that constructs of 'satisfaction' derived from the qualitative data did not always correspond to the structured ratings of

TABLE 20 Characteristics of the interview sample (n = 28)

Disease characteristics	n (%)	Demographic characteristics	n (%)
Diagnosis		Age	
Ulcerative colitis	16 (57)	Under 30 years at recruitment	5 (18)
Crohn's disease	12 (43)	30–50 years at recruitment	13 (46)
Duration of disease		51+ years at recruitment	10 (36)
< 2 years at recruitment (new)	4 (14)	Gender	
3–5 years at recruitment (mid)	8 (29)	Male	12 (43)
6+ years at recruitment (long)	16 (57)	Female	16 (57)
Symptoms since recruitment		Marital status	
Stable (no symptoms)	16 (57)	Partnered	19 (68)
Unstable (intermittent)	9 (32)	Single	9 (32)
Chronic (uncontrolled)	3 (11)	Employed?	
		Yes	19 (68)
		No	9 (32)

the questionnaire (quantitative) data used to measure outcomes in the main trial. Given the opportunity to talk freely, some patients were less positive about their satisfaction with the different parts of the intervention than they indicated on the questionnaire. These results indicate that the quantitative data may be less sensitive and underestimate the problems with the process of the intervention.

Interviewed patients were asked about their general overall satisfaction with the intervention and how they felt about being in the trial and from the responses a pattern of three groups of patients emerged:

- patients who reported that they were very satisfied with their care (VS) and who benefited from the process of the intervention ($n = 17$);
- patients who were satisfied with their care (S) but had some reservations about certain aspects of the process of the intervention ($n = 6$);
- patients who were not satisfied with their care (NS) and who perceived no benefits from being in the trial ($n = 5$).

Satisfaction with the intervention has been used as a heuristic device to map which parts of the intervention worked for patients and the underlying associated processes and influences.

Matrix 1: patterns of coping resources and overall satisfaction

Although there was considerable variability across these three groups in terms of disease characteristics (type and stage of disease and symptoms during trial), Matrix 1 (Table 21) demonstrates that all patients in the NS group had unstable or chronic symptoms that remained uncontrolled during the trial. The NS group appeared to have fewer available coping resources (x) than other groups, with three of the five patients living alone and expressing feelings of social isolation. The worst case in the NS group was a woman with long-term Crohn's disease (802) who had suffered recent loss of material resources (loss of job, income and housing), and had insufficient physical (constantly in pain and incapacitated), psychological (depression and inability to control life events) and social resources (living alone and isolated from support). The preferred coping strategies of patients in each group are also indicated in Matrix 1, (x) indicating that some patients chose to carry on as normal and to put their illness 'out of mind' (emotion-focused coping), whereas others, with the exception of newly diagnosed patients, coped by

actively seeking information and support from as many sources as possible (problem-focused coping).

Existing coping resources and social context of the sample

In general, in relation to the personal and social context of the management of illness, the importance of work as a context for managing illness and coping resource was a prominent feature of people's accounts of how they had managed the illness to date. People frequently report experiencing problems at work in managing acute symptoms. There are also those who relied on work as a means of control and whose self-management was regulated by sustaining a working life.

"I'm a learning support worker but if it wasn't for my work – which I love and which keeps me going – I don't think I could keep positive about my illness"

(1124, NS group, female, CD, aged 29)

Patients who reported more satisfaction with the intervention were seemingly more able to regulate, control and normalise their illness at work. Those in manual and physical occupations had less flexibility in their working routines than patients who were self-employed or in professional occupations and also felt more precarious in terms of their prospects of continuing employment.

"It's hard to get jobs when you're my age so if they're going to make someone redundant I might be the first person to go – so I decided to say nothing ... I'm a fitter and I changed my shifts to a night job because I can work inside on nights with less people around to know that I'm not feeling so good."

(1404, VS group, male, UC, aged 47)

Some patients felt supported in the workplace after disclosure but others chose not to disclose details of their illness and tried to hide their symptoms because they considered their disease to be a 'private' matter or because of fear of discrimination in the workplace.

"Everything is fine until they ask for a medical – so now I don't tell anyone. I've not told my present job and I'll just say I have a headache if I'm not well."

(1432, S group, female, CD, aged 21)

Of the five patients who were living on incapacity benefit, the two most vulnerable were those who most regretted having to give up their jobs because of their disease.

"I was working in the food trade. It got embarrassing and they noticed I was having to disappear all the time to the toilet. So in the end I gave my own notice but I wouldn't tell them why – I wanted to keep it private."

(1012, NS group, female, CD, aged 41)

TABLE 21 Matrix 1: satisfaction with intervention and response to illness

Diagnosis gender ID	Satisfied With intervention	Stage of illness ^a	Coping resources available				Coping strategies		Symptoms during year of trial ^b	Fixed appointments retained ^c	No appointments during year (#)	Changes due to trial?	Active information seeker?
			Material	Physical	Psychological	Social	Emotion- focused	Problem- focused					
CD f 1124	NS	Long	x			x		x	Chronic	*doc		No	Yes
CD f 1102	NS	Long					x		Chronic	*doc		No	No
UC f 802	NS	New							Chronic	*joint		No	No
UC m 527	NS	Long	x	x	x			x	Unstable	*doc		No	Yes
CD f 1012	NS	New	x			x	x		Unstable	*joint		No	No
CD m 1410	S	Long	x	x	x	x			Unstable	*doc		Yes	No
CD m 1210	S	Long	x	x	x	x		x	Unstable	*doc		No	Yes
CD m 1001	S	Mid	x		x	x		x	Unstable	*doc		Yes	Yes
UC f 720	S	Long	x	x	x	x			Unstable	*joint		Yes	No
CD f 1432	S	Mid	x	x	x	x	x		Stable		#	Yes	No
UC f 713	S	Mid	x	x	x	x	x		Stable		#	Yes	No
UC f 1107	VS	Mid	x	x	x	x			Unstable	*joint		No	No
UC m 218	VS	Long	x	x	x	x			Unstable			Yes	No
UC m 503	VS	Mid	x	x	x	x	x		Unstable			No	No
UC f 215	VS	New	x	x	x	x	x		Stable		#	Yes	No
CD f 230	VS	Long	x	x	x	x	x	x	Stable	*joint		Yes	Yes
CD m 1017	VS	New	x	x	x	x	x		Stable	*joint		Yes	No
UC m 715	VS	Long	x	x	x	x		x	Stable	*joint		Yes	Yes
CD f 1023	VS	Long	x	x	x	x		x	Stable		#	No	Yes
CD f 1025	VS	Long	x	x	x	x	x		Stable		#	Yes	No
CD m 203	VS	Long	x	x	x	x		x	Stable		#	Yes	Yes
UC f 1429	VS	Mid	x	x	x	x	x		Stable		#	Yes	No
UC f 1418	VS	Long	x	x	x	x		x	Stable	*joint		No	Yes
UC m 1109	VS	Long	x	x	x	x		x	Stable		#	Yes	Yes
UC m 1404	VS	Mid	x	x	x	x	x		Stable		#	Yes	No
UC m 1205	VS	Long	x	x	x	x		x	Stable		#	No	Yes
UC f 1221	VS	Long	x	x	x	x		x	Stable		#	No	Yes
UC f 504	VS	Long	x	x	x	x		x	Stable		#	No	No

^a Stage of illness: new = <2 years; mid = 3–5 years; long = 6+ years at recruitment.
^b Symptoms: stable = no flare-ups or symptoms; unstable = flare-ups + symptom free; chronic = symptoms always present – out of control.
^c fixed appointments retained: *joint = shared decision; *doc = doctor's decision.

The interviews showed that for both male and female patients, jobs are an important resource not only for financial reasons (material resources) but also because they are linked to identity and perceived competence (psychological and social resources) in managing and controlling their illness.

The workings of the intervention

Matrix 2: patterns of changes and constraints

Patients were asked at interview whether the intervention overall had resulted in any changes/benefits for them. Matrix 2 (see Table 22) shows that 15 patients from the two satisfied groups reported one or more (#) benefits associated with different aspects of the package and these results will be reported in later sections. Matrix 2 also shows that patients from all three groups gave one or more reasons (\$) why there were no changes which could be attributed to intervention. These ranged from the poor health and uncontrolled symptoms of the NS patients to the good quality of the service provision pre-trial for the other patient groups. From the interviews, it was possible to identify perceived problems or individual influences (+) perceived by patients (NS + S groups) as constraining the process of the intervention. These constraints (aspects of illness and delivery and quality of care) will be reported in the following sections of the results. The interviews also showed that at the end of the trial, patients in all three groups reported a variety of different concerns (*n*) as shown in Matrix 2 (number of additional concerns). Although 10 of these patients had attended clinic during the year of the trial, none of the reported concerns had been disclosed by them, or investigated by the consultant. Because of the pragmatic nature of the intervention, the results from each aspect of the intervention package will be discussed separately in the following sections. Patients were asked about the different aspects of the intervention because it was recognised that different components would have greater salience than others.

Components of the intervention

The evidence-based guidebook

The provision of the guidebook served two main purposes: to serve as a focus for discussion in negotiation between the patient and the professional about the new system of care enabling a partnership to be formed, and to act as a source of information about the condition and self-care activities. Although the interviews explored in-depth the process of the intervention as a whole, the most positive aspect of the intervention from the patients' perspective was the utility of the

guidebook (the latter seemingly benefited all patients interviewed despite some reservations about other aspects of the intervention package). It was also clear from patient reports that the way in which the guidebook was introduced during the initial consultation varied. Some consultants discussed and reviewed the guidebook jointly with the patient and negotiated and recorded their self-management plan in the book.

"He wrote everything down and he went through the book and he showed me on the diagram where my Crohn's disease was. He said he'd like to monitor me and see how I went and for me to keep a diary, put things in the book and report back – for the purposes of research."

(1023, female, CD, aged 60)

Patients who were less specific in their recall of this process were those who were not apparently given a new self-management plan and those who reported feeling intimidated and felt that the recruitment consultation was rushed.

"He's very kind of – in and out – so you're a bit confused and a bit like – 'Oh what's going on?' and you get 5 minutes if you're lucky. I wasn't particularly sure what I was doing when I left."

(1432, female, CD, aged 21)

Table 23 presents some examples of the responses to the guidebook by patients.

Different utilities

In addition to informing and educating, the guidebook provided reassurance for many and was helpful to patients in a number of different ways. It was an external reference point for assessing the severity of symptoms. The contents of the guidebook prompted some patients to consider their condition in relation to the examples and information provided in the book.

"It made me realise that some are really bad with ulcers and maximum dosage and I haven't got it as bad as some."

(1017, male, CD, aged 24)

Most patients benefited from the explanations of surveillance and treatment and the interpretation of blood test results.

"That was a good thing about the book because I've had a lot of blood tests but I didn't actually know what was normal, but that little chart with all the normal readings was quite helpful. I've got a little card that I have to keep with all my blood tests on and I didn't really know what was normal. I have asked many times about blood tests and the answer I usually got was 'don't worry, it's normal' but what's normal? So they don't tell you exactly what's normal, but the book did."

(1023, female, CD, aged 60).

A strong theme emerging from the responses to the guidebook was its extended use which benefited

TABLE 22 Matrix 2: changes, constraints to the process and additional concerns

ID	Satisfied	Diagnosis	Length	No. of changes due to intervention ^a				No. of constraints to the process of the intervention ^a				No. of additional concerns (n) ^b	No. appts during year X ^c	Symptoms during year
230	VS	CD	Long	#	#	#	#					-		Stable
1025	VS	CD	Long	#	#	#	#					-	X	Stable
215	VS	UC	New	#	#			+				1	X	Stable
218	VS	UC	Long	#	#							-		Unstable
203	VS	CD	Long	#	#							-	X	Stable
715	VS	UC	Long	#	#							-		Stable
1429	VS	UC	Mid	#	#							2	X	Stable
1109	VS	UC	Long	#	#							-	X	Stable
1017	VS	CD	New	#	#							2		Stable
1404	VS	UC	Mid	#	#							-	X	Stable
1410	S	CD	Long	#				+	+	+	+	-		Unstable
1432	S	CD	Mid	#				+	+	+	+	5	X	Stable
720	S	UC	Long	#				+	+	+		3		Unstable
713	S	UC	Mid	#				+	+			-	X	Stable
1001	S	CD	Mid	#				+	+			1		Unstable
				No. of reasons why no change^a				No. of constraints to the process				Additional concerns (n)^b		
1102	NS	CD	Long	\$				+	+	+	+	3		Chronic
527	NS	UC	Long	\$	\$			+	+	+	+	3		Unstable
1124	NS	CD	Long	\$	\$			+	+	+	+	3		Chronic
1012	NS	CD	New	\$				+	+	+	+	-		Unstable
802	NS	UC	New	\$				+	+	+		3		Chronic
1210	S	CD	Long	\$				+	+	+		2		Unstable
1205	VS	UC	Long	\$	\$	\$						-	X	Stable
1221	VS	UC	Long	\$	\$							-	X	Stable
503	VS	UC	Mid	\$	\$							-		Unstable
1418	VS	UC	Long	\$	\$							1		Stable
504	VS	UC	Long	\$	\$							-	X	Stable
1023	VS	CD	Long	\$								1	X	Stable
1107	VS	UC	Mid	\$								1		Unstable

^a # = Each identified change because of the intervention, + = each identified concern/need not met by the intervention, \$ = each reason given for no changes due to intervention.
^b Additional concerns (n) at the end of the trial.
^c X = those who did not have any appointments during the year.

TABLE 23 Opinions of guidebook

Satisfaction groups		
VS, S, NS (n = 19)	New information was gained from guidebook	<i>"It put my mind at rest because some of the information on the Internet was frightening but this had diagrams and information on examinations and things"</i> (720: female, UC)
VS, S (n = 11)	Extended use of guidebook for family and friends	<i>"My wife read that little booklet as well – yes it was helpful for her because sometimes they'd think I was putting it on if I didn't want to go out at weekends"</i> (1404: male, UC) <i>"I showed it to my Mum as well because she was interested and I think you need to read about it to understand it"</i> (230: female, CD)
VS (n = 4)	Reassurance of own condition compared to others	<i>"It made me realise that some are really bad with ulcers and maximum dosage and I haven't got it as bad as some"</i> (1017: male, CD)
VS (n = 2)	Confirmed legitimacy and rights	<i>"I didn't know you could get a card and a key for disabled toilets – I had thought it would be cheating a bit if I did things like that"</i> (1221: female, UC)
VS (n = 1)	More likely to read guidebook when feeling well	<i>"I read bits at a time when I'm feeling well because when you're not you feel down and you wonder what the future holds"</i> (1429: female, UC)
VS, NS (n = 1)	More likely to read guidebook when feeling poorly	<i>I only read it when I started getting fistulas this year then I looked up the section on it in the booklet.</i> (1012: female, CD)
VS, S, NS (n = 8)	Less information gained as previously well informed	<i>"It's a great book, a very good book but I wish I'd been given that book when I first went to see them 8 years ago"</i> (527: male, UC)
VS, S (n = 5)	Guidebook raised some anxiety	<i>"Well I don't think I liked reading all the bad bits because it made me wonder if it could happen to me, but after a couple of weeks I forgot about it"</i> (503: male, UC)

partners and family members, both to inform and raise awareness of the vulnerability of the patient.

"My wife read that little booklet as well – yes it was helpful for her because sometimes they'd think I was putting it on if I didn't want to go out at weekends."
(1404, male, UC, aged 47)

"– even my husband – because at one time he didn't really know much about Crohn's but now if I hear him on the phone talking about it I think 'Gosh, he's got a good knowledge himself as well now'."
(1025, female, CD, aged 48)

Patients who reported that the guidebook raised anxiety did not refer to active information-seeking strategies when asked about the sources of information they used, suggesting that a lack of familiarity with in-depth information may have

created anxiety. Other respondents were more active in this regard in that they proactively sought information from more than one source, for example health professionals, libraries, television, magazines, newspapers, journals, the Internet and/or self-help groups. The main fears concerned potential surgery and cancer risk, which suggests that these had not previously been an area of discussion during earlier contacts with the health service or consultant.

"There are things I would definitely like to know in a non-scary way. I read that little help-manual the other day and there was something about cancer and how you should go for checks and things and I thought – 'Oh that's really scary' – because at one point it says that it's not related and then it said it could be related and my Dad read it as well and it scared him to death."

(1432, female, CD, aged 21)

More importantly, raised anxiety did not detract from the utility patients found for managing illness. Indications were that raised anxiety was transient and not harmful in any long-term sense.

“I don’t like reading all the bad bits – I thought ‘well, could that happen to me?’ – but once I read it – after a couple of weeks I forgot about it.”

(503, male CD, aged 63)

Although some long-term patients considered themselves previously well informed at the start of the trial, many were pleased to learn new information from the guidebook and for some this confirmed the legitimacy of their illness and their rights.

“It was very detailed and there were some things there that I didn’t know – like you could get a card for disabled toilets – things like that. I didn’t actually go for those because I thought perhaps it would be cheating a bit because I don’t think I’m that bad.”

(1221, female, UC, aged 36)

As shown in Table 24, the guidebook increased the knowledge of all patients and was reported to be one of the main changes brought about by the intervention at all stages of the disease.

“What was interesting I think from the book was that I thought that going 10–15 times a day was quite normal because that was me, so for many years I was living in one constant flare-up and I hadn’t realised this, so the book brought quite a few things home to me that I didn’t realise.”

(504, female, UC, aged 47)

Open access

The option and provision of open access was reported as a beneficial change to care. However, there was variability in the way in which the option and take-up of open access for advice and booking appointments operated. It may be remembered that if fixed appointments were retained, patients were also offered open access for telephone

TABLE 24 New information learned from guidebook

Active information seekers	Other patients
Surgery and surveillance	Surgery and surveillance
Diet and symptom-related food	Diet and symptom-related food
Interpretation of blood test results	Own symptoms in relation to others
Medication and treatments	Fistulas
Gender differences	
Social rights	

advice. As indicated in Matrix 1, consultants (*doc) were more likely to make the decision to retain fixed appointments for patients with unstable disease, particularly those with Crohn’s disease. There was also evidence that fixed appointments were negotiated jointly (*joint) to suit the expressed needs of individual patients.

“Yes I still had fixed appointments – he knows I like to go about every two months – just to see and talk to somebody – I prefer someone to keep an eye on me – I feel reassured.”

(1107, female, UC, aged 67)

In general, fixed appointments were retained for those who were unstable at the start of the trial, or for stable patients if they were newly diagnosed or needing the reassurance of regular meetings with the doctor. Two patients (one elderly female and one newly diagnosed female) did not want the option and responsibility of using the open-access facility. The NHS was not always perceived as being flexible to patient’s wishes. One person felt unable to contact the hospital directly and used NHS Direct to mediate contact with the NHS.

“I phoned NHS Direct one night ... and she told me I must ring the clinic and demand an urgent appointment and if not, I must ring her back and tell her.”

(802, female, UC, aged 68)

As indicated in Table 25 the system of open access was more successful for more ‘experienced’ patients whose symptoms were stable, who felt that this option suited their lifestyle and perhaps were more confident in utilising the outpatient services.

“I remember thinking ‘Oh this is a good idea’, I don’t need to come back unless I want to – anything that cuts down on time wasted in a sense – by the time you’re through it’s almost half a day of your time and maybe organising child care for the kids.”

(215, female, UC, aged 40)

For some, just having the option, even though not used, of open access was the main change and benefit gained from being in the trial, because it meant they had control of their care, a factor which was particularly important for patients who were self-employed.

“That was a good help yes, because before that I didn’t have any telephone number I could ring, so that part was a good idea yes – because then I’m in control.”

(527, male, UC, aged 53)

For others, open access reinforced their confidence to self-manage and strengthened the high regard they held for the consultant.

“I feel more in charge of my condition. I know that the phone is there should I need it and I prefer this to having standard appointments. I share the decisions with him and I am prepared to take responsibility myself. With my previous consultant the condition was managed for me and I was told

TABLE 25 Benefits and problems with open access

Satisfaction groups		
VS, S (n = 12)	Open access suits lifestyle	<i>"I run my own business and I don't want to be nipping down to the hospital all the time. I like the flexibility of this – it suits my life and I'm happy to phone if I need advice because he will phone me back"</i> (715: male, UC)
VS, S (n = 4)	Open access increased confidence to self-manage	<i>"I rang up his secretary because the 20 mg dose wasn't bringing it under control, so he rang me back and said to increase the dose to 30 mg straight away and he also faxed my GP"</i> (218: male, UC)
VS, S (n = 3)	Open access increased control over illness	<i>"It's much better for me because I didn't like it when somebody else was controlling it and mostly it was just a waste of time – but when he said I could control my visits myself I said 'if I'm really bad you'll see me'. I mean I'm reasonable and I won't pester them because they've got other people that's worse than me"</i> (1404: male, UC)
NS (n = 2)	Open access option was not wanted	<i>"Oh no, it wouldn't do for me dear. I'd have to be ready for hospital before I'd use open access"</i> (1102: female, CD)
NS (n = 3)	Open access was blocked	<i>"Well I tried ringing his secretary but I didn't get any help from her and she said 'there's nothing I can do' and it's always a six week wait"</i> (1124: female, CD)
NS (n = 1)	Non-assertive elderly patient unable to ask for access	<i>"I phoned NHS Direct one night...and she told me I must ring the clinic and demand an urgent appointment and if not, I must ring her back and tell her"</i> (802: female, UC)

what to do. Since I met this consultant it changed my attitude towards my illness and then it became not something that controlled me but something I can live with and control so that it doesn't affect my life."

(1109, male, UC, aged 46)

Problems and dissatisfaction arose when patients did not feel assertive enough to ask for help, when access was blocked and when negotiated appointments were cancelled. Three patients in the NS group had their requests for access blocked, two of whom were newly diagnosed and one was a long-term patient who was unable to eat solid food. These results suggest that in some cases, the organisational arrangements inside the NHS have difficulties operationalising the principles of open access and self-referral.

Self-management

Patients for whom the intervention worked well reported that the study reinforced their confidence to self-manage and made them feel more in control and positive about their illness. For some, the process of negotiation and clarity of SMPs did not facilitate self-care in the way in which it was

intended. For example, there was little evidence that patients introduced their own ideas about self-care but that appropriate self-care actions were unilaterally defined by the consultant (see also consultant interviews). Most interviewees ($n = 22$) recalled that self-management plans were negotiated and entered into their guidebooks during the first consultation. However, six patients did not have plans recorded in the guidebook, nor did they remember having their current self-care negotiated or re-evaluated. This group tended to be those who were not satisfied with the way the intervention had worked; five were long-term experienced managers and one was newly diagnosed with active disease. Additionally, whilst medication and treatment regimes for relapses were recorded and clearly understood by most patients, there was some ambiguity over the clarity of the definitions of symptomatology constituting a relapse, with some patients ($n = 6$) preferring their own self-definition.

"Actually no, I just worked it out for myself. I didn't ask for his opinions on that to be honest – because if I know it's starting – a flare up for me is not stomach cramps, a relapse

would be if you see any signs of mucus and then I would start with suppositories.”
(1221, female, UC, aged 36)

There were examples too of a lack of clarity about what constituted a relapse and confusion as to exactly how severe the symptoms were supposed to be in order to justify treatment.

“No it wasn’t agreed as to what is a mild relapse, a major relapse or just a bit of a relapse and that’s what I couldn’t put my finger on – it wasn’t really put into terms and I can be a bit of a wimp.”
(1410, male, UC, aged 40)

These problems were particularly distressing for two newly diagnosed patients in the NS group whose disease became active after recruitment.

“What was said was that we would term a relapse as 3 days constant diarrhoea – and like I said, I don’t have proper bowel movements – stools and that – it’s just diarrhoea and most of the time it’s just coloured water. It’s like a bubble that

bursts and its just as if you’re passing water. I’ve got to rush because it’s like wind – never never have I had to get up like this before in the middle of the night.”
(802, female, UC, aged 68)

There was no evidence from the interviews that guided SMPs negotiated with their consultants focused principally on anything other than medication regimes for relapses. The implications of this might be that patients felt they had least independent control over medication and were generally committed to following the agreed prescribed medical management of their disease. In addition however, the majority of patients had their own detailed management plans for diet, eating times and daily routines which they adhered to in order to control symptoms and lead as normal a life as possible at home and at work. There was little evidence that these efforts at self-care were shared with their consultants in the same way in which arrangements for managing

TABLE 26 The process of self-management and self-care

Satisfaction groups		
VS, S, NS (n = 22)	Patients with negotiated SMP	<i>“Well he wrote the medication in the book saying what we did. We always discuss with each other what I do to manage, because I am good at managing and he is happy for me to do so”</i> (715: male, UC)
VS, S, NS (n = 6)	Patients who were not given an SMP	<i>“He knew I was used to managing my condition. He just said this is a book and I wouldn’t be going to see him for a year, just to get in touch if I wasn’t feeling well”</i> (1102: female, CD)
VS, S (n = 23)	Negotiated and clear definitions of flare-up symptoms	<i>“Well I said to him a flare-up is (a) stomach pains (b) mucus or (c) bleeding from the anus – and that’s a flare-up and he totally agrees with that”</i> (715: male, uc)
VS, S, NS (n = 5)	No agreed or clear definitions of flare-up symptoms	<i>“No it wasn’t agreed as to what is a mild flare-up, a major flare-up or just a bit of a flare-up and that’s what I couldn’t put my finger on – it wasn’t really put into terms and I can be a bit of a wimp”</i> (1410: male, CD)
VS, NS (n = 7)	Patient also has self-definitions of flare-up	<i>“– a flare-up for me means urgency to get to the loo perhaps several times a day prompted by stomach cramps. But a flare-up for a doctor would be when you actually start to pass blood”</i> (215: female, UC)
VS, S, NS (n = 19)	Patient self-management by diet and monitoring symptoms	<i>“I’d love to see a nutritionist. I just try to do it myself. I mean diet is such an easy way to sort out things naturally instead of taking lots of drugs”</i> (1432: female, CD)
VS, S, NS (n = 14)	Patient self-management by altering routines at home and work	<i>“I thought I would have to say no to my new job, but then I worked it out that I could travel by train and that’s OK because there’s a toilet on the station and one in the train”</i> (1124: female, CD)

medication were. As a result many concerns about life-style self-management remained undisclosed and discussed with consultants at the end of the trial. *Table 26* gives examples of quotations to illuminate all these issues.

Patient-centred consultations and care

It is important to note that for many patients, the initial consultation at recruitment was the only face-to face contact spent with the consultant during the trial. Additionally opinions about patient-centred care varied depending on whether or not there were extra appointments made

during the year and whether patients experienced continuity of care; the assumption of the study was that continuity is part of patient-centred care.

Continuity of care. As shown in *Table 27*, continuity was an important issue for some patients, whereas others did not object to having to see a different doctor as long as they were confident that the consultant had overall control of a competent team of registrars.

"I've seen about 8 or 10 different doctors under him because every time you go there's different doctors under him. If I don't see him – he's there if the other doctors want to call"

TABLE 27 Patient centredness and continuity of care

Satisfaction groups		
VS, S, NS (n = 28)	The consultant as medical expert	<i>"I wouldn't really go to the GP. I really trust the judgement of my consultant – he's the expert on IBD.</i> (230: female, CD)
S, NS (n = 6)	No continuity of care	<i>"This might sound racist but one doctor I saw was German and the other was a foreigner and I don't think they knew what my case was about. I understand that they have to learn but it felt like a waste of time that I didn't see my doctor"</i> (1410: male, CD)
VS, S (n = 4)	Continuity not an issue	<i>I don't mind as long as everything is fine. I haven't seen my consultant for quite a while now but it's OK because the junior seems to know exactly what he was talking about"</i> (1017: male, CD)
VS, S, NS (n = 8)	No emotional support or empathy from consultant	<i>"On one occasion I went in and I said 'I'm bad today, my stomach is really bloated and I feel a bit emotional' and he said 'Oh don't you cry – it's been one of those mornings'"</i> (1124: female, CD) <i>"I'm usually quiet, I mean I didn't know I was getting these fistulas, I thought they were abscesses so I never mentioned them and I thought he was rather blunt with me but I didn't know it was part of the Crohn's. I don't really talk to him – I have tried"</i> (1012: female, CD)
S, NS (n = 5)	Embarrassment and intimidation during consultation	<i>"I wanted reassurance because I'd started growing a bust – I thought it might be the medication – and this is awful for a bloke. All he did was squeeze them and make a joke and laugh at me, so I didn't speak after that"</i> (1210: male, CD)
NS, S (n = 2)	Patient-centred clinics	<i>"They've sent me appointments for 9 o'clock in the morning and I just found it stupid that all these people with bowel disorders having to go to morning clinics. When I ask for a later appointment they look at you as if you're stupid, so now I tell them 'Look – I've got Crohn's disease and I can't get out of the bathroom for at least 3 hours in the morning'"</i> (1124: female, CD) <i>"I was only about 5 minutes and I wasn't particularly sure what I was doing when I left. It's always so swift when you see him, no matter what time – they seem to be permanently over-booked"</i> (1432: female, CD)

him, that's what happened about my warts see – I don't mind not seeing him as long as I'm seen, because it always gets passed back to him."

(203, male, CD, aged 41)

The main complaints from patients about continuity of care centred on missing case-notes, embarrassment or intimidation in the presence of younger doctors and communication/language difficulties with some doctors.

There was evidence from all three patient groups to suggest that the trial raised patients' expectations of receiving higher levels of empathy and emotional support from doctors during the year of the trial. Continuity of care, however, did not necessarily guarantee improved communication and patient-centredness during the year.

Empathy and emotional support. All patients reported having a satisfactory relationship with their consultants prior to recruitment (see Table 27). Most patients were positive in their recall of the manner in which the intervention was introduced to them and understood by them at the first consultation. There were some examples to suggest that patient-centred care was not established because important individual concerns were left unattended to at the end of the trial.

"The issue always comes up about family and are you going to give it to kids – like a defect. I mean you've got a scar that's really huge so you can't really hide it – people pick up on things and especially with boyfriends it's a bit funny. There is a definite issue about kids and what would happen."

(1432, female, CD, aged 21)

"One aspect I worry about is the possibility of perhaps passing it on to my son – if it's hereditary."

(203, male, CD, aged 41)

Among these additional concerns (see Matrix 2) was the need for information and reassurance about dosage and side-effects of medication, pain control, diet and nutrition, extent of disease and risk of cancer. Issues of importance to women such as future pregnancy, hereditary risk and the influence of menstrual and hormonal changes were also important concerns for younger patients.

"I've been reading things a lot about hormones, where they say your hormones play a big part with Crohn's – during the last few months I've been feeling poorly and it happens quite a lot around the time of ovulation – so I'm all over the place and you don't know if it's your hormones or if you are actually having a relapse."

(1124, female, CD, aged 29)

Although many patients had wanted to discuss some of their concerns with their consultants they had not been able to do so during the year of the trial.

However, the intervention seemed to be more dependent on the closeness of the relationship with the doctor rather than on the narrower concerns of the disease characteristics and symptoms. The most satisfied patients were those who received sympathy and reassurance during their consultations and who were listened to and given time to ask questions.

"With my consultant you can talk to him – I feel I can talk to him and he listens and explains things and if he doesn't agree with you he'll tell you so you know. You can talk to him and feel confident with him and comfortable."

(1107, female, UC, aged 67)

Patients who were the most vulnerable to poor communication and lack of patient-centredness were newly diagnosed patients, those who described themselves as shy or unassertive patients who needed the doctor to instigate or encourage dialogue. Dissatisfaction arose for those who felt intimidated or let down emotionally when their disease became active and difficult to control.

"On one occasion I went in and I said 'I'm bad today, my stomach is really bloated and I feel a bit emotional' – and he said 'Oh don't you cry – it's been one of those mornings'"

(1124, female, CD, aged 29)

The patient-centred clinic. Patients who reported communication and empathy problems were also more likely to be those who had problems negotiating access. It was clear that from the patients' perspective the clinic staff and administrative staff also had a part to play in the patient-centredness of the intervention (see also Table 25). Table 27 gives examples of reported dissatisfaction with rushed appointments, overbooked clinics and problems in negotiating appointments around early morning symptoms. Despite unmet needs and perceived constraints to the process of the intervention, the majority of patients were satisfied with their hospital care and the way the clinics were run. Most patients were accepting and others were resigned to the fact that there might be long waiting times and generally appreciated how hard the staff were working.

Some of these results suggest that communication was poor within and between different sectors of the NHS infrastructure and that in some cases factors external to the patient and the consultant may constrain patient-centredness and the process of the intervention.

Discussion

The findings from this qualitative study were intended to illuminate patient experience of the intervention and new arrangements for managing illness and accessing care. Analysis of the

interviews was informed by the literature on the experience of illness, a review of the qualitative literature on self-care¹⁵⁵ and the theoretical framework on 'stress and coping' discussed in Appendix 11.¹⁵⁴ The interviews captured the richness of the individual experiences of a purposeful sample of patients who had received the intervention and illuminated the processes and influences underlying the success or otherwise of the intervention from the patients' perspective. The strength of the qualitative data is also in demonstrating that the subjective experiences do not always match the responses from the quantitative data, but instead provide new ideas and hypotheses for further research. From the qualitative interviews, it was possible to identify a number of influences which contributed to the success of the process of the intervention.

The evidence-based guidebook was one of the key features of the 'whole systems approach' aimed at improving self-management skills for the test patients in this trial.¹⁸ The interviews highlighted the autonomy and centrality of the guidebook in relation to the intervention as a whole, showing its value as a single entity that was not dependent on shared involvement with the consultant. The guidebook was well received and considered to be beneficial by all patients, including those who were not previously active information seekers, and thus was successful in providing additional coping resources for many. It is also significant that the guidebook was perceived by those interviewed to have increased knowledge and raised awareness of family members to the implications of the disease (poor communication within the family of IBD patients has been shown to be associated with high disease severity¹⁶⁰). Hence our qualitative data suggest that the guidebook was effective because it increased the support offered to the patient, facilitated improvements in family communication and provided additional coping resources for partners and family of IBD patients.

The patient-centred approach during consultations was intended to facilitate and mediate self-management and access to services.^{18,73} Patient-centredness is subject to the willingness of the doctor to listen to the patient and to explore the meaning of the illness experience and identify uncertainties and needs through the use of open-ended questions.¹³¹ From the interviews, however, it was clear that there were problems with communication, patient-centredness and time constraints. All of these factors acted to constrain the process of the intervention for a considerable number of the

patients who retained fixed appointments or requested open access.

The consultants themselves felt that patients with unstable active disease would not be suitable for the intervention (see page 53). Although our results suggest that the most vulnerable and dissatisfied patients were those with active disease, they also had fewer coping resources available to them and thus would be more dependent and expect more from the patient-centredness aspect of the intervention. This is supported by other studies which show that IBD patients report impaired psychological and social functioning at a greater level than physical functioning,^{161,162} suggesting that for patients, these concerns take precedence over the disease variables and need to be identified during consultation. The findings revealed that consultants do not necessarily take on board and incorporate patients' ideas about self-care – this was rarely mentioned in the interviews.

Consistent with diabetes and asthma research,¹⁵³ our interviews have shown that the ability and desire to be actively involved in self-care are disrupted at the onset of new symptoms or crises, causing a greater dependency on doctors. Some patients who were confident self-managers were less likely to be reassessed in the process of the intervention and this is also consistent with the treatment of patients with diabetes, where it is often thought that there is no reason for further education or changes in treatment for those with good metabolic control.⁷⁴ Our interviews have highlighted the difficulties for such patients when the disease becomes active and communication and continuity break down.

The intervention was intended to provide different care for the patients in this trial and expectations for a more holistic approach to care were high for those who retained fixed appointments and those who needed to use the option of open access. The problems identified by patients during consultations included time constraints, lack of continuity, empathy and understanding and failure to encourage dialogue and to identify patient's needs. Although some accepted these difficulties, they also resulted in anger, frustration and feelings of isolation for the most vulnerable.

Interviews with consultants

Debriefing interviews were held with the consultants from the intervention sites at the end of the recruitment period. Interviews with

consultants were shorter and not as in-depth as those with patients. Questions were more structured and the interviews were carried out by four researchers (EN, AR, AK, DO). The purpose was to get immediate reactions about the training undertaken and the experience of introducing the intervention to patients in order to explain and supplement the quantitative data. The cooperation of the consultants in initiating the intervention was crucial (see Appendix 3) as they were expected to use a patient-centred consultation to introduce the key elements to the patients: the guidebook, the SMP and instructions on open access to clinics. A semi-structured interview was used; questions asked are shown in Appendix 12. Eleven interviews, which took between 15 and 30 minutes to complete, were conducted including one interview where the consultant and specialist nurse were interviewed jointly at their request. The interviews were taped and transcribed and the resulting themes included (1) views on the training, (2) the effectiveness and acceptability of the guidebook, (3) the patient-centred intervention and (4) the process of introducing the intervention into normal practice.

Views on the training

Consultants expressed the view that the training mostly replicated their normal practice. The session was viewed mainly as an opportunity to discuss and comment on the study and to make amendments to and seek clarification of the protocol. Although the intervention as outlined in the training sessions was seen as being operational in everyday health settings, there were caveats, in particular that the pressures of time of normal clinics were not considered.

“I think the training was sufficient. You wouldn’t want more than that really to learn to adopt the technique and the chance to put across the package to patients. The training package for patients was very good and has worked very well with patients hasn’t it?”

(ID 8)

“The training was fine, except that I realised that when I got down to a clinic you know, there are all sorts of pressures on you that tend to make you a little bit more pragmatic.”

(ID 5)

The core of the training was to instruct consultants in methods of conducting a patient-centred consultation. Many held the view that they were already committed to practise in a patient-centred way, so the training was not necessary for them although some felt it might have been appropriate for less experienced junior colleagues or conversely, older colleagues who had never received training in patient-centred care.

“It was a little unusual, I suppose if I’m honest I think probably myself and probably some of my colleagues felt that things like sitting down with another colleague and practising interviewing a patient was... I suppose we felt we’d really passed that stage, obviously dealing with a group of all consultants, pretty much, who, you know, we like to think of ourselves, rightly or wrongly, as fairly experienced in that respect. So I didn’t really think I’d gained much from that, but we felt that might have been something that would have been more valuable perhaps for a more junior person. So I didn’t think that was terribly useful, to be honest.”

(ID 18)

Guidebook

All consultants were positive and enthusiastic about the guidebook; it was viewed as being a helpful and non-threatening way of giving a great deal of information to patients. Involvement of patients in the development process had a key impact on acceptability by the consultants, as the book was viewed as being comprehensible to patients as well as containing accurate and honest information. The depth of detail of risk and inclusion of worst case scenarios meant that consultants had to manage the impact of the information and discuss the relevance of the different sections with individual patients.

“I think it’s a completely comprehensive guide. Some patients I think were frightened about the inclusion of everything – again I was at pains to try and make them understand – reassure them – that this was the complete spectrum of IBD and a lot of it might not have any great relevance to them – but it was really to discuss – um – so that they were never caught out by saying – you know – ‘you never told me that could happen’ I think the worst scenario undoubtedly did frighten some.”

(ID 12)

The intervention and the information package were described as making the patient feel special. This was felt to help with the process of self-management.

“Providing patients with specific information and literature like that makes them feel special, which is nice, which is what I like...it did strengthen relations...That’s quite important with chronic disease and I think I learned something from that, about how to make people feel comfortable with their follow up, what’s going on and so on.”

(ID 5)

The patient-centred consultation

All consultants felt that they were already patient-centred and had not had to change their ideal style of practice but rather that participation in the study required them to make time to allow a discursive and open consultation. In most cases, it was felt that the nature of the consultation had not changed dramatically, but that the process was reassuring to patients. The consultants’ expectations were that

patients would be enabled to take on the responsibility of managing their condition and that the approach would suit the majority of patients.

"It seemed to have fulfilled what they were expecting or what they would have liked to have happened and now it's been formalised, they're very pleased. It's helped them to ask more questions because they're more informed, and they've also got a contact number which reassures them, even though they used to have one in our old clinic anyway but I think now it's written down, you know this is who you contact and this is the number you ring gives them a lot of confidence."

(ID 2)

All consultants believed that patients needed guidance on medical treatment. In two cases, consultants intimated that they would take control and impose what they believed to be the correct decision about drug treatment, and their decision was final, suggesting that room for negotiation with patients over this issue was minimal. They did not find that patients disputed their judgements. This indicates that there are areas of management where consultants believe their knowledge and experience supersede the need for a patient-centred approach. A few consultants felt the assumption that establishing a management plan would form part of a mutual discussion was false. Some patients were thought to be not experienced or knowledgeable enough to participate in such a discussion, others were thought to want directive advice from the doctor.

"I suppose partly because I, I suppose perhaps I, sort of, took charge and initiated it really, I suppose I was more or less saying 'This is what I think you should do.' And writing it down and it was pretty rare, I think, in fact, I can't think of anyone that comes to hand, where somebody said 'Well, actually, no. I think this is better.' I don't think I came across that."

(ID 18)

Concerted attempts were made to incorporate patients' ideas into the management plans. There were, however, degrees of acceptance of patients' opinions. It was easy for consultants to accept patients' attempts to change and control aspects of their diet, for example.

"I think that's because if a patient comes to me and says – you know – 'I did it this way and I like doing it this way because it works' I can generally accept that, usually it's things like um – they'll change their diet and do things that way, and if they find it benefits them well that's fine and in terms of the straightforward medical therapy – um you know – generally there weren't any clashes. They know their bodies much better than I do."

(ID 15)

Most consultants felt that for most patients it was relatively easy to establish a management plan. Writing a mutually acceptable plan was

straightforward for stereotypical patients who had a history of successful treatment of relapses with standard drugs – there was a formula to be followed which was easy to explain and which the patient was able to take on board, especially as it was written down. There were problems establishing a plan where the disease was complicated – more likely in Crohn's disease patients. The plan then had to develop into a strategy which was harder to write down – especially in the space available in the book which was felt to be too rigid.

"A lot of those patients you can give them a very formulaic thing to do, you know if stool number equals more than six then do this, if it's less than that then perhaps the Predfoam will be OK. They were easy whereas the people with Crohns who'd had surgery and you know were on Azathioprine and this, that and the other, they were much more difficult really to define what they should do. I tended to, with them you know, very simple, by all means take some Prednisolone but if it's not settling in five days then you'd better give us a ring, or something like that, so they weren't all at sea."

(ID 5)

Writing down a plan did represent a change in practice which was acknowledged by most consultants to be of benefit to patients. However, it is worth noting that according to the patient interviews, some consultants did not write plans.

"The other thing that got us to do, that we don't probably do for other patients is actually give them a management plan when they do have a relapse. We sort of do, but we never write it down for anybody and I'm not sure how many of them actually remember what we tell them. So actually writing it down ...for the patients that helps yes."

(ID 15)

Participating in the study made some consultants realise or confront the problem that patients often had their own interpretation of what constituted a relapse which differed from the medical view. There had been lack of clarity in the past and there were comments that in some cases a certain amount of discussion was needed to change patients' views on what type of relapse warranted treatment. Consultants felt that patients needed clear direction on when they should seek advice because a relapse was not responding to treatment.

"At the end of the consultation we would ask the patient to describe a relapse to us – and we would say 'yes that's right' and at the end of the consultation we would just make sure before the patient went that they were clear on when a relapse occurs and what to do."

(ID 9)

Introducing the intervention into normal practice

Although all could see advantages of incorporating the whole system of management,

there were concerns about introducing it into routine practice. The process was seen as formalising current practice and giving patients more clarity on what was expected of them – in effect, giving them permission to self-manage. The intervention was felt to be easy for most patients to take on board because they were not being asked to start new treatment but only take what they knew worked for them, a limited view of self-management. It was a way to improve relations with patients and make them feel they were being properly looked after. None could see any problems in using the guidebook routinely, other than the initial cost of purchase, which was viewed as a minimal but worthwhile investment by hospital Trusts.

“I think the idea in the first place was the way I and many of my colleagues are actually doing but in almost a haphazard way rather than the formalised process of the trial.”

(ID 12)

Consultants who participated in the study were aware that the recruitment consultation would be of longer duration than a normal follow-up appointment. It was apparent that there were times when a pragmatic approach was adopted and attempts were made to fit a patient-centred consultation into the time allocated for a normal follow-up appointment as the over-riding concern was to reduce disruption to the running of the clinics. However, the bonus of introducing the system was that it should eventually cut out unnecessary visits and lead to more time being available to spend with the type of patients the consultants viewed as those who really need to be seen. The intervention was seen as an investment of time but current pressures of patient numbers at outpatient clinics meant that it was often very difficult to find the time to invest at the outset.

“The difficulties being in routine practice or in this research project has been being able to give patients that time – so logistically it’s not easy I mean there were some days, regretfully when you’d given me patients and I just couldn’t accommodate them, which was a bit of a nuisance. I’ve also had one or two people come back for further visits and they forget the booklet.”

(ID 14)

The open access to clinics was not generally seen as a problem, although there was some concern that a few patients might abuse such a system and make frequent demands for clinic appointments that were not appropriate. Conversely, open access was seen as a problem for some patients who it was felt would avoid any contact with the hospital either because of timidity or because they refused to acknowledge the seriousness of their condition. It was thought possible to fit patients into a clinic

within 7–10 days of their phone-call request. There might be a danger of patients swamping a clinic if there is no control over when they are booked in. One consultant thought a specific phone-in clinic might be an answer.

“There are also those who are over-confident about their own abilities and would keep on trying to make themselves well because they don’t like hospitals. They might stay away when really they ought to perhaps be presenting.”

(ID 8)

Consultants had firm ideas about the sort of patients for whom the intervention would be most suited. On the whole it was felt that the majority of those with IBD would benefit at some point in their illness career. It was strongly felt by nearly all the consultants that the self-management aspect of the intervention was really only suitable for those whose condition was stable. Consultants expressed the view that it takes time to determine how well someone responds to treatment and people were felt to need to gain experience of living with a condition to become familiar with signs of relapse and to know when they should seek help.

“Patients that are familiar with the disease and familiar with the pattern of it. I think it seems quite a sensible arrangement for most of them actually, so they don’t take a lot of convincing.”

(ID 7)

Some consultants felt uneasy about the possibility of losing control of certain types of patient as they thought it possible that particular patients would not be able to cope with the responsibility of self-management and open access to clinics. Some patients were viewed as needing regular contact with the hospital for a number of reasons: because they need the support which is not available elsewhere; because they are viewed as denying their problem and are likely to do nothing about it unless coerced to attend clinic regularly; because they want a paternalistic approach.

“The younger adolescent who doesn’t want anything, don’t wanna have Crohns, they don’t want anything to do with it and they also rather reject this kind of approach basically cos they don’t want to have anything wrong with them at all and they want to deny everything.”

(ID 5)

However, as a group, IBD patients were felt to be people who take an active interest in their condition and motivated to self-manage: “They know when they’re not right”. They were perceived as regarding visits to hospital when they were well as a waste of time.

Some consultants appear not to have given the full intervention to patients they considered unsuitable.

TABLE 28 To show views and assumptions about the intervention

	Researchers' assumptions	Medical views	Patients' views
Guidebook	<ol style="list-style-type: none"> 1. Involvement of patients in development to ensure relevance and usability. 2. Inclusion of evidence-base for treatment will encourage concordance with treatment. 3. Lay experience will make information come alive. 4. Good design and plain English will make book more readable, increasing knowledge and understanding. 5. A record-book with an individualised self-management plan will be a useful tool. 	<ol style="list-style-type: none"> 1. Helpful and non-threatening source of information. 2 and 3. Acceptable to patients, but certain aspects not relevant to all so best used as point of discussion in consultation. 4. Quality product, initial investment may be hard to find. 5. Book represents a contract with patient. Some sections of record book difficult to fill in. Keeping a diary of symptoms may make some patients anxious. 	<ol style="list-style-type: none"> 1 and 2. Well-received, new information about condition and treatment options gained from book. Able to compare own condition to others. Some anxieties about surgery and risk of cancer. 3. Book used with family members. 4. Of benefit both to previous information seekers and those who had never sought out information. 5. Keeping record of symptoms only helpful to some.
Patient-centred consultation	<ol style="list-style-type: none"> 1. This approach will encourage a partnership where impact of disease on patient can be discussed. 2. A treatment and management regime can be established through negotiation. 3. Patients will communicate better with their doctor. 4. Patients will take on responsibility of self-management. 5. The training introduced the research and the skills necessary to conduct a patient-centred consultation. 	<ol style="list-style-type: none"> 1. Patients perceived as pleased and reassured by approach. 2 and 3. It was utilised to change practice by some – opening up the consultation and incorporating patients' ideas in management plans. Consultants more likely to impose decisions on drug treatment and accept patients' decisions on dietary control. 4. Not all patients deemed able to take on self-management. 5. The patient-centred approach reflected normal or ideal practice. Time needed for a patient-centred consultation was an organisational constraint. 	<ol style="list-style-type: none"> 1. The consultation made patients feel special and reinforced their confidence to self-manage. 2 and 3. Some expected better communication and emotional support from their consultant, there were undisclosed needs and concerns. Not enough support about diet. 4 and 5. For some, there were no recognisable changes to the consultation format as they had a good relationship with the consultant or were already competent self-managers. Poor continuity of care was a problem for some.

continued

TABLE 28 To show views and assumptions about the intervention (cont'd)

	Researchers' assumptions	Medical views	Patients' views
Guided self-management	<ol style="list-style-type: none"> 1. An SMP written into the guidebook should improve treatment concordance and lead to faster and more effective self-treatment of flare-ups. 2. It will provide clarity for the patient on the symptoms of a flare-up. 3. Provide guidance on when they should seek help. 	<ol style="list-style-type: none"> 1. Considered suitable for those with stable condition and history of successful treatment with standard drugs. 2. The process was felt to formalise what patients were expected to do and reassure them that they were taking the right actions. This was a change in practice and thought to be beneficial to patients. 3. For complex disease, it was hard to write down a strategy that was easy to follow. 	<ol style="list-style-type: none"> 1. Change was noticed in the negotiation of the SMP. Some experienced self-managers did not get the opportunity to negotiate a plan. 2. Generally more clarity over the definition of a flare-up but deciding on when it was appropriate to self-treat remained a problem for some as ambiguity remained about definition of a flare up. 3. Self-management not an option when very ill.
Open access	<ol style="list-style-type: none"> 1. Allowing patients to phone to arrange an appointment should cut down on the number of unnecessary visits (when patient managing well) and reduce the number of DNAs. 2. This should increase patient satisfaction and lead to more cost-effective use of health service resources. 	<ol style="list-style-type: none"> 1. This was not seen as a problem, possible to fit patients into clinic within 7–10 days of request. Concern that some patients might not acknowledge the seriousness of their condition and avoid hospital contact. 2. Not so suitable for those with an unstable condition where different treatments being tried. 	<ol style="list-style-type: none"> 1. Open access suited the lifestyle and way of coping of patients, particularly those with busy working lives or young children. 2. Most patients valued this change, they felt more positive and in control. Some were wary of using open access and there were some experiences of access being blocked by hospital administration. Fixed appointments were negotiated by a few and for some patients, open access was not offered as an option.

It was understood from the start of the trial that certain patients who were unstable would remain on fixed appointments and not be given a management plan but would still receive the book and patient-centred consultation, but some consultants were more likely to have excluded patients than others.

The question of making a judgement about suitability of patients for self-management was felt to require the experience and skill of a consultant. This was felt to be something that was not possible to do until the patient had had several appointments.

"I think I know, but this is all down to me thinking I know, and I might be dreadfully wrong, but I think I know people, or I can judge people to look after themselves if I think they've got it in them. And often they come back and they say 'Look I don't know if I did the right thing but I have had this symptom and I did that' and I might say 'you did the right thing' or perhaps 'next time do it this way'."

(ID 15)

Consultants wanted evidence from the study before full commitment to the approach could be adopted. Such evidence could be used as a lever to effect change and the approach taken up for other chronic conditions. Suggestions were made about organisational changes needed to help roll-out:

- use of extra staff and a specified run-in period when the system is first set up
- set up information technology to keep a register of patients to allow long-term follow-through
- work with GPs and surgeons to establish guidelines
- educate patients as to how to get back into the system
- regular letters to patients to check on address
- annual appointments to review treatment
- specific phone contact through secretaries rather than through the hospital appointment system.

The approach was viewed as being something you could not withdraw from the patient once they had been introduced to it. Two consultants stated categorically that initiation of self-management should be done at consultant level. However, a specialist nurse who was interviewed considered that the intervention was very suitable for a nurse-led clinic where there was more time to educate and share decisions with patients.

"I think this system of care for inflammatory bowel disease – we would like to adopt, especially with a nurse-led clinic – where we can give that much time to individual patients."

(ID 9)

Discussion

This group of gastroenterologists who were randomly selected to be in the intervention arm of the trial gave support to an approach to improve patients' ability to self-manage because it closely mirrored their favoured mode of practice and was felt likely to appeal to patients. *Table 28* summarises the assumptions underlying the research and the views of the consultants and patients. The main findings were as follows: the information source was universally acceptable; the approach led to greater clarity for patients and enabled them to take on the responsibility of self-management and open access was workable although operational changes would be needed before it could be introduced for all chronically ill patients. Although there was agreement that the whole systems approach was the way forward for patient care, there were concerns about determining which patients were suitable and the point at which they should be entered into the system. Yet to be ascertained is who would be best placed to introduce patients to the new system and provide them with support and advice in the future. Some consultants felt that specialist nurses would provide continuity, but it is debatable as to whether this would be a safe or cost-effective way to introduce guided self-management.

Chapter 6

Cost-effectiveness of a whole systems approach to self-management in IBD

Introduction

This chapter describes the cost-effectiveness analysis which was undertaken alongside the randomised controlled trial. The objective of the analysis was to assess the cost-effectiveness of a whole systems approach to self-management in IBD when compared with routine practice. Costs were estimated from the perspective of the NHS and effects were assessed in terms of health gain expressed as quality-adjusted life-years (QALYs). In addition, the aim was to estimate the probability that self-management is cost-effective over a range of values of decision makers' willingness to pay for an additional QALY.

Methods

Patient sample

The economic analysis is based on the trial assessing the impact of a package comprising a patient-orientated, evidence-based self-help guidebook and patient-centred consultations on disease management and satisfaction in IBD. The patient sample is the same as for the clinical trial that has been detailed earlier. For the economic analysis, 651 patients who returned either or both of the patient questionnaires were included in the analysis.

The trial was randomised with the participating hospital as the unit of randomisation with the patient as the unit of analysis. Patients were based in 19 (mutually exclusive) hospitals, each with a gastroenterology department. This trial design has implications for the economic analyses that are discussed below.

Sources of data

Resource use

Data on resource use for the economic analysis were obtained from three separate sources: the patient questionnaires (at entry to and exit from the study), patient diaries and examination of patients' medical records. Data from entry and exit questionnaires were collected at baseline and at follow up 12 months later. Patients completed their own diary over 12 months, recording clinical

outcomes such as relapses and resource use variables such as visits to the GP.

In the base-case analysis (i.e. the analysis using data that are considered the most realistic), medical records were used as the source of inpatient stays, outpatient visits, time of the initial consultation (to estimate the cost of the intervention) and medication. The exit questionnaires were used for estimates of GP visits.

Where outpatient appointments were cancelled, it was assumed that there was a zero opportunity cost (i.e. other patients can be seen instead). On the other hand, DNAs are costed at the full cost of an outpatient attendance, as there is little opportunity to fill the appointment.

The cost of the intervention being evaluated in the trial was estimated from resource use data from the clinical trial applied to national pay scale figures used in the Netten and Curtis document.¹⁶³ Resource use associated with giving the self-management intervention (i.e. the extra time devoted by the consultant at the initial appointment) was recorded in the entrance questionnaire. Additional resource use required to explain the intervention was also costed into the analysis. The intervention also included the provision of a guidebook. Although this was not costless, when spread across the large number of IBD patients who could use the book, the cost becomes negligible and was not included in the analysis.

Unit costs

Unit cost data were obtained from a number of sources. Inpatient cost per day and outpatient cost per visit for attendances related to IBD were both based on national estimates for gastroenterology departments.¹⁶³ Estimates were inflated to a 1999–2000 price base using the Health Service Cost index.¹⁶⁴ For inpatient stays and outpatient visits not related to IBD, the national estimate for the relevant specialty was employed.¹⁶³

Given that drug costs have been accounted for elsewhere and a need to avoid double-counting,

the cost of inpatient stays has been estimated based on the 'hotel' costs of the stay, a figure that reflects basic nursing care and nominal overheads. In particular, hotel costs are defined as 'allocated costs' including portering, laundry, administration and nursing, but excluding medical costs, theatre costs, drug costs and laboratory costs. An estimate of the proportion of total costs accounted for by these 'hotel costs' was obtained from the NHS Scotland dataset (NHS Scotland, Cost Book data 1999–2000), and applied to the cost per day estimate. Figures for the cost per day were then reduced accordingly, and the product of length of stay and cost per day was used to estimate inpatient cost for each patient.

For outpatient appointments, all IBD appointments took place at the gastroenterology department of the centre at which the patient was based, and were costed using national unit costs.¹⁶³ For appointments which are not directly a result of IBD but are related to the condition, a 'generic' outpatient attendance cost was employed.¹⁶³

The cost of a GP visit was derived from Netten and Curtis estimates.¹⁶³ The unit cost estimate includes cost of training and direct care support staff and is inflated to a 1999–2000 price base.

The cost of the intervention was estimated by recording the additional consultant time spent with patients in the treatment group. Estimates of the cost of consultants' time were again based on Netten and Curtis' figures,¹⁶³ while the same source was used to estimate the additional cost of an auxiliary nurse to explain the rationale for the intervention to patients.

Medication costs

For medication, unit costs were taken from the British National Formulary (BNF) for March 2000.¹⁶⁵ Only drugs in the 5-aminosalicylic acid (5-ASA) and corticosteroid classes were considered. These made up over 75% of the drugs used and are the drugs typically associated with IBD. Drug costs were estimated using a weighted cost per milligram for the relevant drug class and administration route (oral, enema or suppository), and multiplying this by the number of milligrams per day and the number of days for which the patient was prescribed the medication. Weights were calculated by finding the total cost of each drug prescribed in England using Department of Health data in England in 2000¹⁶⁶ and dividing by total number of drugs prescribed in that class.

Several assumptions were necessary owing to incompleteness in the medication records. Specifically, where no size of tablet or dose was given, that most commonly prescribed in trial patients with complete information was used. The cost of drugs dispensed 'as required' was not included because no information was available on dose. Obviously this underestimated the cost of drug use, but other overestimates were likely to offset this. For instance, some drugs would have had a reducing dose over the period which was not incorporated into the analysis.

Health states and quality of life

The EQ-5D instrument was used to measure patients' health states and to ascribe those states values.¹⁶⁷ The EQ-5D questionnaire was given to patients at baseline and 12-month follow up, alongside the entry and exit questionnaires. This instrument measures patient health status across five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). Three possible responses (no problems, moderate problems or severe problems) are given by the patient for each of these dimensions reflecting the patient's perception of their health state.

EQ-5D scores at baseline and follow up were converted to a 'utility' score based on a 'tariff' derived from interviews with 3395 members of the UK public.¹⁶⁸ The two trial groups were compared in terms of mean changes (compared with baseline) in QALYs over the 12-month period. This was achieved by plotting the EQ-5D utility at baseline and at each intermediate point and calculating the area under the curve to estimate QALYs gained (or lost) for each patient. As there was only one follow-up point (at 1 year) in this instance, the area under the curve is simply the change in score divided by two.

Methods of analysis

Missing data and imputation

For the questionnaire data, 16 patients did not return an entrance questionnaire but subsequently returned the exit questionnaire. All other patients completed an entrance questionnaire. Other than for these 16 patients, any item that is missing in the entrance questionnaire (including the EQ-5D scores) is through non-completion by patient. For the exit questionnaire, 100 patients did not complete/return.

Thirteen patients did not have their medical records accessed, 10 as they could not be located and three because they withdrew consent during the trial period. Hence the data on inpatient stays

and outpatient attendances, both IBD and non-IBD related, are missing for these patients. Drug data were missing for 13 patients, and GP visits were missing in 242 instances (owing either to the diary not being returned, GP visits not being completed or the diary being unusable).

There is no formal test to verify the assumption that data are missing at random (MAR), and this assumption is often chosen as a starting point when data are missing.¹⁶⁹ If there is concern that data are not MAR, it is possible in principle to run the multiple imputation procedure using a model that reflects hypothesised differences between individuals with complete data and individuals with incomplete observations. The results obtained from the two models under the MAR and non-MAR assumption can then be compared to obtain a measure of the sensitivity of the inference to the missing data process. In practice, to model a non-MAR process is not a trivial task, and it has been demonstrated that exploring the assumption of MAR relies on strong assumptions which are not themselves testable.¹⁷⁰ Therefore, for this analysis it was assumed that data were MAR.

Missing data were imputed using SOLAS,¹⁷¹ using the Propensity Score method (a non-parametric approach). Multiple imputation replaces each missing value with several imputed values instead of just one.¹⁷¹ This gives a fuller reflection of the uncertainty surrounding which value to impute. For this analysis five datasets were generated, each with a different set of imputed values.

Values were imputed for each of the dimensions of the EQ-5D (rather than total score), and for each missing item of resource use (rather than total cost). In a few instances imputation resulted in values that were implausible. For example, negative values of resource use were generated, in which case the value zero was substituted. Non-whole number values were also generated on occasion for EQ-5D dimensions that prevent the use of the EQ-5D tariff; in these instances, where a value between zero and one was generated, the value one was substituted. Similarly, for values between one and two, the value two was substituted and for values over two the value three was substituted.

Incremental cost-effectiveness ratios and net monetary benefits

Traditionally, economic analyses involve the calculation of incremental cost-effectiveness ratios (ICERs), where mean differences in costs and effects under the treatment and control arms were

presented with 95% CIs. The ICER is calculated from the mean difference in cost and effect between the two treatment options. Algebraically, the ICER is represented as

$$\text{ICER} = \frac{C_1 - C_0}{E_1 - E_0} = \Delta C / \Delta E$$

where C_i are sample mean costs and E_i are sample mean effects. These statistics are calculated in this analysis. However, interpretation of ICER statistics that cover more than one quadrant of the cost-effectiveness plane is troublesome, and recent papers have advocated the net benefit approach to cost-effectiveness analysis.^{172,173}

This approach can be performed for this study quite simply. From the five datasets generated through multiple imputation, the net monetary benefit (NMB) (the expression of cost and benefit per patient on a single monetary scale) was calculated for each group. For specific levels of a decision maker's maximum willingness to pay for a QALY, the NMB of a strategy can be estimated using the following equation:

$$\text{NMB} = (\lambda \times \text{QALYs}) - \text{cost}$$

where λ is the decision-maker's willingness to pay for a gain of a QALY.

For instance, if treatment A has a mean cost of £100,000 and generates a mean of five QALYs with a QALY valued at £30,000, then the NMB associated with treatment A is £50,000 [(5 × £30,000) – £100,000].

It is also possible to express NMB at the patient level by multiplying each patient's QALY score by the decision maker's assumed maximum value and subtracting that patient's costs. The patient-level NMB is used in the regression analysis described in the next section.

Clearly, the NMB is dependent on the value that is placed on the QALY, but results of the analyses indicate how sensitive the results are to changes in this value. However, the uncertainty surrounding the NMB statistic can be used to identify the probability that a strategy is cost-effective using the cost-effectiveness acceptability curve (CEAC).¹⁷⁴ The CEAC is a graphical representation of the probability of an intervention being cost-effective over a range of monetary values for a decision-maker's willingness to pay for an additional unit of health gain. The probability of an intervention being cost-effective

will differ according to the valuation the decision-maker places on a QALY. For this analysis, the values zero, £1,000, £10,000, £20,000, £30,000, £50,000 and £100,000 were used as a range of the decision-maker's willingness to pay for a health gain of one QALY. The value zero is equivalent to a comparison of the groups in terms of total costs as outcomes are not considered (valued at zero).

Adjustment for clustering

The clinical study was a cluster randomised trial where hospitals, or more precisely hospital gastroenterology departments, rather than individual patients were allocated to either the treatment arm or the control arm. Patients within a centre are more likely to show similarities to each other than patients in different centres, hence standard statistical methods are inappropriate. Therefore, although the unit of analysis for the cost-effectiveness analysis was the patient, data were analysed in such a way as to account for the clustering effect associated with randomisation by centre. Regression methods were employed using random effects across centres to allow for clustering. Regression techniques were performed on each of the five datasets generated from the multiple imputation described above. The intervention group was used as the sole independent variable, with NMB the dependent variable.¹⁷⁵

Using treatment arm as the independent variable means that the coefficient on the treatment arm variable (dummy) is equivalent to the incremental NMB between the two groups.

Regressions were performed on each of the seven values of a decision-maker's willingness-to-pay for a gain in a QALY (from £0 to £100,000) on each of the five datasets generated above. This results in five different estimates of incremental NMB between the groups for each value willingness-to-pay value, with corresponding standard errors. For the purposes of generating a CEAC, one estimate of NMB and its p -value are required. Therefore, pooling the estimates and their standard errors is required; this is discussed in the following section.

Derivation of pooled means, standard errors and p values from five imputed datasets

Regression results can be used to obtain a CEAC by plotting $1 - p/2$ against λ , where λ is the decision maker's maximum willingness-to-pay for a gain in QALY and p is the p -value associated with the null hypothesis that the coefficient on the treatment arm is zero; from a Bayesian perspective

this can be interpreted as the probability of the intervention being cost-effective. However, in this instance, owing to the multiple imputation performed to deal adequately with uncertainty associated with replacing missing data, five datasets were generated, each with a different coefficient on the treatment arm and, consequently, a different p -value for each regression on each dataset. Therefore, we need a method of 'pooling' the mean and standard error estimates, which can then be used to calculate a pooled p -value for each value of λ . Schafer¹⁷⁶ used the following method to estimate 'pooled' means and standard errors from multiple imputations:

- (a) The mean. Calculation of the 'pooled' mean is simply the average across the datasets i.e.:

$$\bar{Q} = m^{-1} \sum \hat{Q}(\ell)$$

where m is number of imputations and $\hat{Q}(\ell)$ is the mean of each dataset.

- (b) To obtain a standard error estimate for the 'pooled' mean \bar{Q} , both the between-imputation variance and the within-imputation variance must be calculated.

The between-imputation variance can be estimated as

$$B = (m - 1)^{-1} \sum (\hat{Q}(\ell) - \bar{Q})^2$$

where m is the number of imputations. The within-imputation variance can be calculated as

$$U = m^{-1} \sum U(\ell)$$

where $U(\ell)$ is the variance around the mean in each dataset.

The estimated total variance is

$$T = (1 + m^{-1}) B + U$$

This assumes that the sample is large enough to be approximately normally distributed and that tests and intervals based on this normal approximation are appropriate.

From this point, where we have a 'pooled' mean and standard error, a p -value can be derived. Thus we have derived an estimate of a single p -value for each value of λ that deals adequately with the uncertainty surrounding the missing data.

Cost-effectiveness acceptability curve

The CEAC reflects the probability of an intervention being cost-effective at a given value of λ . It can be generated quite simply as $1 - p$ -value for the coefficient of the treatment arm dummy and then plotted for differing values of λ . At a value of $\lambda = 0$, the CEAC reflects a comparison in costs between the two arms, and as λ tends to infinity, the CEAC tends towards a comparison of the outcome measure.

TABLE 29 Mean resource use in the two groups over the (12-month) study period

	Treatment <i>n</i> = 285 (SE ^a of the mean)	Control <i>n</i> = 366 (SE ^a of the mean)
GP visits	1.62 (0.067)	2.10 (0.082)
IBD outpatients	2.01 (0.063)	3.22 (0.059)
IBD related outpatient	0.20 (0.018)	0.23 (0.019)
Other outpatients	0.26 (0.023)	0.36 (0.028)
IBD-related length of stay	1.01 (0.162)	1.18 (0.125)
Other length of stay	0.13 (0.025)	0.22 (0.037)
Mean no. of drugs over study period	1.49 (0.062)	1.53 (0.053)

^a SE, standard error.

TABLE 30 Unit costs of resources used

	Unit cost (£)	Source
GP visits	18.22	Netten and Curtis, 2000 ¹⁶³
IBD outpatients	73.88	Netten and Curtis, 2000 ¹⁶³
IBD-related outpatients	68.82	Netten and Curtis, 2000 ¹⁶³
Other outpatients	68.82	Netten and Curtis, 2000 ¹⁶³
IBD hotel cost per inpatient day	128.04	Netten and Curtis, 2000 ¹⁶³
Other hotel cost per inpatient day	122.54–235.74	Netten and Curtis, 2000 ¹⁶³
Medication	Various	BNF ¹⁶⁵
Intervention cost	8.87	Netten and Curtis, 2000 ¹⁶³

Sensitivity analysis

The primary economic analysis uses the full patient sample of 651 in two groups and employs the 'best' estimates of unit cost. However, even within a stochastic analysis, sensitivity analysis can be performed to confirm the robustness of the results to variability. Two sensitivity analyses were performed, the first a complete case analysis (CCA) where only those patients with complete data are considered, the second varying the most important unit cost variables.

Results

Resource use

Mean levels of resource use are presented in *Table 29*. These estimates include resource use data estimated using the multiple imputation method described above but do not adjust for clustering.

For all the variables above, self-management resulted in a reduction in resource use, which ultimately results in a difference in total cost between the two groups. Particularly striking is the difference in the number of IBD outpatient visits, which is over 60% higher in the control group. This is not offset by increases in resource use elsewhere (e.g. in GP visits). Use of medication was

slightly lower in the self-management group, although this is partly offset by the intervention costs (estimated at around £9) for this group.

Unit costs

Unit cost estimates used in the analysis can be found in *Table 30*.

IBD-related outpatient contacts are those which are not a direct result of the condition but have an association with the condition.

Health states

The patient responses to the EQ-5D questionnaire at baseline and follow-up for the two groups are presented in *Table 31*. Again, these data are not adjusted for clustering in the trial. Data are presented as percentages of patients in each category (one, two and three) for each dimension of the EQ-5D.

Table 32 shows the mean utilities after application of the tariff at baseline and follow-up. Both groups report slightly reduced scores at follow-up, with the treatment group scores falling by slightly more than the control group. These scores are not adjusted for the effect of clustering.

Based on these estimates, changes in QALYs can be estimated as in the next section.

TABLE 31 Percentage of patients in each EQ-5D dimension by group at baseline and follow-up

	Treatment (n = 285)						Control (n = 366)					
	% of patients in baseline health state			% of patients in follow-up health state			% of patients in baseline health state			% of patients in follow-up health state		
	1	2	3	1	2	3	1	2	3	1	2	3
Mobility	78	22	0	72	27	1	79	20	0	69	30	1
Self-care	90	10	0	87	13	0	91	9	0	87	13	0
Usual activities	61	37	2	60	36	4	64	33	3	57	37	6
Pain/discomfort	36	57	7	38	53	9	35	57	8	35	57	8
Anxiety/depression	60	38	2	56	39	5	54	41	5	47	46	7

TABLE 32 Mean EQ-5D score at baseline and follow-up by group

	Baseline mean score (SE of mean)	Follow-up mean score (SE of mean)
Treatment (n = 285)	0.7453 (0.0070)	0.7071 (0.0079)
Control (n = 366)	0.7288 (0.0065)	0.6909 (0.0071)

TABLE 33 Mean change in QALYs over 12-month period

	Intervention n = 285 (SE of the mean)	Control n = 366 (SE of the mean)
Mean QALY gain	-0.01892 (0.0100)	-0.01870 (0.0071)

TABLE 34 Total costs (£) in the two groups over 12 month period

	Intervention (n = 285)	Control (n = 366)
GP visits	29.44	38.18
IBD outpatients	148.44	237.98
IBD-related outpatients	13.83	15.91
Other outpatients	17.86	24.69
IBD hotel cost per inpatient day	129.83	150.45
Other hotel cost per inpatient day	16.35	27.53
Medication	557.22	575.01
Intervention cost	8.87	0.00
Total cost	922	1070

Quality-adjusted life-years

As with the resource use data, mean change in the number of QALYs is presented in *Table 33*. Note that both groups are slightly worse off in that they report a reduction in QALYs over the 12-month period. These estimates are adjusted to account for the clustering effect of the centre and are based on merged values from the five datasets.

These differences are very small and do not approach conventional levels of statistical significance, but indicate that the control group performs slightly better in that the loss in QALYs is marginally lower in this group than the intervention group.

Total cost

The difference in total cost between the two groups is presented in *Table 34*. These estimates allow for the clustering effect of centre and are again based on the merged dataset.

Incremental cost-effectiveness ratio

In this instance, standard care is associated with a slightly better QALY profile, but at a higher cost. Specifically, standard care results in a QALY gain compared with shared care of 0.00022, and an increased cost of £148 per patient. Using the ICER calculation in the section 'Adjustment for clustering' (p. 58), this results in an incremental cost per QALY of £676,417 for the usual care

control group, which is likely to be far in excess of values currently deemed acceptable to healthcare funders.

Because there are problems in interpreting confidence intervals around ICERs where data occupy more than one quadrant of the ICER plane, uncertainty is dealt with using the NMB approach and the generation of CEACs. The results of these analyses are presented below.

Net monetary benefits and CEAC

Clearly, the value of NMB is dependent on the scale of a decision maker's willingness-to-pay (λ) for an additional QALY. The probability of an intervention being cost-effective will also depend on this value. In *Figure 7*, λ is varied between zero (where gains in QALYs are not valued at all) and £100,000. In the base case analysis represented by the highest of the three lines at the intersection with the vertical axis, it can be seen that a zero value of λ gives a probability of self-management being cost-effective of over 90%. In effect, this is saying that there is a probability of over 90% that self-management is cost saving, as we have placed no value on QALY gains. The probability of self-management being cost-effective declines as the value placed on λ increases. At $\lambda = £30,000$, an estimate frequently stated to be the borderline value for the NHS, self-management has a probability of around 63% of being cost-effective. At $\lambda = £100,000$, this probability declines to 51.8%, and eventually at extremely

high values of λ (around £650,000, the value of the ICER), the probability of self-management being cost-effective drops below 50%, as the very small loss in quality of life is valued very highly. However, for all plausible values of λ , in the base case analysis, self-management is more likely than standard management to be cost-effective.

Sensitivity analysis

Although the form of stochastic analysis performed above addresses a large amount of uncertainty in the analysis, it is still appropriate to perform sensitivity to allow for variability and methodological uncertainty.

Complete case analysis

This analysis is based on the sample of patients with complete data, $n = 463$, with 249 patients in the control group and 214 in the intervention group. The point estimates in this instance show similar results to the imputed analysis (see the section 'Incremental cost-effectiveness ratio', p. 60), though in this instance the impact on QALY scores is very slightly in favour of the intervention group. The results of this analysis have been transformed into an NMB framework and appear in *Figure 7*. These results show the intervention to have a higher probability of being cost-effective than the analysis using imputed data, but would not alter the decision at any value of λ , although the difference in QALYs between the groups slightly favours the treatment group in this

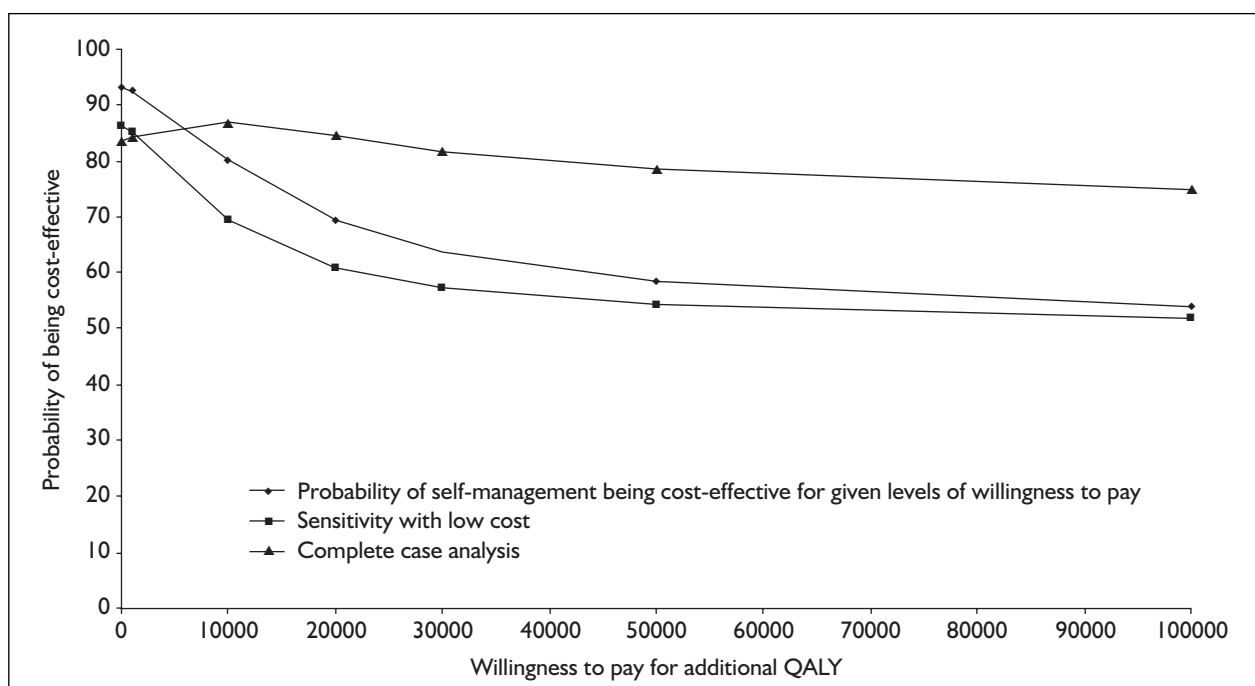


FIGURE 7 Cost-effectiveness acceptability curve for self-management

analysis. The reduction in cost in this analysis was £134 in favour of the intervention, and this analysis also demonstrated a more favourable QALY change of 0.00524 compared with the control group.

Using lower unit cost estimates for hospital-based services

One of the main factors driving the difference in costs between the two groups was the lower hospital-based resource use in the self-management group. Therefore, to reflect the fact that national figures were used in the unit cost estimates of outpatient attendances and inpatient stays, and that these may not reflect opportunity costs in the actual setting, other estimates were employed. Specifically, the lowest cost per outpatient attendance (at a gastroenterology department) and inpatient cost per day were applied to the appropriate resource use data. The results are presented in *Figure 7*, where the lowest line shows the lower unit costs. Clearly, the likelihood of self-management being cost-effective is reduced in this scenario, and this is reflected by the line lying under the base case line for all values of λ . Nevertheless, at a λ of £30,000, self-management has a probability of over 56% of being cost-effective. The cost saving associated

with the intervention in this scenario is reduced to £80, yielding an ICER for standard care of approximately £365,000.

Implications for the NHS

Given the analysis above, scarce NHS resources would be likely to be best allocated using the self-management model in the treatment of IBD. While substantial uncertainty exists at reasonable values of willingness to pay (λ), the self-management model is more likely to be cost-effective than existing practice.

Conclusions

The analysis above shows that, for most reasonable values of a decision-maker's willingness-to-pay for an additional QALY, self-management is likely to be cost-effective. This is despite a small reduction in the QALY score in this group when compared with the control group, and is therefore dependent on costs being reduced. This is achieved by hospital-based attendances (both inpatient and outpatient) being considerably lower in the self-management group resulting in a lower total cost per patient in this group.

Chapter 7

Discussion

Clinical outcomes

The clinical outcome data show that the 'whole systems approach' to self-management reduced the use of hospital services and led to a significant reduction in the number of relapses reported by patients in the treatment group when compared with a group of patients receiving usual care. Intervention group patients were significantly more enabled to understand and manage their condition following the initial patient-centred consultation, but this effect did not last throughout the 12 months of the study. The qualitative interviews with patients and consultants indicated that not all patients had received a self-management plan or full open access to clinics (many still retained fixed outpatient clinic appointments). As this was a pragmatic study, it was considered important to single out the outcomes for those patients who had had the full intervention. Analysis on the group who had been given a self-management plan by their consultant duplicated the findings from the main analysis, that is, they had increased enablement, fewer relapses and fewer hospital appointments, made more appointments for themselves and were less likely to DNA – in all cases producing a significantly better outcome. For both the main group and the compliance analysis group, there were no changes indicated in the QoL measures or the anxiety and depression measures.

QoL outcome

Improvement in disease-related QoL was used to determine the sample size for this study; however, our results showed that although QoL improved for those in the intervention group it did not reach significance. In retrospect, this is not surprising as the duration of measurement (12 months) was unlikely to be long enough for the intervention to make an impact on disease symptoms. The IBDQ was originally developed for clinical trials¹³⁷ and has been shown to be a valid measure of the efficacy of drug treatment in IBD,¹⁷⁷ but recent randomised trials of health service-related interventions for patients with IBD have shown no changes in IBDQ.^{73,121}

Enablement (PEI) and satisfaction (CSQ)

We hypothesised that the initial patient-centred

consultation would improve patients' ability to self-manage and used the PEI as an indicator of changes in patients' self-efficacy.¹⁷⁸ The PEI has not previously been used in a specialist care setting but enablement has been proposed as an alternative outcome to satisfaction.¹³⁹ There was a significant improvement in the PEI for patients in the intervention arm following the initial consultation; however, patient satisfaction did not improve significantly. This indicates that the PEI and the CSQ were measuring different effects of the consultation and that the patient-centred consultation left patients feeling more enabled but not necessarily more satisfied. The qualitative interviews showed that patients were already very satisfied with the care they were receiving from their consultant.

Relapses

One of the problems in determining the effect of the intervention in patients with IBD is that there is no clinical measurement for self-monitoring outcomes such as blood glucose levels in diabetes and peak flow measurements in asthma. The measurement that we used is a patient-centred self-reporting of relapses and their duration. Based on indications from our previous work,⁷³ we hypothesised that self-management would lead to relapses of shorter duration because of faster initial treatment. There was little difference between the two groups in the delay between relapses starting and commencement of treatment and we found no difference in relapse duration, but there was a significant reduction in the number of relapses in the intervention group, which was not expected. Although this could be explained by faster, more effective treatment, it is unlikely that such an effect would be significant within a 12-month period. A probable interpretation is that patients in the intervention group were better able to recognise the medical symptoms of an IBD relapse and not record non-IBD related gastrointestinal problems as relapses, whereas those in the control group were more likely to record such problems as relapses.

Doctor visits

These were significantly reduced for the intervention group, who on average had one fewer hospital visit over the year than those in the

control group. This was the key factor in reducing costs for patients in the self-managing intervention group. Patients reported how many appointments they had made themselves and how many had been made by the hospital. The finding that patients in the intervention group did make significantly more appointments for themselves than patients in the control group indicates that the system worked. The number of visits to the GP was not changed by the intervention, which indicates that patients were able to self-manage their condition without recourse to their GP.

Intervention strategies

The research design involved evaluation of a complex intervention and it is not possible to use quantitative analysis to measure the effect size of the individual strategies. The qualitative analysis allowed us to disentangle the effects of the different strategies.

The guidebook

The information was viewed positively by all participants and was the part of the intervention that was most successful overall. The key to its acceptance was the method of development, that is, the involvement of patients throughout the development process, use of evidence-based medicine and inclusion of lay experience. The rationale for the development process was to produce information that was empowering to the patient,⁸¹ enabled greater involvement in decision-making and encouraged self-management. Many educators hold the view that patients need written information because they are unable to recall what they have been told in a consultation^{179,180} and the assumption is made that information will improve compliance with treatment.⁸¹

Evaluation work on the guidebook used in this study showed that doctors viewed the guidebook as a back-up to information given during a consultation; however, patients stated the book contained information they had never been given before and found the inclusion of lay experiences therapeutic and reassuring.⁷⁹ In the study reported here, the guidebook was utilised as a tool during the consultation to achieve a partnership in planning a system of self-management; consultants had to work with patients to clarify which sections were of relevance to their current situation. This process builds on research findings that written information alone is not enough to change behaviour and enable patients to undertake self-management.^{4,88,100}

Patient-centred consultation

The perceived effectiveness of the patient-centred approach was less clear as it was harder to disentangle from the other factors of the intervention. A patient-centred approach was felt to be important by patients and being in the study raised expectations for some that their questions and needs would be answered. Most patients were already highly satisfied with their relationship with their consultant and did not feel that that had changed. This aspect of the intervention was very dependent on the constraints of the outpatient clinic infrastructure, the clinic load and time available per patient. Any problems were compounded by poor continuity of care in subsequent outpatient visits and an unstable disease condition. The consultants viewed the patient-centred approach as the most satisfying way of giving care, but it was evident that they wanted to retain control over management decisions concerning drug treatment. However, in cases where they did cede control to patients over issues of diet, there was a danger that some patients were left feeling unsupported and unclear about what they should do when these were the issues they most wanted to discuss.

The patient-centred training was used as a method to change professional response to enable them to find ways to integrate the patients' perspectives into the consultation.¹¹⁵ Research on training professionals in patient-centred care has had mixed results. A randomised controlled trial of patient-centred care in diabetes¹¹⁸ found that patients reported better communication with doctors and nurses and increased satisfaction but there was evidence that these patients had poorer disease control, implying that focus on disease management had been lost. Analysis of the effects of the training on beliefs, attitudes and behaviour of the professionals in this study found that trained nurses became less keen on a patient-centred approach during the trial and had reduced confidence in their ability to deliver it – there were no such effects for GPs.⁷⁸ There were considerable perceived time constraints for both nurses and GPs.

A randomised controlled trial to measure the effects on asthma patients of education to change the behaviour of physicians had more positive outcomes.⁷² Children treated by trained physicians had fewer symptoms and reduced health care utilisation. The authors argue that self-regulation “is the process of observing, making judgements and reacting realistically and appropriately to one's own efforts to manage a task. It is a means by which patients determine what they will do, given their

specific goals, social context and their perceptions of their own ability.¹⁵ To be effective, patient education for self-management should go beyond technical and medical concerns and incorporate the patient's interests and concerns. This is reflected in a qualitative study of health professionals views on guided self-management plans for asthma which concluded that a more patient-centred, patient-negotiated approach is required.¹⁸¹

Guided self-management

Guided self-management and writing a joint SMP were thought by the consultants to give clarity and act as a contract with the patient. This was effective for those who actually received a plan: it gave them the confidence to take control of treatment and reassurance in how to recognise a relapse. Writing a SMP was judged by consultants as being effective for patients who had a stable pattern of disease. The plan and discussion were felt to reassure patients, provide clarity and lead to greater concordance with treatment. Patients welcomed this clarity and involvement in writing the plan, although there was still ambiguity about the definition of a relapse requiring medical treatment. Patients who were very ill did not want the option of guided self-management, and this accords with findings for asthma patients.¹⁸²

Most work on guided self-management has been in the fields of asthma and diabetes, where the concept has been well researched and become established in practice. Other chronic conditions where self-management has been studied include arthritis,^{64,183} chronic pain,¹⁸⁴ bulimia nervosa,⁷ patients receiving oral anti-coagulation therapy⁸ and our work on ulcerative colitis.⁷³ Reported positive outcomes are similar to those found in this study and include improved symptoms, increased satisfaction, reduced health service use and increased QoL.⁶ The findings by Jones and colleagues¹⁸¹ of a mismatch in the views of health professionals and asthma patients about guided self-management and what patients should be doing to control symptoms underscores our belief that a patient-centred approach is a vital part of introducing guided self-management. They found that professionals were unenthusiastic about self-management plans and patients did not regard their asthma as a chronic condition needing regular monitoring and treatment adjustment.

Open access

Open access was greatly appreciated by most patients and, when it worked well, it gave patients greater confidence to self-manage. When it failed to allow fast access to clinics, it had the potential to

undermine the effectiveness of self-management. Some patients were reluctant to lose their fixed appointments because of fear of being unable to get back into the system again. Patients did not abuse the system; there was no evidence that any patients were making unnecessary appointments. Consultants were concerned that a few patients would avoid contacting the hospital because they would not acknowledge the seriousness of their condition. It is likely that this group of patients already have high clinic non-attendance rates so it would seem appropriate to pay greater attention to negotiation and clarification of when they should seek help during consultations.

The findings add weight to previous work that open access is safe for patients with IBD and reduces demand for health service resources.^{73,121} Organisational limitations are a concern and trying to initiate a patient-centred approach imposes time constraints which can cause problems for health professionals.⁷⁸

The condition of IBD is well suited for a system of guided self-management. The embarrassing nature of the symptoms is isolating, so although there is a good patient support group, many do not want to become involved and are reliant on healthcare professionals for support and information. Only 17.2% of this sample group were members of NACC (the patient support group), which is lower than the 25% reported in a recent survey.¹⁰² We have shown that people can be instructed in how and when to self-treat by their consultant, and the qualitative interviews indicate a consensus in the types of patients considered suitable for the intervention. Our findings add weight to the positive outcomes reported in studies of guided self-management in other chronic conditions.

Unused or missing data

Patients wrote many comments on the questionnaires and in the diaries. These have not been included in the qualitative analysis as it was decided to base this on the in-depth interviews.

Economic analysis

The cost-effectiveness analysis shows that, for most reasonable values of a decision-maker's willingness-to-pay for an additional QALY, self-management is likely to be cost-effective. This is achieved by hospital-based attendances (both

inpatient and outpatient) being considerably lower in the self-management group, resulting in a lower total cost per patient in this group.

However, the results of the sensitivity analysis show that self-management may have only a slight advantage over standard management in terms of the probability of being cost-effective. Complete case analysis favoured the intervention more than the analysis of imputed data, although the decision would not be different. Missing data are a common problem in economic evaluations and imputation is a commonly used tool to deal with the issue. Multiple imputation is a method of imputation that deals with the uncertainty around the imputed value in a more accurate manner than other forms of imputation and prevents a large reduction in the power of the study. The fact that the complete case analysis and the imputed analysis showed differing results in terms of QALY gains (imputed analysis showed a very small advantage to the control group while the complete case analysis showed a similarly small advantage to the treatment group) suggests that there was a systematic difference between the missing and complete data and/or a relatively large degree of uncertainty around the QALYs gained.

The cost-effectiveness analysis was based on the comparison of differences in NHS costs with differences in changes in QALYs as measured and valued using the EQ5D. The purpose of using QALYs was to be able to assess the value for money of the intervention against a common metric of health gain as used to evaluate more conventional health care interventions and programmes, for example as part of the National Institute for Clinical Excellence's Technology Appraisal Programme.¹⁸⁵ The main conclusion of the analysis is that the intervention represents a cost-effective use of resources is driven, however, not by changes in health outcomes (in fact, patients in the intervention group had a very slightly greater reduction in QALYs, relative to baseline, over the period), but by savings in resource use such as outpatient and inpatient hospital contacts.

Nevertheless, on balance, the base case analysis and sensitivity analyses both favour self-management over standard management of IBD, although any substantial changes in unit cost data may require a reassessment of the evidence.

Other possible outcomes

Although this was a patient-centred intervention, it might have been valuable to have obtained a

medical opinion on the patients' disease status at the start and end of the study to determine whether this tallied with the patient's view and, if not, to explore why. We did not measure patients' social function; it is possible that the intervention might have improved patients' ability to interact with others.

Internal validity

Methodology

Randomisation by hospital site rather than by individual patient was necessary because of the training element of the intervention; this might be criticised as leading to a potential imbalance as teaching hospitals, for example, might carry a caseload of more complex cases. However, as the groups were well balanced at baseline in terms of clinical and demographic characteristics, site randomisation appears to have worked satisfactorily. High rates of follow-up were obtained although diary completion was poor, which made it harder to interpret outcomes dependent on diary data such as relapse duration and time between onset of relapse and treatment. Problems with diary use are recognised; the diaries in this study were designed to be used as a ledger, to be filled out as an event occurred,¹⁸⁶ but this can be a strain when a person is ill and make completion less likely. There is also the issue of literacy; those with poor literacy are less likely to complete diaries.¹⁸⁷

There is a strong possibility that some of the consultants were more enthusiastic about the study than others and that some may have been selective about the patients to whom they were willing to give the full intervention. However, analysis showed that there were no significant predictors for the patients who were given the full intervention (determined as those who reported receiving an SMP), so lack of a full intervention is probably related to the consultant seen. As this was a pragmatic trial of a complex intervention delivered through a diverse group of hospital specialists, it is perhaps unsurprising that not all eligible patients received the full intervention. The most likely explanation for variation in compliance between centres was due to a variation in degree of engagement by consultants in the principles of patient-centred self-management. Some consultants expressed strong ideas about who was suitable for the intervention and were reluctant to give patients more control. This is also illustrated by what happened at recruitment; consultants in both arms of the study withdrew similar numbers of potential subjects before consent was sought.

These patients were considered to be too physically or mentally ill to cope with questionnaires. This did not bias the results, as baseline data were similar for both groups.

External validity

The similarity in baseline characteristics between the two groups suggests that the results from the intervention group may be generalised to the IBD patient population. Threats to external validity come from the patients who gave consent but were removed from the trial by the consultant. As shown in *Figure 2*, this is a small number of patients (17 in total) and although there are no entrance questionnaire data for this group, they were included in the follow-up. Consultants were asked to give reasons for withdrawing patients from the study; in the main these were because the patient was considered not suitable owing to the severity of illness. This means there is a possibility that trial patients were not representative of all eligible patients with IBD, as those who were very poorly may have been withdrawn at some centres.

Limitations of the research

Our study has shown that most IBD patients are both willing and able to self-manage their condition and achieve benefit from so doing. Such a desire to self-manage is also reflected in our

finding that many patients in the control centres were covertly self-treating relapses without seeking medical advice. This may be why we did not find any overall reduction in relapse duration between the groups. We also found that many patients in the control group were treating non-disease-related symptoms as relapses; indeed, many were using prednisolone in high doses without clinical guidance (we were expecting 0% self-treatment with corticosteroids in this group), using drugs stockpiled at home from unused prescriptions.

The additional time burden of patient-centred education was also reported by some consultants to limit delivery of the intervention and, indeed, some patients did not feel that they were given the opportunity to discuss all the issues they wanted. There are acknowledged difficulties in allocating time during busy outpatient clinics. Our study has demonstrated, however, that the time taken to introduce patients to self-management is more than offset by a reduction in number of outpatient follow-up visits, a benefit that would be expected to steadily increase with time.

Some consultants did express concern that patients who were given the option of self-referral might avoid contacting the hospital and thereby put themselves at risk. Although we found no evidence for this, it could be addressed by paying greater attention to the negotiation and clarification of appropriate self-referral during management of disease relapse.

Chapter 8

Conclusions

Implications for the NHS

The profile of disease has changed dramatically over the life of the NHS, with a marked reduction in the number of acute, self-limiting illnesses and a rise in the number of people living with chronic diseases. The health service has to respond to the changing demographics of disease and to the changing expectations of patients by modifying traditional practices which have often been physician-centred and disempowering to patients.

Many patients with chronic diseases receive long-term hospital follow-up by specialist clinicians, resulting in over 15 million annual consultations in England alone. These consultations present an opportunity for clinicians to engage patients in the process of decision-making and to develop disease-management processes where patients take a greater role in the ongoing monitoring and management of their disease. Studies of this process have demonstrated improved clinical outcomes, increased patient satisfaction and reduced health service utilisation, but this approach remains patchy and underdeveloped in most areas of chronic disease management.

There are several obstacles to change, including lack of time in clinics for new interventions, lack of adequate information to underpin patient participation, anxieties about the safety of self-management and the attitudes of some clinicians to change. Furthermore, chronic disease management in the NHS is based around regular 'routine' hospital visits, determined in advance at the previous visit, whereas most chronic diseases follow an unpredictable course, making it unlikely that consultations will coincide with times of greatest clinical need. Access to clinicians between appointments depends on clinic availability and patients may either consult their general practitioner, wait for a hospital appointment or initiate treatment themselves (20% of patients with ulcerative colitis self-treat, sometimes inappropriately) when their symptoms relapse.

Until recently, the debate about management of chronic diseases has concentrated on discharge from hospital and transfer of follow-up to primary care as the main alternative. Studies suggest that

up to 48% of patients undergoing long-term hospital follow-up could be discharged to family practitioners. However, most primary care physicians see few patients with uncommon chronic diseases such as ulcerative colitis and Crohn's disease (5–6/2000 patients), and most are unwilling to take on sole responsibility for managing them. Open access clinics are preferred by patients and general practitioners, and can reduce routine hospital visits, but patients still need to see a doctor before treatment of a relapse can begin, which inevitably delays onset of therapy.

The current study challenges traditional secondary care management of IBD by introducing a package of interventions to promote greater patient participation in treatment and decision-making and provision of access on request instead of prearranged hospital appointments. Although it is accepted that not all elements of this package are appropriate for all patients, the concept of a whole systems approach, incorporating evidence-based patient-centred interventions where possible, underpinned the ethos of the study.

The results of this trial are clear. Patients receiving the intervention require fewer hospital visits without compromising health or psychological outcomes and the intervention is preferred by the majority of patients when compared with traditional management. The qualitative data suggested that this was frequently because of a perceived increase in control over not only illness management but also access and use of health services when these were required. Economic evaluation demonstrates cost-effectiveness. Most of the clinicians participating in the study favoured this approach to management of their IBD patients but highlighted a number of reservations relating to restrictions imposed by current working arrangements and choice of patients who would be appropriate for the new system of management. Patient respondents also endorsed this approach. Nonetheless, it is clear from the analysis of qualitative interviews with patients that there is still room for consultants to learn from and more fully integrate the insights and expertise that patients bring with them in the disease-management strategies of chronic illness.

In order to implement the intervention, we would suggest a system of screening for appropriate patients and a number of changes to the current system for managing patients with IBD. It is apparent from detailed data analysis and from the qualitative interviews with patients that those with uncontrolled symptoms or complex disease are least likely to benefit from self-management training and require ongoing regular specialist follow-up. There are also patients whose symptoms are inactive, but who choose to continue with their current system of management. There should be clinical freedom to decide the most appropriate system of management as part of the shared decision-making process between clinician and patient. Those patients who do not wish to or are unable to participate in self-management training can be offered supportive information which would allow them to participate as informed partners in the choices of treatment and medical consultations should facilitate shared decision-making. The evidence favours opportunities for guided self-management being available if and when the patient's symptoms are adequately controlled or if they choose this approach at any time during the course of their illness. For the majority of patient's whose symptoms are well controlled, the whole systems approach to management could be offered as an alternative to current management. Additionally, to ensure adequate patient choice, alternative and additional support may need to be developed and offered to people whose adverse social and psychological circumstances undermine their capacity and resources to engage fully with self-management strategies.

NHS changes required to facilitate implementation

In order to implement the findings of the study, hospitals would need to undertake certain actions, including provision of written information to patients, development of new clinic templates to allow time for patient-centred consultations, modification of follow-up strategies and training consultants to be patient-centred.

Information

Patients require good quality information in order to participate as partners in the management of chronic diseases. Currently, the NHS does not provide written information and the only sources available to patients are the leaflets provided by drug companies. Those patients who join NACC have access to more detailed information but only about a quarter of patients are members. We recommend that all patients be provided with

information to support their role in chronic disease management.

Self-management training

Adequate time is required to provide self-management training for those patients who are willing and for whom it is appropriate. For most of the clinicians who participated in the study, finding extra time in clinics was difficult. Most clinics run at full capacity, and there is no reserve in the system to provide patients with 20 or 30 minutes without delaying other patients and the clinic overrunning. Until all suitable patients who are currently in the system are trained, it is necessary to allocate extra time for the intervention and this will require an alteration to the clinic template. We would suggest allocating a double follow-up slot for patients with IBD for their next follow-up visit at which the intervention would be provided. Written information could be provided in advance so that the patient is able to participate more fully in the self-management discussion.

Training for health professionals

Few health professionals would claim not to be patient-centred in their approach to the management of people with chronic diseases. Quantifying patient-centredness is difficult and depends on proxy measures such as actions to elicit patient views, incorporation of patient preferences into management plans and listening to patients. Some of the components are inherent to the personality and character of the clinician and these are unlikely to be influenced by training, but many facets of patient-centred care are synonymous with good communication and as such can be taught. Many clinicians undertook their training when communication skills were not part of the medical school curriculum and, as we have shown in this study, several consultants found a single session of patient-centred training useful, although all believed that they already practised patient-centred medicine.

We suggest that patient-centred communication should be an integral part of all medical school curricula with updates throughout doctors' careers (similar to maintenance of other transferable skills and ethics), funded as part of the study leave programme.

Currently, health professionals are not trained in methods to promote and support self-care, and experimental models could be explored and training strategies developed for medical and nursing students. Such training should be based on

a recognition of the benefits of patients' experience and expertise, which generate new insights which can be incorporated into health professionals' chronic disease management skills and knowledge.

Follow-up on request

It is not normal NHS policy for patients to refer themselves to hospital at will. This study has highlighted a number of the difficulties with implementing this system, including obstruction by well-meaning booking staff, over-booked clinics and patients deferring appointments because of lack of confidence. Patients must be given clear instructions about who to call to make appointments, and all appropriate staff, including receptionists, secretaries and clinic nurses, should be aware of the system. Where there is an IBD specialist nurse, this may be the most appropriate person to take calls from patients and to triage according to urgency and clinic availability. In the long term, we would anticipate a reduction in the number of IBD patients attending clinic, and suggest that a number of clinic slots be kept free to accommodate patients who are self-referring.

Another problem with the current system is that many hospital computer systems consider that a patient is discharged if they have not had a hospital appointment for over 1 year. This then causes difficulties if a patient wishes to be seen without a new referral from their GP. Where these systems are operating, it will be necessary to override this default position. Some clinicians may choose to speak to patients before providing an appointment or use telephone consultations to complement their routine practice. This has the advantage of solving minor problems without the need for a hospital visit, and again allows for triaging of the most urgent cases.

'Permission' to access services based on patients' perceived need for contact should self-management strategies fail needs to be reinforced by those who are responsible for organising and those who have contact with patients in outpatient departments.

Patient-centred consultation

Our whole approach to self-management is patient-centred from involvement of patients in the development of information to the patient-centred consultation and the personal SMP. Medical students now receive education and training in patient-centred care and consultants have indicated that they favour a patient-centred approach; however, current time constraints

preclude most consultants from practising in a patient-centred way during a normal out-patient consultation. Provision of a double follow-up appointment slot should allow time for self-management training to be conducted in a patient-centred way. However, it may be that health professionals require more specific training relating to promotion of self-management skills in patients. The NHS is proposing a national training programme for patients to become 'expert patients' and it would seem appropriate to provide training for health professionals in how to support and encourage patients to maintain their expertise in self-management.

Recommendations for future research

Organisation of self-management programmes

Research is needed to determine the optimum methods of screening patients for their suitability for self-management and ways to ensure that self-managing patients are not lost to the system but can be readily contacted if, for example, new treatments become available. Booking systems for clinics need to be adapted to allow self-managing patients to self-refer quickly and we need to find out the most appropriate methods or technologies for doing this. Patients making outpatient appointments on the basis of their own judgements about chronic illness management needs to be fostered.

Future studies involving interviews with hospital managers – who were not involved in this study – would be interesting and might help illuminate ways to introduce change.

Eliciting patients' preferences for self-management

Some patients welcome the opportunity to self-manage their condition whereas others do not. In order to provide appropriate individualised care, organisations need to take patients' preferences for self-management into account when planning care and further research is needed to find out practical ways of doing this.

Training health professionals

There is a need to explore models for training health professionals (as individuals and as teams) in ways to promote and support self-care.

Long-term clinical effects

There is little evidence on the long-term effects

of empowering patients with chronic illness to self-manage. We do not know whether this group will have improved health outcomes compared with patients who are more dependent on health professionals. This study and other work has looked at outcomes after 1 year, but it is likely that significant morbidity and mortality effects will take several years to determine. Many patients in the study did not return to clinic during the course of the year, so there is also a need to establish how well open access functions over a long period and whether clinics and patients revert to a system of fixed appointments.

We had hoped to use the results from this study to prove our hypothesis that faster treatment results in relapses of a shorter duration. We were not able to show any effect and it is likely that a more focused and tightly controlled study should be undertaken to investigate this.

Other chronic conditions

We believe that the whole systems approach we have advocated will be transferable to other chronic conditions, but it would be a good test of the robustness for a different team to study the approach with another condition.



Acknowledgements

We would like to thank the staff at all the outpatient clinics involved in this study, particularly the consultants' secretaries, nurses and clerical staff. Thanks are also due to staff in the medical records departments for their help and efficiency. We particularly want to thank all the patients involved in the study for their cooperation and enthusiasm and for the effort they put in to filling in the questionnaires and diaries. Sharing their experiences with us has been vital to gaining an understanding of the positive and negative effects of the type of intervention.

The authors want to thank and acknowledge the work of Linda Gask (Reader in Psychiatry, University of Manchester) who helped to design the patient-centred training programme for consultants and who led the training sessions and the work of Dianne Oliver, Angela Swallow and Moonira Patel-Mohammed who helped with the data collection and entry.

The study could not have taken place without the cooperation of the consultants involved who are all part of the North-West Regional Gastrointestinal Research Group: Dr Ahluwalia, Stepping Hill Hospital; Dr Boyes, Tameside General Hospital; Dr Brown, Royal Lancaster Infirmary; Dr Butcher, Southport and Formby DGH; Dr Crampton, Wythenshawe Hospital; Dr Dawson, Arrowe Park Hospital; Dr Drake, Chorley and South Ribble; Dr Foster, Macclesfield District General Hospital; Dr George, Birch Hill Hospital; Dr Goodman, Bury General Hospital; Dr Green, Burnley General Hospital; Dr Higham, Royal Lancaster Infirmary; Mr Hutchinson, Halton General Hospital; Professor Krasner, Fazakerley Hospital; Dr Linaker, Warrington Hospital; Paul Madigan, Specialist Nurse, Whiston Hospital; Dr McLinden, Whiston Hospital; Dr Morris, Royal Liverpool and Broadgreen Hospital; Dr O'Toole, Fazakerley Hospital; Dr Summerton, Trafford General Hospital; Dr Temperley, Royal Preston Hospital; and Dr Whorwell, Withington Hospital.



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Appendix I

Estimate of current costs to the NHS of treating inflammatory bowel disease

Current costs to the NHS of treating IBD have been estimated through data obtained from Inflammatory Bowel Disease Guidelines produced by the British Society for Gastroenterology and patient data from Salford and Trafford Health Authority. There are no centrally collected data on costs of treating IBD currently available.

These are the minimum costs assuming 200,000 patients with IBD and 8000 new cases per year; 1–2 visits to clinic per year and assumed for established patients and 3–4 visits in the first year for new patients.

These data exclude costs for flare-ups, parenteral nutrition, elemental diets, emergency surgery and

	Cost (£ million)	
	Established patients (200,000)	New patients (8,000)
Drugs	36	1.6
Follow-ups	7	1.6
Investigations	10	3
Surgery	3	3

non-surgical inpatient treatment – a realistic estimate of £10–20 million. The overall costs to the NHS of current treatment of IBD is £75–85 million.

Appendix 2

Letter sent to North West consultants inviting them to participate in the study

Dear

We are delighted to be able to tell you that we have been funded by the NHS R&D Health Technology Assessment Programme under the area:- 'different techniques of shared clinical decision making', to conduct the following research in the North West Region:

A randomised controlled trial to assess the impact of a package comprising a patient orientated, evidence-based self-help guidebook and patient-centred consultations on disease management and satisfaction in inflammatory bowel disease.

We are writing to ask if your department would be willing to participate in this large, multi-centre, controlled clinical trial to assess the impact of an alternative method of treatment and follow-up for patients with inflammatory bowel disease. The study will take place in 16 gastroenterology outpatient departments in the North West. Your department has been randomly selected to be a participant in the research which will commence in January 1999. The study has been given ethical approval from the North West Multi-Centre Research Ethics Committee.

As you will be aware, patient partnership is high on the political agenda of the current government. This study is based on the findings of a randomised controlled trial we have recently completed which shows that a combination of self-management and follow-up on request can reduce the number of consultations by two-thirds and also improves disease management. The method has been found acceptable to patients and their doctors.

If you agree to take part in this important study, your centre will be randomised to be in either the control group or an intervention group.

Patients in the control hospitals will receive treatment and follow-up as usual. Patients in the hospitals randomised to the test group will receive the following interventions:

- Patients will be provided with an innovative, evidence-based guidebook which encourages patients to participate in decisions about their medical and surgical care and participation in self-management of their disease where this is possible;
- Patients will be provided with a self-management regime based on your personal practice and written in consultation with the patient; and
- Patients will have open access to follow-up clinics instead of routine appointments.

40 patients with IBD will be recruited from those attending outpatient clinics where they will be interviewed by the researcher.

If your hospital is randomised to the intervention group, you and your team will be asked to participate in a one-off two hour training session during which the principles of patient-centred management will be discussed and the practicalities of guided self-management explained in detail. The session will be informal and will incorporate the use of video-feedback training. The timing and venue of this session will be arranged at your convenience and 2 hours of CME credit have been agreed.

Being part of this trial should not involve any additional work. Suitable patients would be recruited, interviewed and monitored by our own researchers using questionnaires and hospital notes.

We would be very grateful for your help with this study and would be delighted to visit you if you would like to discuss the trial further before making a commitment. If you and your colleagues are happy at this stage to take part in this study, you need take no further action other than to return the attached question sheet. We will arrange a mutually convenient time to conduct the training session in March.

Please could you send back the question sheet in the envelope enclosed. Thank you.

Yours sincerely,

Anne Kennedy
Research Fellow

On behalf of:

David Thompson
Professor of Gastroenterology

Andrew Robinson
Clinical Lecturer

Appendix 3

Notes for consultants on how to conduct the intervention consultation

Test sites

Notes for consultants

The consultation:

- Start the patient-centred consultation:
 - Address the impact of the disease on the patient
 - Establish what treatment works
- Introduce the guidebook – go through the sections
- Explain shared care and check the patient is confident about it
- Negotiate a self-management plan with the patient
- Write the self-management plan in the guidebook
- Do a copy of the self management plan for your records and to send to the GP
- Give the patient a contact number to ring for advice and appointments and tell the patient to say that they are in the trial when they ring so it can be recorded
- Several fixed appointments may be needed if the patient is unstable but no more appointments to be given once the self-management plan has been established
- Remind patient of the importance of completing the diary the researcher has already given and explained to the patient
- Ensure a system is in place for monitoring bloods and urine if necessary

After the consultation:

- If the patient rings for any advice, please keep a record of this on the form provided by the researcher.

Appendix 4

Instructions included in the record book on when to make an urgent outpatient appointment

Please phone the following number to get an urgent outpatient appointment if your flare-up does not respond to treatment, or if you are worried about anything to do with your ulcerative colitis (or Crohn's disease).

Phone number:

You are welcome to ring up for an outpatient appointment at any time if you need to discuss your illness with the doctor or nurse. However, you should definitely ring for an appointment in the following circumstances:

- If you are treating a flare-up yourself and you are no better within 7 days.
- If your flare-up comes back as soon as you stop or reduce your treatment.
- If you need to use more than 2 courses of steroid tablets in a year.
- If you are losing weight without dieting.
- If you are losing blood from your bowel between flare-ups.
- If you have any other worrying symptoms.

Appendix 5

Unpublished scales

Entrance questionnaire

A. Trial information:

1. Trial number
2. Hospital
3. Consultant
4. Patient notes number

B. Patient information:

1. Name
2. Address Postcode
3. Age in years
4. Tel. No
5. G.P.
6. Marital status Children (No)
7. Which of the following best describes your main activity?

In employment or self employment full time	<input type="checkbox"/>
In employment or self employment part time	<input type="checkbox"/>
Retired	<input type="checkbox"/>
Housework	<input type="checkbox"/>
Student	<input type="checkbox"/>
Seeking work	<input type="checkbox"/>
Other (please specify)	<input type="checkbox"/>
8. a) Did your education continue after the minimum school leaving age? YES NO
 b) How old were you when you left full time education?
9. Do you have a degree or equivalent professional qualification? YES NO
10. Are you:

a current smoker	<input type="checkbox"/>
an ex-smoker	<input type="checkbox"/>
a never smoker	<input type="checkbox"/>
11. Are you currently taking part in any other trials/research?
12. a) Do you pay for your prescriptions? YES NO
 b) Do you have a season ticket for your medication? YES NO
13. Have you ever used the Internet to get information? YES NO
 If yes, what kind of information?

C. Details about IBD

1. First diagnosed
2. Extent
3. Severity
4. When was the last flare-up?
5. How many flare-ups in a year?
6. Number of visits for IBD in the last year to: i) hospital outpatients
- ii) G.P.

Patients were asked to complete the following question after they had seen the doctor:

Can you say approximately how long your consultation lasted today? minutes

Additional questions for follow-up questionnaire

All patients

1. If you are employed, what is your occupation?
2. If you have children, how many are under 18 years old?
3. Do you belong to a patient support group for people with Colitis/Crohn's disease? Yes No
If yes, have you joined in the last 12 months? Yes No
4. Have you obtained information about your condition in the past 12 months from any of the following: (if so please tick as many boxes as appropriate)

Health professional	<input type="checkbox"/>
Other people with your condition	<input type="checkbox"/>
Friends or relatives	<input type="checkbox"/>
Books	<input type="checkbox"/>
Leaflets	<input type="checkbox"/>
Newspapers/magazines	<input type="checkbox"/>
Videos	<input type="checkbox"/>
TV or radio	<input type="checkbox"/>
Internet	<input type="checkbox"/>
Other (please describe)	<input type="checkbox"/>
Did not look for information	<input type="checkbox"/>
5. **How would you describe your symptoms in the past 12 months?** (tick one box)
 - No symptoms at all
 - Some symptoms always present
 - Flare-ups followed by symptom-free periods
6. **How many flare-ups have you had since the start of this study?**
7. **How many visits have you made to your GP about your IBD in the last 12 months?**
8. **How many visits have you made to your hospital IBD doctor in the last 12 months?**
9. **How many of your outpatient visits have been**
 - a: arranged by the hospital?
 - b: arranged by yourself?
10. **Does your hospital have a system that allows you to make urgent appointments by phone?** Yes No
If yes, how long do you have to wait for an urgent appointment?

5. **Did you take the guidebook to your outpatient clinic visits?** (please circle) Yes No
6. **Did you take the guidebook to your GP visits?** (please circle) Yes No
7. **Have you shown the guidebook to anyone else?** (please circle) Yes No
8. **Has using the guidebook helped you to make any decisions with your doctor or on your own about your treatment?** (please circle)
- a) With the doctor Yes No
- b) On my own Yes No

9. **If it has helped you to make decisions, can you describe the types of decisions you have made**
(please circle one answer for each question)

- a) **Decisions about medicine**
- | | | | |
|-------------------|----------------|----------------|-----------|
| Changing the drug | Doctor decided | Joint decision | I decided |
| Changing the dose | Doctor decided | Joint decision | I decided |
- b) **Decisions about surgery**
- | | | | |
|---------------------------|----------------|----------------|-----------|
| Whether to have operation | Doctor decided | Joint decision | I decided |
| Type of operation | Doctor decided | Joint decision | I decided |
- c) **Decisions about surveillance**
- | | | | |
|--------------------------|----------------|----------------|-----------|
| To start surveillance | Doctor decided | Joint decision | I decided |
| To stop surveillance | Doctor decided | Joint decision | I decided |
| To continue surveillance | Doctor decided | Joint decision | I decided |
- d) **Any other decisions?**

10. **How useful to you are the different sections of the guidebook?**

(tick appropriate boxes)

	No use	Some use	Very useful
Introduction	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tests and treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Surgery	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Surveillance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Record book	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Self-management plan	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Appendix 6

The diary

Research diary

Thank you for taking part in this study. We are very interested to know what you do when you have a flare-up of your Inflammatory Bowel Disease, what your symptoms are like and how long they last for. It is often difficult to remember exact details after the event, particularly if there have been a few episodes and so **we ask you to please fill in the diary at the time of a flare-up**. The information is very important if we are to improve the service we offer you and other people with Inflammatory Bowel Disease and we are grateful to you for your time and effort.

Instructions:

There are three sections to this booklet – one for giving details about your flare-ups (Section 1), one for giving details about visits to the doctor (Section 2) and one for giving details about your treatment (Section 3).

We want you to keep a record for the 12 months of the study.

Section 1 – Diary of symptoms/flare-ups

Please fill in this section every time you have a flare-up of your Inflammatory Bowel Disease. If you run out of space, contact Dr. Anne Kennedy on 0161 275 7601 for another diary.

Section 2 – Visits to the doctor

Please fill in a different page for every visit you make to the doctor **because of your Inflammatory Bowel Disease**. This includes the GP, hospital doctor and emergency departments. Can you also please complete the questions that follow the doctor visit page, after each visit to see the **hospital doctor**.

If you run out of space, contact Dr. Anne Kennedy on 0161 275 7601 for another diary.

Section 3 – Treatment

Please fill in this section to tell us about the drugs you have taken, any complementary medicine you have received or any surgery you have had over the course of the study.

Thanks again – without this information we couldn't do the study.

Flare-up 1

Date flare-up started _____ Date flare up ended _____

1. What are your symptoms?

2. How long after your flare-up began did you start treatment? (days and hours please)

Days/Hours _____

3. What did you do about your symptoms? (Please tick the appropriate box)

Went to the see the GP

Made a hospital appointment

Started treatment yourself

Other, please specify _____

(PLEASE REMEMBER TO GO TO SECTION 2 (DOCTOR VISITS) EVERY TIME YOU VISIT THE DOCTOR)

4. What treatment did you start?

5. Did you have to change treatment ? YES NO

If yes, what did you take? _____

When your symptoms have returned to normal, please fill in the following questions. The answers should refer to this flare-up only.

6. Please give the date the flare-up ended at the top of this page.

7. How many times did you visit the hospital because of your flare-up? _____

8. How many times did you see your GP because of your flare-up? _____

9. How much time did you lose from work/school (including seeing the doctor)?

IF YOU HAVE ANY MORE FLARE-UPS PLEASE GO TO FLARE-UP 2 AND COMPLETE THE QUESTIONS. THANK YOU.

Section 2 Details about visits to the doctor

Doctor visit 1 _____ Date _____

Who did you see today?

- GP at the surgery (Please fill in this page but not the questions 1–18
 GP at home that follow this page if you saw your GP)
- Hospital doctor at outpatients (Please fill in this page and the questions 1–18
 Hospital doctor at casualty that follow this page if you saw a hospital doctor)

If you went to the hospital, what was the name of the doctor you saw and how long did the consultation last?

Doctor's name _____ Length of consultation _____ minutes

Why did you go to see the doctor today?

Please estimate the total time from leaving home or work until you got back

_____ hours _____ minutes

How did you travel there and back?

Travel there

- Bus/train Single fare £__ . __ p
 Taxi Single fare £__ . __ p
 Walked
 Ambulance
 Car How many miles there and back? _____ miles

Travel back

- Bus/train Single fare £__ . __ p
 Taxi Single fare £__ . __ p
 Walked
 Ambulance

Did you have to take time off work to go?

YES NO
 If YES how much time did you have to take off? _____ hours _____ minutes

Did you incur a financial loss because of your visit to the GP or hospital?
 YES NO
 If YES how much pay did you lose? £__ . __ p

Did a member of the family or a friend go with you?

YES NO
 If YES did they have to take time off work?

YES NO
 If YES how much time? _____ hours _____ minutes

Appendix 7

Information from medical records

Patient Name	Date of recruitment
DOB	End Date
Hospital	Study ID
Trialnum	

1. Diagnosis

UC		Crohn's		Other diagnoses (from letters)
Proctitis		Colon		
Left sided		Small bowel		
Total		Perianal		
		Other		

2. Investigations

Investigation	In pt or out-pt	Date	In pt or out-pt	Date	In pt or out-pt	Date
Sigmoidoscopy						
Colonoscopy						
Barium enema						
Small bowel enema						
CT abdomen						
Abdominal X-ray						
Upper intestinal gastroscopy						

3. Is there a letter to the GP regarding details of self-management plan?

	Date	Yes	No
What does this include			
• Signs of flare-up		Yes	No
• Drugs for maintenance		Yes	No
• Drugs for flare-up		Yes	No
• Details of open access		Yes	No
• Details about blood tests for monitoring therapy		Yes	No
• Other			
.....			

4. Is there a confirmation letter to patient regarding study? Yes No

All other outpatient visits

	Other appointments kept	DNA	Cancelled
Total since recruited			
Total for previous year			

Nb. Note if there are letters regarding attendance at other hospital outpatient departments

6. Hospital admissions for IBD since recruitment

Type of ward	Number of nights	Details of surgery or medical treatment

Type of ward (eg: Medical or surgical, Short-stay/Day care, intensive care)
(NB. Record investigations in section 2)

7. Other hospital admissions since recruitment

Type of ward	Number of nights

Type of ward (eg: Medical or surgical, Short-stay/Day care, intensive care)

8. Drugs used during the year*

Drug	Dose *	Date	Dose *	Date	Dose *	Date
Mesalazine (Asacol, Pentasa, Salofalk)						
Balsalazide (Colazide) – note: withdrawn in Dec 99						
Olsalazine (Dipentum)						
Sulphasalazine (Salazopyrin)						
Cholestyramine						
Budesonide (Entocort)						
Prednisolone						
Metronidazole (Flagyl)						

Enemas	Dose *	Date	Dose *	Date	Dose *	Date
Colifoam						
Predenema						
Predfoam						
Predsol						
Asacol						
Pentasa						
Salofalk						
Salazopyrin						
Entocort						

Suppositories	Dose *	Date	Dose *	Date	Dose *	Date
Asacol						
Pentasa						
Salofalk						
Salazopyrin						
Prednisolone						

DOSE – if information is there, please code if it says it's prescribed for 1). Maintenance treatment.
2). Flare-up only, or 3). Mix of both

Immunosuppressants	Dose	Date	Dose	Date	Dose	Date
Azathioprin (Imuran)						
Cyclosporin						
Methotrexate						
5-Mercaptopurine						

Antidiarrhoeals	Dose	Date	Dose	Date	Dose	Date
Loperamide (Imodium)						
Lomotil						
Codeine phosphate						
Bran						
Ispaghula husk						
Methylcellulose						
Sterculia (Normacol)						

Nutritional Supplements	Dose	Date	Dose	Date	Dose	Date
Elemental 028						
Ensure						
Ensure plus						
Enrich						
Entura						
Entura Plus						
Enlive						
Fortisip						
Fortimal						

Antidepressants	Dose	Date	Dose	Date	Dose	Date
Amitriptyline: Lentizol, Tryptizol, Triptafen						
Clomipramine: Anafranil						
Dothiepin: Prothiaden						
Imipramine: Tofranil						
Lofepamine: Gamanil						
Citalopram: Cipramil						
Fluoxetine: Prozac						
Paroxetine: Seroxat						
Sertraline: Lustral						

Appendix 8

Strategy for recruitment

1. Researcher will look through notes before clinic to identify:
 - (a) Patients with diagnosed IBD who have previously attended clinic.
 Excluded:
 - (b) Those under 16.
 - (c) Those who do not read English.
2. In test centres, make a list of all eligible patients and number them in the order in which they are booked in to attend clinic (if more than one is booked in at the same time, number them alphabetically). If there are more than six eligible patients then we will have to select randomly those who will be approached to take part in the study.

We aim to recruit a maximum of three patients per clinic in the test centres. We can recruit as many as we are able to in the control centres.

3. Researcher will approach patients as they enter the clinic (each one in the control centres but only those who have been randomly selected in the test centres) and give them information about the study. If they agree to participate they will be consented prior to consultation and labels will be attached to notes indicating patient is to take part in study.

Note if patient has not arrived in clinic at their appointed time, treat them as a DNA (did not attend) and approach the next patient on your original list.

Consent means test patients understand they will:

- Work with their consultant to write a management plan.
- Find a way to make hospital visits more convenient.
- Keep a diary for 12 months.
- Complete a questionnaire after each appointment during the study.

Consent means control patients understand they will:

- Be taking part in a study of ways to manage IBD better and make hospital visits more convenient.
- Keep a diary for 12 months.
- Complete a questionnaire after each appointment during the study.

4. Patients will complete entrance questionnaires before first consultation.
5. Consultants in test sites will:
 - (a) Give a patient-centred consultation.
 - (b) Introduce the guidebook to the patient.
 - (c) Negotiate self-management plan with patient.
 - (i) This may need several fixed appointments if patient's condition is unstable.
 - (d) Explain self-referral – give contact telephone number.
 - (i) No more fixed appointments once self-management plan established.
 - (e) Send copy of self-management plan to GP.
 - (f) Ensure system in place for monitoring bloods and urine if necessary.
6. Consultants on control sites will not change their method of consultation or referral.

Method used to select patients randomly at intervention sites

If there were more than six eligible patients identified at a clinic, then the following method of randomisation was employed.

We want:

1. To recruit up to three patients/consultant/clinic.
2. To try to recruit a sample which contains patients who attend:
 - (a) early
 - (b) middle
 - (c) late
 because it is possible the early patients will be the 'well' ones and the late patients will be the 'poorly' ones.
3. There are likely to be high numbers of DNAs at these clinics – the sampling must allow us to account for these and quickly substitute another patient.

Operating procedure for sampling

1. If ≤ 6 eligible patients for each consultant – then recruit as they come to clinic until three patients have been recruited.
2. If > 6 eligible patients for each consultant – then use systematic sampling where E is

determined by shaking a dice (note: E must be $\leq F$). Then select every F where:

$$F = \text{number of eligible patients divided by } 3$$

3. Select three patient numbers: E , $E + F$, $E + 2F$
If selected patient is a DNA at the time expected or does not give consent, then select the next patient on the original eligible list.

When $E = F$ when you have 9, 12, 15, 18 or 21 eligible patients the last patient is selected and there is a danger that this patient may DNA. So for this number of eligible patients we need to have spare patients at the end so subtract 2 from N (number of eligible patients)

Examples:

7 eligible patients: $F = 2$

When $E = 1$ then select
patient numbers 1, 3, 5

When $E = 2$ then select
patient numbers 2, 4, 6

12 eligible patients: $F = 3$ (12-2 divided by 3)

When $E = 1$ then select
patient numbers 1, 4, 7

When $E = 2$ then select
patient numbers 2, 5, 8

When $E = 3$ then select
patient numbers 3, 6,
9 with 10, 11, 12 as
spares

Strategy for patient follow-up

In order to obtain the maximum possible response rate, the following strategy was used:

1. First follow-up letter sent 1 year after date of recruitment plus:
 - (a) questionnaire booklet
 - (b) diary response slip detailing why diary not returned
 - (c) stamped addressed envelope.
2. Phone to remind patient after 2 weeks and offer opportunity to complete questionnaire over the phone or ask if they need another questionnaire.
3. If no response to phone, or number unavailable, check with consultant's secretary to see if there is a change of address or death of patient.
4. If unable to contact by phone, send the final reminder letter containing refusal options.
5. When questionnaires are returned, send thank-you letter and appropriate information guidebook for control patients.

Appendix 9

Patient information letter and consent forms

Invitation to take part in a research project

A randomised controlled trial to assess the impact of a package comprising a patient orientated, evidence-based self-help guidebook and patient-centred consultations on disease management and satisfaction in inflammatory bowel disease.

We invite you to take part in a research project which we believe to be of importance. To help you understand what the research is about, we are providing you with the following information which we want to be sure you understand before you agree to take part. Be sure to ask any questions you have about the information which follows, and we will do our best to explain and to provide any further information you need.

You were chosen to take part in this study because you have inflammatory bowel disease. This study will look at:

- ways to make hospital visits more convenient to you; and
- ways you can manage your condition better.

We want to find out if the type of information and consultations patients receive has an effect on quality of life and the symptoms of inflammatory bowel disease. This study aims to find out what people feel about their condition and how it is controlled, how satisfied they are with their treatment and how involved they feel in it, how they use the NHS and what they do to manage their inflammatory bowel disease.

- You will be in the study for about 1 year. Some of you will be asked to give your opinions of the study in an interview at the end of the year.

- Some of you who take part in this study will work with your consultant to develop a written self-management plan.
- You will all be given a guidebook about inflammatory bowel disease. Half of you will be given this guidebook by your consultant at the start of the study and half of you will get the guidebook at the end of the study.

If you decide to take part in the study, you will be interviewed by the researcher and be asked to fill in questionnaires:

1. At the start of the study.
2. After any visit to outpatients when you see a doctor.
3. One year after starting the study.

During the year of the study, you will be asked to keep a diary about your inflammatory bowel disease and treatment.

After the first interview, the questionnaires will be sent and returned by post. The researcher may need to contact you by phone. Your GP will be told you are taking part in this study. Any information you give and any information taken from your medical notes will remain confidential.

You are free not to take part in the study and may withdraw from the study at any time. This will not affect your medical treatment.

If you have any questions, please contact:
Anne Kennedy, National Primary Care Research and Development Centre, 5th Floor Williamson Building, The University of Manchester, Oxford Road, Manchester M13 9PL
Telephone: 0161 275 7601

Patient consent forms

Consent form

Thank you for agreeing to take part in this study for patients with inflammatory bowel disease:

A randomised controlled trial to assess the impact of a package comprising a patient orientated, evidence-based self-help guidebook and patient-centred consultations on disease management and satisfaction in inflammatory bowel disease.

I
agree to take part in the above named study.

I have read the patient information sheet and I understand that I may withdraw from the study at any time.

I understand that my hospital consultant and my GP will be told that I am taking part in this study.

Signed.....

Date.....

Consent form for audio-taping

Thank you for agreeing to be interviewed as part of a study for patients with inflammatory bowel disease:

A randomised controlled trial to assess the impact of a package comprising a patient orientated, evidence-based self-help guidebook and patient-centred consultations on disease management and satisfaction in inflammatory bowel disease.

I
agree to being audio-taped during an interview for the above named study.

I understand that I may withdraw from the study at any time.

Signed.....

Date.....

Appendix 10

Scoring for diary quality

- 1 = complete record Score 1 if the diary has a full record for each flare-up and doctor visit which tallies with number given in exit questionnaire for flare-ups and visits. A score of 1 is appropriate if there are no data in the diaries or the diary is missing but the patient has had no flare-ups or visits to the doctor.
- 2 = some usable data Score 2 if the diary has entries which are not complete but are usable.
- 3 = data not interpretable Score 3 if the diary is not useful or it is not possible to tell what the data mean. A score of 3 is appropriate if the diary is missing but the patient has reported flare-ups or hospital visits elsewhere.

The information in the diaries was cross-checked with the information given in the exit questionnaires and that obtained from the medical records.

Scoring for flare-ups

- 1 = meets medical criteria For patients diagnosed with ulcerative colitis and Crohn's colitis, score 1 if flare-up:
Lasts for a minimum of 3 days and is treated.
For example, if an episode is said to last from 3 to 7 days, has been treated and has got better, then it will count as a flare-up.
Symptoms include: bleeding, loose motions/diarrhoea, and /or pain.
- 2 = meets patient's criteria This may apply to Crohn's patients whose flare-ups may only last a day and also to some ulcerative colitis patients. Symptoms may include pain, tiredness, mouth ulcers, loose motions or blockage.

Appendix I I

The cognitive theory of stress and coping developed by Lazarus and Folkman¹⁵⁴

In the **primary appraisal** stage, the disease could be perceived by the patient as either benign-positive (irrelevant), challenging or harmful/threatening.¹⁸⁸ Hence a patient will appraise IBD as stressful if it involves harm, threat or challenge or if it is unpredictable and outside of personal control. In the **secondary appraisal** phase, individual, family and environmental assets and coping resources are evaluated and efforts made to master, reduce or tolerate the demands of the situation (Lazarus and Folkman,¹⁵⁴ p. 141).

The four main groupings of **coping resources** are *Material resources*, such as finance, housing, income, education and employment; *Physical resources*, such as health, fitness, stamina, ability to meet physical demands of everyday life; *Psychological resources*, including beliefs, attitudes, personality, problem-solving ability, confidence in ability to get help required and sense of control over the events in one's life; *Social resources*, which refer to those to whom the patient can turn to for emotional and practical help and support and include the marital relationship, family relationships, friends, neighbours, work colleagues and professionals.

The availability of a coping resource does not necessarily mean that a person will use that

resource. However, the lack of a resource can make a person more vulnerable to stress whereas the presence of a resource may offer some resistance and opportunities to manage stress. Hence coping resources ultimately inform the choice of coping strategies employed to deal with the illness.

Coping is defined as a person's cognitive or behavioural efforts to manage the external and internal demands of a situation.¹⁸⁹ The coping process can be categorised as two major inter-relating functions. **Emotion-focused coping** is the (palliative) attempt to regulate the emotions and manage the distress or uncertainty generated by the illness. For example, patients may opt to distance themselves by trying to carry on life as normal, putting the problem out of mind, or by denying its existence.¹⁹⁰ **Problem-focused coping** involves behaviours such as actively seeking information and support, learning new skills and actively participating in the treatment. One or both forms of coping may be used and strategies may change in times of transition, and there is no evidence to suggest that either one is more effective than the other for perceptions of health and well-being in IBD patients.¹⁶²

Appendix 12

Debriefing interview with intervention site consultants

1. How easy or difficult has it been to incorporate the intervention into your day-to-day practice?
Introduction of guidebook – difficult/easy
How much time did it take?
How did it fit into the organisation and running of clinics?
2. Do you intend to carry on with all or any aspects of this intervention?
What do you think might be the barriers to introducing this routinely into clinics?
3. Was the training sufficient for you to work with patients in patient-centred way?
Gaps and views about this.
4. Did giving a patient-centred consultation work well with all types of patients?
Who do you think it worked particularly well for and who/type of patient did it not work so well for? Why do you think that was?
In what ways did the patient-centred approach differ from your ordinary way of working with patients?
5. What problems did you encounter in establishing self-management with patients?
Time restraints
Establishing symptoms of flare-up
Writing management plan
At what point in patient's illness would it be best to introduce self-management?
6. To what extent did you find that patients brought their own ideas on shared care to the consultation?
Did they make any suggestions? If not, why not.
Did you have any difficulties in terms of a clash between things suggested by patients and your own knowledge expertise – How were these handled in the consultation?
7. What advantages and disadvantages do you think this system has in relation to the management of patients with IBD?
What are your views on self-care and its impact on your relationship with the patient and their ability to manage their illness?
Do you anticipate any problems with the open access to clinics?
8. Views on effectiveness of guidebook
Are there aspects you think should be changed?
Was the guidebook used as a point of dialogue in the consultation?
9. How has the guidebook impacted on communication and doctor–patient relationship?
Did the intervention make communication with patients easier/more effective?



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The Correspondence Page on the HTA website (<http://www.ncchta.org>) is a convenient way to publish your comments. If you prefer, you can send your comments to the address below, telling us whether you would like us to transfer them to the website.

We look forward to hearing from you.