

# 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

<b>Submission date</b> 25/04/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/04/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/11/2022	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.npcrdc.man.ac.uk/ResearchDetail.cfm?ID=8>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

HTA 96/11/02

## **Study information**

### **Scientific Title**

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

### **Study objectives**

To determine if an expensive, comprehensive guidebook promoting patient choice combined with physicians trained in patient-centred care and use of the guidebook improves patient satisfaction, health, quality of life, perceptions of control, anxiety levels, ability to self-treat and leads to cost effective use of NHS services.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

### **Study type(s)**

Not Specified

**Participant information sheet**

**Health condition(s) or problem(s) studied**

Inflammatory bowel disease

**Interventions**

A multi-centre (16 centres, 40 subjects from each centre, 640 in total) 2-armed RCT, comparing benefits of guidebook plus patient-centred care versus standard patient care using validated questionnaires, patients diaries and qualitative interviews with patients and clinicians.

1. Guidebook plus patient-centred care
2. Standard patient care using validated questionnaires, patients diaries and qualitative interviews with patients and clinicians.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

1. Patient satisfaction
2. Health
3. Quality of life
4. Perceptions of control
5. Anxiety levels
6. Ability to self-treat
7. Cost effective use of NHS services.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/01/1999

**Completion date**

31/12/2001

**Eligibility****Key inclusion criteria**

1. Established ulcerative colitis or Crohn's disease
2. 16 years +
3. Able to write English
4. Attending follow-up clinics

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

640

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/01/1999

**Date of final enrolment**

31/12/2001

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

National Primary Care Research & Development Centre

Manchester

United Kingdom

M13 9PL

## **Sponsor information**

**Organisation**

Department of Health (UK)

**Sponsor details**

Quarry House

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**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/en/index.htm>

**ROR**

<https://ror.org/03sbpja79>

## Funder(s)

**Funder type**

Government

**Funder Name**

NIHR Health Technology Assessment Programme - HTA (UK)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

Not provided at time of registration

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	HTA monograph	01/02/2003		Yes	No