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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

Submission date	Recruitment status	[_] Prospectively registered
25/04/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/04/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/11/2022	Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

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(s)

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.

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
National Primary Care Research & Development Centre
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
Department of Health (UK)

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

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?
Results article	HTA monograph	01/02/2003		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes