

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

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

Study design

Randomised controlled trial

Primary study design

Interventional

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