

Randomised controlled trial: impact of a patient information leaflet on satisfaction with care, knowledge and QOL in irritable bowel disease

Submission date 29/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/11/2014	Condition category Digestive System	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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
N0025172370

Study information

Scientific Title

Study objectives

This study is designed to determine whether there is a benefit in terms of satisfaction with care, disease-specific knowledge and QOL for inflammatory bowel disease patients who receive education about their illness by means of an information leaflet compared to those who do not.

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)

Quality of life

Health condition(s) or problem(s) studied

Digestive System: Irritable Bowel Disease (IBD)

Interventions

The first phase of project is distribution of leaflets to 20 volunteer patients and nursing staff and doctors. Comments will be invited on the sheets and returned to investigators. Eligible patients will be identified from out-patients and invited to participate, and if they fill out a questionnaire will be later interviewed. Within 2 weeks of baseline assessment patients will be randomised into two groups with Crohn's Disease and Ulcerative Colitis. A further questionnaire will be sent via post at 3 and 12 months after recruitment followed by a further interview at 6-12 months at clinic appointment.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/12/2007

Eligibility**Key inclusion criteria**

300 IBD patients

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/12/2005

Date of final enrolment

01/12/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

AintreeTrust

Liverpool

United Kingdom

L9 7AL

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type

Government

Funder Name

Aintree Hospitals NHS Trust (UK)

Funder Name

NHS R&D Support Funding (UK)

Results and Publications

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

Not provided at time of registration