ISRCTN55878813 https://doi.org/10.1186/ISRCTN55878813

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 06/11/2014	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr CKW Luces

Contact details
AintreeTrust
University Hospital Aintree
Lower Lane
Liverpool
United Kingdom
L9 7AL
+44

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/2005

Completion date
01/12/2007

Eligibility

Key inclusion criteria
300 IBD patients

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
300 IBD patients

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
England

United Kingdom

Study participating centre

AintreeTrust
Liverpool
United Kingdom
L9 7AL

Sponsor information

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

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Aintree Hospitals NHS Trust (UK)

Funder Name
NHS R&D Support Funding (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration