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

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

# 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

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

## Study design

Randomised controlled trial

## Primary study design

Interventional

## 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