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The effect of enhanced pre-operative information on patient recovery following colorectal surgery: a randomised controlled trial.

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 04/02/2014	**Condition category** Surgery	[_] Individual participant data [_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0084151426

Study information

Scientific Title

Study objectives
1. To assess the acceptability and psychological effects of fast-track surgery
2. To perform an economic analysis of fast-track surgery
3. To examine the role of enhanced pre-operative information in fast-track surgery
4. To examine the relationship between the stress response and length of stays

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)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Colorectal

Interventions
Recruitment for this study will occur in consecutive patients attending preassesment clinics. Randomisation will be performed at a remote site and accessed by telephone. A computer generated permuted block randomisation technique will be employed.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure

1. Psychological effects and acceptability will be assessed by Hospital Anxiety and Depression Score (HADS).
2. The economic analysis will be based on the EuroQol.
3. The RCT will be assessed by 6 item Spielberger anxiety inventory
4. Physiological stress will be assessed by salivary IgA levels

Secondary outcome measures
Not provided at time of registration

Overall study start date
07/09/2004

Completion date
01/08/2007

Eligibility

Key inclusion criteria
1. Age over 16
2. Undergoing colorectal resections or colostomy/ileostomy formation or closure

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
Minimum of 15 patients

Key exclusion criteria
1. Visual impairment
2. Inadequate comprehension to understand pre-op information and sign consent form

Date of first enrolment
07/09/2004

Date of final enrolment
01/08/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Castle Hill Hospital
Cottingham
United Kingdom
HU16 5JQ

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
The North and South Bank Research and Development Consortium

Funder Name
NHS R&D Support Funding

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