ISRCTN67674151 https://doi.org/10.1186/ISRCTN67674151

A nurse-led intervention to enhance medication adherence in ulcerative colitis (UC) using a concordance-led consultation

Submission date 14/04/2004	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 28/04/2004	**Overall study status** Completed	
Last Edited 07/07/2017	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Greg Rubin

Contact details
NoReN Office
The Health Centre
Sunningdale Drive
Eaglescliffe
Stockton-on-Tees
United Kingdom
TS16 9EA

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

A nurse-led intervention to enhance medication adherence in ulcerative colitis (UC) using a concordance-led consultation

Study objectives
Concordance is an effective way of prescribing medicines based upon a partnership approach between the prescriber and patient. Patient preferences, beliefs and experiences are explored as part of the consultation in order to reach an agreement about how the patient can take their medicines effectively.

We would like to know whether a consultation based on these principles and delivered by a specialist nurse results in increased adherence with maintenance medication for patients with ulcerative colitis who are not currently adherent. We are also interested in whether change in medication adherence also results in improved quality of life, reduced disease activity and reduced number of relapses for patients.

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)
Treatment

Health condition(s) or problem(s) studied
Ulcerative colitis

Interventions
Intervention:
A nurse-led consultation lasting a minimum of 30 minutes. Patients beliefs and attitudes to medication adherence are discussed, strategies developed to increase adherence and information and support regarding management of their ulcerative colitis will be offered. The intervention will be delivered using a concordance-led consultation.

Control:
No intervention.

Intervention Type
Behavioural

Primary outcome(s)
The proportion of patients in the subject and control groups for whom an increase in adherence with medication is observed. Adherence will be calculated as the percentage of dispensed medications that have been used with adherence defined as taking more than 4 months supply

in 6-month period. Adherence therefore is measured as a dichotomous variable (adherent yes /no).

Key secondary outcome(s))
Changes in IBD-specific quality of life, disease activity and relapse rates in both subject and control groups throughout the 6-month follow-up period. Additional explanatory variables are: illness perception (IPQ-R), beliefs about medicines (BMQ), self reported medication adherence, preferred role in the decision making process (Degner) and the demographic variables previously outlined.

Completion date
01/06/2005

Eligibility

Key inclusion criteria
Adults aged over 16 years with a diagnosis of ulcerative colitis (histologically proven), whose disease has been present for at least one year and who are found, from prescribing records, to be taking aminosalicylate (ASA) therapy at suboptimal levels (defined as using anything less than 8 months supply of aminosalicylates in a 12 month period). Patients who have been specifically told to stop taking their 5ASA medication will be screened out at the stage of initial patient invitation. Eligible patients who subsequently undergo total colectomy and therefore no longer require 5ASA therapy will no longer be eligible for inclusion in the study and will be classified as 'drop-out'.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Patients with self-limiting colitis or those whose UC has been diagnosed in the past year will be excluded. Patients aged less than 16 years are not eligible for inclusion and patients with significant neurological impairment such that they could not participate in the consultation will also be excluded.

Date of first enrolment
01/06/2004

Date of final enrolment
01/06/2005

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NoReN Office
Stockton-on-Tees
United Kingdom
TS16 9EA

Sponsor information

Organisation
Northern Primary Care Research Network (NoReN) (UK)

Funder(s)

Funder type
Industry

Funder Name
Procter and Gamble Pharmaceuticals (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration