

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/04/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/07/2017	Condition category Digestive System	<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

Contact name

Prof Greg Rubin

Contact details

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

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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).

Secondary outcome measures

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.

Overall study start date
01/06/2004

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

Age group
Adult

Sex
Both

Target number of participants
106

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**

England

United Kingdom

Study participating centre

NoReN Office

Stockton-on-Tees

United Kingdom

TS16 9EA

Sponsor information**Organisation**

Northern Primary Care Research Network (NoReN) (UK)

Sponsor details

The Health Centre

Sunningdale Drive

Eaglescliffe

Stockton-on-Tees

United Kingdom

TS16 9EA

Sponsor type

Government

Funder(s)

Funder type

Industry

Funder Name

Procter and Gamble Pharmaceuticals (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