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J Williams,[1*] I Russell,[2] D Durai,[1] W-Y Cheung,[1] A Farrin,[3] K Bloor,[4] S Coulton[4] and G Richardson[4]

[1] University of Wales Swansea, UK
[2] University of Wales Bangor, UK
[3] University of Leeds, UK
[4] University of York, UK

* Corresponding author

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The research reported in this monograph was commissioned by the HTA Programme as project number 97/37/09. The contractual start date was in September 2001. The draft report began editorial review in May 2005 and was accepted for publication in February 2006. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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Abstract

What are the clinical outcome and cost-effectiveness of endoscopy undertaken by nurses when compared with doctors? A Multi-Institution Nurse Endoscopy Trial (MINuET)

J Williams,[1*] I Russell,[2] D Durai,[1] W-Y Cheung,[1] A Farrin,[3] K Bloor,[4] S Coulton[4] and G Richardson[4]

[1] University of Wales Swansea, UK
[2] University of Wales Bangor, UK
[3] University of Leeds, UK
[4] University of York, UK
* Corresponding author

Objectives: To compare the clinical outcome and cost-effectiveness of doctors and nurses undertaking upper and lower gastrointestinal endoscopy.
Design: The study was a pragmatic randomised controlled trial. Zelen's randomisation before consent was used to minimise distortion of existing practice in the participating sites. An economic evaluation was conducted alongside the trial, assessing the relative cost-effectiveness of nurses and doctors.
Setting: The study was undertaken in 23 hospitals in England, Scotland and Wales. In six hospitals nurses undertook both upper and lower gastrointestinal endoscopy, yielding a total of 29 'centres'. The study was coordinated and managed from Swansea. Randomisation, data management and analysis were undertaken at York. Analysis was by intention-to-scope.
Participants: Sixty-seven doctors and 30 nurses took part in the study. Of 4964 potentially eligible patients, 4128 (83%) were randomised. Of these, 1888 (45%) were recruited to the study from 29 July 2002 to 30 June 2003.
Interventions: The procedures under study were diagnostic upper gastrointestinal endoscopy and flexible sigmoidoscopy undertaken by nurses or doctors, with or without sedation, using the preparation, techniques and protocols of participating hospitals.
Main outcome measures: Primary outcome measure was the Gastrointestinal Symptom Rating Questionnaire (GSRQ). The secondary outcome measures were EuroQol (EQ5D), Gastrointestinal Endoscopy Satisfaction Questionnaire (GESQ), State–Trait Anxiety Inventory (STAI), cost-effectiveness, immediate and delayed complications, quality of examination by blinded assessment of endoscopic video recordings, quality of procedure reports, patients' preferences for operator 1 year after endoscopy, and new diagnoses at 1 year.
Results: The two groups were well matched at baseline for demographic and clinical characteristics. Significantly more patients changed from a planned endoscopy by a doctor to a nurse than vice versa, mainly for staffing reasons. There was no significant difference between the two groups in the primary or secondary outcome measures at 1 day, 1 month or 1 year after endoscopy, with the exception of patient satisfaction at 1 day, which favoured nurses. Nurses were significantly more thorough in the examination of stomach and oesophagus, but no different from doctors in the examination of duodenum and colon. There was no significant difference in costs to the NHS or patients, although doctors cost slightly more. Although quality of life measures showed improvement in some scores in the doctor group, this did not reach traditional levels of statistical significance. Even so, the economic evaluation, taking account of uncertainty in both costs and quality of life, suggests that endoscopy by doctors has an 87% chance of being more cost-effective than endoscopy by nurses.
Conclusions: There is no statistically significant difference between doctors and nurses in their clinical effectiveness in diagnostic endoscopy. However, nurses are significantly more thorough in the examination of oesophagus and stomach, and patients are significantly more satisfied after endoscopy by a nurse. Endoscopy by doctors is associated with better outcome at 1 year at higher cost, but overall is likely to be cost-effective. Further research is needed to evaluate the clinical

outcome and cost-effectiveness of nurses undertaking a greater role in other settings, to monitor the cost-effectiveness of nurse endoscopists as they become more experienced and to assess, the effect of increasing the number of nurse endoscopists on waiting times for patients, and the career implications and opportunities for nurses who become trained endoscopists. Evaluation of the clinical outcome and cost-effectiveness of diagnostic endoscopy for all current indications is also needed.

Contents

List of abbreviations

ADS	Aberdeen Dyspepsia Scale
ASA	American Society of Anesthesiologists physical status classification
ASGE	American Society for Gastrointestinal Endoscopy
BSG	British Society of Gastroenterology
CEAC	cost-effectiveness acceptability curve
CI	confidence internal
CRS	Central Randomisation Service
FS	flexible sigmoidoscopy
GERD-HRQLS	Gastro-Esophageal Reflux Disease Health Related Quality of Life Scale
GESQ	Gastrointestinal Endoscopy Satisfaction Questionnaire
GI	gastrointestinal
GORD	gastro-oesophageal reflux disease
GSRQ	Gastrointestinal Symptom Rating Questionnaire
HES	Hospital Episode Statistics for England
HRQoL	health-related quality of life
IBD	inflammatory bowel disease
IBS	irritable bowel syndrome
IBS QOL	Irritable Bowel Syndrome Quality of Life Questionnaire
ICER	incremental cost-effectiveness ratio
JAG	Joint Advisory Group on gastrointestinal endoscopy
LREC	Local Research Ethics Committee
LVCF	last value carried forward
MAR	missing at random
MCS	mental component score
MEBT	member of endoscopy booking team
mGHAA-9	modified Group Health Association of America 9-item instrument
MINuET	Multi-Institution Nurse Endoscopy Trial
MREC	Multicentre Research Ethics Committee
NICE	National Institute for Health and Clinical Excellence
NMB	net monetary benefit
NTN	national trial number
OGD	oesophagogastroduodenoscopy
OPCS	Office for Population Censuses and Surveys
PCS	physical component score
PEDW	Patient Episode Database for Wales
QALY	quality-adjusted life-year
RCT	randomised controlled trial
SD	standard deviation
SF-36	Short Form with 36 Items
STAI	State–Trait Anxiety Inventory
UK IBDQ	United Kingdom Inflammatory Bowel Disease Questionnaire
WTE	whole time equivalent

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.

Executive summary

Background

Nurses are increasingly undertaking both upper and lower gastrointestinal endoscopy. Although uncontrolled studies suggest that nurse endoscopists are competent, and appreciated by patients, no pragmatic randomised trial of this change in role has yet been reported. If the role of nurses in endoscopy is to be developed, the implications for the workforce also need to be analysed.

Objectives

The objectives were to compare the clinical outcome and cost-effectiveness of doctors and nurses undertaking upper and lower gastrointestinal endoscopy by measuring:

- acceptability to patients
- quality of the process
- outcome for, and value to, patients
- resources consumed by the NHS and by patients
- the relative cost-effectiveness of nurses and doctors.

If the results confirmed the acceptability of endoscopy by nurses, a further objective was to develop an economic model to predict the effect of an increase in these specialists on the labour market and also the training implications.

Design

The study was a pragmatic randomised controlled trial. Zelen's randomisation before consent was used to minimise distortion of existing practice in the participating sites. An economic evaluation was conducted alongside the trial, assessing the relative cost-effectiveness of nurses and doctors.

Setting

The study was undertaken in 23 hospitals in England, Scotland and Wales. In six hospitals nurses undertook both upper and lower gastrointestinal endoscopy, yielding a total of 29 'centres'. The study was coordinated and managed from Swansea. Randomisation, data management and analysis were undertaken at York. Analysis was by intention-to-scope.

Participants

Sixty-seven doctors and 30 nurses took part in the study. Of 4964 potentially eligible patients, 4128 (83%) were randomised. Of these, 1888 (45%) were recruited to the study from 29 July 2002 to 30 June 2003.

Interventions

The procedures under study were diagnostic upper gastrointestinal endoscopy and flexible sigmoidoscopy undertaken by nurses or doctors, with or without sedation, using the preparation, techniques and protocols of participating hospitals.

Main outcome measures

The primary outcome measure was the Gastrointestinal Symptom Rating Questionnaire (GSRQ).

Secondary outcome measures were the EuroQol (EQ5D), Gastrointestinal Endoscopy Satisfaction Questionnaire (GESQ), the State–Trait Anxiety Inventory (STAI), cost-effectiveness, immediate and delayed complications, quality of examination by blinded assessment of endoscopic video recordings, quality of procedure reports, patients' preferences for operator 1 year after endoscopy, and new diagnoses at 1 year.

Results

The two groups were well matched at baseline for demographic and clinical characteristics. Significantly more patients changed from a planned endoscopy by a doctor to a nurse than vice versa, mainly for staffing reasons. There was

no significant difference between the two groups in the primary or secondary outcome measures at 1 day, 1 month or 1 year after endoscopy, with the exception of patient satisfaction at 1 day, which favoured nurses. Nurses were significantly more thorough in the examination of stomach and oesophagus, but no different from doctors in the examination of duodenum and colon. There was no significant difference in costs to the NHS or patients, although doctors cost slightly more. Although quality of life measures showed improvement in some scores in the doctor group, this did not reach traditional levels of statistical significance. Even so, the economic evaluation, taking account of uncertainty in both costs and quality of life, suggests that endoscopy by doctors has an 87% chance of being more cost-effective than endoscopy by nurses.

Conclusions

There is no statistically significant difference between doctors and nurses in their clinical effectiveness in diagnostic endoscopy. However, nurses are significantly more thorough in the examination of oesophagus and stomach, and patients are significantly more satisfied after endoscopy by a nurse. Endoscopy by doctors is associated with better outcome at 1 year at higher cost, but overall is likely to be cost-effective.

Implications for healthcare

Nurses can undertake diagnostic endoscopy safely and effectively. However, doctors are more likely to be cost-effective. If decision-makers nevertheless choose to continue the current trend towards diagnostic endoscopy undertaken by nurses rather than doctors, this has implications for human resources, training and governance. We estimate that two nurse endoscopists will be needed per endoscopy unit.

Recommendations for research

The following are indicated for areas of future, further research:

- evaluation of the clinical outcome and cost-effectiveness of nurses undertaking full colonoscopy, therapeutic endoscopy and oesophagogastroduodenoscopy and flexible sigmoidoscopy in other settings
- monitoring the cost-effectiveness of nurse endoscopists as they become more experienced
- assessment of the effect of increasing the number of nurse endoscopists on waiting times for patients
- evaluation of the clinical outcome and cost-effectiveness of diagnostic endoscopy for all current indications
- assessment of the career implications and opportunities for nurses who become trained endoscopists.

Chapter 1
Introduction

Nurses are increasingly undertaking gastrointestinal (GI) endoscopy. In 2004, a survey of 196 endoscopy units registered with the Joint Advisory Group on gastrointestinal endoscopy (JAG) in the UK identified 149 nurse endoscopists in post in 96 units (64% of the 150 units that responded). Of these 149 nurses, 32% were performing upper GI, 55% lower GI and 13% combined upper and lower GI endoscopies.[1] This represents a significant increase in numbers when compared with figures from October 2000.[2] A survey in the USA in 1999 revealed that 15% (24 of 164) of units in a gastroenterology fellowship programme use paramedical personnel to perform flexible sigmoidoscopy[3] and this role was approved by state boards of nursing in most states.

The British Society of Gastroenterology (BSG)[4] and United Kingdom Central Council for Nursing approve the role of nurses in diagnostic oesophagogastroduodenoscopy (OGD) or flexible sigmoidoscopy (FS). The American Society for Gastrointestinal Endoscopy recommends the performance of screening FS by non-physician endoscopists.[5]

The introduction of nurse endoscopy training and performance of FS by nurses was reported in 1977 from the Mayo Clinic,[6] USA. Subsequent studies showed the feasibility of colorectal screening by FS using nurse endoscopists.[7,8] Several single-centre studies confirmed that trained nurse endoscopists could perform screening FSs safely and accurately.[9,10] A single-centre randomised trial demonstrated no significant differences in polyp detection rates or complications between nurses and doctors[11] and a further single-centre study showed no clinically significant differences in patient satisfaction.[12]

The first UK study on nurse practitioner FS training and an evaluation of their prospective performance in symptomatic patients was published in 1998.[13] Smale and colleagues published an observational study showing that nurses can perform routine diagnostic OGD safely in clinical practice.[14]

To date there has been no randomised, controlled trial (RCT) to evaluate both the clinical outcome and cost-effectiveness of upper or lower GI endoscopies undertaken by nurses. A rigorous multi-centre pragmatic RCT is timely.

Chapter 2
Methods

The study was a pragmatic RCT designed to assess clinical and cost-effectiveness of endoscopy undertaken by nurses compared with the same procedures undertaken by doctors.

Participating sites

Hospitals in the UK with nurse endoscopists undertaking independent upper GI endoscopy or FS lists were invited to participate in the study. They were first contacted through the BSG newsletter, when the application for funding was in preparation. Those hospitals which showed initial interest were contacted when the outline application for funding was accepted, and a collaborators' meeting was held to inform the preparation of the full bid to the HTA Programme. When funding was secured, sites were contacted again individually before the study began in September 2001. Other centres that had not responded to the initial call, but where it was known that a nurse endoscopist was operating, were invited to participate at this time. Details of the participating sites are given in the Acknowledgments (p. 67).

Participating patients

Patients over the age of 18 years referred for upper GI endoscopy (OGD) or FS for the investigation of GI symptoms were considered for the study.

Patients with dyspeptic symptoms (nausea, vomiting, heartburn, indigestion, flatulence, early satiety, epigastric pain or discomfort), weight loss, anorexia or anaemia were included if they satisfied local criteria for OGD by a nurse endoscopist. Patients presenting with dysphagia, those in whom it was already known at the time of booking that a therapeutic procedure would be required, those already taking part in another trial and those thought unable to comply with the trial were excluded.

Patients referred for the investigation of rectal bleeding or change in bowel habit were included if they satisfied local criteria for FS by a nurse endoscopist. Patients were excluded if it was already known at the time of booking that a therapeutic procedure would be required or the patient was already taking part in another trial or was thought to be unable to comply with the trial.

Intervention

The procedures under study were diagnostic upper GI endoscopy (OGD) or FS undertaken by nurses or doctors, with or without sedation using the preparation, techniques and protocols of participating hospitals.

Objectives

We tested the null hypothesis that there is no difference in the clinical or cost-effectiveness of FS and OGD undertaken by nurses and that of the same procedure undertaken by doctors. Our objectives were:

1. To compare:
   (a) the acceptability to patients of endoscopies undertaken by nurses or doctors
   (b) the quality of the process of these procedures when undertaken by nurses or doctors
   (c) the outcome for and value to patients of these procedures when undertaken by nurses or doctors
   (d) the resources consumed by the NHS and by patients through these procedures when undertaken by nurses or doctors
   (e) the relative cost-effectiveness of doctors and nurses.
2. To develop an economic model to predict the effect of nurse endoscopies on the labour market and training requirements for clinical nurse specialists.

Outcome measures used

The primary outcome measure used was the Gastrointestinal Symptom Rating Questionnaire (GSRQ).[15] Secondary outcome measures used were anxiety scores from the State–Trait Anxiety

Inventory (STAI), both before (six-Item version, STAI:Y-6)[16] and after (20-item version, STAI)[17] endoscopic examination; Short Form with 36 Items (SF-36);[18] EuroQol (EQ5D);[19] and Gastrointestinal Endoscopy Satisfaction Questionnaire (GESQ).[20]

Baseline data collection

- patient refusal or failure to attend
- endoscopist (including training and experience and clinical approach) (Appendix 1)
- patient demographic details
- preparation given (e.g. purge, enema)
- reason for examination
- STAI 6, SF-36, EQ5D, GSRQ (Appendix 2).

Clinical procedures

- Endoscope used.
- Distance inserted.
- Sedation given and or topical anaesthesia used, including quantity.
- Other medication used, including quantity.
- Duration of examination.
- Findings (all procedures were documented on video and the tapes sent to Swansea. A 10% stratified, random sample was analysed, using a structured technique. The videos of all those patients in whom there were procedure complications or post-procedural dissatisfaction were also analysed).
- Procedures undertaken (e.g. biopsies, polyp removal) at initial endoscopy or subsequently.
- Complications to patient or endoscope, including resulting resource costs.
- Need for assistance, including duration and source of this assistance.
- Need for subsequent investigation, including resulting resource costs.
- Biopsy results.

One day after procedure

Repeat STAI (20-item), EQ5D, SF-36 (acute version), cost questionnaire, endoscopy satisfaction questionnaire (GESQ) together with initial response to endoscopy. Information given (Appendix 3).

One month after procedure

Repeat STAI (20-item), SF-36, EQ5D and GSRQ together with all healthcare use over the preceding month (cost questionnaire). Contact with endoscopist. Information given (Appendix 4).

Twelve months after procedure

Repeat STAI (20-item), SF-36, EQ5D and GSRQ together with all hospital care use over the preceding year (cost questionnaire) and patient preferences for nurse or doctor in any subsequent endoscopy (Appendix 5).

Resources used

Where possible, the units of resources consumed were derived from the trial clinical proformas and the three patient questionnaires.

Patient costs over the 12-month period of the study were estimated from three sources: GP records, patients' medical records and patient questionnaires.

We estimated the costs of initial and continuing training for nurse endoscopists and of providing them with medical supervision.

Sample size

We used the GSRQ as the main outcome measure. Analysis of the scale development data with 351 patients showed that there were at least three subscales. After standardising these subscales to have a minimum of 0 and a maximum of 100, we estimated that their standard deviations were 17, 19 and 21. We aimed to recruit a total of 1500 patients so as to yield 1000 complete records among 30 operators. The target sample would then have about 80% power to detect a difference of five points on each of the GSRQ subscales, provided that the intra-operator correlation did not exceed 0.02.

Concurrent validation showed that the GSRQ had four subscales, with standard deviations of 18, 29, 25 and 22. As the number of operators was then approaching 100, the target sample of 1000 complete records would have about 80% power to detect a difference of five points on three of the GSRQ subscales, provided that the intra-class correlation did not exceed 0.02. To achieve the same power for the fourth factor would need complete records for more than 1300 patients.

Randomisation

Allocation

Randomisation was undertaken by telephone contact from participating sites with the University of York Central Randomisation Service (CRS). In hospitals where lists for endoscopy were booked in the name of nurses and doctors in advance, randomisation stratified by hospital took place before patients were called. Patients were told whether a nurse or doctor was undertaking the procedure and given the opportunity to request a change of operator. Patients were asked for their informed consent on arrival in the department, both for the procedure and to take part in the trial. Since patient refusal to have an endoscopy undertaken by a named practitioner was an important outcome of endoscopy, this use of Zelen's randomised consent design was pragmatic and appropriate, minimising the distortion of existing practice. To ensure unbiased conclusions, we used source of referral (outpatient or primary care) as a post-stratification factor of sampled patients before analysing.

Sequence generation

The sequence generation was conducted using Visual Basic and involved a two-stage process. First, the allocation sequence was generated for allocation to a doctor or nurse endoscopist using random combinations of random permutations of two, four or six size blocks. In order to stratify by centre, separate allocation strings were generated for each centre and, within each centre, separate allocation strings were generated for patients undergoing OGD or FS. Second, after a patient had been allocated to either a nurse or doctor endoscopist, a simple randomisation procedure allocated the patient to a specific doctor or nurse within the hospital.

Implementation

The CRS at York was provided with details of all participating doctors and nurses by each centre. A member of the local endoscopy booking team (MEBT) was trained by the Multi-Institution Nurse Endoscopy Trial (MINuET) study coordinator to list all consecutive referrals on to a local trial register that allocated a local study number to each patient. The MEBT then completed a study form (Form B, Appendices 6 and 7) for each patient to establish eligibility and telephoned York to randomise patients. The CRS checked eligibility for each over the telephone and recorded the data before allocating eligible patients a national trial number (NTN) and endoscopist, initially by allocation to a doctor or nurse, and then allocation to a specific endoscopist, based on the availability of doctor or nurse endoscopists in each hospital.

The MEBT booked each eligible patient to the specified endoscopist list as randomised and faxed a study form for each patient to York before the planned procedure date. The MEBT sent the patient a study information leaflet, sample consent form and baseline questionnaires (Appendix 2), when informed of the procedure date. If the patient requested a change of endoscopist or the date, they were rebooked as requested but still remained in the trial. York followed up the centres if the planned procedure date was not received within 7 days of randomisation. After endoscopy, the participating centres faxed the study form to York, to confirm whether a patient consented, the actual procedure date and who conducted the endoscopy. York followed up the centres if the actual procedure date was not received within 7 days of the planned procedure date.

Statistical methods

The primary analysis was by intention-to-scope. A secondary analysis was performed on the treatment actually received/actual endoscopist (for new GI diagnoses at 12 months post-endoscopy only). All significance tests were two-sided.

Patients who were randomised but then either did not attend for endoscopy or declined to take part in the trial were compared with trial patients for baseline characteristics, including age and sex, presenting complaints and degree of urgency, to check for bias due to differential drop-out. Prior to analysis of trial patients, differences between randomised groups at baseline were tested, in order to ensure that the Zelen design did not result in imbalanced groups.

The primary outcome measure was the four-factor GSRQ, measured at 1 year. The factor structure of this measure was determined using baseline data prior to the trial analysis. As the four factors of the GSRQ had skewed distributions with a sizable number of patients reporting no symptoms (i.e. a score of zero) on at least one factor, the analysis is two-stage. First, ordered logistic regression was performed to generate *p*-values for the difference between the randomised groups, adjusting for relevant covariates [centre, type of procedure (FS or OGD), age and baseline score]. The dependent variable was the 1-year GSRQ score split into five ordered categories (zero symptoms and four roughly equal groups of increasing severity of symptoms). As there are four factors for the GSRQ, a Bonferroni correction was applied to the

p-values. The interaction between randomised group (endoscopist) and type of procedure was investigated, by including the interaction term in the regression model and testing its significance. Second, analysis of covariance used the 1-year GSRQ score as the dependent variable with covariates as listed above, to generate estimates and confidence intervals (CIs) for the mean difference between randomised groups.

Secondary outcomes, STAI, SF-36 and EQ5D (all measured at 1 day, 1 month and 1 year) and the GSRQ (at 1 month) were compared between randomised groups at each time point. Analysis of covariance was used for STAI, SF-36 and EQ5D. The follow-up score for each patient was used as the dependent variable. The baseline score was used as a covariate, plus centre, type of procedure and age. Ordered logistic regression and analysis of covariance were used for the 1-month GSRQ as outlined for the primary outcome above.

The GESQ was only measured at one time point (1 day) and each of the four factors were compared between randomised groups to assess differences in patient satisfaction using two sample *t*-tests. In addition, the proportion of patients changing endoscopist was compared between groups.

Patient preferences at 1 year, as defined by each patient's first-ranked preference, were compared between randomised groups using a χ^2 test.

The numbers of new GI diagnoses made within 12 months of endoscopy were compared between randomised groups using a χ^2 test. There were two comparisons: **any** new diagnoses and **major** new diagnoses, such as cancer, peptic ulcer, coeliac disease, inflammatory bowel disease and colonic polyps.

The endoscopist questionnaire data were summarised by randomised group. No formal statistical analysis was performed on these data.

Missing data were handled in two ways. First, missing items within individual outcome measures were treated according to the instructions for that particular measure. Second, the proportion of non-responders was compared between the treatment groups. Responders and non-responders (i.e. those patients who agreed to take part in the trial but then did not respond to questionnaires) were compared for baseline characteristics including age, sex, presenting complaints, degree of urgency, physical and mental health and GI symptoms. A sensitivity analysis was undertaken by excluding centres where large numbers of patients changed endoscopist post-randomisation.

Comparison of performance by operator

We compared the performances of doctors and nurses in undertaking endoscopic procedures using two sources of data – clinical records and video recordings. Endoscopists were asked to record details of the endoscope used; drugs given; distance the scope was inserted (for FS); duration of examination; immediate complications; and need for assistance (Appendix 8). The data extracted were compared between doctors and nurses by χ^2 and *t*-tests.

Drug usage, including sedation and need for reversal agents, was collected for all trial patients. The endoscopist completed this detail in Form I, the immediate complication form (Appendix 8). This information was also recorded routinely in the endoscopy report. Information for drug usage was collected from both of these sources to yield nearly complete data. The SPSS statistical package was used for analysis.

Performance was also assessed by blended analysis of a random sample of video recordings of OGD and FS procedures. Details are given in Chapter 5.

Endoscopists routinely record findings at endoscopy on a report form which is retained in the hospital notes and sent to the referring doctor. Many different formats for recording are used in the NHS but standards for the quality of the report have been set by the BSG.[21] Copies of endoscopy reports were analysed to determine the drugs given, the findings noted at endoscopy and the completeness of endoscopy reporting in comparison with the BSG standards. The data were extracted from copies of the reports from which the identity and profession of the operator could not be determined.

The BSG guidelines[21] recommend 31 specific items as essential components of an endoscopy procedure report. The completeness of endoscopy reports was assessed by collecting copies of actual endoscopy reports recorded on trial patients. A structured form, based on the BSG guidelines, was developed to record completed data items in the reports. This was initially piloted with endoscopy reports from MINuET pilot patients and then used in the main trial. Two reviewers (DD, LD) performed data extraction and any questions

arising as to whether documentation met quality criteria were resolved by consensus. To eliminate bias, reviewers were blinded to centre and endoscopist identity before data extraction from endoscopy reports.

The SPSS statistical package was used for analysis. The χ^2 test was used to compare compliance with various criteria.

Hospital case notes were scrutinised 1 year after the procedure was undertaken and from these the incidence of late complications, subsequent contact with health professionals and final diagnosis and incidence of new diagnoses were determined (Appendix 9). This was supplemented by a questionnaire which was completed by a member of the primary care team responsible for the patient (Appendix 10).

The results of these analyses are given in Chapter 4.

Economic issues

The aim of the economic analysis was to estimate the relative cost-effectiveness of nurses and doctors performing upper and lower GI endoscopy. This is described in detail in Chapter 6.

Outcome measures

The outcome measure for the economic analysis was the quality-adjusted life-year (QALY). This is a composite measure of health utility calculated by 'weighting' each period of follow-up time by the value corresponding to the health-related quality of life (HRQoL) during that period.[22]

HRQoL was assessed using the EuroQol (EQ5D) questionnaire. The EuroQol is a validated generic health-related preference-based measure comprising five items covering mobility, self-care, usual activities, pain, anxiety and depression, each with three levels of severity (no problems, some problems, a lot of problems).[23]

Resource use

Resource use data were collected from a variety of sources including patient questionnaires and hospital and primary care records. Details are given in Chapter 6. The forms used are shown in Appendices 13 and 14.

Unit costs

Unit costs were estimated from routine and/or published literature, for example NHS reference costs, published cost estimates and NHS salary scales. Details are given in Chapter 6.

Cost-effectiveness analysis

All analyses of relative cost-effectiveness were performed on an intention-to-treat basis. The time horizon of the analysis was 1 year, causing no necessity to discount either costs or effects. The price year for this analysis was 2002/2003. Full details of the methodology for the cost-effectiveness analysis can be found in Chapter 6.

Human resource implications

If nurse endoscopy is taken up widely in the NHS, it could have a substantial impact on the NHS workforce and on skill mix in UK NHS hospital trusts. In order to estimate the potential impact on NHS Trusts, the following analysis was carried out:

- Data were extracted from Hospital Episode Statistics for England (HES) and from the Patient Episode Database for Wales (PEDW) in order to determine the scale of patient episodes where upper or lower GI endoscopy was the primary procedure.
- Data on the average time of endoscopy procedures (as carried out by nurses or doctors) was used to give a crude estimate of the amount of contact patient time (by nurses or doctors) needed for endoscopies.
- Combining these data, using a set of relatively simplistic assumptions, the number of specialist nurses required was determined, and some implications were drawn for the amount of doctor time released.
- Using published training guidelines, responses to the survey questions on training and published unit cost data, an estimate of the cost of training nurse endoscopists was made.

Validation of outcome measures

A validation and feasibility study took place from January to April 2002 in a hospital near Swansea that was not a study centre and participating centres. The aim was:

- to develop and validate two new outcome measures – the GSRQ and the GESQ
- to test other data collection instruments.

Gastrointestinal Symptom Rating Questionnaire (GSRQ)

Valid instruments are needed to assess and monitor the progress of patients attending with GI symptoms. There are many disease-specific instruments but few are applicable to all GI conditions. The best known system-specific instrument, the GIQLI,[24] was validated for use with patients with confirmed diagnoses. There is no instrument validated for use at referral, that is, before diagnosis.

Therefore, we developed the system-specific GSRQ and tested it on 351 patients in Neath General Hospital (not in the main study) through correlation with patients' general health as measured by SF-36 and appropriate disease-specific questionnaires – the UK Inflammatory Bowel Disease Questionnaire (UK IBDQ)[25] (an anglicised enhanced version of the McMaster IBDQ[26]), the Aberdeen Dyspepsia Scale (ADS),[27] the Gastro-Esophageal Reflux Disease Health Related Quality of Life Scale (GERD-HRQLS)[28] and the Irritable Bowel Syndrome Quality of Life Questionnaire (IBS QOL).[29] In this way, we followed Streiner and Norman's approach[30] by developing the questionnaire and then piloting it on patients with known GI disorders [dyspepsia, gastro-oesophageal reflux disease (GORD), inflammatory bowel disease (IBD), irritable bowel syndrome (IBS)].

We then validated it concurrently with 1800 new patients taking part in MINuET. Underlying dimensions were analysed by principal component analysis. Internal consistency was assessed with Cronbach's alpha. Construct validity of the questionnaire was evaluated through correlation with patients' general health as measured by SF-36. Reproducibility was assessed in patients reporting no change in health status. Responsiveness for those reporting a change was evaluated with the responsiveness ratio.

Factor analysis showed four dimensions underlying GI symptoms reported by these patients:

1. upper GI – heartburn, reflux, nausea, retching, vomiting, food sticking in gullet, eating restricted, lack of appetite
2. lower GI – frequent bowel movements, loose stools, urgent need to empty bowel
3. wind-related symptoms – upper abdominal discomfort, belching, wind from bowel, trapped wind, gurgling in stomach
4. defecation-related symptoms – hard stools, constipation, incomplete bowel emptying, bleeding in back passage.

There was good internal consistency within these dimensions, with Cronbach's alpha ranging from 0.70 to 0.85.

Construct validity was demonstrated by statistically significant correlations between the four GSRQ dimensions and three SF-36 subscales: physical functioning ($r = -0.14$ to -0.30, $p < 0.001$); role functioning – physical ($r = -0.21$ to -0.33, $p < 001$) and role functioning – mental ($r = -0.22$ to 0.31, $p < 0.001$).

Good reproducibility for patients who reported no change in health status was shown by intraclass correlation coefficients between 0.71 and 0.79 ($p < 0.001$).

For patients who reported an improvement in health status, the responsiveness ratio ranged from 0.27 to 0.77; for patients who reported a deterioration in health, the responsiveness ratio ranged from 0.07 to 0.40.

These results show that the GSRQ is a valid questionnaire for assessing GI symptoms with good internal consistency, four interpretable factors and demonstrable construct validity, reproducibility and responsiveness. The validation of this instrument is described in more detail in the section 'Annex A' (p. 10).

Gastrointestinal Endoscopy Satisfaction Questionnaire (GESQ)

Patient satisfaction with endoscopy is an important outcome measure and quality indicator.[31] Although we considered a modified version of the Group Health Association of America nine-item instrument (mGHAA-9), this has been shown to lack content validity for measuring patient satisfaction with endoscopy.[32]

We therefore developed and validated a questionnaire for use in this study. Items known to affect patient satisfaction were identified from the literature.[32] A 24-item questionnaire was then developed from the mGHAA-9 with additional items important to patient satisfaction. Content validity was assessed by an expert panel that included expertise in gastroenterology, outcome measurement and psychology. In the validation study, two groups completed GESQ 1 day after endoscopy – patients attending a local endoscopy unit, a sample of whom were interviewed on questionnaire content, and patients in a pilot phase of the main study. A patient representative and endoscopy staff from the local hospital commented on content. The questionnaire was

then modified to form the GESQ for the main MINuET study and concurrent validation.

To validate the questionnaire, 93 of 125 patients from local hospitals (20 of them interviewed) and 94 of 157 patients from the MINuET pilot completed the initial questionnaire. In the main study, 1536 of 1782 consented main trial patients returned the updated version. Content validity was demonstrated from patient and endoscopy staff feedback on the questionnaire and patient interviews. Factor analysis revealed four subscales, all with high internal reliability: skills and hospital (seven items, $\alpha = 0.83$); pain or discomfort during and after endoscopy (four items, $\alpha = 0.84$); information before endoscopy (five items, $\alpha = 0.80$); and information after endoscopy (five items, $\alpha = 0.76$). On the basis of high frequencies and low item-total correlation, we excluded three items.

This validation showed that the GESQ is a valid, reliable, interpretable and acceptable tool to measure patient satisfaction with upper or lower GI endoscopy. The validation is described in more detail in the section 'Annex B' (p. 12).

Ethics

The study was approved by the Multi-centre Research Ethics Committee (MREC) for Wales. Participating centres obtained approval from the Local Research Ethics Committee (LREC), R&D organisation and Caldicott guardian. Randomisation occurred before consent, but patients were sent a patient information leaflet and sample consent form more than 24 hours before attending for endoscopy. Written, informed consent was obtained by local collaborators when patients attended for the procedure. Ethics approval for the feasibility study was obtained from the Swansea Local Research Ethics Committee.

Pilot study

The aim of the pilot study was to test the feasibility of the recruitment process and the acceptability of the data collection instruments to patients and collaborators. The pilot took place during March to April 2001, when participating centres were each asked to recruit 10 patients. Twenty-four hospitals took part in the pilot (three in the OGD arm, 13 in the FS arm and eight in both arms of the study). Sixteen of these hospitals were in England, seven in Scotland and one in Wales.

The initial intention was to recruit 1500 patients into separate OGD and FS arms of the study, with the aim of achieving 1000 complete records for each procedure. The pilot study found that the recruitment process was less effective than had been hoped: only half of the patients who were randomised were recruited to the trial (*Figure 1*). As a result, participating sites were asked to double the number of patients randomised from 54 to 108 (FS) and from 108 to 216 (OGD). Some

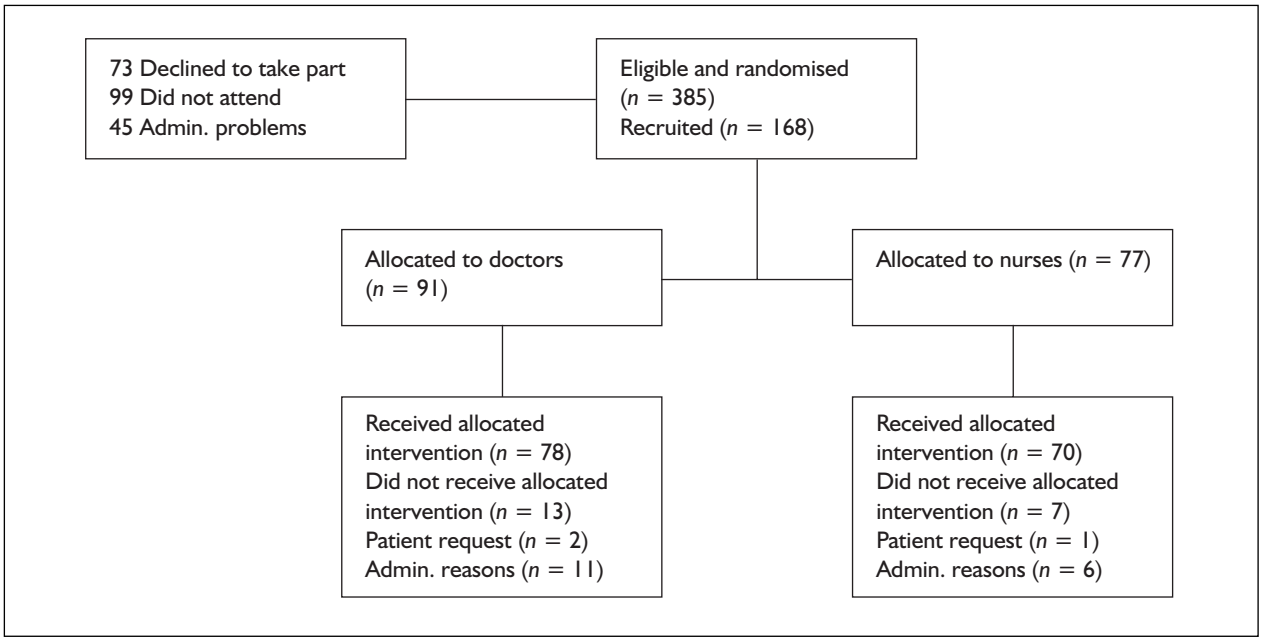

FIGURE 1 *Flow of patients through pilot study*

simplification of the outcome questionnaires was also made. In spite of this, the rate of recruitment into the main study was lower than intended. After 4 months of the main study, a decision was taken to amalgamate the two arms of the study and recruit 1500 patients in all, with the aim of achieving 1000 complete records for a combined analysis.

Protocol amendments

A protocol amendment to amalgamate the two arms of the study and to compare cost-effectiveness of endoscopies in general rather than by the site of endoscopy was approved by MREC and the HTA programme.

Annex A Development and validation of the Gastrointestinal Symptom Rating Questionnaire (GSRQ)

Introduction

Monitoring and enhancement of a patient's HRQoL is an important element of research and healthcare. GI symptoms are common in the adult and elderly population in North America,[33] Europe[34] and the UK.[35] The prevalence of upper GI symptoms in Europe ranged from 25 to 35%[36] and that of lower GI symptoms from 3 to 22%.[37,38] It is estimated that up to 40% of adults in the UK suffer from GI symptoms in any one year.[39–41] About 50% of the new outpatient referrals to hospital gastroenterology departments were from patients presenting with GI symptoms but with no identifiable structural or biochemical abnormality.[42,43] Valid instruments are needed to assess and monitor the progress of patients attending with GI symptoms.

It is well recognised that GI symptoms have an adverse impact on patients' well-being and their ability to enjoy day-to-day activities.[44] Reviews[45–47] have identified an exponential growth of the number of reports describing the development of disease-specific quality of life measures, for IBD, IBS, dyspepsia, GORD, liver disease and GI malignancy.[46] However, there remain many disorders with no available instruments. Furthermore, it is not appropriate to use disease-specific instruments for newly referred patients in whom a diagnosis has not yet been made. Generic instruments, such as the SF-36,[18] Psychological General Wellbeing Scale[48] and Sickness Impact Profile[49] could be applied to those patients whose symptoms have not yet been diagnosed, and have been used to assess the HRQoL of GI patients. However, there are concerns that these instruments might miss small but clinically important changes.[45] An optimum approach would be to use a system-specific instrument, one developed for all GI disorders. However, there are very few such instruments and the most widely reported, the GIQLI,[24] is validated for use with patients with confirmed diagnosis. We have found no instrument that has been validated for use at referral before a diagnosis has been made. Our aim was to develop and validate a symptom-rating questionnaire to monitor the health status of patients with GI symptoms, before and after a diagnosis has been made.

Methods

We adapted Streiner and Norman's approach[30] to develop a gastrointestinal symptom rating scale in the following stages:

- item generation
- pilot study at a local hospital for initial validation
- main study for concurrent validation in the context of a national multi-institution nurse endoscopy trial (MINuET).

Item generation

After a detailed review of the literature using the search terminology 'quality of life', 'questionnaire', 'validation' and 'gastroenterology', we identified the items covered by the UK IBDQ,[25] the ADS,[27] the GERD-HRQLS[28] and the IBS QOL[29] as the most relevant for a GI symptom rating scale. A panel with expertise in gastroenterology, psychology, outcome measurement and methodology reviewed these items and developed the GSRQ.

Initial validation

The questionnaire was piloted with patients with known GI disorders (dyspepsia, GORD, IBD, IBS) at a local hospital not involved in MINuET. Patients were invited to complete, at home, a questionnaire containing the GSRQ, cost-effectiveness and semi-structured questions asking for patients' comments on GSRQ at baseline and 4 weeks.

Main study

The questionnaire was then tested with patients taking part in MINuET. Patients completed a questionnaire containing the GSRQ and cost-effectiveness at recruitment, 1 month and 12 months.

Psychometric analysis

Underlying dimensions were analysed by principal component analysis. Internal consistency was assessed with Cronbach's alpha. Construct validity of the questionnaire was evaluated through correlation with patients' general health as measured by cost-effectiveness. Reproducibility was assessed in patients reporting no change in health status with intraclass correlation. Responsiveness for those reporting a change was evaluated with the responsiveness ratio. Items with high responses on one category (more than 80%) and low correlation were excluded owing to poor discriminatory value. An independent psychometrician was invited to review the analysis.

Results

Item generation

The questionnaire contained six sections. Each section contained two components: the presence of symptoms and the impact of these symptoms on daily living.

Initial validation

There were 571 patients who agreed to take part in the initial validation; 351 returned the baseline questionnaire and 308 the 4-week questionnaire. Analysis of preliminary findings from the initial validation showed three dimensions underlying GI symptoms reported by these patients (upper GI symptoms; lower GI – frequent bowel movements and related symptoms; and lower GI – constipation-related symptoms). Good internal consistency was recorded among the dimensions (α range 0.86–0.91).

Construct validity was demonstrated by statistically significant correlations between the three GSRQ dimensions with five of the eight cost-effectiveness subscales (physical functioning, role physical, pain, general health and role emotional). The upper GI dimension was also correlated with the cost-effectiveness mental health subscale. Analysis of the semi-structured questions showed that patients found the questionnaire easy to complete and there was no question they did not wish to answer. Further tests of the psychometric properties of the questionnaires for patients presenting with GI symptoms but no fixed diagnosis were carried out in the main study.

Main study

The questionnaire was tested with 1782 patients who consented to take part in MINuET. Of these, 1773 completed the GSRQ. Factor analysis showed four dimensions underlying GI symptoms reported by these patients:

1. upper GI – heartburn, reflux, nausea, retching, vomiting, food sticking in gullet, eating restricted, lack of appetite
2. lower GI – frequent bowel movement, loose stools, urgent need to empty bowel
3. wind-related symptoms – upper abdomen discomfort, belching, wind from bowel, trapped wind, gurgling in stomach
4. defecation-related symptoms – hard stools, constipation, incomplete bowel emptying, bleeding from back passage.

Good internal consistency was recorded among the dimensions (α range 0.70–0.85).

Construct validity was demonstrated by statistically significant correlations between the four GSRQ dimensions with three cost-effectiveness subscales: physical functioning (r = –0.14 to –0.30, $p < 0.001$); role functioning-physical (r = –0.21 to –0.33, $p < 001$) and role functioning – mental (r = –0.22 to 0.31, $p < 0.001$).

Good reproducibility was recorded for patients who reported no change in health status (intraclass correlation = 0.71–0.79, $p < 0.001$).

For patients who reported an improvement in health status, the responsiveness ratio ranged from 0.27 to 0.77; for patients who reported a deterioration in health, the responsiveness ratio ranged from 0.07 to 0.40.

Discussion

The questionnaire was systematically developed and piloted. Patients with a variety of GI symptoms from 24 hospitals across UK were involved in testing the questionnaire as part of an RCT. The analysis was also thoroughly reviewed by psychometricians, statisticians and outcome specialists.

Many patients did not have some of the symptoms described in the GSRQ and skipped the questions related to the impact of these symptoms on their daily living. These items were excluded from the calculation of the total score but, of necessity, were kept in the questionnaire to provide additional information about symptom impact on daily living for those who did have the symptoms.

Conclusion

The GSRQ is a valid questionnaire for assessing GI symptoms with good internal consistency, four interpretable factors and demonstrable construct validity, reproducibility and responsiveness.

Annex B Development and validation of the Gastrointestinal Endoscopy Satisfaction Questionnaire (GESQ)

Introduction

Patient satisfaction with endoscopy is an important outcome measure and quality indicator. The American Society for Gastrointestinal Endoscopy (ASGE) recommends six quality indicators to be routinely collected in all patients undergoing GI endoscopy[31] and patient satisfaction is one of them. The European Society of Gastrointestinal Endoscopy has also recommended such a process. Some endoscopy units in the UK have started collecting this as measure of quality in endoscopy.[50]

The mGHAA-9 is the best known tool for measuring patient satisfaction[31] and has been recommended by the ASGE. However, there is an absence of data on the validity of this instrument in an endoscopy population. The instrument was found to be inadequate for assessing endoscopy procedural satisfaction as it did not include all factors necessary for patient satisfaction, especially pain control during and after endoscopy.[51] Other instruments either lack details of validation[52] or have been developed to measure patient satisfaction with care other than that of endoscopy, using in-depth interviews.[12]

Although qualitative methods such as in-depth interviews have a role in assessing patient satisfaction, there are important resource implications for both patients and staff. An analysis of 195 studies found few that reported psychometric analysis during development and validation of the instrument.[53] Patchy evidence of reliability or validity data were found in 46% of the 195 studies. Of these, 76 reported content validity, 14 criterion validity with patient's intent to return as the most frequently used criterion, four reported construct validity and 34 reported internal consistency of the scale with 31 using Cronbach's alpha to measure this. Because of the shortfall of available scales, we therefore chose to develop and validate a questionnaire for use in the MINuET study.

Methods

We adapted Streiner and Norman's approach[30] and developed the GESQ in the following stages:

- item generation
- pilot study for initial validation
- main study for concurrent validation in a national multi-institution nurse endoscopy trial (MINuET).

Item generation

A detailed review of the literature was carried out using the search terminology 'patient satisfaction, endoscopy, gastrointestinal endoscopy, upper gastrointestinal endoscopy, colonoscopy, flexible sigmoidoscopy, endoscopic retrograde cholangio pancreotography (ERCP), gastroscopy'. The instruments reported in four papers were found to contain the items most relevant for assessing patient satisfaction with endoscopy.[12,31,51,52] A panel that included expertise in gastroenterology, outcome measurement and methodology and psychology assessed the items generated and developed the GESQ.

Initial validation

Initial validation took place during the pilot phase of the MINuET study and at a local hospital, which was not a MINuET study site. A specialist registrar administered the questionnaires to patients attending for GI endoscopy. Patients were asked to complete a questionnaire containing the GESQ and four open-ended questions to identify any ambiguity of the questions and also to identify any additional questions relevant to patient satisfaction with GI endoscopy. Informed consent was obtained and patients were asked to complete the questionnaire 1 day after endoscopy and return it by post.

In addition to semi-structured questions, patient input was obtained by interviews with a subsample of patients and comments from a patient representative in the local hospital. Endoscopy staff (physician and nursing staffs) from the local hospital also commented on content of the questionnaire.

Main study

Following the initial validation, the questionnaire was then tested with patients taking part in the main MINuET study. Patients completed a questionnaire containing the GESQ 1 day after endoscopy. Reminders were sent to non-responders at 2 and 4 weeks.

Analysis

Face and content validity were assessed in the item generation and initial validation stages, with input from the expert panel and from patients.

Items with high responses on one category (more than 80%) and low correlation were excluded

owing to poor discriminatory value. Acceptability was assessed by response rate. Underlying dimensions were analysed by principal component analysis. Internal consistency was assessed with Cronbach's alpha.

Results

Item generation

After expert review of items identified from the literature, a 24-item GESQ was developed with most of the items on a five-point scale. The systematic literature review and the input from the expert panel contributed to the content validity of the questionnaire.

Initial validation

There were 125 patients attending a local hospital and 157 patients from the MINuET pilot invited to take part in the initial validation of the GESQ. Ninety-three patients recruited at the local hospital and 94 from the MINuET sites returned the completed questionnaire. Twenty patients from the local hospital were interviewed.

All patients (n = 187) reported that the GESQ included all relevant items. This showed that patients considered GESQ as having face validity. Patients also reported the instrument to be readable and acceptable.

Three items were found to have high response on one category (100%). Two of these items were dropped ("Did more than one person give you an explanation of what would happen during your endoscopy?" and "If more than one person explained your endoscopy to you, did you find this confusing?"). The third item "Did the person who performed the endoscopy give you the explanation?", was retained as it had specific relevance to the MINuET trial.

Two interviewees reported some difficulties with the questions "How much pain or discomfort did you experience during endoscopy?" and "How much pain or discomfort did you experience after endoscopy?". After discussion with the research team, the two questions were split into four separate questions asking patients' experience of pain or discomfort during and after endoscopy. Two other patients reported difficulty in answering a question relating to facilities in the endoscopy suite. This was changed to just one aspect of the suite, namely the comfort of the recovery area.

Main study

In the main study, 1536 of 1782 consented main trial patients returned the updated version of GESQ. The high response rate indicated that patients found the GESQ acceptable.

Three items were excluded on account of high response on one category (>80%) and low item-total correlation (<0.35):

- How much information was sent before your endoscopy?
- Before you had your endoscopy, how much explanation did you receive about what would happen during your endoscopy?
- Did the person who performed your endoscopy give you the explanation before endoscopy?

Factor analysis of 21 items revealed four subscales with high internal consistency: skills and hospital (seven items, $\alpha = 0.83$), pain or discomfort during and after endoscopy (four items, $\alpha = 0.84$), information before endoscopy (five items, $\alpha = 0.80$), and information after endoscopy (five items, $\alpha = 0.76$). These four subscales are clinically relevant and correspond to patient satisfaction domains identified in previous studies.

Discussion

The questionnaire was systematically developed and piloted. Patients with a variety of GI symptoms from 24 hospitals across the UK were involved in testing the questionnaire as part of an RCT. The analysis was also thoroughly reviewed by psychometricians, statisticians and outcome specialists.

More work could be done to establish the construct validity and criterion validity of the GESQ. One possible way is to assess construct validity of the GESQ by examining the correlation between patient satisfaction data and reported complications of endoscopy. There is some evidence that patients experiencing complications after endoscopy are less satisfied and less likely to return for a repeat endoscopy.[54] As endoscopy complications are rare, this would require a sample much larger than in the present study. Another possible approach would be to correlate the patient satisfaction data with the change in SF-36 scores at 1 day after endoscopy and see whether patients reporting higher satisfaction levels have better general health. However, there is no research evidence supporting this approach. Furthermore, a substantial number of patients would have sedation for endoscopy, which might affect their satisfaction with the procedure (in terms of pain control) and their perceived general health in different ways. Previous studies have used patients' intent to return as a criterion for

validating satisfaction questionnaires. We also collected patients' preference data at 1 year post-endoscopy, asking patients whether they would recommend endoscopy to a friend by the same endoscopist, a different endoscopist or not at all based on their experience with endoscopy. It is possible to use this to test for construct validity to see whether more satisfied patients recommended further endoscopy to a friend. However, the 1-year time lapse between endoscopy and the intent to recommend might have diluted any possible correlation between satisfaction and intent to recommend. Practical difficulties have to be overcome before assessing the construct and criterion validity of the GESQ and any findings must be carefully interpreted.

Conclusion

This validation showed that the GESQ is a valid, reliable, interpretable and acceptable tool to measure patient satisfaction with upper or lower GI endoscopy.

Chapter 3

Results – primary and secondary outcomes

Twenty-three hospitals took part in the main trial, three recruiting patients only for OGD, 14 for FS only and six for both OGD and FS. Sixteen of these hospitals were in England, six in Scotland and one in Wales. Patients were recruited into the study from 29 July 2002 to 30 June 2003.

Participant flow and recruitment

Participant flow is summarised in *Figure 2* and *Table 1*. In total, 4128 patients were randomised, 2078 (50.3%) to a doctor endoscopist and 2050 (49.7%) to a nurse endoscopist. Randomisation and entry to the trial by type of procedure are shown in *Table 2*. Randomisation and entry by centre are shown in *Figure 3*.

The two groups were broadly similar in age, sex, type of access and presenting symptoms (*Table 3*).

In total, 2226 (53.9%) randomised patients were booked for an FS whereas 1902 (46.1%) were booked for an OGD procedure. Of the randomised patients, 3133 (75.9%) attended for endoscopy, 1546 (49.3%) in the doctor group and 1587 (50.7%) in the nurse group. Of these, 1888 agreed to take part in the trial. This represents

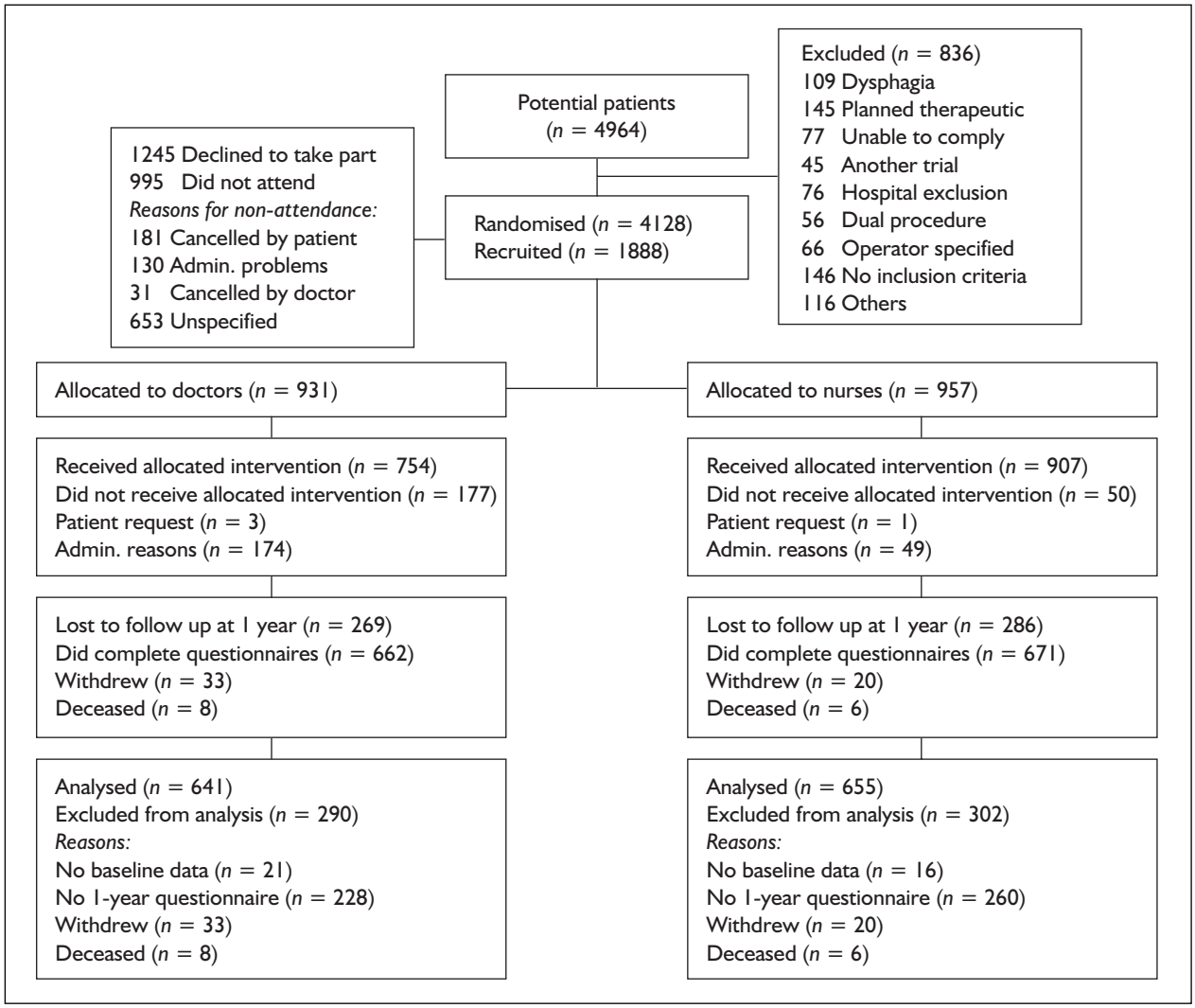

FIGURE 2 *Flow diagram of progress through the trial*

45.7% of those randomised and 60.3% of those attending their appointment. The numbers agreeing to the trial in the two randomised groups were similar: 931 in the doctor group (44.8% of those randomised, 60.2% of those attending) and 957 in the nurse group (46.7% of those randomised, 60.3% of those attending).

The baseline characteristics of the randomised patients who did not take part in the trial are shown in *Table 4*.

TABLE 1 *Overall randomisation and entry to trial*

	Total	Doctor	Nurse
Randomised	4128	2078	2050
(% of randomised)		(50.3)	(49.7)
Attended	3133	1546	1587
(% of randomised)	(75.9)	(74.4)	(77.4)
Agreed to trial	1888	931	957
(% of randomised)	(45.7)	(44.8)	(46.7)
Procedure/details completed	1823	896	927
(% of trial patients)	(96.6)	(96.2)	(96.9)
Changed profession	226	177	49
(% of trial patients)	(12.0)	(19.0)	(5.1)

Baseline data

Endoscopist experience

A comparison of endoscopist experience is given in *Table 5*. More doctors than nurses took part in the study. Doctors had received less formal training than nurses, but showed evidence of greater experience in the number and range of procedures undertaken. All doctors could administer sedation but only two-thirds of nurses would do this. All nurses reported that they

TABLE 2 *Randomisation and entry to trial by type of procedure*

	FS			OGD		
	Total	Doctor	Nurse	Total	Doctor	Nurse
Randomised (% of randomised)	2226	1117 (50.2)	1109 (49.8)	1902	961 (50.5)	941 (49.5)
Attended (% of randomised)	1777 (79.8)	866 (77.5)	911 (82.1)	1356 (71.3)	680 (70.8)	676 (71.8)
Agreed to trial (% of randomised)	1099 (49.4)	550 (49.2)	549 (49.5)	789 (41.5)	381 (39.6)	408 (43.4)
Procedure/details completed (% of trial patients)	1072 (97.5)	534 (97.1)	538 (98.0)	751 (95.2)	362 (95.0)	389 (95.3)
Changed profession (% of trial patients)	123 (11.2)	91 (16.5)	32 (5.8)	103 (13.1)	86 (22.6)	17 (4.2)

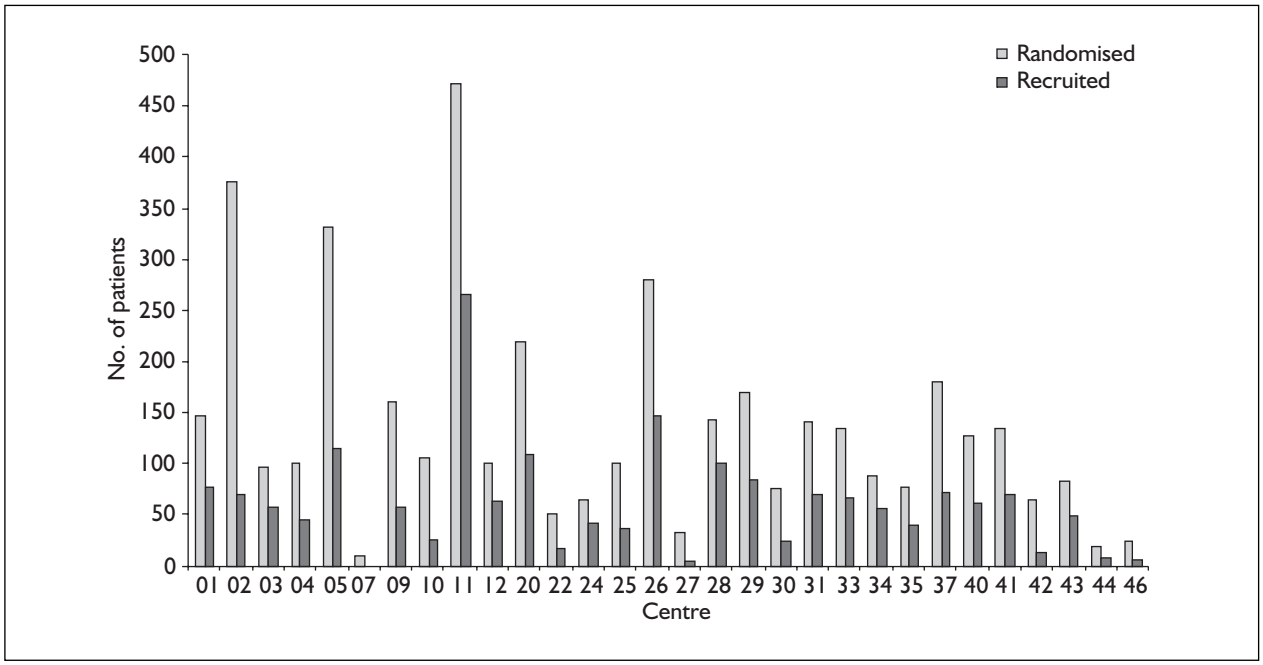

FIGURE 3 *Recruitment by centre*

TABLE 3 *All randomised patients – baseline characteristics*

Characteristic	Doctor (*n* = 2078)	Nurse (*n* = 2050)
Age (years)		
Mean (SD)	53.3 (16.2)	52.8 (16.2)
Range	18.0–99.9	18.0–95.9
Sex		
No. of females	1137	1114
(%)	(54.7)	(54.3)
Degree of urgency (%)		
Very urgent	25 (1.2)	26 (1.3)
Urgent	191 (9.2)	193 (9.4)
Soon	622 (29.9)	642 (31.3)
Routine	1240 (59.7)	1189 (58.0)
Presenting symptoms (%)		
OGD patients:		
Dyspeptic symptoms	883 (91.9)	868 (92.2)
Weight loss	69 (7.2)	50 (5.3)
Anaemia	100 (10.4)	100 (10.6)
Anorexia	23 (2.4)	20 (2.1)
FS patients:		
Bleeding per rectum	787 (70.5)	798 (72.0)
Change in bowel habit	479 (42.9)	471 (42.5)
No. attending endoscopy (%)	1546 (74.4)	1587 (77.4)
No. consenting to trial (%)	931 (44.8)	957 (46.7)
No. followed up at 12 months (% of recruited patients)	662 (71.1)	671 (70.1)

TABLE 4 *Patients who did not take part in the trial compared with trial patients*[a]

	Refused consent/did not attend		Trial patients	
Characteristic	**Doctor (*n* = 1147)**	**Nurse (*n* = 1093)**	**Doctor (*n* = 931)**	**Nurse (*n* = 957)**
Age (years)				
Mean (SD)	54.0 (16.96)	52.9 (17.06)	52.4 (15.17)	52.6 (15.08)
Sex				
No. of females (%)	657 (57.3)	607 (55.5)	480 (51.6)	507 (53.0)
Degree of urgency (%)				
Very urgent	8 (0.7)	11 (1.0)	17 (1.8)	15 (1.6)
Urgent	116 (10.1)	123 (11.3)	75 (8.1)	70 (7.3)
Soon	342 (29.8)	338 (30.9)	280 (30.1)	304 (31.8)
Routine	681 (59.4)	621 (56.8)	559 (60.0)	568 (59.4)
Presenting symptoms (%)				
OGD patients:				
Dyspeptic symptoms	530 (91.4)	476 (89.3)	353 (92.7)	392 (96.1)
Weight loss	42 (7.2)	33 (6.2)	27 (7.1)	17 (4.2)
Anaemia	67 (11.6)	71 (13.3)	33 (8.9)	29 (7.1)
Anorexia	15 (2.6)	16 (1.9)	8 (2.1)	10 (2.5)
FS patients:				
Bleeding per rectum	384 (67.7)	394 (70.4)	403 (73.3)	404 (73.6)
Change in bowel habit	251 (44.3)	237 (42.3)	228 (41.5)	234 (42.6)

[a] There was no significant difference between trial and non-trial patients for any characteristics.

TABLE 5 *Endoscopist experience* n *(%)*

	Doctors (*n* = 67)	Nurses (*n* = 30)		Doctors (*n* = 67)	Nurses (*n* = 30)
No. of OGD endoscopies performed			Dilation of strictures:		
1–500	6 (9)	5 (31)	Independent	49/65 (75)	0/19 (0)
501–1000	7 (11)	2 (13)	Supervised	7/65 (11)	3/19 (16)
1001–5000	34 (52)	6 (38)	Stent insertion:		
5001–10,000	10 (15)	3 (19)	Independent	31/65 (48)	0/19 (0)
10,001+	8 (12)	0 (0)	Supervised	3/65 (5)	0/19 (0)
No. of flexible sigmoidoscopies performed			PEG tube insertion:		
1–250	6 (10)	2 (7)	Independent	49/65 (75)	2/19 (11)
251–500	10 (16)	7 (26)	Supervised	8/65 (12)	3/19 (16)
501–1000	3 (5)	4 (15)	Hot biopsy:		
1001–4000	33 (53)	12 (44)	Independent	61/65 (94)	12/19 (63)
4001–10000	9 (15)	2 (7)	Supervised	0/65 (0)	4/19 (21)
10001+	1 (2)	0 (0)	Polypectomy:		
No. of colonscopies performed			Independent	63/65 (97)	11/19 (58)
1–50	2 (4)	1 (50)	Supervised	1/65 (2)	5/19 (26)
51–100	3 (5)	1 (50)	Endoscopic mucosal resection:		
101–250	4 (7)	0 (0)	Independent	25/65 (38)	0/19 (0)
251–1000	12 (21)	0 (0)	Supervised	2/65 (3)	0/19 (0)
1001+	36 (63)	0 (0)	**Formal endoscopy training**	25/67 (37)	27/30 (90)
Perform independent endoscopies			Mean no. of courses attended	0.5	1.2
OGD	67/67 (100)	16/30 (53)	**JAG certificate for any course**	5/25 (20)	1/27 (4)
FS	64/67 (96)	27/30 (90)			
Colonoscopy	59/67 (88)	2/30 (7)	**Monitor endoscopic activities**	41/45 (91)	30/30 (100)
Perform therapeutic procedures	64/65 (99)	19/29 (66)	**Routinely see patients in:**		
Injection of ulcers:			Pre-endoscopy clinic	11/66 (17)	4/30 (13)
Independent	54/65 (83)	0/19 (0)	Post-endoscopy clinic	12/66 (18)	5/30 (17)
Supervised	2/65 (3)	3/19 (16)			
Banding and injection of varices:					
Independent	43/65 (66)	1/19 (5)			
Supervised	2/65 (3)	0/19 (0)			

routinely monitor their endoscopic activity but 9% of doctors did not do this. There was no significant difference between the two groups in their routine practice with regard to pre- and post-endoscopic assessment in outpatients.

Participants

The subset of randomised patients who agreed to take part in the trial was similar in their characteristics at recruitment (*Table 6*) between the randomised groups. There were three differences between the groups. OGD patients in the nurse group were more likely to have dyspeptic symptoms (96.1%) and less likely to have had a previous barium enema (2.5%) than OGD patients in the doctor group (93% had dyspeptic symptoms and 5.5% had a previous barium enema). Patients in the nurse group scored lower on the physical component score (PCS) of the SF-36 than those in the doctor group {mean 44.4 [standard deviation (SD) 7.5] versus mean 45.2 (SD 7.2); $p = 0.03$}. However, as more than 30 characteristics were compared and only these three differences showed a p-value of less than 0.05, the differences are mostly likely due to chance rather than a real difference between the groups.

Preparation for the procedure

There was no difference between the two groups in the type of bowel preparation used (*Table 7*), or in the quality of the preparation of the bowel for FS, as reported by the endoscopist (*Table 8*).

Questionnaire response rates

Follow-up rates were good: 1782 (94.4%) patients completed the baseline questionnaire, 1536 (81.4%) the 1-day questionnaire, 1427 (75.6%) the 1-month questionnaire and 1333 (70.6%) the 1-year questionnaire, which contained the primary outcome measure. Response rates were similar for both randomised groups at all time points; for instance, 662 (71.1%) patients responded in the

TABLE 6 *All recruited trial patients – baseline characteristics*

Characteristic	Doctor (*n* = 931)	Nurse (*n* = 957)	*p*-Value
Age (years)			
Mean (SD)	52.4 (15.17)	52.6 (15.08)	0.8[a]
Sex – n (%)			
No. of females (%)	480 (51.6)	507 (53.0)	0.5[b]
ASA class – *n* (%)			
I (healthy patient)	596 (64.0)	571 (59.5)	0.2[c]
II (mild systemic disease – no functional limitations)	197 (21.2)	224 (23.4)	
III (severe systemic disease + definite functional limitation)	22 (2.4)	26 (2.7)	
VI (severe systemic disease + acute unstable problems)	2 (0.2)	0 (0.0)	
Missing	*114 (12.2)*	*138 (14.4)*	
Type of referral – *n* (%)			
Outpatient	306 (32.9)	327 (34.2)	0.9[c]
Open access	384 (41.2)	397 (41.5)	
Rapid access	115 (12.4)	114 (11.9)	
Not recorded	*126 (13.5)*	*119 (12.4)*	
Type of access – *n* (%)			
Very urgent	17 (1.8)	15 (1.6)	0.8[c]
Urgent	75 (8.1)	70 (7.3)	
Soon	280 (30.1)	304 (31.8)	
Routine	559 (60.0)	568 (59.4)	
Symptoms – *n* (%)			
OGD patients:			
Dyspeptic symptoms	353 (92.7)	392 (96.1)	0.04[b]
Weight loss	27 (7.1)	17 (4.2)	0.09[b]
Anaemia	33 (8.9)	29 (7.1)	0.4[b]
Anorexia	8 (2.1)	10 (2.5)	0.8[b]
FS patients:			
Bleeding per rectum	403 (73.3)	404 (73.6)	0.9[b]
Change in bowel habit	228 (41.5)	234 (42.6)	0.7[b]
Previous endoscopy – *n* (%)	**181 (19.4)**	**182 (19.0)**	
OGD patients:			
OGD	62 (18.9)	65 (17.8)	0.7[b]
FS/colonoscopy	41 (12.5)	38 (10.4)	0.4[b]
Barium enema	18 (5.5)	9 (2.5)	0.04[b]
FS patients:			
OGD	51 (10.4)	48 (9.8)	0.8[b]
FS/colonoscopy	53 (10.8)	56 (11.5)	0.7[b]
Barium enema	74 (15.1)	80 (16.4)	0.6[b]
GSRQ – mean (SD)			
Scored 0 (no symptoms)–100			
Factor 1: upper GI	18.4 (18.29) *n* = 867	18.2 (18.91) *n* = 904	0.8[a]
Factor 2: lower GI	29.1 (29.35) *n* = 865	28.9 (29.21) *n* = 900	0.9[a]
Factor 3: wind	42.1 (25.84) *n* = 868	41.5 (25.34) *n* = 906	0.6[a]
Factor 4: defaecation	21.6 (21.84) *n* = 864	22.8 (22.92) *n* = 899	0.3[a]
EQ-5D – mean (SD)			
Scored 0 (poor health)–1	0.68 (0.267) *n* = 835	0.66 (0.285) *n* = 867	0.3[a]
SF-36 – mean (SD)			
Scored 0 (poor health)–100			
Physical functioning	73.3 (28.73) *n* = 859	71.0 (29.47) *n* = 891	0.1[a]
Social functioning	49.6 (10.66) *n* = 856	49.4 (10.34) *n* = 876	0.6[a]
Role limitation – physical	69.0 (31.91) *n* = 833	66.9 (32.53) *n* = 870	0.2[a]
Role limitation – mental	74.5 (29.48) *n* = 832	73.2 (29.98) *n* = 860	0.4[a]
Mental health	62.5 (11.30) *n* = 857	61.5 (11.41) *n* = 881	0.08[a]
Vitality	53.1 (11.83) *n* = 867	52.8 (12.02) *n* = 885	0.6[a]
Pain	51.1 (9.62) *n* = 850	51.6 (9.41) *n* = 866	0.3[a]
General health	57.9 (12.51) *n* = 845	57.1 (12.54) *n* = 874	0.2[a]
Change in health	57.7 (20.30) *n* = 867	58.4 (21.07) *n* = 896	0.5[a]
PCS	45.2 (7.20) *n* = 782	44.4 (7.49) *n* = 812	0.03[a]
MCS	41.8 (6.88) *n* = 782	41.7 (7.01) *n* = 812	0.7[a]
STAI – mean (SD)			
Scored 20 (high anxiety)–80			
State anxiety	42.8 (14.58) *n* = 819	42.1 (14.48) *n* = 840	0.3[a]

[a] Two sample *t*-test.
[b] Fisher's exact test.
[c] χ^2 test.

TABLE 7 *Bowel preparation before FS*

From Form 1	*n* (%) Doctor (*n* = 448)	Nurse (*n* = 469)	*p*-Value
Bowel preparation used?			
Yes	429 (96)	447 (95)	0.75
Source: endoscopists' assessment.			

TABLE 8 *Quality of bowel preparation for FS*

From Form 1	*n* (%) Doctor (*n* = 448)	Nurse (*n* = 469)	*p*-Value
Quality of bowel preparation			
Very good	121 (25)	113 (23)	0.36
Good	167 (35)	185 (38)	
Satisfactory	116 (24)	119 (25)	
Poor	67 (14)	54 (11)	
Very poor	7 (2)	13 (3)	
Source: endoscopists' assessment.			

TABLE 9 *Questionnaire response rates for all trial patients*

	Total (*n* = 1888)	Doctor (*n* = 931)	Nurse (*n* = 957)
Baseline (%)	1782 (94.4)	873 (93.8)	909 (95.0)
1 day (%)	1536 (81.4)	743 (79.8)	793 (82.9)
1 month (%)	1427 (75.6)	702 (75.2)	725 (75.8)
1 year (%)	1333 (70.6)	662 (71.1)	671 (70.1)

TABLE 10 *Questionnaire response rates by type of procedure*

	Flexible sigmoidoscopy			OGD		
	Total (*n* = 1099)	Doctor (*n* = 550)	Nurse (*n* = 549)	Total (*n* = 789)	Doctor (*n* = 381)	Nurse (*n* = 408)
Baseline (%)	1023 (93.1)	508 (92.4)	515 (93.8)	759 (96.2)	365 (96)	394 (97)
1 day (%)	906 (82.4)	451 (82.0)	455 (82.9)	630 (79.8)	292 (77)	338 (83)
1 month (%)	841 (76.5)	425 (77.3)	416 (75.8)	585 (74.3)	277 (73)	309 (76)
1 year (%)	779 (70.6)	395 (71.8)	384 (69.9)	554 (70.2)	267 (70)	287 (70)

doctor group and 671 (70.1%) in the nurse group at 1 year (*Table 9*).

There was no difference in response rates by type of procedure, as shown in *Table 10*.

Non-responders to the 1-year questionnaire were different in a number of baseline characteristics to those who responded. Non-responders were more likely to be younger, in poorer physical and mental health, less anxious and report more GI symptoms on all four factors of the GSRQ (*Table 11*).

Primary outcome

GSRQ at 1 year

For each of the four factors of the GSRQ, patients in both groups reported lower levels of symptoms at 1 month post-endoscopy than immediately prior

TABLE 11 *Baseline characteristics for responders and non-responders at 1 year*

Characteristic	Responded at 1 year: mean (SD)		*p*-Value
	No (*n* = 555)	Yes (*n* = 1333)	
Quantitative characteristic			
Age	46.3 (15.8) *n* = 555	55.1 (14.0) *n* = 1333	<0.001
EuroQol	0.63 (0.30) *n* = 456	0.68 (0.27) *n* = 1246	<0.001
PCS – SF-36	45.1 (7.70) *n* = 424	44.7 (7.23) *n* = 1170	0.4
MCS – SF-36	40.3 (7.33) *n* = 424	42.3 (6.73) *n* = 1170	<0.001
STAI (6)	45.9 (14.8) *n* = 443	41.2 (14.2) *n* = 1216	<0.001
GSRQ: upper GI	22.3 (19.8) *n* = 486	16.8 (17.9) *n* = 1285	<0.001
GSRQ: lower GI	31.8 (30.1) *n* = 482	27.9 (28.9) *n* = 1283	0.02
GSRQ: wind	44.9 (26.1) *n* = 488	40.6 (25.3) *n* = 1286	0.01
GSRQ: defaecation	21.3 (21.9) *n* = 483	21.3 (21.9) *n* = 1280	0.03
Binary characteristic			
Female	269 (48.5)	718 (53.9)	0.03
Urgency:			
Routine	334 (60.2)	793 (59.5)	0.6
Soon	175 (31.5)	409 (30.7)	
Urgent	40 (7.2)	105 (7.9)	
Very urgent	6 (1.1)	26 (2.0)	
Type of procedure:			
OGD	320 (57.7)	779 (58.4)	0.8
FS	235 (42.3)	554 (41.6)	

TABLE 12 *GSRQ scores – unadjusted figures: mean score[a] (SE)*

Factor	Doctors			Nurses		
	Baseline Max. *n* = 868	1 month Max. *n* = 701	1 year Max. *n* = 660	Baseline Max. *n* = 906	1 month Max. *n* = 724	1 year Max. *n* = 667
Factor 1: upper GI	18.4 (0.62)	13.3 (0.60)	12.4 (0.60)	18.2 (0.63)	14.4 (0.62)	12.9 (0.63)
Factor 2: lower GI	29.1 (1.00)	24.9 (0.99)	21.9 (0.98)	28.9 (0.97)	23.6 (0.97)	22.8 (0.98)
Factor 3: wind	42.1 (0.88)	34.7 (0.95)	33.2 (0.95)	41.5 (0.84)	35.1 (0.89)	31.7 (0.93)
Factor 4: defaecation	21.6 (0.74)	20.2 (0.83)	18.1 (0.79)	22.8 (0.76)	21.1 (0.81)	20.6 (0.84)

[a] Scored 0 (no symptoms)–100.

to their endoscopy, and the level of symptoms decreased still further at 1 year (*Table 12*). Patients reported highest levels of wind-related symptoms, followed by lower GI symptoms, upper GI symptoms and, lastly, defecation-related symptoms (which included constipation or bleeding seen on defecation). Overall mean upper GI symptoms decreased from 18.3 (SD 18.6) at baseline to 13.9 (SD 16.3) at 1 month and to 12.7 (SD 15.9) at 1 year. Lower GI symptoms decreased from 29.0 (SD 29.3) at baseline to 24.2 (SD 26.2) at 1 month and to 22.3 (SD 25.0) at 1 year. Wind-related symptoms decreased from 41.8 (SD 25.6) at baseline to 34.9 (SD 24.6) at 1 month and to 32.5 (SD 24.3) at 1 year. Defecation-related symptoms decreased from 22.2 (SD 22.4) at baseline to 20.6 (SD 21.9) at 1 month and to 19.3 (SD 20.8) at 1 year.

Both groups of patients followed a similar pattern over time, although patients in the doctor group experienced a slightly higher level of wind-related symptoms and a slightly lower level of defecation-related symptoms than patients in the nurse group at baseline (but not statistically significant) (*Figures 4–7*).

For both types of procedure there was a marked improvement in upper GI and wind-related symptoms at 1 month and 1 year post-endoscopy. For loose bowel and defaecation-related symptoms there was an improvement for flexible sigmoidoscopy patients but less of an improvement for OGD patients (*Tables 13* and *14*).

After adjusting for baseline GSRQ score, hospital, type of procedure (OGD or FS) and age using

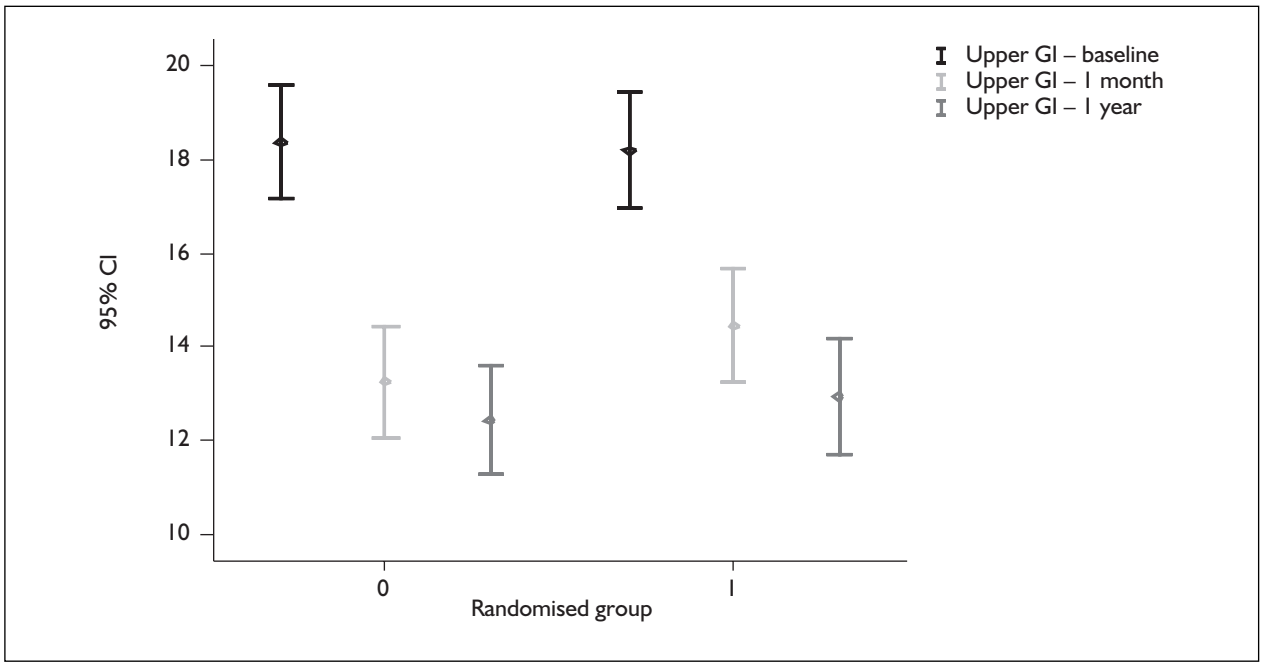

FIGURE 4 *Baseline, 1-month and 1-year GSRQ scores by randomised group: GSRQ factor 1 – upper GI (0 = doctor group; 1 = nurse group)*

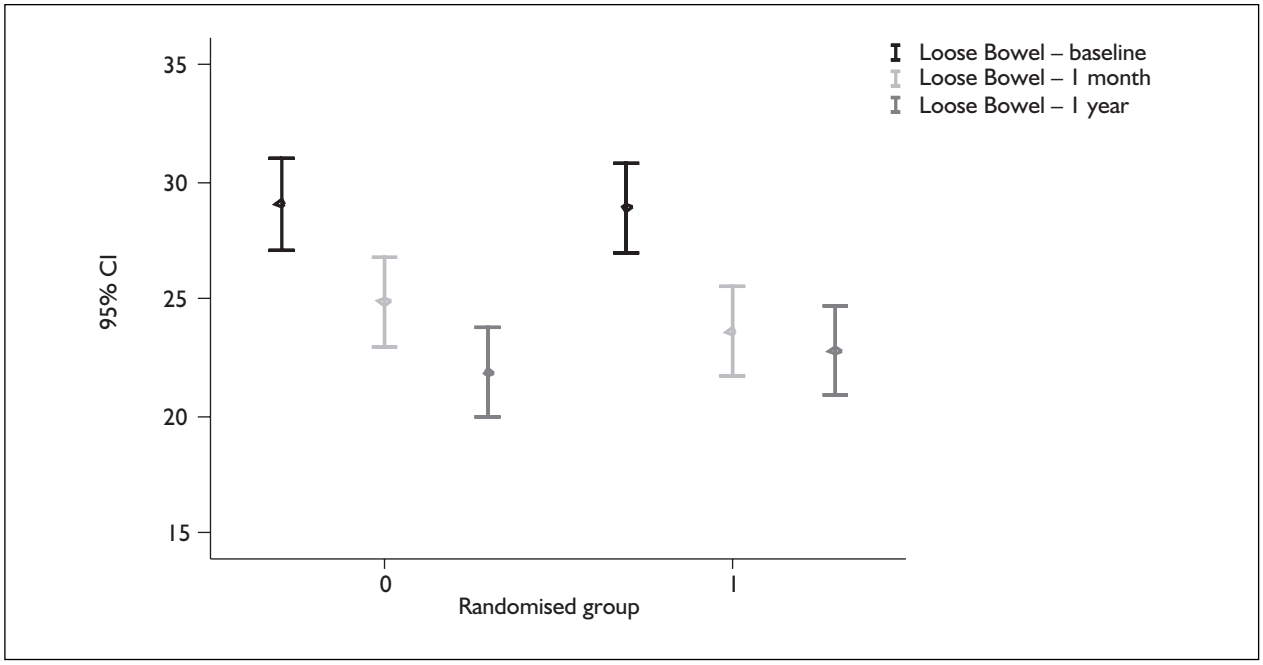

FIGURE 5 *Baseline, 1-month and 1-year GSRQ scores by randomised group: GSRQ factor 2 – loose bowel (0 = doctor group; 1 = nurse group)*

analysis of covariance, there was no evidence of a statistically significant difference between the patients in the doctor group and those in the nurse group on any of the four GSRQ factors at 1 year (*Table 15*). Mean differences were 0.61 (95% CI –1.92 to 0.70; $p = 0.363$) for upper GI symptoms, 1.46 (95% CI –3.67 to 0.75; $p = 0.194$) for lower GI symptoms and 1.23 (95% CI –3.10 to 0.64; $p = 0.198$) for defecation-related symptoms, all in favour of a better outcome following endoscopy by a doctor. For wind-related symptoms the mean difference was 0.98 (95% CI –1.04 to 3.00; $p = 0.340$) in favour of nurses. This finding did not change when the data were analysed by type of procedure.

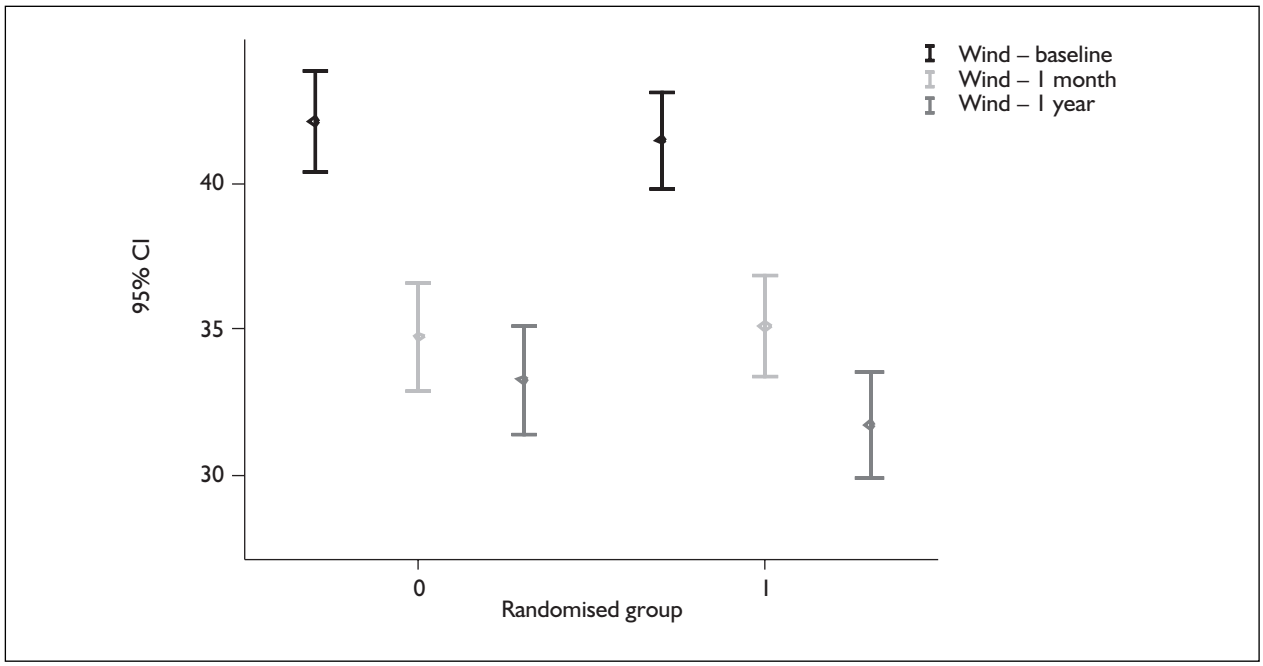

FIGURE 6 *Baseline, 1-month and 1-year GSRQ scores by randomised group: GSRQ factor 3 – wind (0 = doctor group; 1 = nurse group)*

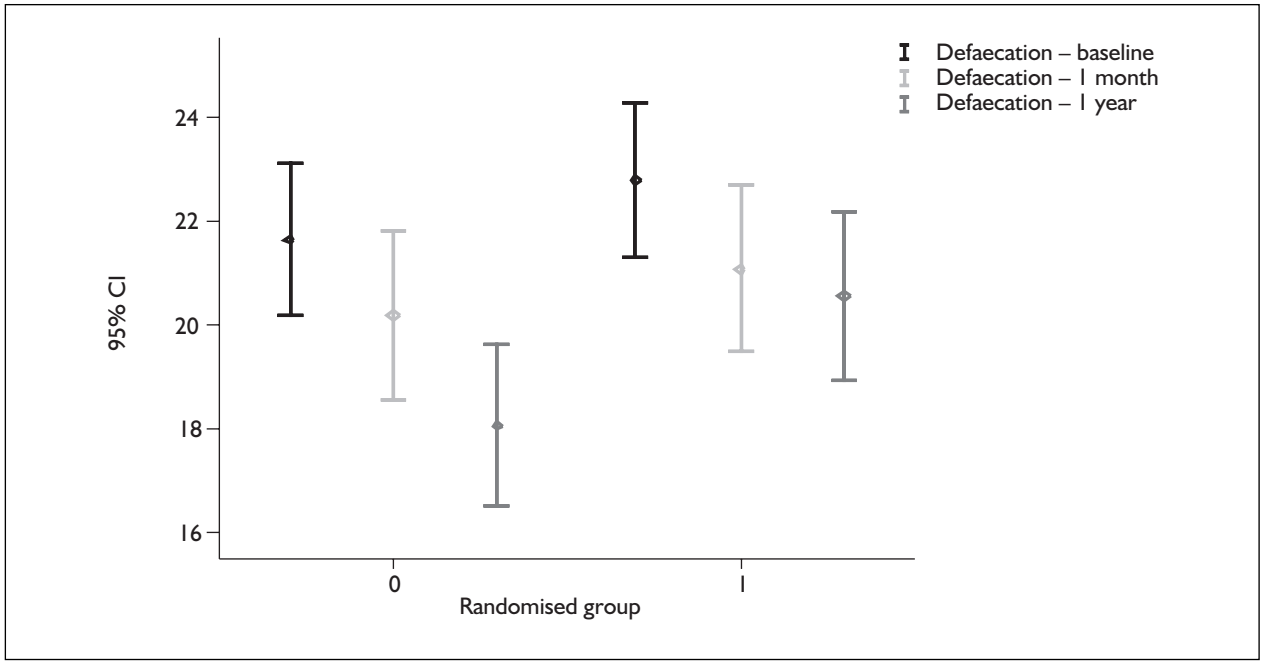

FIGURE 7 *Baseline, 1-month and 1-year GSRQ scores by randomised group: GSRQ factor 4 – defaecation (0 = doctor group; 1 = nurse group)*

Overall change from baseline

Across all trial patients, there was a highly significant improvement at 1 year post-endoscopy for all four GSRQ factors. The greatest improvement was seen for wind-related symptoms (mean 8.25; 95% CI 7.12 to 9.39) and the smallest improvement for defaecation-related symptoms (mean 2.02; 95% CI 0.94 to 3.09). Smaller but still significant improvements were detected at 1 month post-endoscopy for lower GI symptoms, upper GI symptoms and wind-related symptoms; however, the mean improvement for defaecation-related symptoms was not statistically significant (mean 0.87; 95% CI –0.07 to 1.81).

TABLE 13 *GSRQ scores – unadjusted figures for OGD patients: mean score[a] (SE)*

Factor	Doctors			Nurses		
	Baseline Max. *n* = 364	1 month Max. *n* = 277	1 year Max. *n* = 267	Baseline Max. *n* = 392	1 month Max. *n* = 309	1 year Max. *n* = 285
Factor 1: upper GI	25.5 (1.00)	16.9 (1.02)	15.5 (1.08)	25.2 (1.01)	17.6 (1.01)	15.9 (1.09)
Factor 2: lower GI	21.8 (1.35)	20.6 (1.39)	20.3 (1.45)	23.4 (1.31)	21.8 (1.40)	21.6 (1.43)
Factor 3: wind	48.3 (1.31)	39.8 (1.51)	36.8 (1.55)	45.9 (1.25)	37.5 (1.31)	34.7 (1.45)
Factor 4: defaecation	18.8 (1.10)	20.8 (1.39)	17.5 (1.25)	18.5 (1.04)	19.0 (1.18)	18.6 (1.21)

[a] Scored 0 (no symptoms)–100.

TABLE 14 *GSRQ scores – unadjusted figures for FS patients: mean score[a] (SE)*

Factor	Doctors			Nurses		
	Baseline Max. *n* = 504	1 month Max. *n* = 424	1 year Max. *n* = 393	Baseline Max. *n* = 514	1 month Max. *n* = 415	1 year Max. *n* = 382
Factor 1: upper GI	13.2 (0.70)	10.9 (0.73)	10.3 (0.68)	12.8 (0.71)	12.1 (0.76)	10.8 (0.73)
Factor 2: lower GI	34.3 (1.37)	27.7 (1.35)	23.0 (1.31)	33.1 (1.37)	25.0 (1.33)	23.7 (1.34)
Factor 3: wind	37.6 (1.14)	31.4 (1.20)	30.9 (1.19)	38.1 (1.11)	33.3 (1.21)	29.4 (1.21)
Factor 4: defaecation	23.7 (0.99)	19.8 (1.04)	18.5 (1.01)	26.0 (1.07)	22.6 (1.12)	22.0 (1.14)

[a] Scored 0 (no symptoms)–100.

TABLE 15 *Primary outcome measure – differences in 1-year GSRQ scores: adjusted mean score[a] (SE)*

Factor	Doctor Max. *n* = 641[b]	Nurse Max. *n* = 655[b]	*p*-Value	Difference[c] (95% CI)
Factor 1: upper GI	11.76 (0.69) *n* = 634	12.37 (0.70) *n* = 645	0.363	–0.61 (–1.92 to 0.70)
Factor 2: lower GI	21.35 (1.16) *n* = 624	22.82 (1.17) *n* = 639	0.194	–1.46 (–3.67 to 0.75)
Factor 3: wind	32.62 (1.06) *n* = 635	31.64 (1.07) *n* = 646	0.340	+0.98 (–1.04 to 3.00)
Factor 4: defaecation	18.68 (0.98) *n* = 623	19.91 (0.991) *n* = 639	0.198	–1.23 (–3.10 to 0.64)

[a] Adjusted for baseline score, centre, type of procedure and age using analysis of covariance. Scored 0 (no symptoms)–100.
[b] Max. *n* = total number of patients with baseline data who completed the 1-year questionnaire.
[c] Difference = doctor – nurse, hence a negative difference indicates that patients in the nurse group score worse on average than patients in the doctor group and a positive difference indicates that patients in the nurse group score better on average than patients in the doctor group.

When the two groups were compared, there was no significant difference in the change in GSRQ scores following endoscopy by a doctor or a nurse, at either 1 month or 1 year.

Secondary outcomes

GSRQ at 1 month

After adjusting for baseline GSRQ score, hospital, type of procedure and age using analysis of covariance, there was no evidence of a statistically significant difference between the patients in the doctor group and those in the nurse group on three of the four GSRQ factors at one month (*Table 16*). For lower GI symptoms the mean difference was 0.77 (95% CI –1.21 to 2.75; $p = 0.447$) in favour of nurses, for wind-related symptoms the mean difference was 0.87 (95% CI –2.66 to 0.92; $p = 0.342$) in favour of doctors and for defecation-related symptoms the mean difference was 0.69 (95% CI –1.03 to 2.42; $p = 0.431$) in favour of nurses. However, for upper GI symptoms at 1 month there was slight evidence of a statistically significant difference between patients in the doctor group and those in the

TABLE 16 *Secondary outcome measure – differences in 1-month GSRQ scores: adjusted mean score[a] (SE)*

Factor	Doctor Max. n = 681[b]	Nurse Max. n = 706[b]	p-Value	Difference[c] (95% CI)
Factor 1: upper GI	12.60 (0.58) n = 675	13.80 (0.57) n = 701	0.036	–1.20 (–2.33 to –0.080)
Factor 2: lower GI	25.03 (1.02) n = 675	24.26 (1.01) n = 698	0.447	+0.77 (–1.21 to 2.75)
Factor 3: wind	34.39 (0.92) n = 677	35.25 (0.91) n = 703	0.342	–0.87 (–2.66 to 0.92)
Factor 4: defaecation	21.33 (0.90) n = 672	20.63 (0.88) n = 695	0.431	+0.69 (–1.03 to 2.42)

[a] Adjusted for baseline score, centre, type of procedure and age using analysis of covariance. Scored 0 (no symptoms)–100.
[b] Max. n = total number of patients with baseline data who completed the 1-month questionnaire.
[c] Difference = doctor – nurse, hence a negative difference indicates that patients in the nurse group score worse on average than patients in the doctor group and a positive difference indicates that patients in the nurse group score better on average than patients in the doctor group.

nurse group: the mean difference was 1.20 (95% CI –2.33 to 0.08; $p = 0.036$) in favour of doctors. When Bonferroni correction is applied owing to the number of multiple tests conducted, this p-value would have to be less than 0.0125 in order to provide statistical evidence of a difference between groups. Hence it can be concluded that this difference is likely to have arisen by chance and it is unlikely that there is a true difference between patients in the doctor group and those in the nurse group.

SF-36 at 1 day, 1 month and 1 year

Patients in both groups reported improved SF-36 scores on five of the eight subscales at 1 year post-endoscopy compared with before endoscopy (physical functioning, role limitation due to physical problems, role limitation due to mental problems, mental health and vitality). However, social functioning, pain and general health were lower at 1 year than at baseline for both groups. Similarly, for both groups, the PCS was lower at 1 year, whereas the mental component summary (MCS) was higher at 1 year (*Table 17*).

After adjusting for baseline SF-36 score, hospital, type of procedure and age using analysis of covariance, there was no evidence of a statistically significant difference between the patients in the doctor group and those in the nurse group on any of the eight subscales or two summary scores at one day (*Table 18*) or one month (*Table 19*). However, at 1 year, although there was no evidence of a difference between groups on seven subscales or two summary scores, there was slight evidence of a statistically significant difference for social functioning: the mean difference was 1.10 (95% CI –2.15 to 0.06; $p = 0.039$) in favour of doctors (*Table 20*). When Bonferroni correction is applied owing to the number of multiple tests conducted, this p-value would have to be less than 0.005 in order to provide statistical evidence of a difference between groups. Hence it can be concluded that this difference is likely to have arisen by chance and it is unlikely there is a true difference between patients in the doctor group and those in the nurse group.

Anxiety at 1 day, 1 month and 1 year

Although patients in both groups reported slightly increasing levels of anxiety over the trial (*Table 17*), after adjusting for baseline anxiety, hospital, type of procedure and age using analysis of covariance, there was no evidence of a statistically significant difference in anxiety levels between the patients in the doctor group and those in the nurse group at 1 day (*Table 18*), 1 month (*Table 19*) or 1 year (*Table 20*).

Patient satisfaction

Patient satisfaction differed markedly between patients in the doctor group and those in the nurse group, as measured at 1 day post-endoscopy by the GESQ. There was strong evidence of a statistically significant difference in favour of nurses on all four factors of the GESQ (*Table 21*). The largest difference was for 'information after endoscopy' (mean difference 4.84; 95% CI 2.53 to 7.15; $p < 0.001$), followed by 'pain and discomfort' (mean difference 3.35; 95% CI 1.19 to 5.50; $p < 0.01$), 'information before endoscopy' (mean difference 2.97; 95% CI 1.45 to 4.48; $p < 0.001$) and 'skills and hospital' (mean difference 2.57; 95% CI 1.35 to 3.79; $p < 0.001$).

OGD and FS patients expressed different levels of satisfaction. In general, OGD patients were more satisfied than FS patients, although OGD patients were much less satisfied about information received after their endoscopy (*Table 22*). The differences in satisfaction between patients in the doctor group and those in the nurse group were

TABLE 17 *Secondary outcome measures (SF36, STAI) – unadjusted figures: mean score (SE)*

	Doctor				Nurse			
	Baseline Max. *n* = 867[a]	**1 day Max. *n* = 731[a]**	**1 month Max. *n* = 697[a]**	**1 year Max. *n* = 657[a]**	**Baseline Max. *n* = 891[a]**	**1 day Max. *n* = 784[a]**	**1 month Max. *n* = 720[a]**	**1 year Max. *n* = 667[a]**
EQ-5D[b]	0.676 (0.00924)	0.708 (0.00968)	0.720 (0.00983)	0.725 (0.0102)	0.663 (0.00969)	0.706 (0.00951)	0.706 (0.0102)	0.703 (0.0110)
SF-36[c]								
Physical functioning	73.3 (0.98)	73.2 (1.06)	73.9 (1.11)	74.0 (1.14)	71.0 (0.99)	72.8 (1.00)	71.9 (1.10)	72.2 (1.13)
Social functioning	49.6 (0.36)	47.8 (0.40)	49.5 (0.38)	48.9 (0.36)	49.4 (0.35)	48.1 (0.37)	49.1 (0.35)	48.2 (0.38)
Role limitation – physical	69.0 (1.11)	73.9 (1.16)	71.9 (1.17)	71.8 (1.23)	66.9 (1.10)	73.1 (1.09)	69.8 (1.16)	69.9 (1.21)
Role limitation – mental	74.5 (1.02)	78.1 (1.07)	78.6 (1.05)	77.6 (1.10)	73.2 (1.02)	78.9 (1.01)	77.4 (1.08)	76.5 (1.14)
Mental health	62.5 (0.39)	64.8 (0.44)	63.9 (0.39)	63.3 (0.42)	61.5 (0.38)	64.7 (0.42)	63.5 (0.41)	63.0 (0.41)
Vitality	53.1 (0.40)	56.6 (0.49)	54.6 (0.41)	53.6 (0.46)	52.8 (0.40)	57.3 (0.42)	53.8 (0.42)	53.1 (0.42)
Pain	51.1 (0.33)	48.3 (0.36)	50.0 (0.35)	49.9 (0.34)	51.6 (0.32)	48.8 (0.34)	50.3 (0.35)	49.9 (0.34)
General health	57.9 (0.43)	56.9 (0.45)	57.4 (0.46)	56.5 (0.49)	57.1 (0.42)	56.4 (0.46)	56.6 (0.48)	55.9 (0.47)
PCS	45.2 (0.26)	44.7 (0.25)	44.7 (0.27)	44.8 (0.28)	44.4 (0.26)	44.3 (0.25)	44.1 (0.28)	44.3 (0.28)
MCS	41.8 (0.25)	43.2 (0.25)	43.0 (0.25)	42.5 (0.26)	41.7 (0.27)	43.7 (0.24)	43.0 (0.26)	42.4 (0.27)
STAI[d]								
State anxiety	42.8 (0.51)	39.2 (0.49)	38.7 (0.51)	38.3 (0.51)	42.1 (0.50)	38.8 (0.45)	38.3 (0.50)	38.4 (0.52)
Trait anxiety	NA	40.7 (0.47)	39.5 (0.48)	39.4 (0.48)	NA	40.3 (0.44)	39.8 (0.48)	39.6 (0.50)

NA, not applicable.
[a] Max. *n* = maximum number of patients with data for any one subscale.
[b] Scored 0 (poor health)–1.
[c] Scored 0 (poor health)–100.
[d] Scored 20 (high anxiety)–80.

TABLE 18 *Differences in 1-day secondary outcome measures: adjusted mean score[a] (SE)*

	Doctor Max. *n* = 717[b]	Nurse Max. *n* = 771[b]	*p*-Value	Difference[c] (95% CI)
EQ-5D[d]	0.705 (0.009) *n* = 672	0.707 (0.009) *n* = 718	0.820	+0.002 (–0.016 to 0.020)
SF-36[e]				
Physical functioning	72.62 (0.663) *n* = 700	73.56 (0.643) *n* = 748	0.165	+0.94 (–0.39 to 2.27)
Social functioning	47.59 (0.543) *n* = 690	47.95 (0.528) *n* = 730	0.513	+0.37 (–0.73 to 1.46)
Role limitation – physical	73.93 (1.055) *n* = 675	74.76 (1.016) *n* = 727	0.441	+0.83 (–1.28 to 2.94)
Role limitation – mental	79.00 (1.082) *n* = 678	80.05 (1.046) *n* = 726	0.345	+1.05 (–1.13 to 3.23)
Mental health	65.35 (0.546) *n* = 693	65.43 (0.531) *n* = 737	0.895	+0.074 (–1.02 to 1.17)
Vitality	56.20 (0.597) *n* = 702	56.93 (0.581) *n* = 744	0.228	+0.74 (–0.46 to 1.93)
Pain	48.19 (0.489) *n* = 696	48.67 (0.477) *n* = 725	0.340	+0.48 (–0.51 to 1.46)
General health	56.53 (0.458) *n* = 684	56.75 (0.443) *n* = 723	0.633	+0.22 (–0.70 to 1.14)
PCS	44.52 (0.221) *n* = 623	44.49 (0.214) *n* = 661	0.887	–0.033 (–0.48 to 0.42)
MCS	43.56 (0.291) *n* = 623	43.98 (0.281) *n* = 661	0.169	+0.42 (–0.18 to 1.01)
STAI[f]				
State anxiety	38.63 (0.450) *n* = 667	38.96 (0.436) *n* = 703	0.475	+0.33 (–0.57 to 1.23)

[a] Adjusted for baseline score, centre, type of procedure and age using analysis of covariance.
[b] Max. *n* = total number of patients with baseline data who completed the 1-day questionnaire.
[c] Difference = nurse – doctor, hence a negative difference indicates that patients in the nurse group score worse on average than patients in the doctor group and a positive difference indicates that patients in the nurse group score better on average than patients in the doctor group.
[d] Scored 0 (poor health)–1.
[e] Scored 0 (poor health)–100.
[f] Scored 20 (high anxiety)–80.

TABLE 19 *Differences in 1-month secondary outcome measures: adjusted mean score[a] (SE)*

	Doctor Max. *n* = 681[b]	Nurse Max. *n* = 706[b]	*p*-Value	Difference[c] (95% CI)
EQ-5D[d]	0.712 (0.010) *n* = 648	0.705 (0.010) *n* = v661	0.495	–0.007 (–0.027 to 0.013)
SF-36[e]				
Physical functioning	73.41 (0.773) *n* = 666	73.40 (0.762) *n* = 689	0.984	–0.016 (–1.51 to 1.48)
Social functioning	49.46 (0.514) *n* = 660	48.86 (0.510) *n* = 673	0.511	–0.61 (–1.61 to 0.40)
Role limitation – physical	72.17 (1.064) *n* = 645	71.76 (1.050) *n* = 668	0.703	–0.40 (–2.48 to 1.67)
Role limitation – mental	78.59 (1.113) *n* = 647	77.92 (1.100) *n* = 662	0.550	–0.66 (–2.83 to 1.51)
Mental health	63.68 (0.527) *n* = 664	63.61 (0.523) *n* = 679	0.887	–0.074 (–1.10 to 0.95)
Vitality	54.26 (0.552) *n* = 672	53.76 (0.549) *n* = 686	0.356	–0.51 (–1.58 to 0.57)
Pain	50.36 (0.476) *n* = 660	50.52 (0.474) *n* = 667	0.743	+0.16 (–0.78 to 1.09)
General health	57.58 (0.540) *n* = 657	57.12 (0.534) *n* = 672	0.387	–0.46 (–1.51 to 0.59)
PCS	45.00 (0.242) *n* = 598	44.75 (0.239) *n* = 612	0.308	–0.25 (–0.73 to 0.23)
MCS	42.90 (0.302) *n* = 598	42.92 (0.298) *n* = 612	0.957	+0.016 (–0.60 to 0.61)
STAI[f]				
State anxiety	37.71 (0.535) *n* = 634	37.86 (0.528) *n* = 645	0.772	+0.15 (–0.89 to 1.20)

[a] Adjusted for baseline score, centre, type of procedure and age using analysis of covariance.
[b] Max. *n* = total number of patients with baseline data who completed the 1-month questionnaire.
[c] Difference = nurse – doctor, hence a negative difference indicates that patients in the nurse group score worse on average than patients in the doctor group and a positive difference indicates that patients in the nurse group score better on average than patients in the doctor group.
[d] Scored 0 (poor health)–1.
[e] Scored 0 (poor health)–100.
[f] Scored 20 (high anxiety)–80.

TABLE 20 *Differences in 1-year secondary outcome measures: adjusted mean score[a] (SE)*

	Doctor Max. *n* = 641[b]	Nurse Max. *n* = 653[b]	*p*-Value	Difference[c] (95% CI)
EQ-5D[d]	0.722 (0.012) *n* = 610	0.704 (0.012) *n* = 620	0.122	–0.018 (–0.041 to 0.005)
SF-36[e]				
Physical functioning	73.76 (0.950) *n* = 631	73.01 (0.963) *n* = 639	0.414	–0.75 (–2.56 to 1.06)
Social functioning	48.88 (0.548) *n* = 625	47.78 (0.555) *n* = 627	0.039#	–1.10 (–2.15 to –0.055)
Role limitation – physical	72.77 (1.218) *n* = 609	72.10 (1.228) *n* = 621	0.441	–0.67 (–3.00 to 1.65)
Role limitation – mental	78.20 (1.325) *n* = 609	77.93 (1.339) *n* = 616	0.837	–0.27 (–2.81 to 2.28)
Mental health	62.79 (0.566) *n* = 621	62.92 (0.575) *n* = 628	0.831	+0.12 (–0.97 to 1.20)
Vitality	53.24 (0.599) *n* = 628	53.04 (0.608) *n* = 635	0.724	–0.20 (–1.34 to 0.95)
Pain	50.18 (0.496) *n* = 624	50.11 (0.504) *n* = 621	0.882	–0.071 (–1.02 to 0.88)
General health	55.46 (0.595) *n* = 609	55.09 (0.598) *n* = 631	0.525	–0.37 (–1.50 to 0.77)
PCS	45.03 (0.227) *n* = 559	44.61 (0.278) *n* = 575	0.130	–0.41 (–0.95 to 0.12)
MCS	42.61 (0.342) *n* = 559	42.51 (0.344) *n* = 575	0.757	–0.10 (–0.77 to 0.58)
STAI[f]				
State anxiety	38.25 (0.607) *n* = 599	38.81 (0.613) *n* = 594	0.344	+0.56 (–0.60 to 1.72)

[a] Adjusted for baseline score, centre, type of procedure and age using analysis of covariance.
[b] Max *n* = total number of patients with baseline data who completed the 1-year questionnaire.
[c] Difference = nurse – doctor, hence a negative difference indicates that patients in the nurse group score worse on average than patients in the doctor group and a positive difference indicates that patients in the nurse group score better on average than patients in the doctor group.
[d] Scored 0 (poor health)–1.
[e] Scored 0 (poor health)–100.
[f] Scored 20 (high anxiety)–80.

TABLE 21 *Patient satisfaction – GESQ (1 day post-endoscopy): mean score[a] (SE)*

Factor	Doctor Max. *n* = 737	Nurse Max. *n* = 789	Difference[b] 95% CI
Factor 1: skills and hospital	14.54 (0.46)	11.97 (0.42)	2.57*** (1.35 to 3.79)
Factor 2: pain and discomfort	33.60 (0.80)	30.25 (0.75)	3.35** (1.19 to 5.50)
Factor 3: information quality before endoscopy	21.24 (0.54)	18.27 (0.55)	2.97*** (1.45 to 4.48)
Factor 4: information after endoscopy	21.97 (0.88)	17.13 (0.79)	4.84*** (2.53 to 7.15)

[a] Scored 0 (satisfied)–100 (unsatisfied).
[b] * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$.

TABLE 22 *Patient satisfaction – GESQ (1 day post-endoscopy) for OGD patients: mean score[a] (SE)*

Factor	Doctor Max. *n* = 290	Nurse Max. *n* = 337	Difference[b] 95% CI
Factor 1: skills and hospital	13.84 (0.71)	11.45 (0.63)	2.39* (0.53 to 4.25)
Factor 2: pain and discomfort	26.11 (1.09)	24.44 (1.08)	1.67 (–1.36 to 4.70)
Factor 3: information quality before endoscopy	18.94 (0.76)	17.25 (0.78)	1.69 (–0.47 to 3.85)
Factor 4: information after endoscopy	26.29 (1.57)	21.47 (1.46)	4.81* (0.58 to 9.05)

[a] Scored 0 (satisfied)–100 (unsatisfied).
[b] * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$.

TABLE 23 *Patient satisfaction – GESQ (1 day post-endoscopy) for FS sigmoidoscopy patients: mean score[a] (SE)*

Factor	Doctor Max. *n* = 447	Nurse Max. *n* = 452	Difference[b] 95% CI
Factor 1: skills and hospital	14.99 (0.61)	12.36 (0.56)	2.64** (1.01 to 4.26)
Factor 2: pain and discomfort	38.46 (1.05)	34.57 (0.99)	3.88** (1.04 to 6.73)
Factor 3: information quality before endoscopy	22.73 (0.74)	19.04 (0.75)	3.69*** (1.63 to 5.76)
Factor 4: information after endoscopy	19.43 (1.03)	14.23 (0.85)	5.20*** (2.60 to 7.80)

[a] Scored 0 (satisfied)–100 (unsatisfied).
[b] * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$.

TABLE 24 *Trial patients changing allocated endoscopist*

	n (%)		
	Doctor (*n* = 931)	Nurse (*n* = 957)	*p*-Value
Change of endoscopist	177 (19.0)	50 (5.2)	<0.001
Reason for change:			
Patient request	3 (1.7)	1 (2.0)	
Staffing problems	112 (63.3)	20 (40.0)	
Clinical reason	1 (0.6)	7 (14.0)	
Administrative reason	4 (2.3)	10 (20.0)	
No reason given	42 (23.7)	4 (8.0)	
Reason unclear	15 (8.5)	18 (36.0)	

again markedly in favour of nurse for FS patients, with slightly higher mean differences than overall (*Table 23*). However, for OGD patients the differences in satisfaction between groups were less but still in favour of nurses (*Table 22*). Two factors were statistically significant: 'information after endoscopy' (mean difference 4.81; 95% CI 0.58 to 9.05; $p < 0.05$) and 'skills and hospital' (mean difference 2.39; 95% CI 0.53 to 4.25; $p < 0.05$), but there was no evidence that the other two factors, 'pain and discomfort' and 'information before endoscopy', were different between the two groups.

Patient acceptability

A total of 227 patients changed from their randomised endoscopist (*Table 24*). In the doctor group, 177 (19%) patients were endoscoped by a nurse, whereas only 50 (5%) patients in the nurse group were endoscoped by a doctor. Most of these changes were due to staffing issues, such as the endoscopist being required for other duties in the hospital, away or otherwise. This was much more common in the doctor group (63 versus 40%), but was not a uniform finding across all centres.

Patient preferences

When asked at 1 year post-endoscopy, patients in both groups overwhelmingly recommended endoscopy, regardless of whether it was performed by a doctor or a nurse (87% of patients in the doctor group and 91% of patients in the nurse group) (*Table 25*). A very small minority of patients

TABLE 25 *Patients' preferences at 1 year (first-ranked option)*

	n[a] (%)		
	Doctor (*n* = 385)	Nurse (*n* = 414)	*p*-Value[b]
Would recommend endoscopy with either doctor or nurse	333 (87)	376 (91)	0.046
Would recommend endoscopy with doctor	38 (10)	20 (5)	
Would recommend endoscopy with nurse	4 (1)	7 (2)	
Would not recommend endoscopy	10 (3)	11 (3)	

[a] *n* = Number of patients with a valid first-ranked preference.
[b] Obtained from a χ^2 test.

did not recommend endoscopy at all (3% of patients in both groups). The dominant finding was that patients would be happy to be endoscoped by either a doctor or a nurse. Of the small number who expressed a preference, there was a significant difference in favour of doctors.

The results for OGD and FS patients were similar to this overall finding, although fewer patients in the nurse OGD group did not recommend endoscopy at all (1%) (*Table 26*) whereas fewer patients in the nurse FS group recommended a doctor endoscopist (4%) (*Table 27*).

New diagnoses at 1 year

During the 12 months after endoscopy very few patients were diagnosed with a new GI complaint. There is no evidence that the numbers differ across the two groups, 14 (1.7%) in the doctor group and 10 (1.2%) in the nurse group (*Tables 28* and *29*). Less than half of those with new GI diagnosis had a major GI diagnosis, which might have been missed at a previous endoscopy; again proportions were similar between the two groups (0.7 versus 0.5%). New major diagnoses were defined as GORD, peptic ulcer, cancer of oesophagus, cancer of

TABLE 26 *Patients' preferences at 1 year (first-ranked option) for OGD patients*

	***n*[a] (%)**		
	Doctor (*n* = 142)	**Nurse (*n* = 170)**	***p*-Value[b]**
Would recommend endoscopy with either doctor or nurse	124 (87)	155 (91)	0.45
Would recommend endoscopy with doctor	12 (9)	11 (7)	
Would recommend endoscopy with nurse	1 (1)	2 (1)	
Would not recommend endoscopy	5 (4)	2 (1)	

[a] *n* = Number of patients with a valid first-ranked preference.
[b] Obtained from a χ^2 test.

TABLE 27 *Patients' preferences at 1 year (first-ranked option) for FS patients*

	***n*[a] (%)**		
	Doctor (*n* = 385)	**Nurse (*n* = 414)**	***p*-Value [b]**
Would recommend endoscopy with either doctor or nurse	209 (86)	221 (91)	0.017
Would recommend endoscopy with doctor	26 (11)	9 (4)	
Would recommend endoscopy with nurse	3 (1)	5 (2)	
Would not recommend endoscopy	5 (2)	9 (4)	

[a] *n* = Number of patients with a valid first-ranked preference.
[b] Obtained from a χ^2 test.

TABLE 28 *New GI diagnoses in 1 year since endoscopy analysed by intention-to-scope*

	***n* (%)**		
	Doctor (*n* = 818)	**Nurse (*n* = 853)**	***p*-Value[a]**
Patients with a new GI diagnosis	14/818 (1.7)	10/853 (1.2)	0.4
Patients with a new major GI diagnosis	6/818 (0.7)	4/853 (0.5)	0.5

[a] Fisher's exact test.
Source of data: primary and secondary care records at 1 year.

TABLE 29 *New GI diagnoses in 1 year since endoscopy analysed by operator*

	n (%)		
	Doctor (*n* = 706)	**Nurse (*n* = 965)**	***p*-Value[a]**
Patients with a new GI diagnosis	15/706 (2.1)	9/965 (0.9)	0.059
Patients with a new major GI diagnosis	6/706 (0.8)	4/965 (0.4)	0.338

[a] Fisher's exact test.
Source of data: primary and secondary care records at 1 year.

stomach, Barrett's oesophagus, oesophageal varices and coeliac disease following upper GI endoscopy, and colonic polyps, carcinoma of colon, microscopic colitis, diverticulosis, proctitis, ulcerative colitis, Crohn's disease and non-specific colitis following FS.

Chapter 4

Results – comparison of clinical process by operator

This chapter gives the result of a comparison of clinical processes when endoscopy is undertaken by doctors or nurses. The analysis is by operator rather than by intention-to-scope. The subsequent clinical outcome and investigations undertaken were also analysed. The data were extracted from forms completed at the time of the endoscopy (Appendix 8) and from hospital case notes scrutinised at 1 year (Appendix 9). Data were also obtained by postal questionnaire from primary care records (Appendix 10).

To extract clinical and cost-effective data from hospital case notes, all trial centres were visited (by DD) 1 year after the last patient had been recruited at each centre. Case notes were found and reviewed for 1674 patients (86% of those recruited). Of these, 711 (42%) were endoscoped by a doctor and 963 (58%) by a nurse, reflecting the greater transfer of randomised patients from doctors to nurses for the actual procedure.

Drugs used at endoscopy

Information was available for 663 of OGD patients (239 in the doctor group and 424 in the nurse group) (*Table 30*). There were no significant differences in the use of lignocaine spray alone (54 and 56.4%) or use of diazemulus in the doctor and nurse groups. Midazolam alone was used in 40.2% and both midazolam and lignocaine spray in 5.9% in the doctor group. In comparison, midazolam alone was used in 24.5% and both midazolam and lignocaine spray in 17.9% in the nurse group. Nurses were using combined modality significantly more in comparison with doctors ($p < 0.05$ on χ^2).

A total of 105 patients (96.2%) in the doctor group and 172 (92.5%) in the nurse group had a midazolam dose of 5 mg or below (*Table 31*). No reversal agents were used in either group. Diazemulus dose is shown in *Table 32*.

TABLE 30 *Drugs used for OGD*

Doctor or nurse	Parameter	Type of sedation				Total
		Lignocaine spray	Midazolam	Both midazolam and spray[a]	Diazemulus	
Doctor	Count	129	96	14	0	239
	Expected count	132.7	72.1	32.4	1.8	239.0
	% within doctor or nurse	54	40	6	0	100
	% within type of sedation	35	48	16	0	36
	% of total	20	15	2	0	36
Nurse	Count	239	104	76	5	424
	Expected count	235.3	127.9	57.6	3.2	424.0
	% within doctor or nurse	56	25	18	1	100
	% within type of sedation	65	52	84	100	64
	% of total	36	16	12	1	64
Total	Count	368	200.0	90	5	663
	Expected count	368.0	200.0	90.0	5.0	663.0
	% within doctor or nurse	56	30	14	1	100
	% within type of sedation	100	100	100	100	100
	% of total	56	30	14	1	100

[a] One patient in the doctor group had both diazemulus and spray.
Source of data: endoscopy procedure reports and Form 1.

TABLE 31 *Dose of midazolam used for OGD*

Dose (mg)	Doctor Midazolam dose		Nurse Midazolam dose	
	Count	%	Count	%
1.0			1	1
2.0	2	2	9	5
2.5	13	12	49	27
3.0	8	7	27	15
3.5	6	6	7	4
4.0	33	30	38	21
5.0	43	39	41	22
6.0			6	3
6.5			1	1
7.0	2	2		
7.5	1	1	1	1
Mean dose (mg)	4.27		3.67[a]	

[a] Difference is statistically significant, $p < 0.0001$ (independent *t*-test).
Source of data: endoscopy procedure reports and Form 1.

TABLE 32 *Dose of diazemulus used for OGD*

Dose (mg)	Doctor Diazemulus dose		Nurse Diazemulus dose	
	Count	%	Count	%
10.0	1	1	2	1
15.0			2	1
20.0			1	1

Source of data: endoscopy procedure reports and Form 1.

Of 471 patients who had an FS performed by a doctor, 26 had midazolam, one both midazolam and pethidine and one buscopan also. Of 581 patients who had the procedure performed by a nurse, 26 had midazolam and three midazolam and buscopan. The dose of midazolam used was comparable in both groups (*Table 33*).

Distance inserted for flexible sigmoidoscopy

There was no difference between the two groups in the distance the endoscope was inserted into the colon, as recorded by the endoscopist (*Table 34*).

For OGD, nurses took slightly longer than doctors with a mean duration of 19.83 minutes compared with 18.78 minutes (95% CI around the difference –5.84 to 3.75).

TABLE 33 *Dose of midazolam used for FS*

Dose (mg)	Doctor Midazolam dose		Nurse Midazolam dose	
	Count	%	Count	%
1			1	4
2	1	4	2	8
3	1	4	9	35
3	7	26	8	31
4	2	7.4	2	7.7
5	5	56	4	15
8	1	4		
Mean dose (mg)	4.3		3.07[a]	

[a] Difference is statistically significant, $p < 0.0001$ (independent *t*-test).
Source of data: endoscopy procedure reports and Form 1.

TABLE 34 *Distance sigmoidoscope inserted*

	Mean (SD)		
	Doctor (n = 507)	Nurse (n = 507)	Difference (95% CI)
Distance inserted (cm)	55.2 (15.10)	55.8 (13.76)	–0.62 (–2.4 to 1.2)

Source of data: endoscopists' assessment as recorded on study Form 1.

TABLE 35 *Duration of examination*

Time (minutes)	Doctor	Nurse	*p*-Value
All procedures	23.5	22.41	NS
OGD	19	20	NS
FS	26	24	NS

NS, not significant.
Source of data: observation of endoscopy lists.

For FS, doctors' time was 27.79 minutes, whereas nurses' time was shorter at 24.25 minutes (95% CI around the difference in means (–0.468 to 7.55) (*Table 35*).

Clinical findings

This information was collected from actual endoscopy reports collected during trial recruitment, histology findings and final diagnosis for presenting symptoms from patients' medical records 1 year after recruitment. There was no

TABLE 36 *Findings at OGD*

Finding	Doctor (n = 289) Endoscopist diagnosis		Nurse (n = 434) Endoscopist diagnosis	
	Count	%	Count	%
Normal	87	30	79	18
Oesophagitis	68	24	90	21
Barrett's oesophagus	21	7	21	5
Oesophageal ulcer	1	0	2	0.5
Schatzki's ring	0	0	3	1
Oesophageal varices	1	0.5	1	0.5
Achalasia	1	0.5	0	0
Gastric ulcer	3	1	1	0.5
Duodenal ulcer	11	4	10	2
Gastric and duodenal ulcer	1	0.5	2	0.5
Ulcer scar/deformity	6	2	14	3
Intubation unsuccessful	1	0.5	3	1
Suspected oesophageal carcinoma	0	0	1	0.5
Pharyngeal pouch	0	0	2	0.5
Limited examination	1	0.5	1	0.5
Suspected gastric carcinoma	0	0	1	0.5
Oesophageal dysmotility	10	4	3	1
Duodenal tumour	1	0.5	0	0
Multiple (gastritis/duodenitis/hiatus/polyps)	76	26	200	46

Source of data: endoscopy procedure reports.

significant difference in the major diagnosis when procedures were performed by nurses in comparison with doctors.

Findings at endoscopy (OGD)

Some 30.1% of endoscopies were reported as normal by doctors and only 18.2% by nurses (*Table 36*). Slightly more pathology was reported in the doctor arm (7.3% Barrett's oesophagus, 5.1% peptic ulcer) in comparison with nurses (4.8% Barrett's oesophagus, 3% peptic ulcer). However, there were more multiple diagnoses including gastritis, duodenitis, hiatus hernia, gastric polyps and two cancers (one oesophageal and one gastric cancer) reported by nurses.

Histological findings (OGD)

Eight-two (30.6%) patients in the doctor arm and 202 (50.4%) of patients in the nurse arm had biopsies taken for histology (*Table 37*). This difference was statistically significant on χ^2 ($p < 0.0001$). There were no statistically significant differences in major findings but there was a difference in the proportion of patients with *H. pylori*-positive ($p < 0.01$) and negative gastritis ($p < 0.006$).

TABLE 37 *Histology results following OGD*

Results[a]	Actual endoscopist	
	Doctor (n = 268)	Nurse (n = 401)
Normal	24	49
Oesophagitis	9	23
Barrett's oesophagus	9	18
Benign gastric ulcer	1	1
H. pylori-positive gastritis*	9	33
H. pylori-negative gastritis**	19	56
Cancer of oesophagus	0	1
Cancer of stomach	0	1
Non-adenomatous polyp	4	10
Coeliac disease	0	2

[a] *$p < 0.01$; ** $p < 0.006$
Source of data: histology reports in hospital.

CLO test for *Helicobacter pylori*

Ninety-seven (37.3%) patients in the doctor arm and 206 (54.2%) patients in the nurse arm had samples taken for a CLO test (*Table 38*). It was positive in 13.8 and 15.3% and negative in 23.5 and 38.9% of patients in the doctor and nurse arms, respectively. The difference in the number of CLO tests taken was statistically significant ($p < 0.0001$).

TABLE 38 *CLO test results*[a]

	Actual endoscopist			
	Doctor (n = 268)		Nurse (n = 401)	
	Count	%	Count	%
Not done	163	63	174	46
Positive	36	14	58	15
Negative	61	24	148	39

[a] $p < 0.0001$.
Source of data: hospital records.

TABLE 39 *Final diagnosis following OGD*[a]

Diagnosis	Actual endoscopist			
	Doctor (n = 268[b])		Nurse (n = 401[b])	
	No.	%	No.	%
Normal	63	24	44	11
Hiatus hernia	54	20	127	32
Gastro-oesophageal reflux	77	29	111	28
Peptic ulcer	12	4	18	4
Carcinoma of oesophagus	0	0	1	0.5
Carcinoma of stomach	0	0	1	0.5
Barrett's oesophagus	16	6	18	4
Oesophageal varices	1	0.5	1	0.5
Coeliac disease	0	0	2	0.5
Minor abnormality	94	35	194	48

[a] Some patients had more than one diagnosis.
[b] n = Number of procedures.
Source of data: hospital records.

Final diagnosis OGD

There was no significant difference in the major diagnosis when procedures were performed by nurses in comparison with doctors (*Table 39*).

Findings at endoscopy (flexible sigmoidoscopy)

Some 45% of patients were reported as normal by doctors and 34.15% by nurses (*Table 40*); 4.7% of the nurses reported that examination was limited compared with 2.4% by doctors. Slightly more colonic polyps were reported by doctors (13.3% versus 12%), but a slight excess of colonic carcinoma (1.7 versus 1.1%) and colitis (5.1 versus 3%) was reported by nurses.

Histological findings (flexible sigmoidoscopy)

A total of 112 (26.5%) patients in the doctor arm and 183 (34.7%) in the nurse arm had samples taken for histology (*Table 41*). The difference was statistically significant ($p < 0.007$). There were no statistically significant differences in histological abnormalities in the two groups. There was more normal histology in the nurse arm in comparison with the doctor arm ($p < 0.0001$).

Final diagnosis flexible sigmoidoscopy

There was no significant difference in the major diagnosis when procedures were performed by nurses in comparison with doctors (*Table 42*).

TABLE 40 *Findings at FS*

Finding	Doctor (*n* = 466) Endoscopist diagnosis		Nurse (*n* = 579) Endoscopist diagnosis	
	Count	%	Count	%
Normal	207	45.0	196	34.1
Limited examination, no abnormality	11	2.4	27	4.7
Diverticulosis	79	17.2	90	15.7
Haemorrhoids	68	14.8	130	22.6
Colitis	14	3.0	29	5.1
Melanosis	0	0	1	0.2
Rectal ulcer	1	0.2	3	0.5
Carcinoma	5	1.1	10	1.7
Colonic polyp	61	13.3	69	12.0
Metaplastic polyp	12	2.6	7	1.2
Non-specific inflammation	2	0.4	8	1.4
Non-specific findings	0	0	4	0.7

Source of data: endoscopy procedure reports.

TABLE 41 *Histology results following FS*

Finding	Actual endoscopist	
	Doctor (*n* = 422)	Nurse (*n* = 528)
Normal[a]	28	79
Adenomatous polyp	29	30
Metaplastic polyp	32	29
Adenocarcinoma	4	7
Ulcerative colitis	4	5
Microscopic colitis	0	2
Proctitis	1	8
Non-specific colitis	3	1
	101	161

[a] Significant difference between doctors and nurses ($p < 0.0001$).
Source of data: hospital records.

Complications to patients and endoscope

There was no significant difference between the number of immediate or delayed complications identified following endoscopy by a doctor or a nurse (*Table 43*).

There were no recorded complications with the endoscope.

Need for assistance

There was no difference between doctors and nurses in the need for assistance during the procedure. Operators were asked to record

TABLE 42 *Final diagnosis following FS*

Diagnosis	Actual endoscopist			
	Doctor (*n* = 422)		Nurse (*n* = 528)	
	No.	%	No.	%
Normal	47	11	47	9
Irritable bowel syndrome	44	10	57	11
Haemorrhoids	142	34	225	43
Colonic polyp	35	8	38	7
Cancer of colon	8	2	10	2
Microscopic colitis	0	0	3	1
Diverticulosis	102	24	114	22
Proctitis	3	1	8	2
Ulcerative colitis	5	1	10	2
Crohn's colitis	1	0	0	0
Non-specific colitis	3	1	0	0

Source of data: hospital records.

TABLE 43 *Complications to patients*

	n (%)	
	Doctor (*n* = 931)	**Nurse (*n* = 957)**
Immediate complications		
None	809 (86.9)	844 (88.2)
Excessive pain	1 (0.1)	1 (0.1)
Other	1 (0.1)	1 (0.1)
Case notes not available	120 (12.9)	111 (11.6)
Delayed complications		
None	809 (86.9)	844 (88.2)
Case notes not available	122 (13.1)	113 (11.8)

Source of data: Form 1 delayed complication form and hospital records.

TABLE 44 *Need for assistance during the procedure*

	n (%)		
	Doctor (*n* = 834)	**Nurse (*n* = 864)**	***p*-Values**
Assistance required?			
Yes	27 (3.2%)	40 (4.6%)	0.17

Source of data: Form 1.

whether "during the procedure did you discuss the findings or receive help from a colleague (excluding endoscopy assistants?)" (*Table 44*).

The 'assistance' required included confirmation of endoscopic findings, help with a diagnostic procedure (including biopsy), help with an unexpected therapeutic procedure, prescribing advice and advice on future management.

Need for subsequent investigation

Tables 45 and *46* describe the investigations requested after the endoscopy, as extracted from the case notes 1 year after the procedure. These were requested for the presenting symptom after recruitment into trial, that is, directly after endoscopy or during subsequent review in the outpatient clinics.

Patients in the OGD arm had a range of GI investigations: repeat OGD (11% in nurse group versus 6% in doctor group), barium enema (4% in nurse group and 3% in doctor group) and colonoscopy (3% in each group). The range of GI-related investigations is listed in *Table 45*.

Patients in the FS arm in both the doctor and nurse group had comparable GI-related investigations: barium enema (15% in the nurse group versus 13% in the doctor group), colonoscopy (10% in the nurse group versus 9% in the doctor group), repeat FS (4% in each group) and OGD (5% in the nurse group versus 1% in the doctor group). The range of GI-related investigations is listed in *Table 46*.

Completeness of endoscopy reporting

There were 735 OGD reports (290 by doctors and 445 by nurses) (*Table 47*). There was no significant difference in 23 of 31 contents demographic details, date of procedure, referral source, endoscopist, whether supervised, indication for procedure, ASA status, instrument used, endoscopic findings, specimens obtained, endoscopic diagnosis, therapeutic interventions, results of therapeutic interventions, extent of examination, limitations of examination, time taken, complications, images, annotated text to images, post-procedure complications, information given, patient satisfaction and final diagnosis.

There was a significant difference in six of 31 contents ($p < 0.05$) favouring nurses in episode type, urgency, sedation, free-text comments, discharge and follow-up arrangements. There was a significant difference favouring doctors in two of 31 contents ($p < 0.05$) for procedure and treatment recommended.

There were 1049 FS reports (470 by doctors and 579 by nurses) (*Table 48*). There was no significant difference in 19 of 31 contents demographic details, date of procedure, referral source,

TABLE 45 *Subsequent investigations following OGD*

Investigation post-procedure	*n*		%	
	Doctor (*n* = 268)	Nurse (*n* = 401)	Doctor	Nurse
Barium enema	8	17	3	4
Barium follow-through	2	0	1	0
Barium meal	2	4	1	1
Barium meal and follow-through	0	1	0	0
Bernstein test	0	1	0	0
Bone scan	0	1	0	0
Bronchoscopy	0	1	0	0
Colonoscopy	8	11	3	3
Computed tomography abdomen	2	8	1	2
Computed tomography abdomen and thorax	0	1	0	0
Computed tomography cologram	0	3	0	1
Endoanal ultrasound	1	0	0	0
ERCP	1	2	0	0
Endoscopic ultrasound	0	1	0	0
FS	7	7	3	2
Magnetic resonance cholangio-pancreatography	2	0	1	0
Magnetic resonance imaging	0	2	0	0
Oesophageal manometry	4	10	1	2
Oesophageal pH monitoring	3	10	1	2
OGD	16	43	6	11
Urea breath test	5	10	2	2
Ultrasound of abdomen	10	15	4	4

Source of data: hospital records examined 1 year post-procedure.

TABLE 46 *Subsequent investigations following FS*

Investigation post-procedure	*n*		%	
	Doctor (*n* = 422)	Nurse (*n* = 528)	Doctor	Nurse
Anorectal physiology	1	1	0	0
Barium enema	56	81	13	15
Barium follow-through	1	3	0	1
Barium meal	0	1	0	0
Barium swallow	2	3	0	1
Bowel transit study	0	1	0	0
Colonoscopy	36	54	9	10
Computed tomography abdomen	9	11	2	2
Computed tomography cologram	0	2	0	0
Defaecating proctogram	1	2	0	0
Endoanal ultrasound	0	4	0	1
FS	18	22	4	4
Gastrografin enema	1	0	0	0
Magnetic resonance imaging	3	4	1	1
Magnetic resonance imaging of liver	0	1	0	0
Oesophageal manometry	2	0	0	0
OGD	6	24	1	5
Proctoscopy and haemorrhoid banding	1	2	0	0
SeHCAT (bile malabsorption study)	0	1	0	0
Urea breath test	1	1	0	0
Ultrasound of abdomen	13	21	3	4
White cell scan	1	3	0	1

Source of data: hospital records examined 1 year post-procedure.

TABLE 47 *Completeness of endoscopy reports: OGD*

Item recorded[a]		Count		Item recorded[a]		Count	
		Doctor (*n* = 290)	Nurse (*n* = 445)			Doctor (*n* = 290)	Nurse (*n* = 445)
Demographic details	Missing	0	0	Results of intervention	Missing	290	445
	Yes[b]	290	445		Yes	0	0
	No[b]	0	0		No	0	0
Date of procedure	Missing	0	0	Extent of examination	Missing	0	1
	Yes	290	438		Yes	289	443
	No	0	7		No	1	1
Episode type*	Missing	136	145	Limitations of examination	Missing	288	429
	Yes	76	196		Yes	2	15
	No	78	104		No	0	1
Urgency*	Missing	0	0	Time taken	Missing	0	0
	Yes	0	31		Yes	1	0
	No	290	414		No	289	445
Procedure**	Missing	0	0	Complications	Missing	290	445
	Yes	287	427		Yes	0	0
	No	3	18		No	0	0
Referral source	Missing	1	1	Images/photographs	Missing	290	445
	Yes	190	278		Yes	0	0
	No	99	166		No	0	0
Endoscopist	Missing	0	0	Annotated text to images	Missing	290	445
	Yes	290	445		Yes	0	0
	No	0	0		No	0	0
Whether supervised	Missing	290	444	Free text comments*	Missing	0	0
	Yes	0	1		Yes	114	330
	No	0	0		No	176	115
Indication for procedure	Missing	0	1	Discharge arrangements*	Missing	0	0
	Yes	261	415		Yes	252	418
	No	29	29		No	38	27
ASA status	Missing	1	1	Follow-up arrangements*	Missing	0	0
	Yes	0	1		Yes	244	413
	No	289	443		No	46	32
Instrument used	Missing	0	0	Treatment recommended**	Missing	0	1
	Yes	209	346		Yes	98	105
	No	81	99		No	192	339
Sedation*	Missing	0	0	Post-procedure complications	Missing	289	445
	Yes	248	433		Yes	1	0
	No	42	12		No	0	0
Endoscopic findings	Missing	1	1	Information given	Missing	1	1
	Yes	289	444		Yes	1	4
	No	0	0		No	288	440
Specimens obtained	Missing	111	100	Patient satisfaction	Missing	290	445
	Yes	179	345		Yes	0	0
	No	0	0		No	0	0
Endoscopic diagnosis	Missing	0	0	Final diagnosis	Missing	2	1
	Yes	274	416		Yes	274	420
	No	16	29		No	14	24
Therapeutic interventions	Missing	290	445				
	Yes	0	0				
	No	0	0				

[a] * $p < 0.05$ favouring nurses; ** $p < 0.05$ favouring doctors in terms of completeness (χ^2).
[b] Yes = details of quality criterion present in the endoscopy report; No = details of quality criterion not present in the endoscopy report.
Source of data: endoscopy procedure reports.

TABLE 48 *Completeness of endoscopy reports: FS*

Item recorded[a]		Count		Item recorded[a]		Count	
		Doctor (*n* = 470)	Nurse (*n* = 579)			Doctor (*n* = 470)	Nurse (*n* = 579)
Demographic details	Missing	0	1	Results of intervention	Missing	373	480
	Yes[b]	470	579		Yes	91	94
	No[b]	1	1		No	7	7
Date of procedure	Missing	1	1	Extent of examination*	Missing	1	0
	Yes	468	579		Yes	442	571
	No	2	1		No	28	10
Episode type*	Missing	37	57	Limitations of examination*	Missing	336	340
	Yes	106	196		Yes	90	190
	No	328	328		No	45	51
Urgency*	Missing	0	0	Time taken	Missing	1	1
	Yes	14	44		Yes	5	12
	No	457	537		No	465	568
Procedure*	Missing	1	0	Complications	Missing	470	581
	Yes	462	579		Yes	1	0
	No	8	2		No	0	0
Referral source	Missing	7	10	Images/photographs	Missing	469	580
	Yes	226	281		Yes	0	1
	No	238	290		No	2	0
Endoscopist	Missing	2	0	Annotated text to images	Missing	469	580
	Yes	464	577		Yes	0	0
	No	5	4		No	2	1
Whether supervised	Missing	469	579	Free text comments*	Missing	1	3
	Yes	0	0		Yes	248	365
	No	2	2		No	222	213
Indication for procedure	Missing	0	0	Discharge arrangements*	Missing	2	1
	Yes	408	501		Yes	274	427
	No	63	80		No	195	153
ASA status	Missing	0	0	Follow-up arrangements*	Missing	4	2
	Yes	2	0		Yes	328	503
	No	469	581		No	139	76
Instrument used*	Missing	0	1	Treatment recommended*	Missing	0	2
	Yes	246	342		Yes	78	128
	No	225	238		No	393	451
Sedation*	Missing	2	1	Post procedure complications	Missing	469	579
	Yes	158	273		Yes	0	0
	No	311	307		No	2	2
Endoscopic findings	Missing	1	0	Information given	Missing	0	1
	Yes	465	578		Yes	49	75
	No	5	3		No	422	505
Specimens obtained	Missing	342	359	Patient satisfaction	Missing	471	579
	Yes	120	201		Yes	0	0
	No	9	21		No	0	2
Endoscopic diagnosis*	Missing	2	2	Final diagnosis	Missing	3	4
	Yes	285	382		Yes	286	362
	No	184	197		No	182	215
Therapeutic interventions	Missing	372	478				
	Yes	99	103				
	No	0	0				

[a] * $p < 0.05$ favouring nurses in terms of completeness (χ^2).
[b] Yes = details of quality criterion present in the endoscopy report; No = details of quality criterion not present in the endoscopy report.
Source of data: endoscopy procedure reports.

endoscopist, whether supervised, indication for procedure, ASA status, endoscopic findings, specimens obtained, therapeutic interventions, results of therapeutic interventions, time taken, complications, images, annotated text to images, post-procedure complications, information given, patient satisfaction and final diagnosis.

There was a significant difference in 12 of 31 contents ($p < 0.05$) favouring nurses in episode type, urgency, procedure, instrument used, sedation, endoscopic diagnosis, extent of examination, limitations of examination, free-text comments, discharge and follow-up arrangements and treatment recommended.

Chapter 5

Performance in GI endoscopy – measurement, validation and comparison of doctors and nurses

Introduction

Performance in GI endoscopy is generally assessed subjectively. Performance may be measured by maintenance of detailed procedure log, direct observation of a procedure by an expert or by review of videotape of the procedure. Although guidelines exist for observational methods to assess endoscopic competence,[55] there is no evaluation tool to measure objectively performance in upper GI endoscopy (OGD) and one is clearly needed.

Analysis of video recording of endoscopic procedures could be reliably quantified and carried out at any convenient time. Our hypothesis is that anyone with knowledge of performing OGD can objectively measure performance in OGD by evaluation of video recordings of the procedure, using a structured form with specific rating scales.

Recently JAG suggested a form for direct assessment of trainees' performance in endoscopy objectively. Previous attempts at objective assessment using score card OGD based on video reviews of endoscopies in biosimulation (the Erlangen Endo-Trainer) model revealed substantial inter-observer variability.[56] Many of the current training programmes for nurse endoscopists utilise video reviews of endoscopic procedures to assess performance of nurse endoscopists and certify them competent.

Evidence exists in surgery, obstetrics and gynaecology that performance can be assessed by review of video recordings using objective structured tools.

Performance in flexible sigmoidoscopy

Assessment of technical quality for FS was undertaken in collaboration with St Mark's Hospital using their scale and scores. The flexi scale had been validated against adenoma detection rates in screening FSs: that is, endoscopists with a good score had a good adenoma detection rate and vice versa.[57]

Sampling for MINuET Flexi evaluation

Five videos per endoscopist per centre were taken to yield a total of 100. These videos were normal procedures with no therapeutic intervention or biopsies. Videos were edited to include only the extubation phase of the procedure and five procedures from each endoscopist were reviewed sequentially on one video. Videos were reviewed independently by three scorers who were blinded to the identity of the centre and endoscopist. They gave an individual score on a five-point scale for each clip and also an overall score for the endoscopist after reviewing five clips together. The form used is shown in Appendix 11.

Statistical analysis

Cohen's kappa was calculated to test inter-rater reliability for scorers. The analysis of difference in FS performance scores between doctors and nurses was calculated using the χ^2 test.

Comparison

Kappa for scorers (1 versus 3, 1 versus 2, 3 versus 2) was found to be low, 0.13 for scores for all the clips (n = 100) and 0.23 (3 versus 2), 0.31 (1 versus 2), 0.58 (1 versus 3) for overall score for endoscopist (n = 20), indicating moderate agreement between two scorers were and some agreement for others. Frequencies for various categories by three scorers for doctors excellent (16, 30, 8%), good (52, 34, 28%), watch carefully (20, 28, 60%) and not good enough (12, 8, 4%) examinations; for nurses excellent (12, 28, 12%), good (48, 30, 8%), watch carefully (30, 30, 72%) and not good enough (10, 12, 8%) examinations (*Table 49*). The difference in scores given by the three scorers did not reach statistical significance.

Performance in oesophagogastroduodenoscopy (OGD) – measurement and validation

Aims

The aim of this aspect of the MINuET study was to develop and validate a tool to measure

TABLE 49 *FS performance scores*

Endoscopist	Score	Scorer 1[a] (%)	Scorer 2[b] (%)	Scorer 3[c] (%)
Doctor	Excellent	16	30	8
	Good	52	34	28
	Watch carefully	20	28	60
	Not good enough	12	8	4
Nurse	Excellent	12	28	12
	Good	48	30	8
	Watch carefully	30	30	72
	Not good enough	10	12	8

[a] Pearson χ^2 test, 0.69; df 3 asymptotic significance (two-sided) = 0.69 (zero cells have expected count less than 5). Minimum expected count 5.5.
[b] Pearson χ^2 test, 0.59; df 3 asymptotic significance (two-sided) = 0.90 [zero cells have expected count less than 5]. Minimum expected count 5.
[c] Pearson χ^2 test, 7.17; df 3 asymptotic significance (two-sided) = 0.07 [but two cells (25%) have expected count less than 5]. Minimum expected count 3.

performance in OGD and test its applicability and, if valid, to use it to assess the technical performance of doctors and nurses. This aspect of the study was the basis for a PhD thesis by DD.

Methods

The development and validation of the study progressed in five stages:

1. Scale development: publications relevant to performance in OGD were identified and reviewed (MEDLINE, EMBASE, CINAHL, textbooks). From those and input from gastroenterologists, a scale was developed.
2. The feasibility of using the scale was assessed in a small prepilot study.
3. To pilot the scale.
4. Final calibration of the scale.
5. Use in main study for concurrent validation.

Materials

In the course of MINuET, endoscopic views of procedures were video recorded by centres and sent to the study team. The videos from the pilot phase of MINuET were used in the prepilot and pilot studies and videos from the main MINuET study were used for concurrent validation and formal operator assessment. The study was approved by the MREC for Wales and respective LRECs. Informed consent was obtained from the patients for the procedures to be video recorded.

Scale development

The scale to measure performance at OGD was developed using quality criteria from textbooks, professional body recommendations and from the literature.[58–61] The final scale used after refinement is shown in Appendix 12.

Scorers

Five examiners took part in the OGD validation study (examiners A, B, C, D and E). All are trained endoscopists and undertake independent endoscopy lists.

Feasibility study

Video recordings from the pilot phase of the MINuET trial were used in this study. Examiners A and D each scored the same 10 videos using the OGD scale followed by a meeting to discuss practicalities.

Pilot phase – OGD validation study

In the pilot phase, examiners A, B and C scored a new set of 10 videos from the MINuET pilot. This was followed by a meeting of the three examiners to compare scores and identify and resolve inconsistencies.

Main study – OGD validation and MINuET

Two samples of 94 each were randomly selected using computer-generated random numbers, stratified by centre and endoscopist. Examiners B and C scored 94 each of the 188 videos. Examiner A scored all 188 sampled videos. Inter-rater reliability was calculated between examiners A and B and also between examiners A and C. Disputes were referred to the fourth examiner, E.

A random sample of 20 videos (one per endoscopist) was selected from the total reviewed by each examiner and scored blind. Each examiner

reviewed at random an additional but repeat 20 videos. Intra-rater reliability for examiners A, B and C was calculated from these scores.

Construct validity of the scale was tested by correlation of the scale with the scores of the GESQ and SF-36. Content validity was by expert opinions and literature review.

Sampling for OGD validation study and MINuET

The following sampling strategy was used to select the videos for evaluation of performance in OGD. Ten videos with recorded procedures from each of the frequent endoscopists (endoscopists who have performed 10 or more trial patients in the study period) were identified. All videos that had been recorded on trial patients were first screened by a member of MINuET clerical support team to confirm that an image was present. Videos were stratified by centres and endoscopists (at least one doctor and one nurse endoscopist per centre). All videos with complete supporting information were included, that is, video with image, returned baseline, 1-day and 1-month questionnaires. If there were more than 10 such sets per centre per endoscopists, 10 videos were randomly selected using computer-generated random numbers (SPSS). If there were less than 10 complete sets, all with 1-day questionnaires were included. This approach was gradually extended to include those videos supported by the maximum information (video with image, 1-day, baseline, 1-month questionnaires). If there were still not sufficient numbers (10), those with images alone were selected to fulfil the remaining quota. To minimise bias, a member of the MINuET team not involved with the clinical care or assessment of the videos coded all sampled videos with a numerical number, which could be matched to the patient's NTN. By this process, all who assessed videos were blinded to endoscopists and centres.

In the pilot study, it was found that some of the videos did not include a complete examination. A doctor F with some experience of observing endoscopies therefore reviewed all the 188 sampled videos. She was shown several complete videos and given photographs showing complete steps in OGD. Any doubtful videos were reviewed by experienced endoscopists. All incomplete videos were replaced by videos selected randomly using the above sampling strategy. In the case of non-availability of such videos, then videos with incomplete images were used.

Statistical analysis for OGD validation and MINuET

The 23 items of the OGD evaluation scale were subjected to principal component analysis. Reliability of the factors was tested by calculating Cronbach's alpha. Inter- and intra-observer reliability of the scale were tested by a two-way random effect model and calculating intra-class correlation using an absolute agreement definition.[62] An Independent-samples *t*-test was conducted to compare the performance scores for the three subscales between doctors and nurses. Average scores by the two scorers were used for comparison. The SPSS (Version 12.5) statistical package was used.

Results – OGD scale validation

Factor analysis

We initially assessed the data for suitability for factor analysis. Many items in the correlation matrix were above 0.3. The Kaiser–Meyer–Olkin value ranges from 0 to 1 with 0.6 suggested as the minimum value for a good factor analysis, and it was 0.839. The Bartlett's test of sphericity should be significant for the factor analysis to be appropriate ($p < 0.05$) and was statistically significant.[63]

Eigenvalues for the three subscales exceeded 1.51. This explained 35, 8.7 and 7.9% of the variance. Scree plot revealed a clear break after three components. The three components were subjected to varimax rotation, which revealed three clinically relevant factor structures with good factor loading. The three components explain 51.7% of the variance. Four items were excluded owing to high frequency count (84, 85, 85 and 95% endorsement on same category). The three subscales and their Cronbach's alpha values are as follows: factor 1, eight items on thoroughness of examination of stomach ($\alpha = 0.87$); factor 2, seven items on technique and examination of oesophagus ($\alpha = 0.7$); factor 3, four items on technique and examination of duodenum ($\alpha = 0.7$). The reliability of the factors was established by acceptable Cronbach's alpha lying between 0.7 and 0.9.[41]

Inter-observer reliability

The intra-class correlation coefficients are 0.90 for the stomach, 0.89 for the duodenum and 0.73 for oesophagus for scorers A versus B and 0.88, 0.89 and 0.67 for A versus C, indicating good reliability (*Table 50*).

TABLE 50 *Inter-observer reliability – OGD*[a]

	Intraclass correlation	
	Scorers A and C	**Scorers A and B**
Oesophagus	0.67	0.73
Stomach	0.88	0.90
Duodenum	0.89	0.89

[a] Two-way random effects model, intraclass correlation coefficient using absolute agreement definition.

Intra-observer reliability

The intra-class correlation coefficient from the scores of the 20 videos viewed the second time for scorer A (stomach 0.95, duodenum 0.84, oesophagus 0.92) and for scorer C (stomach 0.92, duodenum 0.84, oesophagus 0.74) indicated good intra-rater reliability for the two scorers.

Results from MINuET OGD video evaluation

There was a significant difference in mean scores for technique and thoroughness for oesophagus [doctors, mean = 28.70 (SD = 12.77); nurse, mean = 23.66 (SD = 8.82); $t = 3.16$, $p = 0.002$], and thoroughness of examination of stomach [doctors, mean = 54.22 (SD = 20.31); nurse, mean = 43.72 (SD = 13.80); $t = 4.16$, $p < 0.0001$] favouring better examination by nurse (*Table 51*). There was no significant difference in the mean scores for technique and examination of duodenum [doctors mean = 38.14 (SD = 18.07); nurse, mean = 36.19 (SD = 11.32); $t = 0.89$, $p = 0.38$] but still a better score by nurse.

TABLE 51 *Performance at OGD video scores*

	Mean score[a]			
	Doctor (n = 95)	**Nurse (n = 93)**	**Difference (95% CI)**	***p*-Value**
Technique and thoroughness: oesophagus	28.70	23.66	5.05 (1.89 to 8.20)	0.002
Thoroughness: stomach	54.22	43.72	10.50 (5.51 to 15.49)	0.0001
Technique and thoroughness: duodenum	38.14	36.19	1.95 (–2.39 to 6.28)	0.378

[a] Score 0 (best)–100 (worst).

Chapter 6

Cost-effectiveness analysis

Introduction

This chapter describes the cost-effectiveness analysis that was undertaken alongside the RCT. The primary objective of the analysis was to assess the relative cost-effectiveness of nurses and doctors performing upper and lower GI endoscopy. An additional objective was to assess the uncertainty associated with cost-effectiveness by estimating the probability that nurse-delivered endoscopy is cost-effective over a range of values of decision-makers' willingness to pay for an additional QALY.

Methods

The economic analysis was carried out alongside the RCT and assessed the impact of nurses performing upper and lower GI endoscopy compared with doctors performing the same tasks. The patient sample, and therefore the effectiveness data, is the same as for the clinical trial, as detailed in Chapter 2. The economic analysis takes an NHS perspective with effects assessed in terms of health gains, measured in terms of QALYs. All costs and outcomes fell within a 1-year period and therefore discounting was not appropriate. Extrapolation beyond 1 year was not performed as there was no demonstrable difference between groups in factors impacting on long-term health outcomes. The trial was randomised with the patient as the unit of randomisation and also the unit of analysis. This cost-effectiveness analysis takes a Bayesian perspective, accepting the existence of uncertainty by assuming that the relevant parameters are considered to have probability distributions. Hence it is possible, and appropriate, to compute the probability of an intervention, in this case nurse endoscopy, being cost-effective.

Sources of data

Resource use

Information on resources used during endoscopy of trial patients was collected prospectively, and included duration of endoscopy, number of patients endoscoped, staffing levels in each programme and consumables used. Summary resources for each programme were completed by a research fellow observing one doctor and one nurse endoscopy per centre. Some trial patients were included in these lists. The duration of procedures was timed from the extubation of one patient to the extubation of the next. Consumables for therapeutic procedures were excluded. Information collected included duration of endoscopy, number of patients endoscoped, staffing and consumables used. The resource use forms used are shown in Appendix 13 (summary resource timesheet) and Appendix 14 (individual patient resource timesheet).

Data on resource use subsequent to the endoscopy were obtained from examination of patients' medical records and patient questionnaires administered at baseline, 1 month and 1 year (*Table 52*). Any post-endoscopy investigations were collected and costed as an outpatient attendance.

Unit costs

Inpatient cost per day and outpatient cost per visit for attendances were both based on national estimates.[64] Estimates were inflated to a 2002/2003 price base using the Health Service Cost Index.

The cost of a GP visit (both home and surgery) and the cost of a practice nurse visit (home and surgery) were derived from Netten and Curtis estimates.[64] The unit cost estimate includes cost of training in addition to direct care support staff and is inflated to a 2002/2003 price base.

The cost of the intervention was estimated from duration of endoscopy data captured in the clinical trial. Unit cost figures (in cost per minute for either doctor or nurse) estimated from Netten and Curtis[64] were then applied to these estimates of duration of endoscopy. Both groups received input from a support team (including nurses in the department, receptionists, etc.), but for the economic analysis the **additional** cost of providing the doctor- or nurse-based programme is the relevant cost. These costs include the training, capital and overhead costs associated with the additional time.

TABLE 52 *Details of resource use data and unit costs*

Item of resource use	Source of resource use	Source of unit cost data
NHS staff and time	Resource time sheet recorded during endoscopy lists	NHS salary scales
Inpatient stay	Hospital medical records examined at 1 year	Netten and Curtis[64]
Outpatient appointments	Patient questionnaires plus hospital medical records and primary care records at 1 year	Netten and Curtis[64]
GP visits	Patient questionnaires plus hospital medical records and primary care records at 1 year	PSSRU unit costs of health and social care
Medical management, e.g. drugs	Patient questionnaires and GP questionnaire	BNF
Travel to and from appointments	Patient questionnaires at baseline, 1 month and 1 year	Automobile Association
Private medical care	Patient questionnaires at baseline, 1 month and 1 year	PSSRU unit costs of health and social care
Days off work	Not collected	Perspective is the UK NHS and patient

Health states and their value

The EuroQol (EQ5D) instrument[23] was used to measures patients' health states and to ascribe values to these states. This instrument measures patient health status across five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). Three possible responses (no problems, moderate problems or severe problems) are given by the patient for each of these dimensions, reflecting the patient's perception of their health state. This locates each participant into one of 245 mutually exclusive health states, each of which has previously been valued on a scale from zero (equivalent to dead) to one (equivalent to good health), based on interviews with a sample of 3395 members of the UK public.[22]

The two trial groups were compared in terms of mean changes in QALYs over the 1-year period compared with baseline. This was achieved by plotting the EQ5D utility score at baseline and at each intermediate point and calculating the area under the curve to estimate QALYs gained (or lost) for each patient. These estimates were then adjusted for baseline EQ5D as recommended by Manca and colleagues,[65] in addition to including gender and age as covariates.

Methods of analysis

Missing data and imputation

Resource use and EQ5D data were missing in a proportion of patients, with some patients missing both forms of data. There is no formal test to verify the assumption that data are missing at random (MAR), and this assumption is often chosen as a starting point when data are missing.[66] If there is concern that data are not MAR, it is possible in principle to run the multiple imputation procedure using a model that reflects hypothesised differences between individuals with complete data and individuals with incomplete observations. The results obtained from the two models under the MAR and non-MAR assumption can then be compared to obtain a measure of the sensitivity of the inference to the missing data process. In practice, to model a non-MAR process is not a trivial task, and it has been demonstrated that exploring the assumption of MAR relies on strong assumptions which are not themselves testable. Therefore, for this analysis it was assumed that data were MAR.

Two methods were employed to impute missing data. For EQ5D, the last value carried forward (LVCF) was employed, as a patient's last score is likely to be the best predictor of the missing value. For resource use data, a regression-based approach was used to predict missing values, age and gender, and EQ5D scores were used to predict these values. Imputation leads to differences in estimates of final costs. Therefore, resource use data as presented in *Table 53* based on complete data will not tally exactly with total cost estimates presented later in *Table 58*.

Incremental cost-effectiveness ratios and net monetary benefits

Traditionally, cost-effectiveness analysis has involved the calculation of incremental cost-effectiveness

ratios (ICERs), where mean differences in costs and effects in the treatment and control arms are presented with 95% CIs. The ICER is calculated from the mean difference in cost and effect between the two treatment options. These statistics were calculated in this analysis. However, interpretation of ICER statistics that cover more than one quadrant of the cost-effectiveness plane is troublesome, and recent papers have advocated the net benefit approach to cost-effectiveness analysis.[67–69] This approach can be performed for this study fairly simply. Net monetary benefit (NMB) was calculated for each group based on the data from the trial and imputed data. For specific levels of a decision-maker's maximum willingness to pay for a QALY, the NMB of a strategy can be estimated using the following equation:

$$NMB = (\lambda \times QALYs) - cost$$

where λ is equal to the decision-maker's maximum willingness to pay for a QALY. For example, if treatment A has a mean cost of £100,000 and generates a mean of 5 QALYs with a QALY valued at £30,000, then the NMB associated with treatment A is (5 × £30,000) – £100,000 = £50,000.

The NMB is dependent on the value that is placed on a QALY, but results of the analyses indicate how sensitive the results are to changes in this value. Thus the uncertainty surrounding the NMB statistic can be used to identify the probability that a strategy is cost-effective using a cost-effectiveness acceptability curve (CEAC). The CEAC is a graphical representation of the probability of an intervention being cost-effective over a range of monetary values for a decision-maker's willingness to pay for an additional unit of health gain (in this case a QALY). The probability of an intervention being cost-effective will differ according to the valuation the decision-maker places on a QALY. For this analysis, the values £0, £1000, £10,000, £20,000, £30,000, £50,000 and £100,000 were used as a range of the decision-maker's willingness to pay for a health gain of one QALY. The value zero is equivalent to a comparison of the groups in terms of total costs, as outcomes are effectively not considered (or are assumed to be equivalent).

It is also possible to express NMB at the patient level by multiplying each patient's QALY score by the decision-maker's assumed maximum value and subtracting that patient's costs. The patient-level NMB is used in the derivation of the CEACs. As patient-level estimates of NMB are now available, it is possible to determine the joint density of costs and effects by resampling. In this instance, replicated samples were made by drawing from the original sample (with replacement). The mean costs and mean effects were then calculated for the resample. This non-parametric bootstrap was performed 10,000 times, generating 10,000 estimates of mean costs and mean effects. The CEAC is then plotted as the proportion of the NMB estimates that are judged to be cost-effective.

Subgroup analysis

A simple subgroup analysis was performed to examine whether there was a difference between FS and OGD in terms of the most cost-effective method of delivery. For this analysis, QALYs were calculated using the area under the curve. The patients were split into groups according to whether they had FS or OGD. For these subgroups, the costs and effects of the doctor and nurse groups were compared.

Results

Missing data

There were missing data for both resource use and utility data. At baseline there were missing data for 184 (9.7%) of patients' utility data, either because they did not complete the questionnaire or because one of the items within the EQ5D was missing. This figure increased to 489 patients at 1-month follow-up (25.9%) and 576 (30.5%) at 1-year follow-up. For resource use data, 1674 patients (88.7%) had their medical records examined, while 606 patients (32%) did not report their number of GP attendances.

Resource use

Mean levels of resource use are presented in *Table 53*. These estimates utilise resource use data estimated without the imputation method described above (i.e. are based on responders/completers of questionnaires).

For the majority of resource use variables, the nurse-based programme resulted in an increase in resource use. However, these differences were small and were outweighed by the reduced cost of the intervention.

Unit costs

Unit cost estimates and their sources used in the analysis are given in *Table 54*.

Health states

There appears to be little impact in either group on the dimensions measuring usual activities and

TABLE 53 *Mean resource use in the two groups over the 1-year study period*

	Doctor group (n = 953)	Nurse group (n = 928)	Mean difference (95% CI)
GP home visits	0.30	0.17	0.13 (–0.039 to 0.289)
GP surgery visits	4.81	5.05	–0.24 (–0.719 to 0.237)
Practice nurse surgery visits	1.43	1.56	–0.13 (–0.468 to 0.217)
Practice nurse home visits	0.03	0.11	–0.08 (–0.215 to 0.053)
Day hospital attendances	0.27	0.35	–0.075 (–0.141 to 0.009)
Inpatient length of stay	1.10	1.10	0.00 (–0.534 to 0.535)
Outpatient attendances	1.34	1.46	–0.129 (–0.321 to 0.064)
Intervention time (minutes)	23.5	22.41	1.09 (–1.952 to 4.134)

TABLE 54 *Unit costs of resources used*

	Unit cost (£)
GP home visits (cost per visit)	61
GP surgery visits	20
Practice nurse home visits	18
Practice nurse surgery visits	10
Day hospital attendances	74
Inpatient cost per day	Various (range 269–484)
Outpatient attendances	Various (range 75–110)
Intervention (cost per minutes)	0.53 nurse 1.82 doctor

Source of data: Netten and Curtis.[64]

self-care (*Table 55*). Both groups show an improvement in the anxiety/depression and (most notably) pain/discomfort dimensions, and the differences between the two groups slightly favour the doctor group. It is also noteworthy that these changes occur in the first month. On the mobility dimension, both groups are slightly worse, with the nurse group performing slightly worse than the doctor group. The overall QALY scores are summarised in *Table 56*.

Quality-adjusted life-years

Based on these estimates, the difference in total QALYs between the two groups can be estimated and the mean number of QALYs over the 1-year period is presented in *Table 57*. These estimates are based on data that include values imputed for missing values.

These differences are small and are not statistically significant at conventional levels. However, these results indicate a trend towards the doctor group performing slightly better than the nurse group, in that the gain in QALYs is greater. The difference in QALYs is partly explained by difference in baseline characteristics (notably EQ5D score at baseline), and adjusting for these results in the difference in QALYs being reduced to 0.0153 (95% CI –0.008 to 0.039). This estimate is more appropriate and is used in the construction of CEACs. This reflects the finding that EQ5D score at baseline was higher for the

TABLE 55 *Percentage of patients in each EQ5D dimension by group at baseline and 1-year follow-up*[a]

Group		% of patients in health state at baseline			% of patients in health state at 1 month follow-up			% of patients in health state at 1 year follow-up		
		1	2	3	1	2	3	1	2	3
Doctor group (n = 836)	Mobility	69.3	30.7	0	69.4	30.4	0.2	67.8	32.1	0.1
	Self-care	91.0	9.0	0	89.0	11.0	0	88.4	11.1	0.5
	Usual activities	56.9	39.2	3.9	56.3	39.1	4.7	56.5	39.0	4.4
	Pain/discomfort	21.1	68.2	10.6	29.9	61.8	8.3	31.5	59.6	8.9
	Anxiety/depression	50.6	44.1	5.3	56.0	38.6	5.4	54.1	41.2	4.7
Nurse group (n = 868)	Mobility	68.7	30.9	0.5	67.7	32.0	0.3	65.1	34.7	0.2
	Self-care	90.6	9.2	0.2	88.3	11.4	0.3	88.5	11.2	0.3
	Usual activities	54.2	42.3	3.5	53.6	42.4	4.0	54.6	41.6	3.8
	Pain/discomfort	20.6	68.1	11.3	27.0	64.4	8.6	28.4	61.7	9.8
	Anxiety/depression	52.4	41.0	6.6	55.6	38.5	5.9	55.2	38.1	6.7

[a] This table shows the mean EQ5D scores at baseline, 1 month and 1 year.

TABLE 56 *Mean EQ5D score at baseline and follow-up by group*

Group	Baseline	1 month	1 year
Doctor group (*n* = 931)	0.700	0.713	0.710
Nurse group (*n* = 957)	0.689	0.697	0.693
Difference (95% CI)	0.011 (–0.014 to 0.04)	0.016 (–0.009 to 0.041)	0.017 (–0.008 to 0.043)

TABLE 57 *Unadjusted mean change in QALYs per patient over the 1-year period*

Group	Mean QALY	Difference (95% CI)	Difference allowing for baseline characteristics (95% CI)
Doctor group (*n* = 931)	0.712	0.0162 (–0.008 to 0.04)	0.0153 (–0.008 to 0.039)
Nurse group (*n* = 957)	0.695		

TABLE 58 *Total costs per patient in the two groups over the 1-year period*

Cost	Doctor group (*n* = 931)	Nurse group (*n* = 957)	95% CI around difference in mean cost
Primary care costs (£)	135	128	
Secondary care costs (£)	565	538	
Intervention costs (£)	39	16	
Total cost (£)	739	683	56 (–100 to 213)

doctor group. Allowing for this in the analysis reduces the difference between the groups.

Total cost

The difference in total cost between the two groups is presented in *Table 58*. These estimates include the cost of the intervention. The total costs per patient are shown in the table.

There is again considerable uncertainty around these estimates and the difference is not statistically significant at conventional levels. Patients allocated to doctor endoscopy have a slightly higher cost of both primary and secondary care. In addition, the costs of the intervention are higher in the doctor group owing to the higher cost of doctor time compared with nurse time (there was little difference in the duration of the endoscopy between the groups).

Incremental cost-effectiveness ratio

The doctor group is associated with a slightly better QALY profile and a slightly higher cost. Specifically, the doctor group has a 0.0153 QALY gain compared with the nurse group, and an increased cost of around £56 per patient. This results in an ICER of £3660 per QALY.

However, there is a large degree of uncertainty around these results and neither the change in patient outcomes nor the change in costs would approach traditional levels of statistical significance. Therefore, to deal adequately with uncertainty, the NMB approach was used and CEACs were generated.

Net monetary benefits and CEAC

The value of NMB and the resulting probability of an intervention being cost-effective is partly dependent on the value of a decision-maker's willingness to pay (λ) for an additional QALY.

Figure 8 shows the CEAC; λ is varied between zero (where gains in QALYs are not valued at all) and £50,000. In the main analysis with imputed data, it can be seen that a zero value of λ gives a probability of the nurse group being cost-effective of around 78%. In effect, this is saying that there is a probability of 78% that the nurse group was cost saving, as we have placed no value on QALY gains. However, the probability of the nurse being cost-effective decreases as the value placed on λ increases as the doctor is associated with an improved QALY profile. At λ = £30,000, an estimate frequently stated to be the borderline value for the NHS, the nurse-based programme has a probability of only 13% of being cost-effective. Indeed, for all plausible values of λ, in

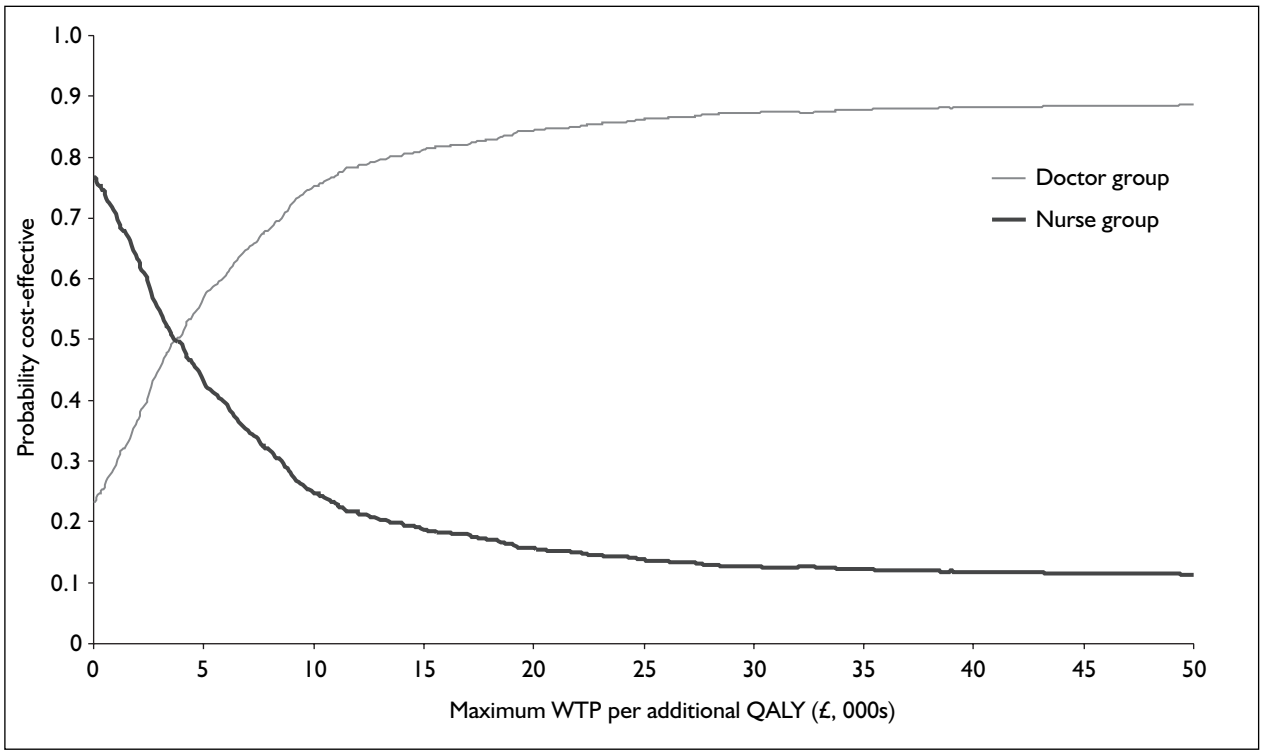

FIGURE 8 *Cost-effectiveness acceptability curve*

the base-case analysis, the doctor group is more likely to be cost-effective than the nurse group.

Sensitivity analysis

Although the form of stochastic analysis performed above addresses a large amount of uncertainty, it is still appropriate to perform sensitivity to allow for variability and methodological uncertainty. Sensitivity analysis was performed for those individuals who had complete data (the complete case analysis) and for the different forms of endoscopy.

Complete case analysis

This analysis is based on the sample of patients with complete patient records and complete EQ5D data. These patients totalled 440, with 227 (51.6%) in the nurse group and 213 (48.4%) in the doctor group, reflecting the distribution of patients between the two groups in the main trial analysis. Although there appears to be a large amount of missing data, the majority of cost data that were missing were the answers to one question, rather than whole questionnaires; similarly with the outcome data, the missing data were frequently only one EQ5D dimension at either baseline or follow-up. The point estimates in this instance show similar results to the results with imputed data. The cost differences in each group were £41 in favour of the nurse group (95% CI –£148 to £231), whereas the QALY difference was 0.021 in favour of the doctors (95% CI –0.02 to 0.06)

Transforming these results into an NMB framework shows the doctor group to have an ICER of about £2062 per QALY, somewhat lower than the imputed data. In the CEAC the doctor group had a lower probability of being cost-effective at usual values of λ than the analysis using imputed data, but this would not alter the decision at any value of λ. However, largely owing to the smaller sample size there is considerably more uncertainty around the results and the probability of the doctor group being cost-effective remains below 84%, no matter what value of λ is used.

FS versus OGD

Subgroups were examined to identify any areas where nurses/doctors were particularly cost-effective. The FS group showed an ICER of £2600 per QALY for the doctor group, with a probability that doctor-delivered endoscopy was cost-effective of 84% at a willingness to pay of £30,000 per QALY. The OGD group showed a higher cost for the doctors, resulting in a higher ICER of £7848, and a probability that doctor-delivered endoscopy

was cost-effective of 78% at a willingness to pay of £30,000 per QALY. These ICERs would both be acceptable for most reasonable values of a decision-maker's willingness to pay for a QALY.

Conclusion

The analysis above shows that, for most reasonable values of a decision-maker's willingness to pay for an additional QALY, endoscopy delivered by doctors is likely to be cost-effective compared with nurse delivery. Although there is some disagreement over what the threshold cost per QALY should be, the National Institute for Health and Clinical Excellence (NICE),[70] has suggested that interventions delivering a cost per QALY of under £20,000 are likely to be an acceptable use of NHS resources. Doctor-delivered endoscopy clearly falls into this range.

The higher probability of doctors being cost-effective compared with nurses is despite a small increase in the costs; the slight improvement in the QALY score in the doctor group outweighs this. However, there is considerable uncertainty around this estimate and a probability of approximately 15–20% that the intervention (that is, nurse-delivered endoscopy) is cost-effective.

It is feasible that the use of the EQ5D and QALYs is not sensitive in this patient population to pick up differences in patients' HRQoL. However, the results of the economic analysis are similar to those of the clinical analysis in that there was a non-significant effect in favour of the doctor group.

There were some missing data in this trial, both on resource use and utility scores. Although imputation is not ideal, the results are robust to these methods, as the complete case analysis shows similar results.

In addition, the time horizon of the study was limited to 1 year. In this patient population, there is the potential for longer term effects (for instance, of missed diagnoses). Ideally, a longer term trial would be conducted but the similarity in terms of immediate and delayed complications suggests that there is little difference between the groups in longer term prognosis.

The interpretation of the clinical and economic results of this trial depends on the paradigm chosen. Classical statistical inference fails to reject the null hypotheses that there is no difference in effectiveness or cost-effectiveness between doctor- and nurse-delivered endoscopy. In contrast, Bayesian inference makes decisions by comparing the estimated cost per QALY with a threshold equal to the most that a decision-maker would pay for a QALY. In MINuET this leads to the conclusion that endoscopy delivered by doctors is likely to be cost-effective at a typical threshold. Bayesian analysis goes further by estimating the probability that the intervention is cost-effective in the sense that the estimated cost per QALY is likely to be less than a given threshold. In MINuET this form of analysis leads to the conclusion that the average doctor endoscopist has a higher probability of being cost-effective than the average nurse endoscopist at commonly used values of willingness to pay for a QALY. This analysis favours endoscopies by doctors, despite doctors costing slightly more than nurses, and resulting in only a small difference in health outcomes. This economic evaluation incorporates uncertainty around the estimates of costs and effects, rather than relying on traditional statistical significance. This methodological framework creates a different interpretation of these interesting clinical trial results.

For most reasonable values of a decision-maker's willingness to pay for an additional QALY, endoscopy delivered by doctors is likely to be cost-effective compared with nurse delivery.

Chapter 7

Workforce implications of nurse endoscopy

Background

The level and mix of staff employed in a healthcare setting is a central determinant of the cost and quality of care delivered.[71] Extensive literature reviews[72–74] have revealed considerable scope for skill mix change, in particular for substitution of doctors by nurses, although the majority of studies are from the USA, and many of the studies reported had substantial methodological weaknesses. Research evidence "can and should be influencing workforce policy".[75]

There are a number of reasons for health managers and policy-makers considering skill mix in healthcare, and a number of factors that drive change in the skill mix of healthcare delivery. The drivers for nurse endoscopy in the NHS include staff shortages (in the medical workforce), particularly given the increasing demand for diagnostic services in order to meet NHS modernisation access targets, 'inappropriate' use of skills, particularly underutilisation of specialist gastroenterology nurses, and service changes, particularly the increasing use of endoscopy and changing indications for referral.

In a service such as healthcare, where staffing costs are responsible for most of the overall expenditure, assessing the cost-effectiveness of changes in skill mix, using robust research designs such as used in the MINuET study, are key to informing future policy change.

In addition to the importance of research in informing policy on skill mix in individual health providers, it is essential to consider the wider impact of change on the healthcare workforce.

To this end, it is important to consider the wider implications of endoscopies carried out by nurses in exploring the impact of this research. In this consideration of the workforce implications, it is assumed that nurse endoscopy is increasingly used in the NHS, despite the cost-effectiveness evidence, driven by other factors, such as medical staff shortages and increasing demand for diagnostic services.

Data source

Data were extracted from HES[76] and the PEDW,[77] alongside data from the MINuET trial, particularly on the duration of endoscopy procedures.

Definitions

The following Office for Population Census and Surveys (OPCS) procedure codes were used:

1. OGD
   - (a) G451 diagnostic fibre-optic endoscopic examination of upper GI tract
   - (b) G458 other specified, diagnostic fibre-optic endoscopic examination of upper GI tract
   - (c) G459 unspecified, diagnostic fibre-optic endoscopic examination of upper GI tract
2. FS
   - (a) H251 diagnostic endoscopic examination of lower bowel and biopsy diagnostic endoscopic examination of lower bowel using fibre-optic sigmoidoscope
   - (b) H258 other specified, diagnostic endoscopic examination of lower bowel using fibre-optic sigmoidoscope
   - (c) H259 unspecified, diagnostic endoscopic examination of of lower bowel using fibre-optic sigmoidoscope

Overall numbers

In the HES and the PEDW, for the year 1 April 2001 to 31 March 2002, the following episodes occurred.

OGD

There were a total of 518,041 episodes in England where upper GI endoscopy was the primary procedure, and 531,206 episodes occurred where OGD was one of the four procedure codes allowable in HES. These occurred in general medicine, gastroenterology and general surgery. Of those where upper GI endoscopy was the primary procedure:

- 77% (400,000) were day cases and 23% (118,000) were ordinary admissions.
- 80% (415,000) were elective admissions and 20% (102,000) were emergency admissions.
- 1.1% (5530) were patients aged under 18 years. The mean age was 59 (SD 17) years; the oldest patient was aged 105.

Secondary procedures: 43% of the episodes had no associated secondary procedure; 57% were associated with another procedure, but a number of these appear to relate solely to the location rather than an actual therapeutic procedure. The most common secondary procedures were colonoscopy and FS.

In Wales there were 33,338 episodes where upper GI endoscopy was the primary procedure, with a total of 34,873 procedures where OGD was one of the 12 available procedure codes. Of those where upper GI endoscopy was the primary procedure:

- 23% (7566) were inpatient admissions. Only 0.3% (109) were listed as day cases but 77% (25,663) were not classified. This is likely to be a difference in data collection methods, and if practice is similar to England these admissions were probably also day cases.
- 80% (26,652) were elective admissions and 20% (6543) were emergency admissions.
- 0.9% (306) were patients aged under 18 years. The mean age was 60 (SD 17) years; the oldest patient was aged 103.

Secondary procedures: 59% of the episodes had no associated secondary procedure; 41% were associated with another procedure, but a number of these appear to relate solely to the location rather than an actual therapeutic procedure. The most common secondary procedures were intravenous injection, stomach intubation and local anaesthetic (this level of detail in secondary procedures probably results from the availability of 12 procedure codes in PEDW compared with four in HES). The most common active secondary procedures, as in England, were FS and colonoscopy.

Flexible sigmoidoscopy

There were a total of 122,088 episodes in England where FS was the primary procedure. A total of 136,082 episodes occurred where sigmoidoscopy was one of the four procedure codes allowable in HES. Again these occurred in general surgery, general medicine and gastroenterology. Of those where sigmoidoscopy was the primary procedure:

- 83% (101,000) were day cases and 17% (21,000) were ordinary admissions.
- 87% (106,000) were elective admissions and 13% (16,000) were emergency admissions.
- 0.9% (1152) were patients aged under 18 years. The mean age was 58 (SD 18) years; the oldest patient was aged 104.

Secondary procedures: 60% of the episodes had no associated secondary procedure; 40% were associated with another procedure, but a number of these appear to relate solely to the location rather than an actual therapeutic procedure. The most common secondary procedure was ligation of haemorrhoid (H254).

In Wales there were 9377 episodes where FS was the primary procedure, with a total of 10,569 procedures where sigmoidoscopy was one of the 12 available procedure codes. Of those where sigmoidoscopy was the primary procedure:

- 13% (1194) were inpatient admissions. Only 0.1% (11) were listed as day cases but 87% (8172) were not classified. This is likely to be a difference in data collection methods, and if practice is similar to England these admissions were probably also day cases.
- 90% (8478) were elective admissions and 9% (866) were emergency admissions.
- 57 (0.6%) patients were aged under 18 years. The mean age was 59 (SD 17) years; the oldest patient was aged 101.

Secondary procedures: 80% of the episodes had no associated secondary procedure; 20% were associated with another procedure, but a number of these appear to relate solely to the location rather than an actual therapeutic procedure. The most common secondary procedures were treatment of haemorrhoid (H253 and H254).

Overall time of endoscopies

On average, OGD procedures take 19 (SD 30) minutes from the extubation of one patient to the extubation of the next patient. Doctors take, on average, 19 (SD 35) minutes, and nurses 20 (SD 27, not a statistically significant difference) minutes.

On average, FS takes 26 (SD 27) minutes, with doctors taking 28 (SD 37) minutes and nurses 24 (SD 15, not a statistically significant difference) minutes.

Using these simplistic assumptions, if all endoscopies are done by nurses, this releases the time of potentially up to 136 whole-time doctors each year in England.

Using alternative assumptions:

1. If nurses do all but 5% of endoscopies (those in patients with severe systemic disease – ASA class III or IV), time of 129 doctors is released.
2. If nurses do half of all endoscopies, time of 68 doctors is released.

NHS workforce implications

The 'median' hospital Trust in England carries out 2488 upper GI endoscopies and 515 FSs every year. In terms of time, this is a total of 788 hours of contact patient time for OGD and 223 hours for FS in this median hospital. Assuming that a specialist nurse works for half a whole time equivalent (WTE) on endoscopy alone, with an overall WTE of 40 hours per week and 40 weeks per year, this means that to transfer **all** endoscopies to a nurse would need 1.25 WTE specialist nurses in a median hospital Trust. Taking out emergency endoscopies, (leaving 80 per cent of OGDs, 87 per cent of sigmoidoscopies) means that 1 WTE specialist nurse would be needed in the median hospital Trust to undertake all elective procedures.

In Wales, overall there are (using primary procedures) 33,338 upper GI endoscopies and 9377 FSs every year. In terms of time, this is a total of 10,557 hours of contact patient time for OGD and 4063 hours for FS. Assuming that a specialist nurse works for half a WTE on endoscopy alone, with an overall WTE of 40 hours per week and 40 weeks per year, this means that to transfer **all** endoscopies to a nurse would need 18.25 WTE specialist nurses in Wales. Taking out emergency endoscopies, (leaving 80% of OGDs and 90% of FSs) means that 15 WTE specialist nurses would be needed in Wales to undertake all elective procedures.

It is important to state that for the English estimates the median is calculated on the basis of frequencies of endoscopies in each English NHS Trust as reported in HES. This may not be representative of an 'average' hospital Trust, and the mean figure is higher (2656 OGDs, 665 FSs), requiring 1.15 WTE specialist nurses to carry out elective endoscopies using the assumptions above. This may still be an underestimate if endoscopies are inappropriately coded to smaller Trusts. If nurse endoscopists are to undertake other duties (and a view was expressed by the trial collaborators that exclusive endoscopic duties would not be welcome), and leave periods are to be covered, 2.0 WTE posts would be required.

In practice, owing to requirements to train junior doctors and the broader remit of specialist gastroenterology nurses, it is unlikely that all elective endoscopies would be performed by nurses. However, in terms of workforce planning, this could be a sensible initial target.

This is likely to release a substantial amount of time of consultants and other doctors in gastroenterology, general medicine and general surgery. It is difficult to speculate on the longer term workforce impact of this released time, particularly as it is dispersed between specialties. There may be benefits resulting from better coordination of elective endoscopy services in terms of management and governance. However, the generally increasing demands on the medical workforce in terms of meeting access and other policy targets, and patient expectations in general, are likely to impede any real workforce 'savings'. The benefits of nurse endoscopy are likely to include release of doctor time and also more appropriate use of staff skills.

Implications for training

The JAG,[78] a group representing the Royal Colleges of Physicians, Surgeons, Radiologists and General Practitioners, has published guidelines for the training, appraisal and assessment of trainees in GI endoscopy. A distinction is made between training for diagnostic and therapeutic endoscopy. At this time, nurses perform only diagnostic endoscopy and, although this may change, it is assumed for the present that nurse training is only required for diagnostic and not therapeutic endoscopy. The JAG (2004) document makes a number of general recommendations on training in GI endoscopy, including:

1. Any practitioner who is to undertake GI endoscopy should receive formal training in the principles and practice of safe endoscopy. Training should include the indications for, in addition to the contraindications to, each type of endoscopic procedure.
2. Endoscopy training should be provided as part of a multi-disciplinary gastroenterology service.

….. GPs, nurses and other non-medical endoscopists who undertake training in GI endoscopy must do so in units approved by the JAG and must register with the JAG.

Recommendations on training in diagnostic OGD include:

1. Trainee endoscopists should attend regular weekly (or more frequent) sessions for at least 6 months.
2. Trainees should carry out at least 200 diagnostic examinations, within the course of a year, under supervision and then undertake further examinations, when judged competent, with a degree of independence in selected cases, to a total minimum of 300 examinations to ensure adequate exposure to a full range of clinical material. The number of trainees working in a unit must therefore be commensurate with the available clinical workload.
3. Trainees should attend a Basic Skills (Foundation course) in endoscopy initiated or compliant with JAG standards.

Recommendations on training in diagnostic FS include:

1. Intended trainees in FS should first acquire basic knowledge of the principles and practice of endoscopy.
2. Each trainee should be able to perform at least 100 procedures within the course of a year and will be considered to have achieved a satisfactory level of competence when able to reach the descending colon where indicated.
3. On the best evidence to date, trainees should perform at least 50 examinations under direct supervision and a further 50 examinations with immediate advice available.
4. Trainees should attend a Basic Skills (Foundation course) in endoscopy and an FS course initiated or compliant with JAG standards.

This has implications for training costs for nurse endoscopists and also, more generally, for the level of endoscopies that should be conducted by doctors in order for them to maintain their skills in order to undertake any high-risk, emergency and therapeutic endoscopies. In addition, if more experienced nurses are to be trained to undertake whole endoscopy lists, a career pathway needs to be developed and the implications for recruitment and retention considered further. This is an area of development for future policy and future research.

In terms of nurse training costs, the Basic Skills endoscopy courses and the FS courses, as run by JAG, are 3-day programmes, carried out in a number of centres (three national, seven regional) throughout the year. The cost of attending this course includes a fee of £650 (although for NHS practitioners in England this fee is covered by central funding), and 3 days of senior nurse time at £158 per day (assuming a G grade nurse; source, PSSRU Unit Costs of Health and Social Care).[79] To carry out both courses there is therefore a total basic training cost of £2248 per nurse. Following this, attending weekly training sessions (assuming 3 hours per session at a cost of £21 per hour)[79] for 6 months costs an additional £1638. Following this basic training, nurses must carry out 200 OGDs and 50 FSs under direct supervision and a further 100 OGDs and 50 FSs before becoming independent practitioners. This is a substantial investment of time and resources, of perhaps £4000 training costs (£1300 covered by central funds for English NHS staff) and perhaps a year's worth of supervision for each nurse endoscopist before it is feasible to release the time of doctors to carry out other tasks.

Chapter 8

Discussion

With two exceptions, we found little significant difference between doctors and nurses in the clinical effectiveness of their performance of diagnostic endoscopy, as measured at 1 day, 1 month and 1 year after procedure. The first exception is patient satisfaction, where patients were significantly more satisfied with nurses 1 day after the procedure. The second exception was in the technical quality of the procedure: we found nurses to be more thorough in the examination of stomach and oesophagus, but no different from doctors in the examination of duodenum and colon.

There was no significant difference in costs to patients, although procedures by doctors cost the NHS £56 more than procedures by nurses. Rather than using traditional methods of statistical inference, the economic analysis estimated the probability that the intervention was cost-effective. In doing so, we accepted that the statistical power of the study was based on the main clinical effectiveness measure (GSRQ) rather than the main economic effectiveness measure (EQ5D). To have powered the study on EQ5D would have required a much larger sample size. The study showed that endoscopy by doctors led to better, although not significantly better, outcomes in three out of four factors (upper GI symptoms; wind; constipation) and worse, but not significantly worse, outcomes in the fourth factor (lower GI symptoms). This was reflected in a non-significant difference in EQ5D scores in favour of doctors, namely an estimated gain of 0.0153 QALYs over 1 year. Since the estimated net cost of this gain was £56, endoscopy by doctors cost only an estimated £3700 to achieve an extra QALY. This is far less than the figure of £30,000 that the NICE has indicated that it may be willing to pay for an extra QALY. Indeed, our economic analysis estimated that, at this value of a QALY, endoscopy by doctors has an 87% chance of being more cost-effective than endoscopy by nurses, whereas nurses have only a 13% chance of being more cost-effective than doctors. Because MINuET had power to test for differences in GSRQ rather than EQ5D, however, there is considerable uncertainty around these estimates.

Nurses undertook endoscopies booked for doctors significantly more often than vice versa, mainly because doctors became unavailable through other commitments. This suggests that the current multi-tasking of doctors may be inefficient. We hope that this will improve as the new consultant contract is implemented.

We sought the views of our collaborators on these findings at a meeting in November 2004. In particular, we asked them to comment on the internal and external validity of these findings and their wider implications. This qualitative form of respondent validation can refine the interpretation of findings.[80] The comments we received from our collaborators have influenced this discussion.

There was no difference in the doses of sedation used at endoscopy by doctors or nurses. However, both groups often gave both midazolam (sedation) and lignocaine throat spray (local anaesthetic) in upper GI endoscopy. This is contrary to best practice guidelines issued by the BSG, which recommend one or the other but not both together. Nurses used the combination significantly more often than doctors. Similarly, the completeness of endoscopy reporting was similar in the two groups but many recommended data items were missing. Although there are no published data on quality of endoscopy reporting, there is evidence that reporting practices vary widely.[81] These findings, relating to both sedation and reporting, suggest that education of both doctors and nurses is required to improve adherence to best practice guidelines.

Internal validity

Referrals for diagnostic upper and lower GI endoscopy come from doctors in both primary and secondary care. Some patients come direct from GPs with 'open access' to endoscopy. Others first receive a medical, surgical or specialist nurse consultation, offered in a general clinic or through a dedicated service such as a 'dyspepsia clinic' or a 'rectal bleeding clinic', whereas others follow admission for an acute problem that may or may

not have resolved. This pragmatic trial sought to recruit patients referred via all these pathways. The balance of patients between groups (*Tables 3* and *4*) suggests that this recruitment process was valid across the 23 participating sites.

Following Zelen, we randomised patients between groups before they consented to take part in the trial. We did this to accommodate without distortion the heterogeneous referral process and the delay from referral to procedure. The loss of potential subjects after randomisation was high, but the numbers agreeing to take part were similar in the two groups, and the characteristics of the patients recruited were representative of the randomised group (*Tables 3* and *6*). Hence we believe that the trial has evaluated doctors and nurses undertaking diagnostic endoscopy on comparable and representative patients.

Our original intention was to conduct two parallel studies, each with 1500 patients, addressing upper and lower GI endoscopy as separate procedures. When it became clear that recruitment would not achieve this intended sample size, however, we sought and received approval to unite the two arms of the study and reduce the sample size to a total of 1500 subjects, to yield 1000 complete records. In the event we recruited 1882 patients. Fortunately, analysis suggested that differences between nurses or doctors were similar in upper and lower GI endoscopy.

The response rates from patients at baseline (94.4%), 1 day (81.4%), 1 month (75.6%) and 1 year (70.6%) were acceptable for a pragmatic trial, and similar in the two groups. The data on patient outcomes and resource use, collected through patient questionnaires 1 year after procedure, were consistent with data obtained from primary and secondary care records examined 10–15 months after procedures. About 90% of these case notes were retrieved and examined.

Most endoscopies in this study were undertaken by a small number of doctors and nurses in each hospital. However, in some there were doctors who performed a small number of procedures, usually because the designated doctor was not available. We believe that this reflects both common practice in the UK and competing demands on doctors' time. We also found that more patients experienced a change of operator from doctor to nurse than from nurse to doctor, usually reflecting managerial and clinical commitments outside the endoscopy unit. It is fortunate that a dedicated member of the nursing staff was usually available when the designated doctor was not.

Of the instruments measuring primary and secondary outcomes, some were already available as validated instruments and others were developed and validated first in the pilot study and then concurrently in the main trial. We needed a generic GI symptom rating scale as patients were recruited into the study before a diagnosis was made. Recent reviews have found many disease-specific instruments to have been poorly evaluated with respect to responsiveness to important clinical changes in the context of multi-centre trials,[45,46] and there has been little systematic development or comprehensive psychometric evaluation of symptom-based scales.[47] For these reasons, we chose to develop and rigorously validate a generic symptom rating scale for this study.

We considered using the incidence of cancers and other major diagnoses as an alternative primary outcome measure, but the numbers detected were too small to have sufficient statistical power to detect a real difference between the two groups. A much larger study would be required.

The value of diagnostic endoscopy *per se* was not addressed in this study but we did find improvement in quality of life following endoscopy by both doctors and nurses, a finding reported before,[82,83] which reflects the value of the procedure even when no abnormality is found. Further research is needed to establish the effectiveness and cost-effectiveness of the procedure for all indications.

We assessed technical competency by analysis of a random sample of video recordings. For upper GI endoscopy, we developed and validated a new assessment technique with high inter-rater variability. For the stomach and oesophagus we found that nurses undertook significantly more thorough examinations. In contrast, we found no difference between the two groups in the examination of the colon, perhaps because the existing instrument was less structured, with lower inter-rater reliability.

External validity

We undertook this pragmatic randomised trial in 23 hospitals in England, Scotland and Wales, including large and small, urban and rural, and teaching and non-teaching. Hospitals volunteered to take part in response to a letter of invitation to

all members of the BSG in 2000, at a time when the numbers of nurse endoscopists in the UK was relatively small.[2] Thirty hospitals expressed initial interest. Seven dropped out between proposal development and the eventual start of the study for a variety of reasons, including staff changes and clinical workload. The number of trained nurse endoscopists has since increased markedly: a survey in 2004 of 196 endoscopy units registered with the Joint Advisory Group on Endoscopic Training and Accreditation (JAG) identified 96 endoscopy units with at least one nurse endoscopist. We and our collaborators believe that the doctors and nurses who participated in the study remain representative of this wider pool of endoscopic expertise in the UK. However, we did not study endoscopic practice in primary care or in diagnosis and treatment units, likely to grow in number in response to current policy in England, because these settings were undertaking few endoscopies when the study was conceived.

The professionals (67 doctors and 30 nurses) who took part were trained in endoscopic practice, but there were differences in the training and experience of the two groups. The training of both nurses and doctors in endoscopy is now formalised and monitored by JAG but about two-thirds of the doctors who took part in the study had acquired their skills largely through unstructured, experiential training in the early days of endoscopy in the UK.

The organisation of endoscopy services was different in many of the participating sites. We believe that this is representative of heterogeneity across the UK. We are currently evaluating the modernisation of endoscopy services in 20 sites in England,[84] and have confirmed this diversity of approach. The recruitment of patients to the study through randomisation before consent was designed to minimise distortion to local clinical practice. Although the number who declined to take part after randomisation was large, the baseline characteristics of the two study groups were comparable. Hence we believe that this study has indeed evaluated the role of nurses in diagnostic endoscopy in representative clinical settings in the UK.

There are differences in the non-endoscopic responsibilities of doctors and nurses. Most of the doctors carried significant clinical responsibilities outside endoscopy and some had additional managerial responsibilities. These demands appear to be the main cause for more patients being changed from doctor to nurse, and may in part account for the greater satisfaction that patients expressed with nurses.

The study addressed only diagnostic endoscopy, with lower GI procedures confined to the left side of the colon, as recommended by the BSG. However, more nurses are now undertaking both therapeutic procedures and full colonoscopy, and this extension of roles may need further evaluation. The BSG also recommends that nurses should only undertake those procedures that do not require intravenous sedation. However, this is now widely practised by nurses; indeed, in this study sedation was given with equal frequency by doctors and nurses.

Our outcome measures were chosen or designed to test whether there are differences in short- and long-term patient-assessed outcomes after endoscopy by doctors or nurses. We used validated measures, or undertook concurrent validation if necessary. Response rates were greater than 70% at 1 year. Those who responded tended to be older than those who did not. After 1 year we also looked at hospital records to detect new diagnoses that might have been missed, and primary care records, with the help of practice staff, to corroborate patient recollection of resources used. The very low incidence of new diagnoses did not differ between the two groups. We believe that it is unlikely that longer follow-up would have yielded any further findings following upper GI endoscopy, but it is possible that missed colonic polyps would remain silent for longer. In summary, we used multiple assessments to triangulate and confirm our findings.

Implications

Our findings confirm and reinforce studies that have suggested that nurses are safe and effective in diagnostic endoscopy.[2,6,7,11,12] Moreover nurses are more thorough in examining the oesophagus and stomach, and patients expressed more satisfaction immediately following an endoscopy by a nurse. In contrast, there was a trend towards more investigations in the year after the primary endoscopic procedure by a nurse. Reasons could include lack of confidence in the findings (either by the nurse operator or by those who saw the patient later), greater thoroughness by nurses in excluding additional pathology and a tendency to investigate an established diagnosis. Whatever the reason, the findings reflect a reported tendency for nurse practitioners to undertake more investigations, thus reducing potential cost savings relative to doctors.[85]

Since doctors also achieved greater health gain, they are much more likely to be cost-effective.

However, we do not know whether nurses will continue to generate more investigations as their levels of experience approach those of doctors. Thoroughness and extra investigations might have been behaviours to compensate for lack of confidence. If so, as nurses' confidence increases with their experience of undertaking endoscopy, these behaviours might decrease. Also, the confidence of colleagues in the findings of nurse endoscopists may increase as nurse endoscopy becomes more established. Hence the relative cost-effectiveness of nurse endoscopy could yet improve. We ourselves plan to throw more light on this by analysing how the experience of all operators in this study affected their performance.

If decision-makers choose to continue the current trend towards more diagnostic endoscopy undertaken by nurses rather than doctors, this has human resource and governance implications. The BSG recommends the development of the nurse's role in endoscopy,[86] drawing attention to the implications for training and clinical governance and proposing that every endoscopy unit should employ at least one trained nurse endoscopist. This implies that at least another 100 nurses (or other professionals) need to be identified and trained. This estimate does not take into account any increase in activity consequent upon the introduction of colorectal cancer screening or the need to give nurse endoscopists other roles, particularly in supporting chronic disease management.

It is likely that such professionals would be found among existing endoscopy assistants. However, it is not clear how many would accept the increased level of responsibility required, an issue raised by our participating nurses when the study findings were discussed. They also mentioned the potential tedium of undertaking endoscopy, suggesting that this role needs to be combined with other specialist nursing tasks, with implications for the total numbers to be recruited. An extension of their role has been, or would be, welcomed by many of the nurses in our study. The assessment of patients and the ability to prescribe medication after the procedure, and in other settings, were among examples given. Some nurses raised concerns about the lack of career structure. In contrast, we judge that experienced nurse endoscopists will be valuable and important trainers of both doctors and nurses.

There is also a need to combine data on waiting times from the NHS performance framework, including the HES and the PEDW, with survey data on the timing of introducing nurse endoscopy services, to estimate the effect of nurse endoscopy on waiting times, through interrupted time series methods. Ideally this requires data for at least 30 months around the introduction of the nurse endoscopist.

In summary, there was no significant difference between doctors and nurses in primary or secondary outcomes at 1 day, 1 month or 1 year after endoscopy, with the exception of patient satisfaction. One day after the procedure, patients were significantly more satisfied with nurses. Nurses were more thorough in the examination of stomach and oesophagus, but no different in the examination of duodenum and colon. There was no significant difference in costs to the NHS or patients. Although quality of life showed a slight benefit to doctors, this did not reach traditional levels of statistical significance. Even so, the economic evaluation, taking account of uncertainty in both costs and quality of life, suggests that doctors are much more likely to be cost-effective than nurses in the current state of their training and experience.

The interpretation of these results depends on the paradigm chosen. Classical statistical inference fails to reject the null hypotheses that there is no difference in effectiveness or costs between doctor- and nurse-delivered endoscopy. In contrast, Bayesian inference makes decisions by comparing the estimated cost per QALY with the maximum that a decision-maker would pay for a QALY, and estimating the probability that the estimated cost per QALY is less than that threshold. In MINuET, this leads to the conclusion that endoscopy delivered by doctors would have an 87% chance of being cost-effective when that threshold is £30,000, a figure that NICE has indicated is the maximum it is willing to pay in the absence of other strong evidence supporting the introduction of the technology.

How should those responsible for the future planning of endoscopy services in the NHS interpret these findings? In deciding between employing doctors and nurses they should consider, *inter alia*, the relative effectiveness and cost-effectiveness of both types of endoscopist, and their availability, both on the labour market and during the working day. Although the primary aim of MINuET was to estimate relative effectiveness and cost-effectiveness, it also showed

that nurses were more likely to take their planned sessions.

Where nurse endoscopists are already in post, there is reassuring evidence that they are safe, competent, more popular with patients and more thorough than doctors. Hence they make an important contribution to GI services, but they are currently less cost-effective than doctors. The economic evidence is not so strong as to suggest any reduction in the existing provision of endoscopies by nurses, but where there is a need for more endoscopy it favours the employment of more medical endoscopists if possible. The training of a nurse endoscopist is likely to be effective, but not as cost-effective, as recruitment of a trained doctor.

Although MINuET has achieved the aims set when it began in 2001, its success and the passage of time have identified five more questions for future researchers:

1. What are the relative effectiveness and cost-effectiveness of nurses and doctors in other procedures, notably therapeutic procedures and full colonoscopy, and in other settings, notably diagnosis and treatment units and primary care?
2. Will the cost-effectiveness of nurse endoscopists improve as they and their colleagues become more confident of their status and their practice?
3. What is the effect of nurse endoscopy on waiting times?
4. Is diagnostic endoscopy, whether undertaken by doctors or by nurses, an effective and cost-effective procedure for all indications?
5. What are the career implications and opportunities for nurses who become trained endoscopists?

Chapter 9
Conclusions

We conclude that there is no statistically significant difference between doctors and nurses in their clinical effectiveness in diagnostic endoscopy. However, nurses are significantly more thorough in the examination of the oesophagus and stomach and patients are significantly more satisfied after endoscopy by a nurse. Endoscopy by doctors is associated with better outcome at 1 year at higher cost, but overall is likely to be cost-effective. For both doctors and nurses, there is a need to improve adherence to best practice guidelines about sedation and the content of endoscopy reports.

Hence nurses can undertake diagnostic endoscopy safely and effectively. However, doctors are more likely to be cost-effective. If decision-makers nevertheless choose to increase the role of nurses in diagnostic endoscopy, this will have implications for human resources, training and governance. We estimate that two nurse endoscopists will be needed per endoscopy unit.

This study has addressed only diagnostic OGD and FS undertaken in traditional secondary care. There is a need to evaluate nurses and other professionals undertaking therapeutic procedures and full colonoscopy, and OGD and FS in other settings. There is also a need to assess the effect of changing roles on career structures for practitioners, and on service delivery, especially waiting times for patients.

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Contribution of authors

Karen Bloor (Senior Research Fellow) was the health economist who analysed the workforce implications. Wai-Yee Cheung (Senior Lecturer) was the co-applicant and patient outcome specialist who validated the GSRQ and GESQ. Simon Coulton (Research Fellow) was the data manager who developed, validated and managed the main database. Dharmaraj Durai (Research Fellow) was the trial coordinator who collected and analysed data from hospital records; and developed, validated and applied the method of assessing the upper GI endoscopy video recordings, validated GESQ and analysed clinical processes data. Amanda Farrin (Senior Medical Statistician) was the co-applicant and trial statistician who analysed and reported the primary and secondary outcome data. Gerry Richardson (Research Fellow) was the health economist who analysed and reported the cost-effectiveness data. Ian Russell (Professor of Public Health) was the co-applicant and trial methodologist who advised the trial team. John G Williams (Professor of Health Services Research) was the principal investigator who led the trial team and was principal author of the final report. All of the authors contributed to the final report.

Local collaborators

Hospital	Lead clinician	Nurse endoscopist(s)
FS		
Ayr Hospital	Mr C Wilson	Ms L McNaughton
Crosshouse Hospital, Kilmarnock	Mr C Morran	Ms K Linton
		Ms S Mair
Darlington Memorial Hospital	Mr K Gunning	Ms C Westwood
Gartnavel General Hospital, Glasgow	Dr PR Mills	Ms I Drummond
George Eliot Hospital, Nuneaton	Mr G Mathew	Ms A Reynolds
Kettering General Hospital	Dr A Hussain	Ms T Brooks
Leicester Royal Infirmary	Dr BJ Rathbone	Ms B Litchfield
Royal Albert Edward Infirmary, Wigan	Dr PW Bliss	Mr P Dereszkiewicz
Monklands Hospital, Airdrie	Dr RJ Holden	Ms L Wood
City General Hospital, Stoke on Trent	Mrs C Hall	Ms D Latham
Northampton General, Hospital	Mr DC Hunter	Ms S Hargreaves
		Ms C Sombach
Oldchurch Hospital, Romford	Mr D Khoo	Ms J Ward
Queen Alexandra Hospital, Portsmouth	Miss A Senapati	Ms A Cantelo-Jones
Queen's Medical Centre, Nottingham	Professor J Scholefield	Ms M Castle
Rotherham General Hospital	Mr RB Jones	Ms J D'Silva

continued

Hospital	Lead clinician	Nurse endoscopist(s)
Royal Glamorgan Hospital, Pontypridd	Dr P Davies	Ms J West
St George's Hospital, London	Mr RJ Leicester	Ms J Ho
Victoria Hospital, Kirkcaldy	Dr G Birnie	Ms A Macdonald
The Royal Sussex County Hospital, Brighton	Dr S Cairns	Ms J Grant
Russells Hall Hospital, Dudley	Dr AN Hamlyn	Ms L Wood
OGD		
Crosshouse Hospital, Kilmarnock	Mr C Morran	Ms K Linton Ms S Mair
Leicester Royal Infirmary	Dr BJ Rathbone	Ms B Litchfield
Royal Albert Edward Infirmary, Wigan	Dr PW Bliss	Mr P Dereszkiewicz
Monklands Hospital, Airdrie	Dr RJ Holden	Ms L Wood
Queen's Medical Centre, Nottingham	Dr S Ryder	Ms B Pick
Royal Shrewsbury Hospital	Dr M Smith	Ms L Bottomley
St John's Hospital, Livingston	Dr AJK Williams	Mr D McDonald
University Hospital Aintree, Liverpool	Professor N Krasner	Mr R Nicholson Ms J McPhillips
Victoria Hospital, Kirkcaldy	Dr G Birnie	Ms A Macdonald

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Appendix 1

Endoscopist training and experience questionnaire

Endoscopist Questionnaire

This questionnaire is devised to get information from all the participating Endoscopists (includes both Doctor and Nurse Endoscopists). Please complete it *before endoscoping for main trial if possible, if not, respond as if at the beginning of the trial*. Please answer all the questions as accurately as you can. This will help us do analysis of covariance by experience.

Endoscopist Name: _____ **Designation:** _____
(*Please state your full name*)

Hospital: _____

Participating Arm: (tick) Flexible Sigmoidoscopy ☐ OGD ☐ Both OGD and Flexi ☐

1. Number of years since qualification _____
2. Date when you started endoscopic training? _____
3. Do you do independent OGD? YES / NO
   If YES, when did you start? _____
4. Do you do independent Flexible sigmoidoscopy? YES / NO
   If YES, when did you start? _____
5. Do you do independent colonoscopy? YES / NO
   If YES, when did you start? _____
6. How many endoscopies have you done to date? (Unsupervised)
   (If this is below 1000, please give number to the nearest 50, otherwise state >1000, >1500 etc.)

Category	Number of endoscopies
OGD	
Flexible sigmoidoscopy	
Colonoscopy	

If <300 in each category please state actual numbers supervised and unsupervised:

Category	Supervised	Unsupervised
OGD		
Flexible sigmoidoscopy		
Colonoscopy		

7. Do you perform any therapeutic procedures? YES / NO
   If YES, please indicate specific procedures on list below (by a tick)
   (**I** = Independent, **S** = under Supervision)

	I	S		I	S
Injection of ulcers			PEG tube insertion		
Banding and injection of varices			Hot biopsy		
Dilatation of strictures			Polypectomy		
Stent insertion			Endoscopic mucosal resection		

Others (Specify) _____

8. Can you administer sedation? YES / NO

   If NO, what is the procedure for patients requiring or requesting sedation?

Training:
(Please provide as much detail as possible for each of the following.)

Did you attend a formal endoscopy-training course? YES / NO

If YES, please state

(a) Number of courses attended

(b) Duration of the course (Total number of days)

Did you receive a JAG certificate for any of the courses following attendance?

Do you monitor your endoscopic activities?
(e.g. through a logbook, computerised endoscopy system or departmental paper records)

Clinical approach (Please delete as appropriate)

Do you routinely see the patients who you will endoscope in a pre-endoscopy clinic? YES / NO

Do you routinely see the patients who you have endoscoped in a post-endoscopy clinic? YES / NO

Signature: ……
Date:
☐☐ – ☐☐ – ☐☐☐☐

Thank you for completing this questionnaire.

Appendix 2

Baseline questionnaire to patients

MINuET Study

Baseline Questionnaire

A questionnaire for people with digestive and bowel disorder

Please complete this questionnaire at home and bring it to your endoscopy appointment

Confidential

PLEASE READ ALL THE INSTRUCTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for agreeing to take part in this study. The answers you give in this questionnaire will help us find out if the treatments you get are helpful for your condition.

The information you provide will be completely confidential and will not affect your treatment in any way.

Please answer all the questions. Although it may seem that questions are asked more than once, it is still important that you answer every one, if you find it difficult to answer a question, do the best you can.

Please follow the instructions for each section carefully.

For each section, if you are asked to put a cross in the box, please use a cross, as if you were filling out a ballot paper, rather than a tick.

For example in the following question, if your answer to the question is yes, you should place a cross firmly in the box next to yes.

Do you drive a car ? Yes ☒

No ☐

PLEASE USE A BLACK OR BLUE PEN. Please do not use a pencil or any other coloured pen.

Please read all the instructions for each section.

Please enter the date you are completing this questionnaire below

		/			/				

dd/mm/yyyy

Please answer the following questions by marking a cross in the box that best describes your symptoms. When answering the questions about the effect on your life, consider how these symptoms prevented you from doing your usual activities during the past 2 weeks.

SECTION I – HEARTBURN

A1. In the last two weeks, how often have you experienced heartburn (a burning sensation behind your breastbone)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A2. In the last two weeks, how often have you had any discomfort in your upper abdomen (above your belly button and below your ribs)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

If you have not had heartburn or upper abdomen discomfort, skip the next question and go straight to Section II over the page

A3. In the last two weeks, how much have the symptoms described in questions A1 and A2 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

SECTION II – REFLUX, NAUSEA AND VOMITING

A4. In the last two weeks, how often have you experienced bitter bile or acid reflux (from the stomach into the throat)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A5. In the last two weeks, how often have you experienced a feeling of nausea or sickness without actually vomiting?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A6. In the last two weeks, how often have you retched or heaved without actually vomiting?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A7. In the last two weeks, how often have you actually vomited?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

If you have not vomited in the past 2 weeks, skip question A8 and go directly to question A9

A8. If you have vomited in the past two weeks, have you seen any blood in the vomit?

- Yes ☐
- No ☐

A9. In the last two weeks, how much have the symptoms described in question A4 to question A8 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

SECTION III – WIND

A10. In the last two weeks, how often have you been bothered by a lot of belching (belching refers to the release of wind from the stomach via the mouth, often associated with feeling less bloated)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A11. In the last two weeks, how often have you been bothered by passing a lot of wind from your bowel?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A12. In the last two weeks, how often have you experienced bloatedness, and or a feeling of trapped wind in your stomach?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A13. In the last two weeks, how often have you experienced loud gurgling noises from your stomach?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A14. In the last two weeks, how much have the symptoms described in question A10 to question A13 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

SECTION IV – EATING AND SWALLOWING

A15. In the last two weeks, how often have you felt that food sticks on the way down your gullet (through the chest into your stomach)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A16. In the last two weeks, how often have your eating habits been restricted because of your condition (examples might be having to eat more slowly, having to take smaller portions or having to eat different foods)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A17. In the last two weeks, have you had a lack of appetite?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A18. In the last two weeks, how much have the symptoms described in question A15 to question A17 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

A19. Have you noticed any change in weight over the last 3 months?

- No, my weight has been stable ☐
- Yes, I have been gaining weight ☐
- Yes, I have been losing weight ☐

SECTION V – BOWEL MOVEMENTS

A20. In the last two weeks, how often have you been bothered by too frequent emptying of your bowels?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A21. In the last two weeks, how often have you been bothered by loose stools?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A22. In the last two weeks, how often have you been bothered by hard stools?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A23. In the last two weeks, how often have you been bothered by constipation (constipation means difficulty in emptying your bowels)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A24. In the last two weeks, how often have you had an urgent need to empty your bowels (this urgent need is often associated with a feeling that you are not in full control)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A25. In the last two weeks, how often have you had a feeling of not completely emptying your bowels?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A26. In the last two weeks, have you had bleeding through your back passage (signs of bleeding include fresh blood, staining of toilet tissue, blood mixed with stools)?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

A27. In the last two weeks, how much have the symptoms described in question A20 to question A26 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

SECTION VI – OTHER QUESTIONS ABOUT SYMPTOMS DESCRIBED IN SECTIONS I TO V

A28. **Compared with 2 weeks ago**, how would you rate these symptoms in general?

- Much better now than 2 weeks ago ☐
- Somewhat better now than 2 weeks ago ☐
- About the same as 2 weeks ago ☐
- Somewhat worse now than 2 weeks ago ☐
- Much worse now than 2 weeks ago ☐

A29. In the last two weeks, how often have these symptoms caused you difficulty in getting to sleep?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most nights ☐
- Every night ☐

A30. In the last two weeks, how often have these symptoms caused you to wake up?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most nights ☐
- Every night ☐

These questions ask for your views about your general health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer each question by marking a cross in the appropriate box. If you are unsure on how to answer a question, please give the best answer you can.

B1. In general, would you say your health is:
(*please place a cross in one box*)

Excellent	**Very Good**	**Good**	**Fair**	**Poor**
☐	☐	☐	☐	☐

B2. **Compared with twelve months ago**, how would you rate your health in general **now**?
(*please place a cross in one box*)

Much better now than twelve months ago	**Somewhat better now than twelve months ago**	**About the same as twelve months ago**	**Somewhat worse now than twelve months ago**	**Much worse now than twelve months ago**
☐	☐	☐	☐	☐

B3. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

(*please place a cross in one box on each line*)

ACTIVITIES	**Yes, limited a lot**	**Yes, limited a little**	**No, not limited at all**
a) **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b) **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
c) Lifting or carrying groceries	☐	☐	☐
d) Climbing **several** flights of stairs	☐	☐	☐
e) Climbing **one** flight of stairs	☐	☐	☐
f) Bending, kneeling or stooping	☐	☐	☐
g) Walking **more than a mile**	☐	☐	☐
h) Walking **several hundred yards**	☐	☐	☐
i) Walking **one hundred yards**	☐	☐	☐
j) Bathing or dressing yourself	☐	☐	☐

B4. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

(*please place a cross in one box on each line*)	**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) Cut down the **amount of time** you spent on work or other activities	☐	☐	☐	☐	☐
b) **Accomplished less** than you would like	☐	☐	☐	☐	☐
c) Were limited in the **kind** of work or other activities	☐	☐	☐	☐	☐
d) Had **difficulty** performing the work or other activities (for example, it took extra effort)	☐	☐	☐	☐	☐

B5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

(*please place a cross in one box on each line*)	**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) Cut down the **amount of time** you spent on work or other activities	☐	☐	☐	☐	☐
b) **Accomplished less** than you would like	☐	☐	☐	☐	☐
c) Did work or other activities **less carefully** than usual	☐	☐	☐	☐	☐

B6. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

(*please place a cross in one box*)

Not at all	**Slightly**	**Moderately**	**Quite a bit**	**Extremely**
☐	☐	☐	☐	☐

B7. How much **bodily** pain have you had during the **past 4 weeks**?

(*please place a cross in one box*)

None	**Very mild**	**Mild**	**Moderate**	**Severe**	**Very severe**
☐	☐	☐	☐	☐	☐

B8. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)

(*please place a cross in one box*)

Not at all	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**
☐	☐	☐	☐	☐

B9. These questions are about how you feel and how things have been with you during the **past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past **4 weeks …**

(*please place a cross in one box on each line*)	**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) Did you feel full of life?	☐	☐	☐	☐	☐
b) Have you been very nervous?	☐	☐	☐	☐	☐
c) Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐
d) Have you felt calm and peaceful?	☐	☐	☐	☐	☐
e) Did you have a lot of energy?	☐	☐	☐	☐	☐
f) Have you felt downhearted and depressed?	☐	☐	☐	☐	☐
g) Did you feel worn out?	☐	☐	☐	☐	☐
h) Have you been happy?	☐	☐	☐	☐	☐
i) Did you feel tired?	☐	☐	☐	☐	☐

B10. During the **past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting friends, relatives, etc.)

(*please place a cross in one box*)

All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
☐	☐	☐	☐	☐

B11. How TRUE or FALSE is **each** of the following statements for you?
(*please place a cross in one box on each line*)

	Definitely true	**Mostly true**	**Don't know**	**Mostly false**	**Definitely false**
a) I seem to get sick a little easier than other people	☐	☐	☐	☐	☐
b) I am as healthy as anybody I know	☐	☐	☐	☐	☐
c) I expect my health to get worse	☐	☐	☐	☐	☐
d) My health is excellent	☐	☐	☐	☐	☐

This section also asks about your health in general. By placing a cross in one box in each group below, please indicate which statement best describes your own health state today.

Do not cross more than one box in each group.

C1. Mobility

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

C2. Self-Care

I have no problems with self-care ☐

I have some problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

C3. Usual Activities (e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

C4. Pain/Discomfort

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

C5. Anxiety/Depression

I am not anxious or depressed ☐

I am moderately anxious or depressed ☐

I am extremely anxious or depressed ☐

In this section a number of statements which people have used to describe themselves are given below. Read each statement then circle the appropriate number below the statement to indicate how you feel right now, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give an answer that seems to describe your present feelings best.

	Not at all	Somewhat	Moderately	Very much
D1. I feel calm	1	2	3	4
D2. I am tense	1	2	3	4
D3. I feel upset	1	2	3	4
D4. I am relaxed	1	2	3	4
D5. I feel content	1	2	3	4
D6. I am worried	1	2	3	4

E1. Please enter your date of birth below

☐☐ / ☐☐ / ☐☐☐☐

dd/mm/yyyy

E2. Please enter your sex below

Male ☐ Female ☐

E3. Please enter your initials in the box below

☐

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

IF YOU HAVE ANY CONCERNS ABOUT YOUR SYMPTOMS PLEASE CONSULT YOUR GP OR HOSPITAL DOCTOR

If you have any general comments about this questionnaire, please write them here.

Appendix 3

One-day post-endoscopy questionnaire to patients

MINuET Study

One Day Post Endoscopy Questionnaire

A questionnaire for people with digestive and bowel disorder

Please complete this questionnaire the day after your endoscopy and return it in the envelope provided

Confidential

PLEASE READ ALL THE INSTRUCTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for agreeing to take part in this study. The answers you give in this questionnaire will help us find out if the treatments you get are helpful for your condition.

The information you provide will be completely confidential and will not affect your treatment in any way.

Please answer all the questions. Although it may seem that questions are asked more than once, it is still important that you answer every one, if you find it difficult to answer a question, do the best you can.

Please follow the instructions for each section carefully.

For each section, if you are asked to put a cross in the box, please use a cross, as if you were filling out a ballot paper, rather than a tick.

For example in the following question, if your answer to the question is yes, you should place a cross firmly in the box next to yes.

Do you drive a car ? Yes ☒

No ☐

PLEASE USE A BLACK OR BLUE PEN. Please do not use a pencil or any other coloured pen.

Please read all the instructions for each section.

Please enter the date you are completing this questionnaire below

		/			/				

dd/mm/yyyy

These questions ask for your views about your general health since your endoscopy. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer each question by marking a cross in the appropriate box. If you are unsure on how to answer a question, please give the best answer you can.

A1 In general, would you say your health is:
(*please place a cross in one box*)

Excellent	**Very Good**	**Good**	**Fair**	**Poor**
☐	☐	☐	☐	☐

A2 Compared with **before your endoscopy was performed**, how would you rate your health in general now? (*please place a cross in one box*)

Much better now than the day before my endoscopy	**Somewhat better now than the day before my endoscopy**	**About the same as the day before my endoscopy**	**Somewhat worse now than the day before my endoscopy**	**Much worse now than the day before my endoscopy**
☐	☐	☐	☐	☐

A3 The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

(*please place a cross in one box on each line*)

ACTIVITIES	**Yes, limited a lot**	**Yes, limited a little**	**No, not limited at all**
a) **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b) **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
c) Lifting or carrying groceries	☐	☐	☐
d) Climbing **several** flights of stairs	☐	☐	☐
e) Climbing **one** flight of stairs	☐	☐	☐
f) Bending, kneeling or stooping	☐	☐	☐
g) Walking **more than a mile**	☐	☐	☐
h) Walking **several hundred yards**	☐	☐	☐
i) Walking **one hundred yards**	☐	☐	☐
j) Bathing or dressing yourself	☐	☐	☐

A4 Since your endoscopy, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

(*please place a cross in one box on each line*)	**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) Cut down the **amount of time** you spent on work or other activities	☐	☐	☐	☐	☐
b) **Accomplished less** than you would like	☐	☐	☐	☐	☐
c) Were limited in the **kind** of work or other activities	☐	☐	☐	☐	☐
d) Had **difficulty** performing the work or other activities (for example, it took extra effort)	☐	☐	☐	☐	☐

A5 Since your endoscopy, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

(*please place a cross in one box on each line*)	**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) Cut down the **amount of time** you spent on work or other activities	☐	☐	☐	☐	☐
b) **Accomplished less** than you would like	☐	☐	☐	☐	☐
c) Did work or other activities **less carefully** than usual	☐	☐	☐	☐	☐

A6 Since your endoscopy, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

(*please place a cross in one box*)

Not at all	**Slightly**	**Moderately**	**Quite a bit**	**Extremely**
☐	☐	☐	☐	☐

A7 How much **bodily** pain have you had **since your endoscopy**?

(*please place a cross in one box*)

None	**Very mild**	**Mild**	**Moderate**	**Severe**	**Very severe**
☐	☐	☐	☐	☐	☐

A8 Since your endoscopy, how much did **pain** interfere with your normal work (including both work outside the home and housework)

(*please place a cross in one box*)

Not at all	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**
☐	☐	☐	☐	☐

A9 These questions are about how you feel and how things have been with you **since your endoscopy**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time since your endoscopy …

(*please place a cross in one box on each line*)	**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) Did you feel full of life?	☐	☐	☐	☐	☐
b) Have you been very nervous?	☐	☐	☐	☐	☐
c) Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐
d) Have you felt calm and peaceful?	☐	☐	☐	☐	☐
e) Did you have a lot of energy?	☐	☐	☐	☐	☐
f) Have you felt downhearted and depressed?	☐	☐	☐	☐	☐
g) Did you feel worn out?	☐	☐	☐	☐	☐
h) Have you been happy?	☐	☐	☐	☐	☐
i) Did you feel tired?	☐	☐	☐	☐	☐

A10 Since your endoscopy, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting friends, relatives, etc.)

(*please place a cross in one box*)

All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
☐	☐	☐	☐	☐

A11 How TRUE or FALSE is **each** of the following statements for you?
(*please place a cross in one box on each line*)

	Definitely true	**Mostly true**	**Don't know**	**Mostly false**	**Definitely false**
a) I seem to get sick a little easier than other people	☐	☐	☐	☐	☐
b) I am as healthy as anybody I know	☐	☐	☐	☐	☐
c) I expect my health to get worse	☐	☐	☐	☐	☐
d) My health is excellent	☐	☐	☐	☐	☐

This section also asks about your health in general. By placing a cross in one box in each group below, please indicate which statement best describes your own health state today.

Do not cross more than one box in each group.

C1. Mobility

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

C2. Self-Care

I have no problems with self-care ☐

I have some problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

C3. Usual Activities (e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

C4. Pain/Discomfort

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

C5. Anxiety/Depression

I am not anxious or depressed ☐

I am moderately anxious or depressed ☐

I am extremely anxious or depressed ☐

In this section a number of questions which people have used to describe themselves are given below. Read each statement then cross the box below the appropriate response to indicate how you feel right now, that is at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best

	Not at all	Somewhat	Moderately so	Very much so
C1. I feel calm	☐	☐	☐	☐
C2. I feel secure	☐	☐	☐	☐
C3. I am tense	☐	☐	☐	☐
C4. I am regretful	☐	☐	☐	☐
C5. I feel at ease	☐	☐	☐	☐
C6. I feel upset	☐	☐	☐	☐
C7. I am presently worrying over possible misfortunes	☐	☐	☐	☐
C8. I feel rested	☐	☐	☐	☐
C9. I feel anxious	☐	☐	☐	☐
C10. I feel comfortable	☐	☐	☐	☐
C11. I feel self-confident	☐	☐	☐	☐
C12. I feel nervous	☐	☐	☐	☐
C13. I am jittery	☐	☐	☐	☐
C14. I feel 'highly strung'	☐	☐	☐	☐
C15. I am relaxed	☐	☐	☐	☐
C16. I feel content	☐	☐	☐	☐
C17. I am worried	☐	☐	☐	☐
C18. I feel over excited and rattled	☐	☐	☐	☐
C19. I feel joyful	☐	☐	☐	☐
C20. I feel pleasant	☐	☐	☐	☐

In this section a number of questions which people have used to describe themselves are given below. Read each statement then cross the box below the appropriate response to indicate how you generally feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe how you generally feel

	Almost never	Sometimes	Often	Almost Always
C21. I feel pleasant	☐	☐	☐	☐
C22. I tire quickly	☐	☐	☐	☐
C23. I feel like crying	☐	☐	☐	☐
C24. I wish I could be as happy as others seem to be	☐	☐	☐	☐
C25. I am losing out on things because I can't make up my mind soon enough	☐	☐	☐	☐
C26. I feel rested	☐	☐	☐	☐
C27. I am 'calm, cool and collected'	☐	☐	☐	☐
C28. I feel that difficulties are piling up so that I cannot overcome them	☐	☐	☐	☐
C29. I worry too much over something that really doesn't matter	☐	☐	☐	☐
C30. I am happy	☐	☐	☐	☐
C31. I am inclined to take things hard	☐	☐	☐	☐
C32. I lack self confidence	☐	☐	☐	☐
C33. I feel secure	☐	☐	☐	☐
C34. I try to avoid facing a crisis or difficulty	☐	☐	☐	☐
C35. I feel blue	☐	☐	☐	☐
C36. I am content	☐	☐	☐	☐
C37. Some unimportant thought runs through my mind and it bothers me	☐	☐	☐	☐
C38. I take disappointments so keenly that I can't put them out of my mind	☐	☐	☐	☐
C39. I am a steady person	☐	☐	☐	☐
C40. I get in a state of tension or turmoil as I think over my recent concerns and interests	☐	☐	☐	☐

This section has been developed with the aim of obtaining YOUR personal views based upon YOUR experience of having an endoscopy. There are no right or wrong answers to any of the questions: simply put a cross in the box that best describes how you think. Your answers will be treated in a confidential manner, and they will not affect your treatment in any way. The information provided will be used to find out how satisfied people are with their endoscopy, and to improve the endoscopy service.

D1 How much information was sent to you before your endoscopy appointment?

Too much	About right	Not enough
☐	☐	☐

D2 How easy to understand was the information that was sent to you before your endoscopy?

Very easy	Easy	Fair	Difficult	Very difficult
☐	☐	☐	☐	☐

D3 Was the information sent to you before your endoscopy appointment useful in answering your questions?

Very useful	Useful	Fair	Not very useful	Not at all useful
☐	☐	☐	☐	☐

D4 Before you had your endoscopy, how much opportunity did you have to ask questions about the endoscopy procedure?

Plenty	A little	None
☐	☐	☐

D5 Before you had your endoscopy, how much explanation did you receive about what would happen during your endoscopy?

Too much	About right	Not enough
☐	☐	☐

If you did not receive an explanation, then please go directly to question D9

D6 How easy to understand was the explanation given to you before your endoscopy?

Very easy	Easy	Fair	Difficult	Very difficult
☐	☐	☐	☐	☐

D7 Was the explanation given to you before your endoscopy useful in answering your questions?

Very useful	Useful	Fair	Not very useful	Not at all useful
☐	☐	☐	☐	☐

D8 Did the person who performed the endoscopy give you the explanation?

Yes	No
☐	☐

D9 How would you rate the communication skills (e.g. courtesy, respect, sensitivity, friendliness) of the person who performed your endoscopy?

Very poor	Poor	Fair	Good	Very good
☐	☐	☐	☐	☐

D10 How would you rate the technical skills (e.g. thoroughness, carefulness, competence) of the person who performed your endoscopy?

Very poor	Poor	Fair	Good	Very good
☐	☐	☐	☐	☐

D11 How would you rate the communication skills (e.g. courtesy, respect, sensitivity, friendliness) of the other staff in the endoscopy unit?

Very poor	Poor	Fair	Good	Very good
☐	☐	☐	☐	☐

D12 How much discomfort did you experience <u>during</u> your endoscopy?

Very severe	Severe	Moderate	Mild	None
☐	☐	☐	☐	☐

D13 How much pain did you experience <u>during</u> your endoscopy?

Very severe	Severe	Moderate	Mild	None
☐	☐	☐	☐	☐

D14 How much discomfort did you experience after your endoscopy?

Very severe	**Severe**	**Moderate**	**Mild**	**None**
☐	☐	☐	☐	☐

D15 How much pain did you experience after your endoscopy?

Very severe	**Severe**	**Moderate**	**Mild**	**None**
☐	☐	☐	☐	☐

D16 After you had your endoscopy, how much opportunity did you have to ask questions about the findings?

Plenty	**A little**	**None**
☐	☐	☐

D17 After you had your endoscopy, how much explanation of the findings did you receive?

Too much	**About right**	**Not enough**
☐	☐	☐

If you did not get an explanation, then please go directly to question D21

D18 Did the person who performed the endoscopy give you the explanation?

Yes	**No**
☐	☐

D19 How easy to understand was the explanation given to you after the endoscopy?

Very easy	**Easy**	**Fair**	**Difficult**	**Very difficult**
☐	☐	☐	☐	☐

D20 Was the explanation given to you after your endoscopy useful in answering your questions?

Very useful	**Useful**	**Fair**	**Not very useful**	**Not at all useful**
☐	☐	☐	☐	☐

D21 How would you rate the comfort of the recovery area in the endoscopy suite?

Very poor	**Poor**	**Fair**	**Good**	**Very good**
☐	☐	☐	☐	☐

D22 Overall, how satisfied are you with your endoscopy?

Very satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
☐	☐	☐	☐	☐

D23 If, in the future, you have another endoscopy, how satisfied would you be to have it done by the same person?

Very satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
☐	☐	☐	☐	☐

D24 How would you rate the overall reputation of the hospital?

Very poor	Poor	Fair	Good	Very good
☐	☐	☐	☐	☐

This section is mainly about the health care you have had BEFORE your endoscopy.
Please read each question carefully. For each question, if you have had no treatment or visits enter '0'.
We would like to know about visits to health professionals *for any reason*, not just your digestive or bowel symptoms.

Care from your GP's surgery

E1 **In the last 3 months**, (before your endoscopy) how often have you consulted any of the following **at your GP's surgery**?

Your own GP or another GP ☐☐
If none enter '0'

Practice nurse ☐☐
If none enter '0'

Other (please specify) _____ ☐☐
If none enter '0'

Other (please specify) _____ ☐☐
If none enter '0'

Care from NHS hospitals

E2 **In the last 12 months**, (before your endoscopy) have you been admitted to a NHS hospital **as an emergency**?

Yes ☐ No ☐

If you have entered 'yes' please indicate below the number of times you have been admitted to an NHS hospital **as an emergency in the past 12 months**

☐☐
If none enter '0'

E3 **In the last 12 months**, (before your endoscopy) have you been admitted to a NHS hospital **not as an emergency**?

Yes ☐ No ☐

If you have entered 'yes' please indicate below the number of times you have been admitted to a NHS hospital, **not as an emergency in the past 12 months**

☐☐
If none enter '0'

E4 **In the last 12 months**, (before your endoscopy) how often have you been seen at a NHS **outpatient clinic**?

by a doctor ☐☐
If none enter '0'

by a nurse practitioner ☐☐
If none enter '0'

by a dietician ☐☐
If none enter '0'

by other (please specify) _____ ☐☐
If none enter '0'

by other (please specify) _____ ☐☐
If none enter '0'

Private Treatment

E5 **In the last 12 months**, (before your endoscopy) have you been admitted to a **private hospital**?

Yes ☐ No ☐

If you have entered 'yes' please indicate below the number of times you have been admitted **to a private hospital in the past 12 months**

☐☐
If none enter '0'

E6 **In the last 12 months**, (before your endoscopy) how often have you consulted **other private health care professionals**?

Doctor ☐☐
If none enter '0'

Physiotherapist ☐☐
If none enter '0'

Alternative therapist (please specify) _____ ☐☐
If none enter '0'

Other (please specify) _____ ☐☐
If none enter '0'

ECONOMIC QUESTIONS

Please answer every question. If you are not sure or cannot remember exact details, please give the best answer you can

Education

F1 Please cross the box which describes when you finished continuous full time education

- 16 years or less ☐
- 17 – 19 years ☐
- 20 years or over ☐

F2 Since first leaving full time education have you undertaken any more full or part time education?

- Yes ☐
- No ☐

Employment

F3 Please cross the box which best describes your current employment status

- Employed full time ☐
- Employed part time ☐
- Self employed ☐
- Unemployed ☐
- Unable to work because of poor health ☐
- Full time student ☐
- Retired ☐

Travel to health care facilities

F4 Travel to hospital (e.g. The hospital you usually attend)

(i) Have you been to this hospital before your endoscopy?

Yes ☐ No ☐

(ii) If yes, what is your usual mode of transport to hospital?
(please place a cross against the mode of transport used)

Private Car	☐	Train/Metro	☐
Bus	☐	Taxi	☐
Ambulance	☐	Hospital Car	☐
Walking	☐	Cycling	☐
Motorbike	☐	Other (please specify in box below)	☐

(iii) What is the distance travelled in miles for the **round trip**? ☐☐☐ Miles

Do you have to pay any other costs, as a result of a typical **round trip** to the the hospital, (e.g. toll or parking fees)? Please give details below

Travel to endoscopy

F5 (i) How did you get to your endoscopy?
(please place a cross against the mode of transport used)

Private Car	☐	Train/Metro	☐
Bus	☐	Taxi	☐
Ambulance	☐	Hospital Car	☐
Walking	☐	Cycling	☐
Motorbike	☐	Other (please specify in box below)	☐

(ii) What is the distance travelled in miles **to the endoscopy**? ☐☐☐ Miles

(iii) How did you return home after your endoscopy?

Private Car	☐	Train/Metro	☐
Bus	☐	Taxi	☐
Ambulance	☐	Hospital Car	☐
Walking	☐	Cycling	☐
Motorbike	☐	Other (please specify in box below)	☐

(iv) What is the distance travelled in miles returning home from the **endoscopy**? ☐☐☐ Miles

Travel to GP

F6. (i) For each of the following modes of transport please put a cross in the modes of transport used in a **typical round trip journey** to your usual GP. For each mode of transport crossed, please enter the distance, to the nearest mile.

Transport		Distance	Transport		Distance
Private Car	☐	☐☐☐ Miles	Train/Metro	☐	☐☐☐ Miles
Bus	☐	☐☐☐ Miles	Taxi	☐	☐☐☐ Miles
Ambulance	☐	☐☐☐ Miles	Hospital Car	☐	☐☐☐ Miles
Walking	☐	☐☐☐ Miles	Cycling	☐	☐☐☐ Miles
Motorbike	☐	☐☐☐ Miles	Other (specify in box below)	☐	☐☐☐ Miles

Do you have to pay any other costs, as a result of a typical **round trip** to the the GP (e.g. toll or parking fees)? Please give details below

Look at the list of medications below. If you take any of the medications listed below, for your digestive or bowel symptoms, please enter the dose of each tablet (this will be written on the tablet box or bottle) and the number of tablets you take each day. Answer 'yes' or 'no' to whether the drug is ongoing (you take it regularly) and if you answer 'no' please enter the average

	Each tablet dose in mg	Number of tablets per day	Is this ongoing?	If not ongoing, average number of tablets taken per month
Indigestion medication				
Omeprazole (Losec)			Yes ☐ No ☐	
Lansoprazole (Zoton)			Yes ☐ No ☐	
Pantoprazole (Protium)			Yes ☐ No ☐	
Rabeprazole (Pariet)			Yes ☐ No ☐	
Ranitidine			Yes ☐ No ☐	
Famotidine (Pepcid)			Yes ☐ No ☐	
Nizatidine			Yes ☐ No ☐	
Cimetidine			Yes ☐ No ☐	
Metaclopramide (Maxolon)			Yes ☐ No ☐	
Domperidone (Motilium)			Yes ☐ No ☐	
Medication for irritable bowel				
Spasmonal			Yes ☐ No ☐	
Merbentyl			Yes ☐ No ☐	
Buscopan			Yes ☐ No ☐	
Colpermin			Yes ☐ No ☐	
Mebeverine (Colofac)			Yes ☐ No ☐	
Anti-diarrhoeal medication				
Loperamide (Imodium)			Yes ☐ No ☐	
Codeine Phosphate			Yes ☐ No ☐	
Cholestyramine			Yes ☐ No ☐	
Co-phenotrope (Lomotil)			Yes ☐ No ☐	

	Each tablet dose in mg	Number of tablets per day	Is this ongoing?	If not ongoing, average number of tablets taken per month
Medication for Colitis				
Mesalazine (Asacol)	☐☐☐	☐☐☐	Yes ☐ No ☐	☐☐☐
Balsalazide (Colazide)	☐☐☐	☐☐☐	Yes ☐ No ☐	☐☐☐
Olsalazine (Dipentum)	☐☐☐	☐☐☐	Yes ☐ No ☐	☐☐☐
Sulfasalazine (Salazopyrin)	☐☐☐	☐☐☐	Yes ☐ No ☐	☐☐☐
Prednisolone	☐☐☐	☐☐☐	Yes ☐ No ☐	☐☐☐
Budesonide	☐☐☐	☐☐☐	Yes ☐ No ☐	☐☐☐
Predsol/Predfoam/Colifoam	☐☐☐	☐☐☐	Yes ☐ No ☐	☐☐☐

If you take any other tablets/liquids for your **digestive or bowel symptoms**, that are not listed, please write the details in the list below. Please include any prescriptions and medicines you buy over the counter from the chemist or supermarket (examples include antacids and laxatives)

Name of medicine	On prescription	Dose in mg or ml	How many times taken per week
_____	Yes ☐ No ☐	☐☐☐	☐☐☐
_____	Yes ☐ No ☐	☐☐☐	☐☐☐
_____	Yes ☐ No ☐	☐☐☐	☐☐☐
_____	Yes ☐ No ☐	☐☐☐	☐☐☐
_____	Yes ☐ No ☐	☐☐☐	☐☐☐
_____	Yes ☐ No ☐	☐☐☐	☐☐☐

If you wish to add any comments regarding your medication, please enter them in the box below

G1 Please enter your date of birth below

		/			/				

dd/mm/yyyy

G2 Please enter your sex below

Male ☐ Female ☐

G3 Please enter your initials in the box below

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

If you have any general comments about your digestive or bowel treatment, or this questionnaire, please write them here.

Once you have completed the questionnaire please return it in the stamped addressed envelope or send to

MINuET Study Team
Health Service Research Trial Support Unit
Department of Health Sciences
2nd Floor
Seebohm Rowntree Building
University of York
Heslington
York YO10 5DD

IF YOU HAVE ANY CONCERNS ABOUT YOUR SYMPTOMS PLEASE CONSULT YOUR GP OR HOSPITAL DOCTOR

Your comments:

Appendix 4

One-month post-endoscopy questionnaire to patients

MINuET Study

One month post endoscopy questionnaire

A questionnaire for people with digestive and bowel disorder

Confidential

PLEASE READ ALL THE INSTRUCTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for agreeing to take part in this study. The answers you give in this questionnaire will help us find out if the treatments you get are helpful for your condition.

The information you provide will be completely confidential and will not affect your treatment in any way.

Please answer all the questions. Although it may seem that questions are asked more than once, it is still important that you answer every one, if you find it difficult to answer a question, do the best you can.

Please follow the instructions for each section carefully.

For each section, if you are asked to put a cross in the box, please use a cross, as if you were filling out a ballot paper, rather than a tick.

For example in the following question, if your answer to the question is yes, you should place a cross firmly in the box next to yes.

Do you drive a car ? Yes ☒

No ☐

PLEASE USE A BLACK OR BLUE PEN. Please do not use a pencil or any other coloured pen.

Please read all the instructions for each section.

Please complete the questionnaire fully and return it in the freepost envelope

Please enter the date you are completing this questionnaire below

		/			/				

dd/mm/yyyy

Please answer the following questions by marking a cross in the box that best describes your symptoms. When answering the questions about the effect on your life, consider how these symptoms prevented you from doing your usual activities during the past 2 weeks.

SECTION I – HEARTBURN

A1 In the last two weeks, how often have you experienced heartburn (a burning sensation behind your breastbone)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A2 In the last two weeks, how often have you had any discomfort in your upper abdomen (above your belly button and below your ribs)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

If you have not had heartburn or upper abdomen discomfort, skip the next question and go straight to Section II over the page

A3 In the last two weeks, how much have the symptoms described in questions A1 and A2 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

SECTION II – REFLUX, NAUSEA AND VOMITING

A4 In the last two weeks, how often have you experienced bitter bile or acid reflux (from the stomach into the throat)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A5 In the last two weeks, how often have you experienced a feeling of nausea or sickness without actually vomiting?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A6 In the last two weeks, how often have you retched or heaved without actually vomiting?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A7 In the last two weeks, how often have you actually vomited?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

If you have not vomited in the past 2 weeks, skip question A8 and go directly to question A9

A8 If you have vomited in the past two weeks, have you seen any blood in the vomit?

- Yes ☐
- No ☐

A9 In the last two weeks, how much have the symptoms described in question A4 to question A8 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

SECTION III – WIND

A10 In the last two weeks, how often have you been bothered by a lot of belching (belching refers to the release of wind from the stomach via the mouth, often associated with feeling less bloated)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A11 In the last two weeks, how often have you been bothered by passing a lot of wind from your bowel?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A12 In the last two weeks, how often have you experienced bloatedness, and or a feeling of trapped wind in your stomach?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A13 In the last two weeks, how often have you experienced loud gurgling noises from your stomach?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A14 In the last two weeks, how much have the symptoms described in question A10 to question A13 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

SECTION IV – EATING AND SWALLOWING

A15 In the last two weeks, how often have you felt that food sticks on the way down your gullet (through the chest into your stomach)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A16 In the last two weeks, how often have your eating habits been restricted because of your condition (examples might be having to eat more slowly, having to take smaller portions or having to eat different foods)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A17 In the last two weeks, have you had a lack of appetite?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A18 In the last two weeks, how much have the symptoms described in question A15 to question A17 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

A19 Have you noticed any change in weight over the last 3 months?

- No, my weight has been stable ☐
- Yes, I have been gaining weight ☐
- Yes, I have been losing weight ☐

SECTION V – BOWEL MOVEMENTS

A20 In the last two weeks, how often have you been bothered by too frequent emptying of your bowels?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A21 In the last two weeks, how often have you been bothered by loose stools?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A22 In the last two weeks, how often have you been bothered by hard stools?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A23 In the last two weeks, how often have you been bothered by constipation (constipation means difficulty in emptying your bowels)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A24 In the last two weeks, how often have you had an urgent need to empty your bowels (this urgent need is often associated with a feeling that you are not in full control)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A25 In the last two weeks, how often have you had a feeling of not completely emptying your bowels?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A26 In the last two weeks, have you had bleeding through your back passage (signs of bleeding include fresh blood, staining of toilet tissue, blood mixed with stools)?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

A27 In the last two weeks, how much have the symptoms described in question A20 to question A26 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

SECTION VI – OTHER QUESTIONS ABOUT SYMPTOMS DESCRIBED IN SECTIONS I TO V

A28 **Compared with 2 weeks ago**, how would you rate these symptoms in general?

- Much better now than 2 weeks ago ☐
- Somewhat better now than 2 weeks ago ☐
- About the same as 2 weeks ago ☐
- Somewhat worse now than 2 weeks ago ☐
- Much worse now than 2 weeks ago ☐

A29 In the last two weeks, how often have these symptoms caused you difficulty in getting to sleep?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most nights ☐
- Every night ☐

A30 In the last two weeks, how often have these symptoms caused you to wake up?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most nights ☐
- Every night ☐

These questions ask for your views about your general health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer each question by marking a cross in the appropriate box. If you are unsure on how to answer a question, please give the best answer you can.

B1 In general, would you say your health is:
(*please place a cross in one box*)

Excellent	**Very Good**	**Good**	**Fair**	**Poor**
☐	☐	☐	☐	☐

B2 Compared with before you had your endoscopy performed, how would you rate your health in general now?
(*please place a cross in one box*)

Much better now than before my endoscopy was performed	**Somewhat better now than before my endoscopy was performed**	**About the same as before my endoscopy was performed**	**Somewhat worse now than before my endoscopy was performed**	**Much worse now than before my endoscopy was performed**
☐	☐	☐	☐	☐

B3 The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

(*please place a cross in one box on each line*)

ACTIVITIES	**Yes, limited a lot**	**Yes, limited a little**	**No, not limited at all**
a) **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b) **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
c) Lifting or carrying groceries	☐	☐	☐
d) Climbing **several** flights of stairs	☐	☐	☐
e) Climbing **one** flight of stairs	☐	☐	☐
f) Bending, kneeling or stooping	☐	☐	☐
g) Walking **more than a mile**	☐	☐	☐
h) Walking **several hundred yards**	☐	☐	☐
i) Walking **one hundred yards**	☐	☐	☐
j) Bathing or dressing yourself	☐	☐	☐

B4 During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

(*please place a cross in one box on each line*)

	All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) Cut down the **amount of time** you spent on work or other activities	☐	☐	☐	☐	☐
b) **Accomplished less** than you would like	☐	☐	☐	☐	☐
c) Were limited in the **kind** of work or other activities	☐	☐	☐	☐	☐
d) Had **difficulty** performing the work or other activities (for example, it took extra effort)	☐	☐	☐	☐	☐

B5 During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

(*please place a cross in one box on each line*)

	All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) Cut down the **amount of time** you spent on work or other activities	☐	☐	☐	☐	☐
b) **Accomplished less** than you would like	☐	☐	☐	☐	☐
c) Did work or other activities **less carefully** than usual	☐	☐	☐	☐	☐

B6 During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

(*please place a cross in one box*)

Not at all	**Slightly**	**Moderately**	**Quite a bit**	**Extremely**
☐	☐	☐	☐	☐

B7 How much **bodily** pain have you had during the **past 4 weeks**?

(*please place a cross in one box*)

None	**Very mild**	**Mild**	**Moderate**	**Severe**	**Very severe**
☐	☐	☐	☐	☐	☐

B8 During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)

(*please place a cross in one box*)

Not at all	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**
☐	☐	☐	☐	☐

B9 These questions are about how you feel and how things have been with you during the **past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past 4 weeks …**

(*please place a cross in one box on each line*)	**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) Did you feel full of life?	☐	☐	☐	☐	☐
b) Have you been very nervous?	☐	☐	☐	☐	☐
c) Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐
d) Have you felt calm and peaceful	☐	☐	☐	☐	☐
e) Did you have a lot of energy?	☐	☐	☐	☐	☐
f) Have you felt downhearted and depressed?	☐	☐	☐	☐	☐
g) Did you feel worn out?	☐	☐	☐	☐	☐
h) Have you been happy?	☐	☐	☐	☐	☐
i) Did you feel tired?	☐	☐	☐	☐	☐

B10 During the **past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting friends, relatives, etc.)

(*please place a cross in one box*)

All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
☐	☐	☐	☐	☐

B11 How TRUE or FALSE is **each** of the following statements for you?
(*please place a cross in one box on each line*)

	Definitely true	**Mostly true**	**Don't know**	**Mostly false**	**Definitely false**
a) I seem to get sick a little easier than other people	☐	☐	☐	☐	☐
b) I am as healthy as anybody I know	☐	☐	☐	☐	☐
c) I expect my health to get worse	☐	☐	☐	☐	☐
d) My health is excellent	☐	☐	☐	☐	☐

This section also asks about your health in general. By placing a cross in one box in each group below, please indicate which statement best describes your own health state today.

Do not cross more than one box in each group.

C1. Mobility

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

C2. Self-Care

I have no problems with self-care ☐

I have some problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

C3. Usual Activities (e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

C4. Pain/Discomfort

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

C5. Anxiety/Depression

I am not anxious or depressed ☐

I am moderately anxious or depressed ☐

I am extremely anxious or depressed ☐

In this section a number of questions which people have used to describe themselves are given below. Read each statement then cross the box below the appropriate response to indicate how you feel right now, that is at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	Not at all	Somewhat	Moderately so	Very much so
D1. I feel calm	☐	☐	☐	☐
D2. I feel secure	☐	☐	☐	☐
D3. I am tense	☐	☐	☐	☐
D4. I am regretful	☐	☐	☐	☐
D5. I feel at ease	☐	☐	☐	☐
D6. I feel upset	☐	☐	☐	☐
D7. I am presently worrying over possible misfortunes	☐	☐	☐	☐
D8. I feel rested	☐	☐	☐	☐
D9. I feel anxious	☐	☐	☐	☐
D10. I feel comfortable	☐	☐	☐	☐
D11. I feel self-confident	☐	☐	☐	☐
D12. I feel nervous	☐	☐	☐	☐
D13. I am jittery	☐	☐	☐	☐
D14. I feel 'highly strung'	☐	☐	☐	☐
D15. I am relaxed	☐	☐	☐	☐
D16. I feel content	☐	☐	☐	☐
D17. I am worried	☐	☐	☐	☐
D18. I feel over excited and rattled	☐	☐	☐	☐
D19. I feel joyful	☐	☐	☐	☐
D20. I feel pleasant	☐	☐	☐	☐

In this section a number of questions which people have used to describe themselves are given below. Read each statement then cross the box below the appropriate response to indicate how you generally feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe how you generally feel

	Almost never	Sometimes	Often	Almost Always
D21. I feel pleasant	☐	☐	☐	☐
D22. I tire quickly	☐	☐	☐	☐
D23. I feel like crying	☐	☐	☐	☐
D24. I wish I could be as happy as others seem to be	☐	☐	☐	☐
D25. I am losing out on things because I can't make up my mind soon enough	☐	☐	☐	☐
D26. I feel rested	☐	☐	☐	☐
D27. I am 'calm, cool and collected'	☐	☐	☐	☐
D28. I feel that difficulties are piling up so that I cannot overcome them	☐	☐	☐	☐
D29. I worry too much over something that really doesn't matter	☐	☐	☐	☐
D30. I am happy	☐	☐	☐	☐
D31. I am inclined to take things hard	☐	☐	☐	☐
D32. I lack self confidence	☐	☐	☐	☐
D33. I feel secure	☐	☐	☐	☐
D34. I try to avoid facing a crisis or difficulty	☐	☐	☐	☐
D35. I feel blue	☐	☐	☐	☐
D36. I am content	☐	☐	☐	☐
D37. Some unimportant thought runs through my mind and it bothers me	☐	☐	☐	☐
D38. I take disappointments so keenly that I can't put them out of my mind	☐	☐	☐	☐
D39. I am a steady person	☐	☐	☐	☐
D40. I get in a state of tension or turmoil as I think over my recent concerns and interests	☐	☐	☐	☐

This section is about any contact you have had with the endoscopy unit since your endoscopy was performed

E1 **Since your endoscopy** have you contacted the endoscopy unit?

Yes ☐ No ☐

If 'Yes', who did you contact

- The person who performed the procedure ☐
- Other staff in the endoscopy unit ☐
- Someone else (specify in box below) ☐

How did you make contact

- Telephone ☐
- Letter ☐
- In person (specify where below) ☐

E2 **Since your endoscopy**, has the endoscopy unit contacted you?

Yes ☐ No ☐

If 'Yes', who contacted you

- The person who performed the procedure ☐
- Other staff in the endoscopy unit ☐
- Someone else (specify in box below) ☐

How were you contacted

- Telephone ☐
- Letter ☐
- In person (specify where below) ☐

This section is about the health care you have had since your endoscopy about one month ago. Please read each question carefully. For each question, if you have had no treatment or visits enter '0' as indicated.
We would like to know about visits to health professionals *for any reason*, not just your digestive or bowel symptoms.

Care from your GP's surgery (since your endoscopy)

F1 **Since your endoscopy** how often have you consulted any of the following at **your GP's surgery**?

Your own GP or another GP ☐☐
If none enter '0'

Practice nurse ☐☐
If none enter '0'

Other (please specify) _____ ☐☐
If none enter '0'

Other (please specify) _____ ☐☐
If none enter '0'

Care from NHS hospitals (since your endoscopy)

F2 **Since your endoscopy** have you been admitted to a NHS hospital **as an emergency**?

Yes ☐ No ☐

If you have entered 'yes' please indicate below the number of times you have been admitted to a NHS hospital **as an emergency since your endoscopy**

☐☐
If none enter '0'

F3 **Since your endoscopy** have you been admitted to a NHS hospital **not as an emergency**?

Yes ☐ No ☐

If you have entered 'yes' please indicate below the number of times you have been admitted to a NHS hospital, **not as an emergency since your endoscopy**

☐☐
If none enter '0'

F4 **Since your endoscopy** how often have you been seen at a NHS **outpatient clinic**?

by a doctor ☐☐
If none enter '0'

by a nurse practitioner ☐☐
If none enter '0'

by a dietician ☐☐
If none enter '0'

by other (please specify) _____ ☐☐
If none enter '0'

by other (please specify) _____ ☐☐
If none enter '0'

Private Treatment (since your endoscopy)

F5 **Since your endoscopy** have you been admitted to a **private hospital**?

Yes ☐ No ☐

If you have entered 'yes' please indicate below the number of times you have been admitted **to a private hospital since your endoscopy**

☐☐
If none enter '0'

F6 **Since your endoscopy** how often have you consulted other **private health care professionals**?

Doctor ☐☐
If none enter '0'

Physiotherapist ☐☐
If none enter '0'

Alternative therapist (please specify) _____ ☐☐
If none enter '0'

Other (please specify) _____ ☐☐
If none enter '0'

Look at the list of medications below. If you take any of the medications listed below, for your digestive or bowel symptoms, please enter the dose of each tablet (this will be written on the tablet box or bottle) and the number of tablets you take each day. Answer 'yes' or 'no' to whether the drug is ongoing (you take it regularly) and if you answer 'no' please enter the average number of tablets you take each month.

	Each tablet dose in mg	Number of tablets per day	Is this ongoing?	If not ongoing, average number of tablets taken per month
Indigestion medication				
Omeprazole (Losec)			Yes ☐ No ☐	
Lansoprazole (Zoton)			Yes ☐ No ☐	
Pantoprazole (Protium)			Yes ☐ No ☐	
Rabeprazole (Pariet)			Yes ☐ No ☐	
Ranitidine			Yes ☐ No ☐	
Famotidine (Pepcid)			Yes ☐ No ☐	
Nizatidine			Yes ☐ No ☐	
Cimetidine			Yes ☐ No ☐	
Metaclopramide (Maxolon)			Yes ☐ No ☐	
Domperidone (Motilium)			Yes ☐ No ☐	
Medication for irritable bowel				
Spasmonal			Yes ☐ No ☐	
Merbentyl			Yes ☐ No ☐	
Buscopan			Yes ☐ No ☐	
Colpermin			Yes ☐ No ☐	
Mebeverine (Colofac)			Yes ☐ No ☐	
Anti-diarrhoeal medication				
Loperamide (Imodium)			Yes ☐ No ☐	
Codeine Phosphate			Yes ☐ No ☐	
Cholestyramine			Yes ☐ No ☐	
Co-phenotrope (Lomotil)			Yes ☐ No ☐	

Medication for Colitis	**Each tablet dose in mg**	**Number of tablets per day**	**Is this ongoing?**	**If not ongoing, average number of tablets taken per month**
Mesalazine (Asacol)	☐☐☐	☐☐☐	Yes ☐ No ☐	☐☐☐
Balsalazide (Colazide)	☐☐☐	☐☐☐	Yes ☐ No ☐	☐☐☐
Olsalazine (Dipentum)	☐☐☐	☐☐☐	Yes ☐ No ☐	☐☐☐
Sulfasalazine (Salazopyrin)	☐☐☐	☐☐☐	Yes ☐ No ☐	☐☐☐
Prednisolone	☐☐☐	☐☐☐	Yes ☐ No ☐	☐☐☐
Budesonide	☐☐☐	☐☐☐	Yes ☐ No ☐	☐☐☐
Predsol/Predfoam/Colifoam	☐☐☐	☐☐☐	Yes ☐ No ☐	☐☐☐

If you take any other tablets/liquids for your **digestive or bowel symptoms**, that are not listed, please write the details in the list below. Please include any prescriptions and medicines you buy over the counter from the chemist or supermarket (examples include antacids and laxatives)

Name of medicine	**On prescription**	**Dose in mg or ml**	**How many times taken per week**
_____	Yes ☐ No ☐	☐☐☐	☐☐☐
_____	Yes ☐ No ☐	☐☐☐	☐☐☐
_____	Yes ☐ No ☐	☐☐☐	☐☐☐
_____	Yes ☐ No ☐	☐☐☐	☐☐☐
_____	Yes ☐ No ☐	☐☐☐	☐☐☐
_____	Yes ☐ No ☐	☐☐☐	☐☐☐

If you wish to add any comments regarding your medication, please enter them in the box below

F1. Please enter your date of birth below

		/			/				

dd/mm/yyyy

F2. Please enter your sex below

Male ☐ Female ☐

F3. Please enter your initials in the box below

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

If you have any general comments about your digestive or bowel treatment, or this questionnaire, please write them here.

Once you have completed the questionnaire please return it in the stamped addressed envelope or send to

MINuET Study Team
Health Service Trial Support Unit
Department of Health Sciences
2nd Floor
Seebohm Rowntree Building
University of York
Heslington
York YO10 5DD

IF YOU HAVE ANY CONCERNS ABOUT YOUR SYMPTOMS PLEASE CONSULT YOUR GP OR HOSPITAL DOCTOR

Your comments:

Appendix 5

One-year post-endoscopy questionnaire to patients

MINuET Study

One Year Post Endoscopy Questionnaire

A questionnaire for people with digestive and bowel disorder

Confidential

PLEASE READ ALL THE INSTRUCTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for agreeing to take part in this study. The answers you give in this questionnaire will help us find out if the treatments you get are helpful for your condition.

The information you provide will be completely confidential and will not affect your treatment in any way.

Please answer all the questions. Although it may seem that questions are asked more than once, it is still important that you answer every one, if you find it difficult to answer a question, do the best you can.

Please follow the instructions for each section carefully.

For each section, if you are asked to put a cross in the box, please use a cross, as if you were filling out a ballot paper, rather than a tick.

For example in the following question, if your answer to the question is yes, you should place a cross firmly in the box next to yes.

Do you drive a car ? Yes ☒

No ☐

PLEASE USE A BLACK OR BLUE PEN. Please do not use a pencil or any other coloured pen.

Please read all the instructions for each section.

Please enter the date you are completing this questionnaire below

		/			/				

dd/mm/yyyy

Please answer the following questions by marking a cross in the box that best describes your symptoms. When answering the questions about the effect on your life, consider how these symptoms prevented you from doing your usual activities during the past 2 weeks.

SECTION I – HEARTBURN

A1 In the last two weeks, how often have you experienced heartburn (a burning sensation behind your breastbone)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A2 In the last two weeks, how often have you had any discomfort in your upper abdomen (above your belly button and below your ribs)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

If you have not had heartburn or upper abdomen discomfort, skip the next question and go straight to Section II over the page

A3 In the last two weeks, how much have the symptoms described in questions A1 and A2 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

SECTION II – REFLUX, NAUSEA AND VOMITING

A4 In the last two weeks, how often have you experienced bitter bile or acid reflux (from the stomach into the throat)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A5 In the last two weeks, how often have you experienced a feeling of nausea or sickness without actually vomiting?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A6 In the last two weeks, how often have you retched or heaved without actually vomiting?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A7 In the last two weeks, how often have you actually vomited?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

If you have not vomited in the past 2 weeks, skip question A8 and go directly to question A9

A8 If you have vomited in the past two weeks, have you seen any blood in the vomit?

- Yes ☐
- No ☐

A9 In the last two weeks, how much have the symptoms described in question A4 to question A8 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

SECTION III – WIND

A10 In the last two weeks, how often have you been bothered by a lot of belching (belching refers to the release of wind from the stomach via the mouth, often associated with feeling less bloated)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A11 In the last two weeks, how often have you been bothered by passing a lot of wind from your bowel?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A12 In the last two weeks, how often have you experienced bloatedness, and or a feeling of trapped wind in your stomach?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A13 In the last two weeks, how often have you experienced loud gurgling noises from your stomach?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A14 In the last two weeks, how much have the symptoms described in question A10 to question A13 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

SECTION IV – EATING AND SWALLOWING

A15 In the last two weeks, how often have you felt that food sticks on the way down your gullet (through the chest into your stomach)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A16 In the last two weeks, how often have your eating habits been restricted because of your condition (examples might be having to eat more slowly, having to take smaller portions or having to eat different foods)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A17 In the last two weeks, have you had a lack of appetite?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A18 In the last two weeks, how much have the symptoms described in question A15 to question A17 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

A19 Have you noticed any change in weight over the last 3 months?

- No, my weight has been stable ☐
- Yes, I have been gaining weight ☐
- Yes, I have been losing weight ☐

SECTION V – BOWEL MOVEMENTS

A20 In the last two weeks, how often have you been bothered by too frequent emptying of your bowels?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A21 In the last two weeks, how often have you been bothered by loose stools?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A22 In the last two weeks, how often have you been bothered by hard stools?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A23 In the last two weeks, how often have you been bothered by constipation (constipation means difficulty in emptying your bowels)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A24 In the last two weeks, how often have you had an urgent need to empty your bowels (this urgent need is often associated with a feeling that you are not in full control)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A25 In the last two weeks, how often have you had a feeling of not completely emptying your bowels?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Everyday ☐

A26 In the last two weeks, have you had bleeding through your back passage (signs of bleeding include fresh blood, staining of toilet tissue, blood mixed with stools)?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

A27 In the last two weeks, how much have the symptoms described in question A20 to question A26 prevented you from doing your usual activities?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

SECTION VI – OTHER QUESTIONS ABOUT SYMPTOMS DESCRIBED IN SECTIONS I TO V

A28 **Compared with 2 weeks ago**, how would you rate these symptoms in general?

- Much better now than 2 weeks ago ☐
- Somewhat better now than 2 weeks ago ☐
- About the same as 2 weeks ago ☐
- Somewhat worse now than 2 weeks ago ☐
- Much worse now than 2 weeks ago ☐

A29 In the last two weeks, how often have these symptoms caused you difficulty in getting to sleep?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most nights ☐
- Every night ☐

A30 In the last two weeks, how often have these symptoms caused you to wake up?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most nights ☐
- Every night ☐

These questions ask for your views about your general health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer each question by marking a cross in the appropriate box. If you are unsure on how to answer a question, please give the best answer you can.

B1. In general, would you say your health is:
(*please place a cross in one box*)

Excellent	**Very Good**	**Good**	**Fair**	**Poor**
☐	☐	☐	☐	☐

B2. **Compared with just before your endoscopy twelve months ago**, how would you rate your health in general **now**?
(*please place a cross in one box*)

Much better now than twelve months ago	**Somewhat better now than twelve months ago**	**About the same as twelve months ago**	**Somewhat worse now than twelve months ago**	**Much worse now than twelve months ago**
☐	☐	☐	☐	☐

B3. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

(*please place a cross in one box on each line*)

ACTIVITIES	**Yes, limited a lot**	**Yes, limited a little**	**No, not limited at all**
a) **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b) **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
c) Lifting or carrying groceries	☐	☐	☐
d) Climbing **several** flights of stairs	☐	☐	☐
e) Climbing **one** flight of stairs	☐	☐	☐
f) Bending, kneeling or stooping	☐	☐	☐
g) Walking **more than a mile**	☐	☐	☐
h) Walking **several hundred yards**	☐	☐	☐
i) Walking **one hundred yards**	☐	☐	☐
j) Bathing or dressing yourself	☐	☐	☐

B4 During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

(*please place a cross in one box on each line*)	**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) Cut down the **amount of time** you spent on work or other activities	☐	☐	☐	☐	☐
b) **Accomplished less** than you would like	☐	☐	☐	☐	☐
c) Were limited in the **kind** of work or other activities	☐	☐	☐	☐	☐
d) Had **difficulty** performing the work or other activities (for example, it took extra effort)	☐	☐	☐	☐	☐

B5 During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

(*please place a cross in one box on each line*)	**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) Cut down the **amount of time** you spent on work or other activities	☐	☐	☐	☐	☐
b) **Accomplished less** than you would like	☐	☐	☐	☐	☐
c) Did work or other activities **less carefully** than usual	☐	☐	☐	☐	☐

B6 During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

(*please place a cross in one box*)

Not at all	**Slightly**	**Moderately**	**Quite a bit**	**Extremely**
☐	☐	☐	☐	☐

B7 How much **bodily** pain have you had during the past 4 weeks?

(*please place a cross in one box*)

None	**Very mild**	**Mild**	**Moderate**	**Severe**	**Very severe**
☐	☐	☐	☐	☐	☐

B8 During the past 4 weeks, how much did **pain** interfere with your normal work (including both work outside the home and housework)

(*please place a cross in one box*)

Not at all	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**
☐	☐	☐	☐	☐

B9 These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks …

(*please place a cross in one box on each line*)	**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) Did you feel full of life?	☐	☐	☐	☐	☐
b) Have you been very nervous?	☐	☐	☐	☐	☐
c) Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐
d) Have you felt calm and peaceful	☐	☐	☐	☐	☐
e) Did you have a lot of energy?	☐	☐	☐	☐	☐
f) Have you felt downhearted and depressed?	☐	☐	☐	☐	☐
g) Did you feel worn out?	☐	☐	☐	☐	☐
h) Have you been happy?	☐	☐	☐	☐	☐
i) Did you feel tired?	☐	☐	☐	☐	☐

B10 During the past 4 weeks, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting friends, relatives, etc.)

(*please place a cross in one box*)

All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
☐	☐	☐	☐	☐

B11 How TRUE or FALSE is **each** of the following statements for you?
(*please place a cross in one box on each line*)

	Definitely true	**Mostly true**	**Don't know**	**Mostly false**	**Definitely false**
a) I seem to get sick a little easier than other people	☐	☐	☐	☐	☐
b) I am as healthy as anybody I know	☐	☐	☐	☐	☐
c) I expect my health to get worse	☐	☐	☐	☐	☐
d) My health is excellent	☐	☐	☐	☐	☐

This section also asks about your health in general. By placing a cross in one box in each group below, please indicate which statement best describes your own health state today.

Do not cross more than one box in each group.

C1. Mobility

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

C2. Self-Care

I have no problems with self-care ☐

I have some problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

C3. Usual Activities (e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

C4. Pain/Discomfort

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

C5. Anxiety/Depression

I am not anxious or depressed ☐

I am moderately anxious or depressed ☐

I am extremely anxious or depressed ☐

In this section a number of questions which people have used to describe themselves are given below. Read each statement then cross the box below the appropriate response to indicate how you feel right now, that is at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best

	Not at all	Somewhat	Moderately so	Very much so
D1. I feel calm	☐	☐	☐	☐
D2. I feel secure	☐	☐	☐	☐
D3. I am tense	☐	☐	☐	☐
D4. I am regretful	☐	☐	☐	☐
D5. I feel at ease	☐	☐	☐	☐
D6. I feel upset	☐	☐	☐	☐
D7. I am presently worrying over possible misfortunes	☐	☐	☐	☐
D8. I feel rested	☐	☐	☐	☐
D9. I feel anxious	☐	☐	☐	☐
D10. I feel comfortable	☐	☐	☐	☐
D11. I feel self-confident	☐	☐	☐	☐
D12. I feel nervous	☐	☐	☐	☐
D13. I am jittery	☐	☐	☐	☐
D14. I feel 'highly strung'	☐	☐	☐	☐
D15. I am relaxed	☐	☐	☐	☐
D16. I feel content	☐	☐	☐	☐
D17. I am worried	☐	☐	☐	☐
D18. I feel over excited and rattled	☐	☐	☐	☐
D19. I feel joyful	☐	☐	☐	☐
D20. I feel pleasant	☐	☐	☐	☐

In this section a number of questions which people have used to describe themselves are given below. Read each statement then cross the box below the appropriate response to indicate how you generally feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe how you generally feel

	Almost never	Sometimes	Often	Almost Always
D21. I feel pleasant	☐	☐	☐	☐
D22. I tire quickly	☐	☐	☐	☐
D23. I feel like crying	☐	☐	☐	☐
D24. I wish I could be as happy as others seem to be	☐	☐	☐	☐
D25. I am losing out on things because I can't make up my mind soon enough	☐	☐	☐	☐
D26. I feel rested	☐	☐	☐	☐
D27. I am 'calm, cool and collected'	☐	☐	☐	☐
D28. I feel that difficulties are piling up so that I cannot overcome them	☐	☐	☐	☐
D29. I worry too much over something that really doesn't matter	☐	☐	☐	☐
D30. I am happy	☐	☐	☐	☐
D31. I am inclined to take things hard	☐	☐	☐	☐
D32. I lack self confidence	☐	☐	☐	☐
D33. I feel secure	☐	☐	☐	☐
D34. I try to avoid facing a crisis or difficulty	☐	☐	☐	☐
D35. I feel blue	☐	☐	☐	☐
D36. I am content	☐	☐	☐	☐
D37. Some unimportant thought runs through my mind and it bothers me	☐	☐	☐	☐
D38. I take disappointments so keenly that I can't put them out of my mind	☐	☐	☐	☐
D39. I am a steady person	☐	☐	☐	☐
D40. I get in a state of tension or turmoil as I think over my recent concerns and interests	☐	☐	☐	☐

This section is mainly about the health care you have had **SINCE** your endoscopy about 12 months ago.
Please read each question carefully. For each question, if you have had no treatment or visits enter '0' as indicated.
We would like to know about visits to health professionals ***for any reason***, not just your digestive or bowel symptoms.

Care from your GP's surgery

E1 **In the last 12 months**, how often have you consulted, for any reason, any of the following **at your GP's surgery**?

Your own GP or another GP ☐☐
If none enter '0'

Practice nurse ☐☐
If none enter '0'

Other (please specify) _____ ☐☐
If none enter '0'

Other (please specify) _____ ☐☐
If none enter '0'

E2 **In the last 12 months**, how often have you consulted, for any reason, any of the following **at home**?

Your own GP or another GP ☐☐
If none enter '0'

Practice nurse ☐☐
If none enter '0'

Other (please specify) _____ ☐☐
If none enter '0'

Other (please specify) _____ ☐☐
If none enter '0'

Care from NHS hospitals

E3 **In the last 12 months**, have you been admitted, for any reason, to a NHS hospital **as an emergency**?

Yes ☐ No ☐

If 'yes' how many times? ☐☐

If none enter '0'

E4 **In the last 12 months**, have you been admitted, for any reason, to a NHS hospital **not as an emergency**?

Yes ☐ No ☐

If 'yes' how many times? ☐☐

If none enter '0'

E5 **In the last 12 months**, how often have you been seen, for any reason, at a NHS hospital **outpatient clinic**?

by a doctor ☐☐ *If none enter '0'*

by a nurse practitioner ☐☐ *If none enter '0'*

by a dietician ☐☐ *If none enter '0'*

by other (please specify) _____ ☐☐ *If none enter '0'*

by other (please specify) _____ ☐☐ *If none enter '0'*

E6 **In the last 12 months**, have you been admitted as a day case for **upper or lower endoscopy**?

Yes ☐ No ☐

If 'yes' how many times for an upper endoscopy? ☐☐ *If none enter '0'*

If 'yes' how many times for a lower endoscopy? ☐☐ *If none enter '0'*

Private Treatment

E7 **In the last 12 months**, have you been admitted to a **private hospital**?

Yes ☐ No ☐

If 'yes' how many times? ☐☐

If none enter '0'

E8 **In the last 12 months**, how often have you consulted **private health care professionals** as an outpatient?

Doctor ☐☐

If none enter '0'

Physiotherapist ☐☐

If none enter '0'

Alternative therapist (please specify) _____ ☐☐

If none enter '0'

Other (please specify) _____ ☐☐

If none enter '0'

Look at the list of medications below. If you take any of the medications listed below, for your digestive or bowel symptoms, please enter the dose of each tablet (this will be written on the tablet box or bottle) and the number of tablets you take each day. Answer 'yes' or 'no' to whether the drug is ongoing (you take it regularly) and if you answer 'no' please enter the average number of tablets you take each month.

	Each tablet dose in mg	Number of tablets per day	Is this ongoing?	If not ongoing, average number of tablets taken per month
Indigestion medication				
Esomeprazole (Nexium)			Yes ☐ No ☐	
Omeprazole (Losec)			Yes ☐ No ☐	
Lansoprazole (Zoton)			Yes ☐ No ☐	
Pantoprazole (Protium)			Yes ☐ No ☐	
Rabeprazole (Pariet)			Yes ☐ No ☐	
Ranitidine (Zantac)			Yes ☐ No ☐	
Famotidine (Pepcid)			Yes ☐ No ☐	
Nizatidine (Axid)			Yes ☐ No ☐	
Cimetidine (Tagamet)			Yes ☐ No ☐	
Metaclopramide (Maxolon)			Yes ☐ No ☐	
Domperidone (Motilium)			Yes ☐ No ☐	
Medication for irritable bowel				
Spasmonal			Yes ☐ No ☐	
Merbentyl			Yes ☐ No ☐	
Buscopan			Yes ☐ No ☐	
Colpermin			Yes ☐ No ☐	
Mebeverine (Colofac)			Yes ☐ No ☐	
Anti-diarrhoeal medication				
Loperamide (Imodium)			Yes ☐ No ☐	
Codeine Phosphate			Yes ☐ No ☐	
Cholestyramine			Yes ☐ No ☐	
Co-phenotrope (Lomotil)			Yes ☐ No ☐	

Medication for Colitis	**Each tablet dose in mg**	**Number of tablets per day**	**Is this ongoing?**	**If not ongoing, average number of tablets taken per month**
Mesalazine (Asacol)			Yes ☐ No ☐	
Balsalazide (Colazide)			Yes ☐ No ☐	
Olsalazine (Dipentum)			Yes ☐ No ☐	
Sulfasalazine (Salazopyrin)			Yes ☐ No ☐	
Prednisolone			Yes ☐ No ☐	
Budesonide (Entocort)			Yes ☐ No ☐	
Predsol/Predfoam/Colifoam/ enemas			Yes ☐ No ☐	

If you take any other tablets/liquids for your **digestive or bowel symptoms**, that are not listed, please write the details in the list below. Please include any prescriptions and medicines you buy over the counter from the chemist or supermarket (examples include antacids and laxatives)

Name of medicine	**On prescription**	**Dose in mg orml**	**How many times taken per week**
_____	Yes ☐ No ☐		
_____	Yes ☐ No ☐		
_____	Yes ☐ No ☐		
_____	Yes ☐ No ☐		
_____	Yes ☐ No ☐		
_____	Yes ☐ No ☐		

If you wish to add any comments regarding your medication, please enter them in the box below

This section asks for your views on who could perform endoscopies for you. Traditionally endoscopy (camera examination of either the stomach or bowel) is performed by doctors. Increasingly this is being done by trained nurses. Half of the patients in the study in which you took part had the endoscopy done by trained doctors and half by trained nurses.

F1. What, in your opinion, are the advantages of having an endoscopy performed by a doctor?

F2. What, in your opinion, are the advantages of having an endoscopy performed by a nurse?

You have a friend with similar symptoms to yours who asks for your advice about having an endoscopy. Please look at the list below and rank your advice to your friend, so that 1 is the option you would strongly advise your friend to have, 2 is the next strongest advice and so on until 4, which is your least likely advice.

F3. I would advise my friend to have an endoscopy, and not to worry whether it was done by a Doctor or Nurse. ☐

F4. I would advise my friend to have an endoscopy, but only if it were done by a doctor. ☐

F5. I would advise my friend to have an endoscopy, but only if it were done by a nurse. ☐

F6. I would advise my friend not to have an endoscopy at all. ☐

G1 Please enter your date of birth below

☐☐ / ☐☐ / ☐☐☐☐

dd/mm/yyyy

G2 Please enter your sex below

Male ☐ Female ☐

G3 Please enter your initials in the box below

☐

G4 If you would like to see a summary of the overall results of the trial when it is complete, please place a cross in this box.

☐

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

If you have any general comments about your digestive or bowel treatment, or this questionnaire, please write them here.

Once you have completed the questionnaire please return it in the stamped addressed envelope or send to

MINuET Study Team
York Trials Unit
Department of Health Sciences
2nd Floor
Seebohm Rowntree Building
University of York
Heslington
York YO10 5DD

IF YOU HAVE ANY CONCERNS ABOUT YOUR SYMPTOMS PLEASE CONSULT YOUR GP OR HOSPITAL DOCTOR

Your comments:

Appendix 6

Form B (OGD)

Centre Number: | Hospital:

Date of Scrutiny: | **Local Study Number:** | **Degree of urgency** (delete as appropriate) Very urgent / Urgent / Routine

Patient's initials: | **Sex** Male | Female (tick)

Date of Birth: (*If patient is less than 18 years of age exclude from trial)*

Inclusion: The patient should have at least one of the following symptoms – please tick YES or NO.

Symptoms	YES	NO	* Dyspeptic symptoms: nausea, vomiting, heartburn, indigestion, flatulence, early satiety, epigastric pain or discomfort
Dyspeptic symptoms*			
Weight loss			
Anorexia			
Anaemia			

If more symptoms please state them here:.....

Exclusion: (please tick either YES or NO for all of the following)	YES	NO
Dysphagia		
Planned therapeutic procedure		
Patient taking part in another trial		
Thought unable to comply with the trial		
Dual procedure (OGD & colon/flexi)		
Operator specified by referring clinician (please specify reason) _____		
Hospital (local) exclusion criteria for a nurse endoscopist list (please specify) _____		

If you have ticked YES for <u>any one</u> of the above exclusion criteria patient must be <u>excluded</u> from the trial.

	YES	NO
Is this patient to be included in the trial?		

If YES telephone YORK for randomisation (01904 434502) who will give you the National Trial Number and name of the endoscopist. Please enter them below.

National Trial Number – | **Allocated Endoscopist:** | **Planned procedure date**

Now photocopy this form and fax it to YORK (01904 434520). See note 5 overleaf.
*Enter patient and GP details in the box below **after** faxing this form to YORK.*

(Patient name & address)	(Name & address of patient's General Practitioner)

Please complete the following on the day of the procedure.

Patient requested change of endoscopist: (tick) Yes | No

Procedure date: | **Procedure done by:**

Patient did not attend: (tick) Outcome: _____

Patient declined to participate in the trial: (tick)

State reasons if done by different endoscopist: _____

Patient wishes General Practitioner to be notified: Yes | No

On the day of endoscopy please fax the completed form to YORK (01904 434520).

Please see reverse of this form for additional information.

1. This Form B should be completed in two stages: (i) on the day of list construction, (ii) on the day of endoscopy after procedure.

2. Each patient on the Trial Register should have a completed Form B. Patients who will be excluded will have only the first half of the form completed.

3. Thought unable to comply means, for example, unable to sign consent, due to any reasons unable to complete questionnaires etc.

4. This form should be faxed to York on two occasions, (i) after endoscopy list construction, (ii) after endoscopy.

5. Make a copy of Form B of the included trial patients and retain as a record in the folder provided. Pin or clip the original Form B to the endoscopy referral letter so that remaining entries will be completed by the endoscopist after the procedure.

6. Place Form Bs of patients excluded from the trial in the folder provided. These will be collected by the trial team for analysis at the completion of recruitment.

7. Patient's label should be affixed in Form B only **after this** has been faxed to York.

8. Do not affix label for those patients excluded from the trial.

9. For those patients who declined to take part or did not attend, use blank labels to cover patient and GP details before faxing.

10. State reasons if procedure is done by different endoscopist, which could be because of patient's preference, allocated endoscopist unavailable to do procedure etc.

11. Contact Durai on 01792 513427 if anything is unclear.

Appendix 7

Form B (FS)

Please complete this section on the day of list construction

Centre Number: ☐ Hospital ☐

Date of Scrutiny: ☐☐☐☐☐☐ **Local Study Number:** ☐☐☐☐ **Degree of urgency** (delete as appropriate) Very Urgent/Urgent/Routine/Soon/. . . . . .

Patient's initials: ☐ **Sex** Male ☐ Female ☐ (tick)

Date of Birth: ☐☐☐☐☐☐ *(If patient is less than 18 years of age, exclude from trial)*

Inclusion: The patient should have at least one of the following symptoms – please tick YES or NO

Symptoms:	YES	NO
Bleeding PR		
Change in bowel habits		

If more symptoms please state them here: .....

Exclusion: (please tick either YES or NO for all of the following)	YES	NO
Planned therapeutic procedure (exception banding or injection of haemorrhoids)		
Patient taking part in another trial		
Thought unable to comply with the trial		
Dual procedure (OGD & colon/flexi)		
Operator specified by referring clinician (please specify reason) _____		
Hospital (local) exclusion criteria for a nurse endoscopist list (please specify) _____		

If you have ticked YES for <u>any one</u> of the above exclusion criteria patient must be <u>excluded</u> from the trial.

	YES	NO
Is this patient to be included in the trial?		

If YES telephone YORK for randomisation (0800 0566682) who will give you the National Trial Number and name of the endoscopist. Please enter them below with the planned procedure date and indicate a morning or afternoon list.

National Trial Number ☐☐ – ☐☐☐☐ ☐☐☐☐ **Allocated Endoscopist:** ☐ **Planned procedure date** ☐☐☐☐☐☐

Now photocopy this form and fax it to YORK (01904 321387). See note 5 overleaf.
*Enter patient and GP details in the box below **after** faxing this form to YORK.*

(Patient name & address)	(Name & address of patient's General Practitioner)

Please complete this section on the day of endoscopy after the procedure

Patient requested change of endoscopist: (tick) Yes ☐ No ☐

Procedure done by: ☐ **Procedure date:** ☐☐☐☐☐☐

State reasons if done by different endoscopist:_____

Patient wishes General Practitioner to be notified: Yes ☐ No ☐

If patient excluded after randomisation, please specify reason: _____

Patient did not attend: (tick) ☐ **If so, rebooked for:** ☐☐☐☐☐☐ **discharged to GP:** ☐

Patient declined to take part in the trial: (tick) ☐

On the day of endoscopy please fax the completed form to YORK (01904 321387).

Please see reverse of this form for additional information

1. This Form B should be completed in two stages: (i) on the day of list construction, (ii) on the day of endoscopy after the procedure.

2. Each patient on the Trial Register should have a completed Form B. Patients who will be excluded will have only the first half of the form completed.

3. Thought unable to comply means, for example, unable to sign consent, due to any reasons unable to complete questionnaires etc.

4. This form should be faxed to York on two occasions, (i) after endoscopy list construction, (ii) after endoscopy.

5. Make a copy of Form B of the included trial patients and retain as a record in the folder provided. Pin or clip the original Form B to the endoscopy referral letter so that remaining entries will be completed by the endoscopist after the procedure.

6. Place Form Bs of patients excluded from the trial in the folder provided. These will be collected by the trial team for analysis at the completion of recruitment.

7. Patient's label should be affixed to Form B only **after this** has been faxed to York.

8. Do not affix label for those patients excluded from the trial.

9. For those patients who declined to take part or did not attend, use blank labels to cover patient and GP details before faxing.

10. State reasons if procedure is done by different endoscopist, which could be because of patient's preference, allocated endoscopist unavailable to do procedure etc.

11. All randomised patients who have consented should be included in the trial unless there are circumstances such as 'unable to complete questionnaires' in which case they can be excluded.

12. Contact Durai on 01792 513427 (mobile 0787 0155 878) if any thing is unclear.

Appendix 8

Form 1

IMMEDIATE COMPLICATIONS FORM

National Trial Number | | | - | | | | - | | | | | **Date of procedure** | | | | | | |

Endoscopist

Procedure (please circle)
OGD / Flexible sigmoidoscopy

ASA status: (please tick)

Class I	Healthy patient	
Class II	Mild systemic disease with no functional limitations e.g. controlled hypertension, mild diabetes, chronic bronchitis, asthma	
Class III	Severe systemic disease with definite functional limitation e.g. brittle diabetes, frequent angina, myocardial infarction	
Class IV	Severe systemic disease with acute unstable problems e.g. recent MI, Congestive Heart failure, acute renal failure	
Class V	Severe systemic disease with imminent risk of death	

DRUGS USED AND QUANTITY

None		Buscopan	
Midazolam		Flumazenil	
Throat spray		Naloxone	
Pethidine		Others (please specify)	. . . . .

ALL PROCEDURES:	**24 hour clock**
Time of extubation of previous patient or start of session*	
Time of intubation of this trial patient	
Time of extubation of this trial patient	

* Please record when the previous patient was extubated (or the list started if this trial patient is the first) regardless of the circumstances. This enables us to estimate how long the room is in use.

FLEXIBLE SIGMOIDOSCOPY ONLY:

Instrument used: sigmoidoscope | | colonoscope | |

Distance inserted: [straight scope] | | cm

Was bowel preparation used? Yes | | No | |

If so, what preparation? (tick)

1. Kleen prep		4. Phosphate enema	
2. Fleet (oral)		5. Fleet (enema)	
3. Picolax		6. Others (please specify)	

What was the quality of bowel preparation? (tick)

Very good | | Good | | Satisfactory | | Poor | | Very poor | |

During the procedure (OGD/flexi), did you discuss the findings or receive any help from a colleague (excluding endoscopy assistants)?	Yes		No	

If yes, please specify.

Outcome/Complications

1. Was the procedure completed as planned? (tick)	Yes		No	
If no, please specify				

2. Did you encounter any difficulties (technical/clinical)? (tick)	Yes		No	
If yes, please specify				

3. Was there any damage to the endoscope? (tick)	Yes		No	
If yes, please specify				

4. Were there any complications during the procedure (technical/clinical)? (tick)	Yes		No	
If yes, please specify				

5. Were there any complications after the procedure (technical/clinical)? (tick)	Yes		No	
If yes, please specify				

6. Was the patient admitted? (tick)	Yes		No	
If yes, please specify reasons and duration				

Appendix 9

Case note extraction form

National Trial Number | | | - | | | | | - | | | | |

Name

DOB | | | | | | |

Sex

Procedure
OGD ☐ Flexi ☐

Date of notes review | | | | | | |

Date for Endoscopy | | | | | | |

Referral Date | | | | | | |

Type of referral
GP ☐ Gastro OPD ☐ GI Surgical ☐ Nurse practitioner ☐ Private Hosp ☐ Others ☐

Type of access Rapid Access ☐ Outpatient ☐ Open Access ☐

Degree of Urgency Routine ☐ Soon ☐ Urgent ☐ Emergency ☐ Unclear ☐

Indications (OGD)	**NA** ☐
Dyspetic Symt	☐
Anaemia	☐
Weight loss	☐
Nausea/Vomiting	☐
Abdominal pain	☐
Haemetemesis	☐
Melaena	☐
Others	☐

Indications (Flexi)	**NA** ☐
Bleeding PR	☐
Change in bowel habit	☐
Diarrhoea	☐
Constipation	☐
Abdominal Pain	☐
Anaemia	☐
Weight loss	☐
Others	☐

Family History of Ca Colon NA ☐ Unclear ☐ Yes ☐ No ☐

Medication		**Dose**
GI Related		
PPI	☐	
H2 Blockers	☐	
Others	☐	
Important Non GI		
NSAID/ COX2/ Aspirin	☐	
Antibiotics	☐	
Others	☐	

Unclear ☐ None ☐

Previous Endoscopies Yes ☐ No ☐ None in notes ☐

					Unclear
OGD	☐	Date			☐
Flexi/Colon	☐	Date			☐
Barium enema	☐	Date			☐

Type of Reporting

Endoscopy report alone	
Endoscopy report and Additional letter	
Comments:	

Intubation success (OGD)					
Yes		No		NA	

Intubation success (Flexi)												
Yes		No		Distance				cm	Unclear		NA	

Biopsy taken: Yes ☐ No ☐

CLO NA ☐ Positive ☐ Negative ☐

Histology results (OGD)		**NA**		Nothing in notes	
Normal		Comments: (Adequacy of biopsy etc)			
Oesophagitis					
Barretts					
Benign oesophageal ulcer					
Benign gastric ulcer					
H pylori + ve gastritis					
H pylori - ve gastritis					
Oesophageal cancer					
Gastric cancer					
Adenomatous polyp					
Metaplastic polyp					
Coeliac disease					
Dysplasia					

Histology results (Flexi)		**NA**		Nothing in notes	
Normal		Comments: (Adequacy of biopsy, polypectomy, etc)			
Adenomatous polyp					
Metaplastic polyp					
Adenocarcinoma					
Ulcerative coliits					
Crohn's colitis					
Microscopic Colitis					
Proctitis					
Non specific colitis					

Complications (Immediate)		**Complications (Delayed)**	
None		None	
Perforation		Perforation	
Bleeding		Bleeding	
Infection		Infection	
Excessive pain		Excessive pain	
Others (Specify)		Others (Specify)	

Subsequent Contacts **None** ☐

Episode 1 ☐ **Code** ☐

Date of episode	**Type**		**Specialty**		**GI Related**		**Consequent to endoscopy**		**Primary Diagnosis**
	OPD		Gastroenterol		Yes		Yes		
	Day case		Respiratory		No		No		
Admission	Inpatient		Cardiology		Comments:				
	No of nights		Gen Surgery						
Discharge	Others		Others						

Findings	NA		Significant		Not Significant		Normal	
Origin of request	NA		Pre scope		From scope		Post scope	

Episode 2 ☐ **Code** ☐

Date of episode	**Type**		**Specialty**		**GI Related**		**Consequent to endoscopy**		**Primary Diagnosis**
	OPD		Gastroenterol		Yes		Yes		
	Day case		Respiratory		No		No		
Admission	Inpatient		Cardiology		Comments:				
	No of nights		Gen Surgery						
Discharge	Others		Others						

Findings	NA		Significant		Not Significant		Normal	
Origin of request	NA		Pre scope		From scope		Post scope	

Episode 3 ☐ **Code** ☐

Date of episode	**Type**		**Specialty**		**GI Related**		**Consequent to endoscopy**		**Primary Diagnosis**
	OPD		Gastroenterol		Yes		Yes		
	Day case		Respiratory		No		No		
Admission	Inpatient		Cardiology		Comments:				
	No of nights		Gen Surgery						
Discharge	Others		Others						

Findings	NA		Significant		Not Significant		Normal	
Origin of request	NA		Pre scope		From scope		Post scope	

Episode 4 ☐ **Code** ☐

Date of episode	**Type**		**Specialty**		**GI Related**		**Consequent to endoscopy**		**Primary Diagnosis**
	OPD		Gastroenterol		Yes		Yes		
	Day case		Respiratory		No		No		
Admission	Inpatient		Cardiology		Comments:				
	No of nights		Gen Surgery						
Discharge	Others		Others						

Findings	NA		Significant		Not Significant		Normal	
Origin of request	NA		Pre scope		From scope		Post scope	

Episode 5 ☐ **Code** ☐

Date of episode	**Type**		**Specialty**		**GI Related**		**Consequent to endoscopy**		**Primary Diagnosis**
☐☐☐☐☐☐	OPD	☐	Gastroenterol	☐	Yes	☐	Yes	☐	
	Day case	☐	Respiratory	☐	No	☐	No	☐	
Admission	Inpatient	☐	Cardiology	☐	Comments:				
☐☐☐☐☐☐	No of nights	☐	Gen Surgery	☐					
Discharge	Others		Others	☐					
☐☐☐☐☐☐									

Findings	NA ☐	Significant	☐	Not Significant	☐	Normal	☐
Origin of request	NA ☐	Pre scope	☐	From scope	☐	Post scope	☐

Episode 6 ☐ **Code** ☐

Date of episode	**Type**		**Specialty**		**GI Related**		**Consequent to endoscopy**		**Primary Diagnosis**
☐☐☐☐☐☐	OPD	☐	Gastroenterol	☐	Yes	☐	Yes	☐	
	Day case	☐	Respiratory	☐	No	☐	No	☐	
Admission	Inpatient	☐	Cardiology	☐	Comments:				
☐☐☐☐☐☐	No of nights	☐	Gen Surgery	☐					
Discharge	Others		Others	☐					
☐☐☐☐☐☐									

Findings	NA ☐	Significant	☐	Not Significant	☐	Normal	☐
Origin of request	NA ☐	Pre scope	☐	From scope	☐	Post scope	☐

Episode 7 ☐ **Code** ☐

Date of episode	**Type**		**Specialty**		**GI Related**		**Consequent to endoscopy**		**Primary Diagnosis**
☐☐☐☐☐☐	OPD	☐	Gastroenterol	☐	Yes	☐	Yes	☐	
	Day case	☐	Respiratory	☐	No	☐	No	☐	
Admission	Inpatient	☐	Cardiology	☐	Comments:				
☐☐☐☐☐☐	No of nights	☐	Gen Surgery	☐					
Discharge	Others		Others	☐					
☐☐☐☐☐☐									

Findings	NA ☐	Significant	☐	Not Significant	☐	Normal	☐
Origin of request	NA ☐	Pre scope	☐	From scope	☐	Post scope	☐

Episode 8 ☐ **Code** ☐

Date of episode	**Type**		**Specialty**		**GI Related**		**Consequent to endoscopy**		**Primary Diagnosis**
☐☐☐☐☐☐	OPD	☐	Gastroenterol	☐	Yes	☐	Yes	☐	
	Day case	☐	Respiratory	☐	No	☐	No	☐	
Admission	Inpatient	☐	Cardiology	☐	Comments:				
☐☐☐☐☐☐	No of nights	☐	Gen Surgery	☐					
Discharge	Others		Others	☐					
☐☐☐☐☐☐									

Findings	NA ☐	Significant	☐	Not Significant	☐	Normal	☐
Origin of request	NA ☐	Pre scope	☐	From scope	☐	Post scope	☐

Episode 9 ☐ **Code**

Date of episode	**Type**		**Specialty**		**GI Related**		**Consequent to endoscopy**		**Primary Diagnosis**
	OPD		Gastroenterol		Yes		Yes		
	Day case		Respiratory		No		No		
Admission	Inpatient		Cardiology		Comments:				
	No of nights		Gen Surgery						
Discharge	Others		Others						

Findings	NA		Significant		Not Significant		Normal	
Origin of request	NA		Pre scope		From scope		Post scope	

Episode 10 ☐ **Code** ☐

Date of episode	**Type**		**Specialty**		**GI Related**		**Consequent to endoscopy**		**Primary Diagnosis**
	OPD		Gastroenterol		Yes		Yes		
	Day case		Respiratory		No		No		
Admission	Inpatient		Cardiology		Comments:				
	No of nights		Gen Surgery						
Discharge	Others		Others						

Findings	NA		Significant		Not Significant		Normal	
Origin of request	NA		Pre scope		From scope		Post scope	

Episode 11 ☐ **Code** ☐

Date of episode	**Type**		**Specialty**		**GI Related**		**Consequent to endoscopy**		**Primary Diagnosis**
	OPD		Gastroenterol		Yes		Yes		
	Day case		Respiratory		No		No		
Admission	Inpatient		Cardiology		Comments:				
	No of nights		Gen Surgery						
Discharge	Others		Others						

Findings	NA		Significant		Not Significant		Normal	
Origin of request	NA		Pre scope		From scope		Post scope	

Episode 12 ☐ **Code** ☐

Date of episode	**Type**		**Specialty**		**GI Related**		**Consequent to endoscopy**		**Primary Diagnosis**
	OPD		Gastroenterol		Yes		Yes		
	Day case		Respiratory		No		No		
Admission	Inpatient		Cardiology		Comments:				
	No of nights		Gen Surgery						
Discharge	Others		Others						

Findings	NA		Significant		Not Significant		Normal	
Origin of request	NA		Pre scope		From scope		Post scope	

Final Diagnosis (following endoscopy, histology and subsequent investigations)

OGD	**NA**		**Flexi**	**NA**	
Normal			Normal		
Hiatus Hernia			IBS		
GORD			Coeliac disease		
Peptic Ulcer			Haemorrhoids		
NUD			Colonic Polyps		
Ca oesophagus			Carcinoma Colon		
Ca stomach			Microscopic Colitis		
Barrett's			Diverticulosis		
Varices			Proctitis		
Polyps			Ulcerative colitis		
Coeliac disease			Crohn's disease		
IBS			Chronic pancreatitis		
Chronic pancreatitis			Non specific colitis		
Gall stones					
Oesophageal dysmotility					
Others			Others		
Unclear			Unclear		
Comments			Comments		

Any new GI diagnosis made during subsequent contact made within 1 year of endoscopy? Yes ☐ No ☐
(relating to original symptoms)

OGD		**Flexi**	
Normal		Normal	
Hiatus Hernia		IBS	
GORD		Coeliac disease	
Peptic Ulcer		Haemorrhoids	
NUD		Colonic Polyps	
Ca oesophagus		Carcinoma Colon	
Ca stomach		Microscopic Colitis	
Barrett's		Diverticulosis	
Varices		Proctitis	
Polyps		Ulcerative colitis	
Coeliac disease		Crohn's disease	
IBS		Chronic pancreatitis	
Chronic pancreatitis		Non specific colitis	
Gall stones			
Oesophageal dysmotility			
Others		Others	
Unclear		Unclear	
Comments		Comments	

Form I Yes / No Consent Form Yes/No

Endoscopy Report Yes / No
(If no collect required information).

Appendix 10

Primary care questionnaire

MINuET Study

Primary Care Questionnaire

Confidential

This questionnaire is about the health care your patient has had since his/her endoscopy and recruitment into the MINuET trial on the date listed on the previous page. For each question, if the patient has had no treatment or visits please enter '0'. We would like to know about consultations ***for any reason***, not just for the patient's digestive or bowel symptoms.

Care from the practice

1. Since the endoscopy, how many times has the patient contacted any of the following?

	At the surgery (If none enter '0')	**At patient's home** (If none enter '0')
GP	☐☐	☐☐
Practice Nurse	☐☐	☐☐
Other (please specify below)	☐☐	☐☐
_____		
Other (please specify below)	☐☐	☐☐
_____		

Care from hospitals

2. Since the endoscopy, how many times has the patient been at a hospital outpatients in any clinic? (Please indicate the specialty and number of times below)

	Number of times (If none enter '0')
Gastroenterology	☐☐
Other specialties (please list and enter number of times)	
_____	☐☐
_____	☐☐
_____	☐☐

3. Since the endoscopy, how many times has the patient attended hospital as a day case? (Please indicate the specialty and number of times below)

	Number of times (If none enter '0')
Gastroenterology	☐☐
Other specialties (please list and enter number of times)	
_____	☐☐
_____	☐☐
_____	☐☐

4. Since the endoscopy, how many nights (in total) has the patient spent at hospital as an inpatient? (Please indicate the specialty and number of times below)

Specialty	**Number of nights** If none enter '0'
_____	☐☐
_____	☐☐
_____	☐☐
_____	☐☐

5. Does this patient currently have a repeat prescription for any of the following drugs? (place a cross in the box to the right of the drug)

Indigestion medications

Omeprazole (Losec)	☐	Lansoprazole (Zoton)	☐
Pantoprazole (Protium)	☐	Rabeprazole (Pariet)	☐
Ranitidine (Zantac)	☐	Famotidine (Pepcid)	☐
Esomeprazole (Nexium)	☐	Cimetidine (Tagamet)	☐
Nizatidine (Axid)	☐	Domperidone (Motilium)	☐
Metaclopramide (Maxolon)	☐		

Medication for irritable bowel syndrome

Spasmonal	☐	Buscopan	☐
Mebeverine (Colofac)	☐	Merbentyl	☐
Colpermin	☐		

Anti-diarrhoeal medications

Loperamide (Imodium)	☐	Cholestyramine	☐
Codeine Phosphate	☐	Co-phenotrope (Lomotil)	☐

Medications for colitis

Mesalazine (Asacol)	☐	Olsalazine (Dipentum)	☐
Prednisolone	☐	Predsol/predfoam/colifoam/enemas	☐
Balsalazide (Colazide)	☐	Sulfasalazine (Salazopyrin)	☐
Budesonide (Entocort)	☐		

6. If this patient takes any other tablets/liquids for digestive or bowel symptoms that are not listed above, please write the details below.

Name of medicine	**On prescription**	**Dose in mg or ml**	**How many times taken per week**
_____	Yes ☐ No ☐	☐☐☐	☐☐☐
_____	Yes ☐ No ☐	☐☐☐	☐☐☐
_____	Yes ☐ No ☐	☐☐☐	☐☐☐

Date of completion ☐☐ / ☐☐ / ☐☐ Signed _____

Thank you for completing this questionnaire

Once you have completed the questionnaire please return it in the stamped addressed envelope or send to address

MINuET Study Team
York Trials Unit
2nd Floor (Area 4)
Department of Health Sciences
Seebohm Rowntree Building
University of York
Heslington
York YO10 5DD

Appendix 11

Final score sheet for video assessment study (extubations)

Video Assessment Study (Extubations) — Final Score Sheet

Patient ID: Scorer: Date:

Please circle the appropriate score. Points 3-7 only need to be completed where relevant

	Excellent	Good	Watch carefully	Not Good Enough	Unacceptable
1. Overall quality of examination ie confidence that no significant lesion missed	A	B	C	D	E
The individual parameters of the examination were scored as follows, scores of 'C' or below need addressing					
2. Time spent viewing the mucosa	A	B	C	D	E
3. Re-examining poorly viewed areas eg proximal sides of folds or following 'slippage'	A	B	C	D	E
4. Suctioning of fluid or faecal pools	A	B	C	D	E
5. Distending the lumen for visualisation	A	B	C	D	E
6. Lower rectal examination	A	B	C	D	E

Appendix 12

OGD evaluation sheet

OGD Evaluation sheet

Video ID:	Scorer:	Date:

Time, you began scoring: ☐☐ hr-☐☐min-☐☐sec

Section A – Dexterity and Safety

This section is to evaluate dexterity and safety of performance of OGD. This includes instrument entry, passage, and manipulation through the mouth, throat, oesophagus, stomach and descending duodenum. Please check various items under each item before you score. Pause the video each time before scoring and rewind as many times as needed to ensure accurate scoring.

1. Oesophageal intubation

Passage under direct vision all the time ☐
Following centre of tongue ☐
Visualising epiglottis ☐
Visualise the cricoarytenoid folds and vocal cords ☐
Insertion posterior to the larynx between the pyriform sinuses ☐
Observing cricopharyngeus relaxation ☐

Flawless technique ☐
Acceptable technique ☐
Unacceptable technique ☐
Dangerous technique ☐
Organ damage ☐

2. Passage through oesophagus

Insertion under direct vision all the time ☐
No mucosal red or white outs ☐
Adequate air insufflation ☐
No mucosal wall collisions ☐
Suctioning any secretions ☐

Flawless technique ☐
Acceptable technique ☐
Unacceptable technique ☐
Dangerous technique ☐
Organ damage ☐

3. Gastric Intubation

Insertion under direct vision ☐
No mucosal red or white outs ☐
Adequate air insufflation ☐
Visualising opening of OG junction ☐
No mucosal wall collisions ☐

Flawless technique ☐
Acceptable technique ☐
Unacceptable technique ☐
Dangerous technique ☐
Organ damage ☐

!!! Now turn to page 4 to mark parts of item 17 & 18 on quality of the observation on insertion and then return to this page to continue with next item!!!

4. Passage through stomach to pylorus

Insertion under direct vision ☐
Just enough air insufflation at proximal stomach ☐
Suctioning any excess secretions from proximal stomach ☐
No mucosal wall collisions ☐
Least mucosal trauma ☐
Following lesser curvature to pylorus ☐

Flawless technique ☐
Acceptable technique ☐
Unacceptable technique ☐
Dangerous technique ☐
Organ damage ☐

5. Passage through pylorus to first part of duodenum

Insertion under direct vision		Flawless technique	
Entering with pylorus at centre of visual field		Acceptable technique	
No red or white outs		Unacceptable technique	
No mucosal wall collisions			
Least mucosal trauma		Dangerous technique	
Not entered		Organ damage	

6. Passage to second part of duodenum

Visualising duodenal bulb first before entry		Flawless technique	
No red or white outs		Acceptable technique	
Insertion under direct vision (or)		Unacceptable technique	
Visualising paradoxical mucosal movement			
Least mucosal trauma		Dangerous technique	
Not entered		Organ damage	

Section B:
The following section is to evaluate thoroughness of performance. Note different rating scale. Consider visibility during insertion and withdrawal before marking.

Content and thoroughness

7. Examination of second part of duodenum*

Endoscope as far as area of papillary orifice		>95% visibility	
Examination of circumference of duodenum		66-95% visibility	
Adequate air insufflation		36-65% visibility	
Suctioning any secretions to improve visibility		5-35% visibility	
Close examination of pathology, if any		<5% visibility	

8. Examination of first part of duodenum**

Examination of all four walls		>95% visibility	
Adequate air insufflation		66-95% visibility	
Suctioning any secretions to improve visibility		36-65% visibility	
Re-entry if fallen out		5-35% visibility	
Close examination of pathology, if any		<5% visibility	

** Allow for partial non-visualisation of the medial proximal second part of duodenum.*
*** It is acceptable if scope fell out into antrum on withdrawal from second part to first part of duodenum. In such case observe whether first part re-entered to complete examination.*

9. Examination of antrum and pylorus

Adequate air insufflation		>95% visibility	
Suctioning any secretions to improve visibility		66-95% visibility	
Visualising all walls of antrum and pylorus		36-65% visibility	
Close examination of pathology, if any		5-35% visibility	
		<5% visibility	

10. Examination of angulus in inversion

Examination under partial inversion of scope
Examining between folds
Close examination of pathology, if any

>95% visibility
66-95% visibility
36-65% visibility
5-35% visibility
<5% visibility

11. Examination of lesser curve

Examination with retroflexion of scope
Adequacy of air insufflation
Suctioning any secretions to improve visibility
Examination between mucosal folds
Closeness to the mucosa
Rotating the scope to 180 degrees
Close examination of pathology, if any

>95% visibility
66-95% visibility
36-65% visibility
5-35% visibility
<5% visibility

12. Examination of cardia

Examination with retroflexion of scope
Adequacy of air insufflation
Suctioning any secretions to improve visibility
Rotating the scope to 180 degrees
Closeness to the mucosa
Close examination of pathology, if any

>95% visibility
66-95% visibility
36-65% visibility
5-35% visibility
<5% visibility

13. Examination of fundus

Examination with retroflexion of scope
Adequacy of air insufflation
Suctioning any secretions to improve visibility
Examination between mucosal folds
Closeness to the mucosa
Rotating the scope to 180 degrees
Close examination of pathology, if any

>95% visibility
66-95% visibility
36-65% visibility
5-35% visibility
<5% visibility

14. Examination of greater curve

Examination with retroflexion of scope
Adequacy of air insufflation
Suctioning any secretions to improve visibility
Examination between mucosal folds
Closeness to the mucosa
Rotating the scope to 180 degrees
Close examination of pathology, if any

>95% visibility
66-95% visibility
36-65% visibility
5-35% visibility
<5% visibility

15. Examination of anterior wall of gastric body

Examination with retroflexion of scope		>95% visibility	
Adequacy of air insufflation		66-95% visibility	
Suctioning any secretions to improve visibility		36-65% visibility	
Examination with straight scope		5-35% visibility	
Examination between mucosal folds		<5% visibility	
Close examination of pathology, if any			

16. Examination of posterior wall of gastric body

Examination with retroflexion of scope		>95% visibility	
Adequacy of air insufflation		66-95% visibility	
Suctioning any secretions to improve visibility		36-65% visibility	
Examination with straight scope		5-35% visibility	
Examination between mucosal folds		<5% visibility	
Close examination of pathology, if any			

17. Examination of OG junction *(Z line or Squamo-columnar junction in particular)*

	On insertion	**On withdrawal**
>95% visibility		
66-95% visibility		
36-65% visibility		
5-35% visibility		
<5% visibility		

18. Examination of oesophagus on insertion | **Examination of oesophagus on withdrawal**

	Upper 1/3	**Middle 1/3**	**Lower 1/3**	**Upper 1/3**	**Middle 1/3**	**Lower 1/3**
>95% visibility						
66-95% visibility						
36-65% visibility						
5-35% visibility						
<5% visibility						

After marking quality of observation on insertion for items 17 & 18, return to page 1 to continue with item 4.!!!

Section C
This section is to evaluate instrument withdrawal. (Check for scope withdrawal under direct vision, at appropriate pace, deflation at cardia). Also comment on technique of J manoeuvre with regard to safety.

	From Duodenum	From Stomach	From Oesophagus
Flawless technique	☐	☐	☐
Acceptable technique	☐	☐	☐
Unacceptable technique	☐	☐	☐
Dangerous technique	☐	☐	☐
Organ damage	☐	☐	☐

Section D – *In this section give an overall score for all components of examination.*

Overall Score	Oesophagus	Stomach	Duodenum	Whole OGD
Complete examination and no concerns over technique or content	☐	☐	☐	☐
Probably complete examination with minor concern over technique or content	☐	☐	☐	☐
Incomplete examination with moderate concern over technique or content	☐	☐	☐	☐
Incomplete examination with major concern over technique or content	☐	☐	☐	☐
Incomplete examination and totally unacceptable technique or content	☐	☐	☐	☐

Section E – Now state your findings from the video of the endoscopy.

Oesophageal abnormalities 1. 2. (Oesophagitis, Barrett's, carcinoma, Varices, Achalasia, Hiatus)	Biopsy Required: Yes ☐ No ☐ Biopsy Taken Yes ☐ No ☐
Gastric abnormalities 1. 2. (Erosions, gastritis, ulcers, malignancy)	Biopsy Required: Yes ☐ No ☐ Biopsy Taken Yes ☐ No ☐
Duodenal abnormalities 1. 2. (Ulcers, duodenitis, atrophy, malignancy)	Biopsy Required: Yes ☐ No ☐ Biopsy Taken Yes ☐ No ☐
FINAL DIAGNOSIS.	* Distal duodenal biopsies depends on indication

If you would like to add any comments about the video please insert it here:

Time when you finished Scoring: ☐☐ hr-☐☐ min-☐☐ sec

Appendix 13

Resource time sheet (summary)

Resource Time Sheet (Summary)

Hospital:

Centre Number: **Date:** **Time of session:**

Endoscopist (please tick) **Doctor** **Nurse Endoscopist**

The questions are intended to allow us to calculate the resource use associated with this endoscopy session. Please could you answer the following questions as fully as possible.

1. How long did this session last? e.g. 3 hours and 30 mins

hours	mins

2a. How many patients were booked for this session?

b. Of these, how many were?

OGD	Flexi	Colonoscopy

3. How many were MINuET patients?

OGD	Flexi

4. How many patients DNA?

5. Of the DNAs, how many were MINuET patients?

6. How many patients had therapeutic procedures?

7. How many patients were seen as an emergency?

8. How many health professional staff were there in the endoscopy room or recovery area?
(Please include the person performing the endoscopy. Do not include anybody in an observational role.)

Type of staff (e.g. doctor (or) staff)	Grade	Amount of time spent in this session (hours & mins)

7. What consumables were used during this endoscopy session? Please give manufacturer where possible and other details about the product, e.g. disposable (D) vs. re-usable (RU).

CONSUMABLES		Manufacturer	D or RU	Number used
Endoscope	Flexible sigmoidoscope			
	Colonscope			
	Gastroscope			
Biopsy forceps				
Polypectomy snare				
Injection needle				
Polyp retrieval grasping forceps				
Polyp retrieval Dormia basket				
Hot biopsy forceps				
Cytology brush				

Consumables continued overleaf, PTO

CONSUMABLES (continued)	Manufacturer	D or RU	Number used
Suction traps			
Cleaning brush			
Variceal bands			
Proctoscope			
Oesophageal dilators			
CLO test kit			
Other (please specify)			

8. Equipment used in this session

EQUIPMENT	Manufacturer	How many times used?
Histology		
Electro surgical equipment		
APC unit		
Any photos taken (number)		
Other (please specify)		

9. Medication used in this session

MEDICATIONS	Dose	Size of vial	Number used
Midazolam			
Throat spray			
Pethidine			
Buscopan			
Fentany l			
Flumazenil			
Naloxone			
Nitrous Oxide gas			
Diazepam			
Adrenaline			
Sclerosants (please specify)			
Other (please specify)			

10. Were there any unusual circumstances?
(e.g. person scheduled to do the endoscopy not present)

.....

.....

.....

.....

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

Appendix 14

Resource time sheet (individual patient)

Resource Time Sheet (Individual Patient)

Hospital:

Centre Number: **Date:** **Time of session:**

Endoscopist (please tick) **Doctor** **Nurse Endoscopist**

Patient (1, 2, 3 etc)				Time went in	Time came out	MINuET	Agreed to participate
	OGD	Flexi	Other	: :	: :	Yes / No	Yes / No

1. What consumables were used? Please give manufacturer where possible and other details about the product, e.g. disposable (D) vs. re-usable (RU).

CONSUMABLES			Manufacturer	D or RU	Number used
Endoscope	Flexible sigmoidscope				
	Colonoscope				
	Gastroscope				
Biopsy forceps					
Polypectomy snare					
Injection needle					
Polyp retrieval grasping forceps					
Polyp retrieval Dormia basket					
Hot biopsy forceps					
Cytology brush					
Suction traps					
Cleaning brush					
Variceal bands					
Proctoscope					
Oesophageal dilators					
CLO test kit					
Other (please specify)					

2. What equipment was used?

EQUIPMENT	Manufacturer	How many times used?
Histology		
Electro surgical equipment		
APC unit		
Any photos taken (number)		
Other (please specify)		

PTO

3. What medication was used?

MEDICATIONS	Dose	Size of vial	Number used
Midazolam			
Throat spray			
Pethidine			
Buscopan			
Fentanyl			
Flumazenil			
Naloxone			
Nitrous Oxide gas			
Diazepam			
Adrenaline			
Sclerosants (please specify)			
Other (please specify)			

4. Were there any unusual circumstances?
(e.g. person scheduled to do the endoscopy not present)

.....

.....

.....

.....

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

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Karen Roberts, Nurse Consultant, Queen Elizabeth Hospital, Gateshead

Dr Vimal Sharma, Consultant Psychiatrist/Hon. Senior Lecturer, Mental Health Resource Centre, Cheshire and Wirral Partnership NHS Trust, Wallasey

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Mrs Stella Burnside OBE, Chief Executive, Office of the Chief Executive. Trust Headquarters, Altnagelvin Hospitals Health & Social Services Trust, Altnagelvin Area Hospital, Londonderry

Ms Tracy Bury, Project Manager, World Confederation for Physical Therapy, London

Professor Iain T Cameron, Professor of Obstetrics and Gynaecology and Head of the School of Medicine, University of Southampton

Dr Christine Clark, Medical Writer & Consultant Pharmacist, Rossendale

Professor Collette Clifford, Professor of Nursing & Head of Research, School of Health Sciences, University of Birmingham, Edgbaston, Birmingham

Professor Barry Cookson, Director, Laboratory of Healthcare Associated Infection, Health Protection Agency, London

Professor Howard Cuckle, Professor of Reproductive Epidemiology, Department of Paediatrics, Obstetrics & Gynaecology, University of Leeds

Dr Katherine Darton, Information Unit, MIND – The Mental Health Charity, London

Professor Carol Dezateux, Professor of Paediatric Epidemiology, London

Mr John Dunning, Consultant Cardiothoracic Surgeon, Cardiothoracic Surgical Unit, Papworth Hospital NHS Trust, Cambridge

Mr Jonothan Earnshaw, Consultant Vascular Surgeon, Gloucestershire Royal Hospital, Gloucester

Professor Martin Eccles, Professor of Clinical Effectiveness, Centre for Health Services Research, University of Newcastle upon Tyne

Professor Pam Enderby, Professor of Community Rehabilitation, Institute of General Practice and Primary Care, University of Sheffield

Mr Leonard R Fenwick, Chief Executive, Newcastle upon Tyne Hospitals NHS Trust

Professor David Field, Professor of Neonatal Medicine, Child Health, The Leicester Royal Infirmary NHS Trust

Mrs Gillian Fletcher, Antenatal Teacher & Tutor and President, National Childbirth Trust, Henfield

Professor Jayne Franklyn, Professor of Medicine, Department of Medicine, University of Birmingham, Queen Elizabeth Hospital, Edgbaston, Birmingham

Ms Grace Gibbs, Deputy Chief Executive, Director for Nursing, Midwifery & Clinical Support Services, West Middlesex University Hospital, Isleworth

Dr Neville Goodman, Consultant Anaesthetist, Southmead Hospital, Bristol

Professor Alastair Gray, Professor of Health Economics, Department of Public Health, University of Oxford

Professor Robert E Hawkins, CRC Professor and Director of Medical Oncology, Christie CRC Research Centre, Christie Hospital NHS Trust, Manchester

Professor Allen Hutchinson, Director of Public Health & Deputy Dean of ScHARR, Department of Public Health, University of Sheffield

Dr Duncan Keeley, General Practitioner (Dr Burch & Ptnrs), The Health Centre, Thame

Dr Donna Lamping, Research Degrees Programme Director & Reader in Psychology, Health Services Research Unit, London School of Hygiene and Tropical Medicine, London

Mr George Levvy, Chief Executive, Motor Neurone Disease Association, Northampton

Professor James Lindesay, Professor of Psychiatry for the Elderly, University of Leicester, Leicester General Hospital

Professor Julian Little, Professor of Human Genome Epidemiology, Department of Epidemiology & Community Medicine, University of Ottawa

Professor Rajan Madhok, Medical Director & Director of Public Health, Directorate of Clinical Strategy & Public Health, North & East Yorkshire & Northern Lincolnshire Health Authority, York

Professor David Mant, Professor of General Practice, Department of Primary Care, University of Oxford

Professor Alexander Markham, Director, Molecular Medicine Unit, St James's University Hospital, Leeds

Dr Chris McCall, General Practitioner, The Hadleigh Practice, Castle Mullen

Professor Alistair McGuire, Professor of Health Economics, London School of Economics

Dr Peter Moore, Freelance Science Writer, Ashtead

Dr Sue Moss, Associate Director, Cancer Screening Evaluation Unit, Institute of Cancer Research, Sutton

Mrs Julietta Patnick, Director, NHS Cancer Screening Programmes, Sheffield

Professor Tim Peters, Professor of Primary Care Health Services Research, Academic Unit of Primary Health Care, University of Bristol

Professor Chris Price, Visiting Chair – Oxford, Clinical Research, Bayer Diagnostics Europe, Cirencester

Professor Peter Sandercock, Professor of Medical Neurology, Department of Clinical Neurosciences, University of Edinburgh

Dr Eamonn Sheridan, Consultant in Clinical Genetics, Genetics Department, St James's University Hospital, Leeds

Dr Ken Stein, Senior Clinical Lecturer in Public Health, Director, Peninsula Technology Assessment Group, University of Exeter

Professor Sarah Stewart-Brown, Professor of Public Health, University of Warwick, Division of Health in the Community Warwick Medical School, LWMS, Coventry

Professor Ala Szczepura, Professor of Health Service Research, Centre for Health Services Studies, University of Warwick

Dr Ross Taylor, Senior Lecturer, Department of General Practice and Primary Care, University of Aberdeen

Mrs Joan Webster, Consumer member, HTA – Expert Advisory Network

Feedback

The HTA Programme and the authors would like to know your views about this report.

The Correspondence Page on the HTA website (http://www.hta.ac.uk) is a convenient way to publish your comments. If you prefer, you can send your comments to the address below, telling us whether you would like us to transfer them to the website.

We look forward to hearing from you.

The National Coordinating Centre for Health Technology Assessment,
Mailpoint 728, Boldrewood,
University of Southampton,
Southampton, SO16 7PX, UK.
Fax: +44 (0) 23 8059 5639 Email: hta@hta.ac.uk
http://www.hta.ac.uk

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