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RESEARCH

Effectiveness of nurse delivered endoscopy: findings from randomised multi-institution nurse endoscopy trial (MINuET)

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ABSTRACT

Objective To compare the clinical effectiveness of doctors and nurses in undertaking upper and lower gastrointestinal endoscopy.

Design Pragmatic trial with Zelen's randomisation before consent to minimise distortion of existing practice.

Setting 23 hospitals in the United Kingdom. In six hospitals, nurses undertook both upper and lower gastrointestinal endoscopy, yielding a total of 29 centres.

Participants 67 doctors and 30 nurses. Of 4964 potentially eligible patients, we randomised 4128 (83%) and recruited 1888 (38%) from July 2002 to June 2003.

Interventions Diagnostic upper gastrointestinal endoscopy and flexible sigmoidoscopy, undertaken with or without sedation, with the standard preparation, techniques, and protocols of participating hospitals. After referral for either procedure, patients were randomised between doctors and nurses.

Main outcome measures Gastrointestinal symptom rating questionnaire (primary outcome), gastrointestinal endoscopy satisfaction questionnaire and state-trait anxiety inventory (all analysed by intention to treat); immediate and delayed complications; quality of examination and corresponding report; patients' preferences for operator; and new diagnoses at one year (all analysed according to who carried out the procedure).

Results There was no significant difference between groups in outcome at one day, one month, or one year after endoscopy, except that patients were more satisfied with nurses after one day. Nurses were also more thorough than doctors in examining the stomach and oesophagus. While quality of life scores were slightly better in patients the doctor group, this was not statistically significant.

Conclusions Diagnostic endoscopy can be undertaken safely and effectively by nurses.

Trial registration International standard RCT 82765705

INTRODUCTION

In the United Kingdom and the United States, gastrointestinal endoscopy is increasingly being carried out by nurses,[1 2] with approval from professional bodies.[3 4] Single centre studies have suggested that this is safe, effective, and acceptable to patients in both countries.[5-11] There has, however, been no rigorous, large scale evaluation of the clinical and cost effectiveness of nurses in this role.

METHODS

Study design and interventions

Our study[12] was a pragmatic randomised trial[13] designed to compare the two procedures undertaken by doctors or nurses, with or without sedation, using the standard preparation, techniques, and protocols of participating hospitals. We measured the quality of the endoscopy, the outcome for patients, and acceptability to patients. We also evaluated the cost effectiveness of nurse endoscopy.[14]

We adopted the Medical Research Council's approach to the evaluation of complex interventions in health care.[15] We treated endoscopy carried out by nurses and the resulting sequence of events as an alternative intervention to endoscopy carried out by doctors and its sequelae. If the resulting pragmatic trial[13] confirmed that each regimen generated similar effectiveness and cost effectiveness, then decision makers would have a sound basis for planning nurse endoscopy.

Recruitment

We invited hospitals in the UK with nurses who were undertaking independent gastrointestinal endoscopy to participate in the study, through the British Society of Gastroenterology (BSG) newsletter or directly if we knew that a nurse endoscopist was employed.

We included patients aged over 18 who had been referred for either procedure with symptoms of dyspepsia (nausea, vomiting, heartburn, indigestion, flatulence, early satiety, epigastric pain or discomfort), weight loss, anorexia, or anaemia, or with rectal bleeding or change in bowel habit, if they satisfied local criteria for the procedure by a nurse endoscopist. We excluded those presenting with dysphagia, known

to need a therapeutic procedure, already taking part in another trial, or unable to comply with the trial.

On receiving referrals for either procedure—that is, before consent[16]—a designated member of the endoscopy booking team at each participating hospital telephoned the remote randomisation service at the University of York. This service stratified patients by hospital and whether they needed oesophagogastroduodenoscopy or flexible sigmoidoscopy and then allocated them at random to endoscopy by doctor or by nurse using a Visual Basic procedure that permuted randomised blocks of random length, thus ensuring balance between groups while protecting against subversion.[12] The designated member then booked the allocated procedure and notified the patient. We gave patients opportunity in advance to request a change of allocation and asked them for informed, written consent when they attended for the procedure. We tested the feasibility of this recruitment process in participating centres before implementation. We estimated the experience of endoscopists with a questionnaire completed before participation.

Outcome measures and data collection

The primary outcome, measured at one year, was patients' self assessed scores on the gastrointestinal symptom rating questionnaire, covering both upper and lower gastrointestinal symptoms.[12] Secondary outcomes included scores on the symptom rating questionnaire at one month and the state-trait anxiety inventory (six item version[17] before endoscopy, 20 item version[18] after), SF-36,[19] and EQ-5D,[20] all measured at baseline, one day, one month, and one year after the procedure. We measured patients' satisfaction after one day using the gastrointestinal endoscopy satisfaction questionnaire.[12] We validated both gastrointestinal questionnaires concurrently.[12]

We compared operators' performance by analysing endoscopic video recordings and extracting data from their clinical records on need for help, drugs given, distance the endoscope was inserted (for flexible sigmoidoscopy), duration of examination, and immediate complications. We assessed video recordings of oesophagogastroduodenoscopy with a measurement scale, which we showed, prospectively and concurrently, to have good face, content, and construct validity and good reliability between and within raters.[12] Three experienced endoscopists, blind to operator and patient, independently reviewed and scored a random sample of 188 recordings of study procedures.

We used a scale developed by colleagues at St Mark's Hospital, London, to assess video recordings of flexible sigmoidoscopies. This scale has been validated by correlation with detection rates for adenoma in screening flexible sigmoidoscopy.[21] We anonymised 100 videos of procedures with reported normal results (five per endoscopist per centre) and edited them to include only the extubation phase of the procedure. Four other experienced endoscopists reviewed and scored them independently.

We compared anonymised copies of endoscopy reports with the British Society of Gastroenterology's standards.[22] We extracted final diagnosis, incidence of late complications, new diagnoses, and subsequent contact with health professionals from hospital records after one year and supplemented this with a questionnaire completed by patients' general practices.

Sample size

The gastrointestinal symptom rating questionnaire (primary outcome) used in our feasibility study and concurrent validation has four subscales. When scored between 0 and 100 points, these have standard deviations between 18 and 29. We calculated that we needed a completed sample of 1300 participants to have 80% power at a significance level of 5% to detect differences of at most five points in these subscales between groups, provided that the mean correlation coefficient between operators was less than 0.02 (very likely according to our feasibility study).

Analysis

The pragmatic nature of our trial required us to analyse participants' outcomes by intention to endoscope so as inform decision making in the real world. We also analysed immediate and delayed complications, quality of endoscopy and corresponding report, patients' preferences, and new diagnoses at one year by operator to compare actual performance of the two professions. All significance tests were two sided. Before analysis,

Table 1 | Training and experience of endoscopist. Figures are numbers (percentages) of doctors or nurses unless stated otherwise

	Doctors (n=67)	Nurses (n=30)
Formal endoscopy training	25/67 (37)	27/30 (90)
Mean No of courses attended	0.5	1.2
No of OGD procedures performed:		
1-500	6 (9)	5 (31)
501-1000	7 (11)	2 (13)
1001-5000	34 (52)	6 (38)
5001-10 000	10 (15)	3 (19)
>10 001	8 (12)	0 (0)
No of flexible sigmoidoscopies performed:		
1-250	6 (10)	2 (7)
251-500	10 (16)	7 (26)
501-1000	3 (5)	4 (15)
1001-4000	33 (53)	12 (44)
4001-10 000	9 (15)	2 (7)
>10001	1 (2)	0 (0)
Performs independent endoscopies:		
OGD	67/67 (100)	16/30 (53)
Flexible sigmoidoscopy	64/67 (96)	27/30 (90)
Colonoscopy	59/67 (88)	2/30 (7)
Performs therapeutic procedures	64/65 (99)	19/29 (66)
Monitors endoscopic activities	41/45 (91)	30/30 (100)
Routinely sees patients in:		
Pre-endoscopy clinic	11/66 (17)	4/30 (13)
Post-endoscopy clinic	12/66 (18)	5/30 (17)

OGD=oesophagogastroduodenoscopy.

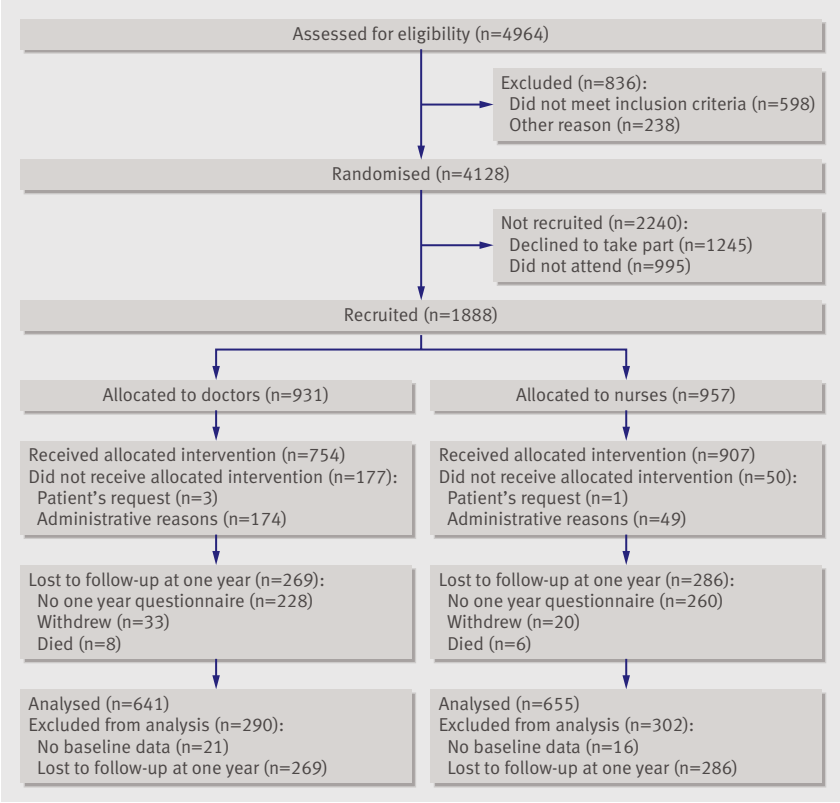

Fig 1 | **Flow diagram of progress through trial**

we tested differences between randomised groups at baseline to ensure that randomisation before consent had not led to unbalanced groups.

We analysed the four factor symptom rating questionnaire in two stages to allow for its skewed distribution in this trial, which reflected the fact that many patients reported no symptoms. Firstly, we used ordered logistic regression to test the symptom rating score at one year (grouped into five ordered categories) for differences between groups after adjusting for covariates (centre, age, baseline score, procedure type, and statistical interaction between group and type of procedure if significant). Secondly, we derived estimates and confidence intervals for mean differences between groups in one year symptom rating scores, and state-trait anxiety inventory, SF-36, and EQ-5D scores by analysis of covariance using the same covariates.

We used *t* tests to compare the four factors of the gastrointestinal symptom rating questionnaire and quantitative aspects of operator performance between groups. We used χ^2 tests to compare patients' preferences between operators at one year, the numbers of new gastrointestinal diagnoses made within 12 months of endoscopy, and binary characteristics of operator performance. We used Cohen's κ to assess the reliability between raters of the St Mark's scale.

We treated missing items within each outcome measure according to the instructions for that measure. We compared responders and non-responders to questionnaires for baseline characteristics including group membership, age, sex, presenting complaints, degree of urgency, physical and mental health, and gastrointestinal symptoms. We undertook a sensitivity analysis by excluding centres where large numbers of patients changed endoscopist after randomisation.

RESULTS

Endoscopist recruitment

Twenty three hospitals participated, of which three recruited patients only for oesophagogastroduodenoscopy, 14 only for flexible sigmoidoscopy, and six for both. These hospitals recruited participants from July 2002 to June 2003. Sixty seven doctors and 30 nurses took part, all of whom were fully trained to practise endoscopy independently (table 1). The doctors had received less formal training than nurses but had more experience in the number and range of procedures undertaken. All doctors but only two thirds of nurses could administer sedation. There was no difference between the two groups in their routine practice before and after endoscopy (table 1).

Recruitment and follow-up of participants

The figure shows the flow of participants through the trial. Table 2 subdivides this by type of procedure.

The characteristics of the randomised patients who did not take part in the trial were not significantly different from those who did. The groups were similar in age, sex, type of access, and presenting symptoms (table 3) and baseline quality of life scores (table 4). Of more than 30 characteristics compared between the two groups, three showed significant differences; as this is little more than expected by chance, it provides little evidence of a real difference between the groups.

Table 2 | **Randomisation and entry to trial by type of procedure and profession (doctor or nurse)*. Figures are numbers (percentages) of patients unless stated otherwise**

	Flexible sigmoidoscopy			OGD		
	Total	Doctor group	Nurse group	Total	Doctor group	Nurse group
Randomised	2226	1117	1109	1902	961	941
Attended (% of randomised)	1777 (80)	866 (78)	911 (82)	1356 (71)	680 (71)	676 (72)
Agreed to trial (% of randomised)	1099 (49)	550 (49)	549 (50)	789 (42)	381 (40)	408 (43)
Procedure/details completed (% of trial patients)	1072 (98)	534 (97)	538 (98)	751 (95)	362 (95)	389 (95)
Changed endoscopist (% of trial patients)	124 (11)	91 (17)	33 (6)	103 (13)	86 (23)	17 (4)

OGD=oesophagogastroduodenoscopy.
*No significant differences between doctors and nurses within type of procedure.

The outcome questionnaire was completed by 1782 (94%) patients at baseline, 1536 (81%) at one day, 1427 (76%) at one month, and 1333 (71%) at one year. As these rates were similar for both randomised groups at all time points, there is little danger of bias.

Patients' outcomes

Table 5 shows that, after adjustment for baseline score, hospital, type of procedure, and age with analysis of covariance, there was no significant difference between the two groups on any of the four factors on the gastrointestinal symptom rating questionnaire at one year. Comparisons within tables 5, 6, and 7 show substantial improvements at one month and further improvements at one year.

Table 6 shows that SF-36 scores improved in both groups on five of the eight subscales at one year. After adjustment for baseline SF-36 score, hospital, type of procedure, and age with analysis of covariance, there was no significant difference between the two groups on any of the eight subscales or two summary scores at one day or one month. At one year there was a significant improvement in social functioning in favour of doctors. Given that the SF-36 gave rise to 24 significance tests, however, this does not provide prima facie evidence of differences between groups.

After adjustment for baseline anxiety, hospital, type of procedure, and age with analysis of covariance, there was no significant difference in anxiety levels between the two groups at any point (table 7). There was a significant difference in patients' satisfaction after endoscopy in favour of nurses on all four factors of the gastrointestinal endoscopy satisfaction questionnaire. The largest difference was for "information after endoscopy," followed by "pain and discomfort," "information before endoscopy," and "skills and hospital" (table 7).

The figure shows that 227 patients changed from their randomised endoscopist, most from doctor to nurse. Almost all of these changes were because of non-availability of the designated endoscopist, rather than the patient's preference. To test whether these changes could have affected our conclusions we repeated our analyses after excluding the three centres where more than 30 patients changed endoscopist. None of our conclusions was sensitive to this change. When asked at one year whether they would recommend an endoscopy to a friend, 87% of patients in the doctor group and 91% in the nurse group recommended endoscopy, whether performed by a doctor or by a nurse.

We analysed findings about process and performance by operator rather than intention to scope. After one year we found and reviewed medical records for 1674 patients (89% of the 1888 recruited), comprising 711 (88%) of the 804 in the doctor group, and 963 (89%) of the 1084 in the nurse group. Fourteen (2%) and 10 (1%) patients, respectively, had received a new gastrointestinal diagnosis in the intervening year (P=0.154 by χ^2 test). There was no evidence that any major pathology had been missed.

Information on sedation for oesophagogastroduodenoscopy was available for 663 patients (239 in the doctor group, 424 in the nurse group). There were no significant differences in use of lidocaine spray or benzodiazepines, but nurses used the combination significantly more often than doctors (18% *v* 6%; P<0.001 by χ^2 test). No reversal agents were used in either group.

There was no difference between the two groups in the distance the endoscope was inserted into the colon or in the mean duration of examination for

Table 3 | Baseline characteristics of all recruited patients by endoscopists (doctor or nurse). Figures are numbers (percentages) of patients unless stated otherwise

	Doctor (n=931)	Nurse (n=957)	P value*
Mean (SD) age (years)	52.4 (15.17)	52.6 (15.08)	0.80†
No of women	480 (52)	507 (53)	0.50‡
ASA class:			
I (healthy patient)	596 (64)	571 (60)	0.20§
II (mild systemic disease, no functional limitations)	197 (21)	224 (23)	
III (severe systemic disease, definite functional limitation)	22 (2)	26 (3)	
VI (severe systemic disease, acute unstable problems)	2 (0.2)	0 (0)	
Missing	114 (12)	138 (14)	
Type of referral:			
Outpatient	306 (33)	327 (34)	0.90§
Open access	384 (41)	397 (42)	
Rapid access	115 (12)	114 (12)	
Not recorded	126 (14)	119 (12)	
Type of access:			
Very urgent	17 (2)	15 (2)	0.80§
Urgent	75 (8)	70 (7)	
Soon	280 (30)	304 (32)	
Routine	559 (60)	568 (59)	
Symptoms			
OGD patients:			
Dyspeptic symptoms	353 (93)	392 (96)	0.04‡
Weight loss	27 (7)	17 (4)	0.09‡
Anaemia	33 (9)	29 (7)	0.40‡
Anorexia	8 (2)	10 (3)	0.80‡
Flexi patients:			
Rectal bleeding	403 (73)	404 (74)	0.90‡
Change in bowel habit	228 (42)	234 (43)	0.70‡
Previous investigation			
Total	181 (19)	182 (19)	—
OGD patients:			
OGD	62 (19)	65 (18)	0.70‡
Flexi/colonoscopy	41 (13)	38 (10)	0.40‡
Barium enema	18 (6)	9 (3)	0.04‡
Flexi patients:			
OGD	51 (10)	48 (10)	0.80‡
Flexi/colonoscopy	53 (11)	56 (12)	0.70‡
Barium enema	74 (15)	80 (16)	0.60‡

OGD=oesophagogastroduodenoscopy; flexi=flexible sigmoidoscopy.
*Because randomisation preceded attendance and consent, formal testing of differences between groups provides check that this procedure, designed to avoid distorting normal practice, has not introduced bias.
†Two sample *t* test.
‡Fisher's exact test.
§χ^2 test.

oesophagogastroduodenoscopy (18.8 minutes for doctors and 19.8 minutes for nurses; difference −1.0 minutes, 95% confidence interval −5.8 to 3.8) or sigmoidoscopy (27.8 *v* 24.2 minutes; 3.0 minutes, −0.5 to 7.6). There was no significant difference in the number of immediate or delayed clinical complications, defects identified in equipment, need for assistance during the procedure, or diagnoses made. Results of upper gastrointestinal endoscopies were reported as normal by 30% of doctors and 18% of nurses (P<0.001 by χ^2 test); the corresponding percentages for flexible sigmoidoscopies were 45% and 34% (P<0.001 by χ^2 test). More patients had biopsies in the nurse group (50% *v* 31% by doctors for oesophagogastroduodenoscopy, P<0.001 by χ^2 test; 35% *v* 27% by doctors for flexible sigmoidoscopy; P=0.006).

Analysis of video recordings of oesophagogastroduodenoscopy showed significantly better (that is, lower) scores by nurses in technique and thoroughness for the oesophagus (mean 23.7 (SD 8.8) *v* 28.7 (SD 12.8) for doctors; *t*=3.16, P=0.002) and stomach (43.7 (SD 13.8) *v* 54.2 (SD 20.3), *t*=4.16, P<0.001). There was no significant difference in the corresponding scores for the duodenum (36.2 (SD 11.3) *v* 38.1 (SD 18.1); *t*=0.89, P=0.38). For flexible sigmoidoscopy, there was no significant difference in the rating of technical performance on the St Mark's scale between the two groups.[21]

In 1784 endoscopy reports (760 by doctors; 1024 by nurses) there was no significant difference in the recording of most items, though type of episode, urgency, sedation, free text comments, discharge, and follow-up arrangements were recorded more consistently and significantly better by nurses. Some items were often omitted by both groups.

Complications

There were no recorded complications with the endoscope. There was no significant difference between the number of immediate or delayed complications identified after endoscopy by a doctor or a nurse.[12]

DISCUSSION

Principal findings

We found little significant difference in the clinical outcomes of diagnostic endoscopy performed by doctors or nurses, as reported by participants at one day, one month, and one year after procedure. Patients were significantly more satisfied with nurses one day after the procedure. Nurses were more thorough in the examination of stomach and oesophagus, carried out more biopsies than doctors, and omitted fewer items from reports.

Strengths and weaknesses of trial

Our pragmatic trial compared endoscopy by nurses and doctors operating in their usual environment with their usual working practices. As endoscopy lists need to be booked well in advance and referral processes were heterogeneous across sites we could not seek consent from patients before randomisation. We therefore used Zelen's design of randomisation before consent. Not surprisingly many potential participants left after randomisation. Nevertheless, we recruited 1888 (60%) of the 3133 eligible patients who attended for the procedure after randomisation. Furthermore, proportions recruited were similar in both groups, and the characteristics of those recruited were representative of those randomised. Thus the trial evaluated doctors and nurses undertaking diagnostic endoscopy on comparable and representative patients.

We assessed patients recruited on the basis of symptoms reported before diagnosis. We found no validated instrument to do this and so developed a system specific gastrointestinal symptom rating questionnaire. We piloted this on 351 patients at Neath Port Talbot Hospital, comparing it with the generic SF36 and four condition specific instruments: the inflammatory bowel disease questionnaire (UKIBDQ), Aberdeen dyspepsia scale (ADS), the gastro-oesophageal reflux disease-health related quality of life scale (GERD-HRQLS), and the irritable bowel syndrome-quality of life (IBS QOL).

We then undertook concurrent validation with 1800 new patients taking part in MINuET. Underlying dimensions were characterised by principal component analysis. Internal consistency was assessed by

Table 4 | Baseline scores of all recruited patients by endoscopists. Figures are numbers (percentages) of patients unless stated otherwise

	Doctor (n=931)	Nurse (n=957)	P value*
GSRQ scores† (range 0 (no symptoms)-100)			
Factor 1: upper GI	18.4 (18.29), n=867	18.2 (18.91), n=904	0.8
Factor 2: lower GI	29.1 (29.35), n=865	28.9 (29.21), n=900	0.9
Factor 3: wind	42.1 (25.84), n=868	41.5 (25.34), n=906	0.6
Factor 4: defecation	21.6 (21.84), n=864	22.8 (22.92), n=899	0.3
EQ-5D scores (range 0 (poor health)-1)			
Overall	0.68 (0.267), n=835	0.66 (0.285), n=867	0.3
SF-36 scores (range 0 (poor health)-100)			
Physical functioning	73.3 (28.73), n=859	71.0 (29.47), n=891	0.1
Social functioning	49.6 (10.66), n=856	49.4 (10.34), n=876	0.6
Role limitation-physical	69.0 (31.91), n=833	66.9 (32.53), n=870	0.2
Role limitation-mental	74.5 (29.48), n=832	73.2 (29.98), n=860	0.4
Mental health	62.5 (11.30), n=857	61.5 (11.41), n=881	0.08
Vitality	53.1 (11.83), n=867	52.8 (12.02), n=885	0.6
Pain	51.1 (9.62), n=850	51.6 (9.41), n=866	0.3
General health	57.9 (12.51), n=845	57.1 (12.54), n=874	0.2
Change in health	57.7 (20.30), n=867	58.4 (21.07), n=896	0.5
Physical component score	45.2 (7.20), n=782	44.4 (7.49), n=812	0.03
Mental component score	41.8 (6.88) n=782	41.7 (7.01), n=812	0.7
State-trait anxiety inventory (range 20 (high anxiety)-80)			
State anxiety	42.8 (14.58), n=819	42.1 (14.48), n=840	0.3

GSRQ=gastrointestinal symptom rating questionnaire.
*Two sample *t* test. Because randomisation preceded attendance and consent, formal testing of differences between groups provides check that this procedure, designed to avoid distorting normal practice, has not introduced bias.
†GSRQ factors: factor 1=upper GI, heartburn, reflux, nausea, retching, vomiting, food sticking in gullet, eating restricted, lack of appetite; factor 2=lower GI, frequent bowel movement, loose stools, urgent need to empty bowel; factor 3=wind related symptoms, upper abdomen discomfort, belching, wind from bowel, trapped wind, gurgling in stomach; factor 4=defecation related symptoms, hard stools, constipation, incomplete bowel emptying, rectal bleeding.

Table 5 | Differences in primary outcome measure; figures are adjusted* mean scores (range 0 (no symptoms)-100) on gastrointestinal (GI) symptom rating questionnaire

	Doctor group		Nurse group		
	No of patients	Mean (SE)	No of patients	Mean (SE)	Difference† (95% CI)
At one month					
Factor 1: upper GI	675	12.6 (0.58)	701	13.8 (0.57)	−1.20 (−2.33 to −0.080)
Factor 2: lower GI	675	25.0 (1.02)	698	24.3 (1.01)	0.77 (−1.21 to 2.75)
Factor 3: wind	677	34.4 (0.92)	703	35.3 (0.91)	−0.87 (−2.66 to 0.92)
Factor 4: defecation	672	21.3 (0.90)	695	20.6 (0.88)	0.69 (−1.03 to 2.42)
At one year					
Factor 1: upper GI	634	11.8 (0.69)	645	12.4 (0.70)	−0.61 (−1.92 to 0.70)
Factor 2: lower GI	624	21.4 (1.16)	639	22.8 (1.17)	−1.46 (−3.67 to 0.75)
Factor 3: wind	635	32.6 (1.06)	646	31.6 (1.07)	0.98 (−1.04 to 3.00)
Factor 4: defecation	623	18.7 (0.98)	639	19.9 (0.99)	−1.23 (−3.10 to 0.64)

*Adjusted for baseline score, centre, type of procedure, and age with analysis of covariance.
†Difference for doctor minus nurse; thus negative difference indicates that patients in nurse group score worse on average than patients in doctor group and positive difference indicates that patients in nurse group score better on average than patients in doctor group.

Crohnbach's α. Construct validity of the questionnaire was evaluated through comparison with patients' general health as measured by the SF-36. We used intraclass correlation to assess reproducibility in patients who reported no change in health status. Responsiveness for those reporting a change was assessed by the responsiveness ratio. In this way we followed established practice by developing the questionnaire clinically, then testing it on patients with known disorders, and finally validating it on a large clinical sample.[22]

Our results showed that the gastrointestinal symptom rating questionnaire is a valid questionnaire for assessing gastrointestinal symptoms with good internal consistency, four interpretable factors, and demonstrable construct validity, reproducibility, and responsiveness.[12] This enabled us to compare both short and long term outcomes from a patient's perspective and also to estimate cost effectiveness.[14] We also assessed 86% of the endoscopy procedures using objective measures: sedation used, duration of examination, lesions detected, biopsies, need for assistance, requests for subsequent investigation, early and late complications, completeness of reports, and new diagnoses at one year. We assessed and compared operator performance by objective comparison of randomly selected video recordings of the procedure (188 for oesophagogastroduodenoscopy, 100 for flexible sigmoidoscopy). We thus comprehensively compared performance and outcome between nurses and doctors.

Our use of multiple assessments also enabled us to triangulate and confirm our findings. The data on participant outcomes and resource use, collected through self completed questionnaires, were consistent with data obtained from primary and secondary care records one year after the procedure. We chose or designed our outcome measures to test for differences in short and long term outcomes as assessed by patients. We used validated measures or undertook concurrent validation if necessary. Response rates were acceptable for a pragmatic trial, and similar in the two groups. The low incidence of new diagnoses did not differ between the two groups. We believe it unlikely that longer follow-up would have yielded further findings after oesophagogastroduodenoscopy, though it is possible that colonic polyps would have remained undetected.

Participating hospitals included large and small, urban and rural, and teaching and non-teaching. Thus trial recruitment reflected variations in the organisation of endoscopy services across the UK. Most endoscopies were undertaken by a small number of doctors and nurses in each hospital. More patients experienced a change of operator from doctor to nurse than vice versa. Most changes from doctor to nurse were because the doctor was unavailable through commitments outside the endoscopy unit, while nurse endoscopists tended to remain in their units. We believe this reflects competing demands on doctors' time and that we have evaluated representative clinical practice in the UK. Thus the strength of our trial lay in comparing the performance of doctors and nurses across a wide spectrum of common indications.

The number of trained nurse endoscopists has increased since the trial, but we judge that those who participated were representative of the growing expertise in endoscopy in the UK. In adopting a pragmatic approach to evaluation we reflected many inherent differences between the two groups of endoscopists, notably in sex and the fact that most doctors had acquired their skills through unstructured, experiential training in the early days of endoscopy, whereas the training of both nurses and doctors is now formalised and monitored. So the trial shows how the performance of the typically female but formally trained nurse endoscopist compares with that of the typically male medical endoscopist who learnt through apprenticeship. That is the question to which those responsible for human resource planning in the NHS were seeking an answer when they asked the National Coordinating Centre for Health Technology Assessment to commission this research.

Strengths and weaknesses in relation to other studies

These findings reinforce results of single centre studies suggesting that nurses can safely and effectively carry out flexible sigmoidoscopy.[5-8] We have confirmed that quality of life improves after endoscopy by both doctors and nurses.[23] This reflects the value of endoscopy even when no abnormality is found. We have also confirmed the findings of a single centre trial that nurses are as competent as doctors in examining the upper gastrointestinal tract.[24]

Implications

Nurses seem to be safe and effective endoscopists, are more thorough than doctors, and more likely to satisfy patients. Use of sedation was similar in both groups, reflecting the tendency of both groups to combine sedation and local anaesthesia to the throat before oesophagogastroduodenoscopy, contrary to the guidelines of the British Society of Gastroenterology. This suggests that both professions can improve adherence to these guidelines.

Unanswered questions

Half of our findings relate to flexible sigmoidoscopy, which examines only the distal half of the colon and is increasingly being replaced by full colonoscopy. As nurses are increasingly undertaking colonoscopy, that will need further evaluation. Our economic evaluation, arising from a different analytical paradigm, suggests that doctors are likely to be more cost effective than nurses in the current state of their training and experience.[14] When deciding whether to develop

Table 6 | Differences in secondary outcome measures SF-36*

	Doctor		Nurse		
	No of patients†	Adjusted† mean (SE) score	No of patients†	Adjusted‡ mean (SE) score	Difference§ (95% CI)
At one day					
Physical functioning	700	72.6 (0.66)	748	73.6 (0.64)	0.94 (−0.39 to 2.27)
Social functioning	690	47.6 (0.54)	730	48.0 (0.53)	0.37 (−0.73 to 1.46)
Role limitation-physical	675	73.9 (1.06)	727	74.8 (1.02)	0.83 (−1.28 to 2.94)
Role limitation-mental	678	79.0 (1.08)	726	80.1 (1.05)	1.05 (−1.13 to 3.23)
Mental health	693	65.4 (0.55)	737	65.4 (0.53)	0.074 (−1.02 to 1.17)
Vitality	702	56.2 (0.60)	744	56.9 (0.58)	0.74 (−0.46 to 1.93)
Pain	696	48.2 (0.49)	725	48.7 (0.48)	0.48 (−0.51 to 1.46)
General health	684	56.5 (0.46)	723	56.8 (0.44)	0.22 (−0.70 to 1.14)
PCS	623	44.5 (0.22)	661	44.5 (0.21)	−0.033 (−0.48 to 0.42)
MCS	623	43.6 (0.29)	661	44.0 (0.28)	0.42 (−0.18 to 1.01)
At one month					
Physical functioning	666	73.4 (0.77)	689	73.4 (0.76)	−0.016 (−1.51 to 1.48)
Social functioning	660	49.5 (0.51)	673	48.9 (0.51)	−0.61 (−1.61 to 0.40)
Role limitation-physical	645	72.2 (1.06)	668	71.8 (1.05)	−0.40 (−2.48 to 1.67)
Role limitation-mental	647	78.6 (1.11)	662	77.9 (1.10)	−0.66 (−2.83 to 1.51)
Mental health	664	63.7 (0.53)	679	63.6 (0.52)	−0.074 (−1.10 to 0.95)
Vitality	672	54.3 (0.55)	686	53.8 (0.55)	-0.51 (−1.58 to 0.57)
Pain	660	50.4 (0.48)	667	50.5 (0.47)	0.16 (−0.78 to 1.09)
General health	657	57.6 (0.54)	672	57.1 (0.53)	−0.46 (−1.51 to 0.59)
PCS	598	45.0 (0.24)	612	44.8 (0.24)	−0.25 (−0.73 to 0.23)
MCS	598	42.9 (0.30)	612	42.9 (0.30)	0.016 (−0.60 to 0.61)
At one year					
Physical functioning	631	73.8 (0.95)	639	73.0 (0.96)	−0.75 (−2.56 to 1.06)
Social functioning	625	48.9 (0.55)	627	47.8 (0.56)	−1.10 (−2.15 to -0.055)
Role limitation-physical	609	72.8 (1.22)	621	72.1 (1.23)	−0.67 (−3.00 to 1.65)
Role limitation-mental	609	78.2 (1.33)	616	77.9 (1.34)	−0.27 (−2.81 to 2.28)
Mental health	621	62.8 (0.57)	628	62.9 (0.58)	0.12 (−0.97 to 1.20)
Vitality	628	53.2 (0.60)	635	53.0 (0.61)	−0.20 (−1.34 to 0.95)
Pain	624	50.2 (0.50)	621	50.1 (0.50)	−0.071 (−1.02 to 0.88)
General health	609	55.5 (0.60)	631	55.1 (0.60)	−0.37 (−1.50 to 0.77)
PCS	559	45.0 (0.23)	575	44.6 (0.28)	−0.41 (−0.95 to 0.12)
MCS	559	42.6 (0.34)	575	42.5 (0.34)	−0.10 (−0.77 to 0.58)

PCS=physical component score; MCS=mental component score.
*Maximum number 737 for doctor group and 79 for nurse group.
†Range 0 (poor health)-100.[18]
‡Difference for score with doctor minus score with nurse, thus negative difference indicates that patients in nurse group score worse on average than patients in doctor group and positive difference indicates that patients in nurse group score better on average than patients in doctor group.
§Adjusted for baseline score, centre, type of procedure, and age using analysis of covariance.

Table 7 | Differences in secondary outcome measures, state-trait anxiety and GESQ

	Doctor		Nurse		
	No of patients*	Adjusted† mean (SE) score	No of patients*	Adjusted† mean (SE) score	Difference‡ (95% CI)
State-trait anxiety inventory, state anxiety§					
One day	667	38.6 (0.45)	703	39.0 (0.44)	0.33 (−0.57 to 1.23)
One month	634	37.7 (0.54)	645	37.9 (0.53)	0.15 (−0.89 to 1.20)
One year	599	38.3 (0.61)	594	38.8 (0.61)	0.56 (−0.60 to 1.72)
GESQ¶ at one day					
Skills and hospital	619	14.5 (0.46)	710	12.0 (0.42)	2.57 (1.35 to 3.79)
Pain and discomfort	622	33.6 (0.80)	710	30.3 (0.75)	3.35 (1.19 to 5.50)
Information before endoscopy	623	21.2 (0.54)	716	18.3 (0.55)	2.97 (1.45 to 4.48)
Information after endoscopy	517	22.0 (0.88)	633	17.1 (0.79)	4.84 (2.53 to 7.15)

*Maximum number 737 for doctor group and 789 for nurse group.
†Adjusted for baseline score, centre, type of procedure, and age using analysis of covariance.
‡Difference for score with doctor minus score with nurse, thus negative difference indicates that patients in nurse group score worse on average than patients in doctor group and positive difference indicates that patients in nurse group score better on average than patients in doctor group.
§Range 20 (high anxiety)-80.[17]
¶Range 0 (satisfied)-100.[12]

endoscopy services through doctors or nurses, planners need to consider the relative clinical effectiveness and cost effectiveness of the two professions. They also need to consider the availability of potential staff, both in the labour market and across the working day. As nurses grow in experience over time, it will be important to continue to monitor effectiveness and cost effectiveness.

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Contributors: JW led the trial team, was principal author, and is guarantor. IR contributed to the design and implementation of the trial and drafting the paper. DD developed, validated, and applied the method of assessing the video recordings, validated the gastrointestinal endoscopy satisfaction questionnaire, collected and analysed clinical data, and contributed to drafting the paper. WYC validated both questionnaires. AF was responsible for the design, conduct and interpretation of the statistical analysis, and contributed to the overall design and implementation of the trial and drafting the paper. KB contributed to analysis and drafting of the paper. SC developed, validated, and managed the main database. GR contributed to drafting of the paper. All authors reviewed successive drafts of both papers.

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WHAT IS ALREADY KNOWN ON THIS TOPIC

Nurses are increasingly undertaking both upper and lower gastrointestinal endoscopy

Single centre studies suggest that nurse endoscopists are competent and are appreciated by patients

WHAT THIS STUDY ADDS

There is no significant difference between doctors and nurses in their clinical effectiveness in diagnostic endoscopy

Nurses are more thorough than doctors in examination of the oesophagus and stomach

Patients are more satisfied after an endoscopy by a nurse

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