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Using photo-documentation to improve detection of stomach and oesophagus problems during endoscopy

Submission date 23/10/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 27/10/2025	**Overall study status** Completed	
Last Edited 27/10/2025	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Stomach and oesophagus problems, including ulcers, polyps and early cancers, are often found using a test called an oesophagogastroduodenoscopy (OGD). This test uses a flexible camera to look at the lining of the upper digestive tract. Although OGD is the best way to detect these problems, sometimes lesions (areas of abnormal tissue) are missed during the procedure.

International guidelines now recommend taking a set of standard photographs during OGD. This is called photo-documentation, and it helps ensure that doctors carefully look at key areas. However, these recommendations are based on low-quality evidence, mostly from observational studies.

The aim of this study is to find out whether using a structured eight-landmark photo-documentation protocol helps doctors detect more lesions during OGD compared to usual practice. By using a high-quality endoscopy simulator rather than real patients, we can test this in a safe and controlled way.

Who can participate?
Participants will be surgical trainees at Senior House Officer (SHO) level. These are doctors in the early years of specialist training.
They must have some prior experience of OGD (either observing or performing it with supervision).
This is not a patient study — only healthy volunteer trainees will take part. There are no restrictions based on sex or age beyond being in postgraduate training.

What does the study involve?
Participants will be randomly assigned to one of two groups:
Control group: Trainees will follow the usual Irish practice of taking two standard photos during OGD.

Intervention group: Trainees will be taught to follow the British Society of Gastroenterology (BSG) eight-landmark photo-documentation protocol, which involves taking photos of eight specific areas.

All trainees will then carry out 10 simulated OGDs (five normal cases and five with visible lesions) using a realistic endoscopy simulator. The simulator works like the real procedure but does not involve patients.

We will measure:
How often trainees correctly detect and identify lesions.
How long they take to complete procedures.
How many and which areas they photograph.
Their baseline knowledge and experience from a short questionnaire.

What are the possible benefits and risks of participating?
There are no medical risks, as this study uses simulation and not real patients.
Trainees may benefit through additional training and feedback that could help improve their future endoscopy practice.
The study will also help us understand whether structured photo-documentation improves lesion detection. This could inform future training and national guidelines.

Where is the study run from?
Royal College of Surgeons in Ireland (RCSI)

When is the study starting and how long is it expected to run for?
The study is planned to start in 2025 and is expected to run for approximately 12 months, including recruitment, data collection, and analysis.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Mr Eoghan Burke, eoghanburke@rcsi.ie

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Mr Eoghan Burke

ORCID ID
https://orcid.org/0000-0001-9809-9405

Contact details
Department of Surgical Affairs, 123 Stephens Green
Dublin
Ireland

D02 YN77
+353 1 402 2100
eoghanburke@rcsi.ie

Additional identifiers

Protocol serial number
REC: 202507024

Study information

Scientific Title
Gastroscopy Improvement (GastroProve) Study: A randomised controlled trial evaluating the effect of structured photo-documentation on lesion detection rates during oesophagogastroduodenoscopy in surgical trainees using high-fidelity simulatio

Acronym
GastroProve

Study objectives
Primary objective:
To determine whether adherence to the British Society of Gastroenterology (BSG) eight-landmark photo-documentation protocol improves pathology detection rates compared to usual practice during simulated oesophagogastroduodenoscopy (OGD) performed by surgical trainees.

Secondary objectives:
1. To compare procedure completion times between the intervention (BSG eight-landmark protocol) and control (usual practice) groups.
2. To assess adherence to photo-documentation guidance, including the number and distribution of anatomical sites imaged.
3. To evaluate baseline trainee experience and knowledge relevant to OGD quality and photo-documentation using a pre-study questionnaire.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/09/2025, Royal College of Surgeons In Ireland (2nd Floor, Ardilaun House, 111 St Stephen's Green, Dublin, D02 YN77, Ireland; +353 1 402 2205; recadmin@rcsi.ie), ref: REC: 202507024

Study design
Single-centre parallel-group double-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Upper gastrointestinal disease, including gastric and oesophageal lesions (e.g., ulcers, polyps, early gastric cancer); quality improvement in oesophagogastroduodenoscopy.

Interventions
Intervention:
Participants in the intervention group will receive structured instruction on the British Society of Gastroenterology (BSG) eight-landmark photo-documentation protocol for oesophagogastroduodenoscopy (OGD). They will then perform 10 simulated OGDs (5 normal cases and 5 with visible pathology) using the Simbionix GI Mentor™ Endoscopy Simulator, applying the eight-landmark photo-documentation protocol during each procedure.

Comparator / Control:
Participants in the control group will receive instruction on standard Irish Key Performance Indicators (KPIs) for OGD photo-documentation (D2 and retroflexed fundus) and will perform the same 10 simulated OGD cases according to their usual practice, without additional guidance on the eight-landmark protocol.

Delivery:
All procedures will be carried out individually by early-stage surgical trainees (SHOs) during scheduled simulation training sessions in a neutral educational setting. Case order is randomised, and trainees are blinded to case content (normal vs pathology).

Randomisation process:
Randomisation will be conducted at two levels: (1) allocation to study arm and (2) case order assignment.

1. Allocation to intervention or control group
Participants will be allocated to the intervention or control arm using a block randomisation schedule with a 1:1 ratio, generated in advance using Sealed Envelope's secure online randomisation service (https://www.sealedenvelope.com). Variable block sizes will be used to reduce the risk of allocation prediction.
The randomisation list will be held by an independent administrator who is not involved in participant recruitment or assessment. Group assignment will be concealed until the point of participation and revealed only after the pre-study questionnaire is completed. This ensures allocation concealment and minimises the risk of selection bias.

2. Case order randomisation
Each participant will complete ten simulator cases (five normal and five containing visible pathology). To minimise any learning or order effects, the order in which these cases are presented will be independently randomised for each trainee. A pre-generated, computer-based random sequence of case IDs will be used to determine the sequence for each participant. This list will be stored securely and accessed only by the session administrator immediately prior to the training session.
Trainees, assessors, and outcome evaluators will remain blinded to the case content (normal vs pathology) throughout the procedure, ensuring that performance is not influenced by expectations.

This two-stage randomisation process provides both balanced group allocation and rigorous control of potential order effects, supporting the methodological integrity of the trial.

Intervention Type

Behavioural

Primary outcome(s)
Lesion detection rate during OGD — proportion of pathology-positive simulated cases in which the trainee correctly identifies a lesion and assigns the correct anatomical localisation, assessed via the simulator's image-based reporting workflow at the end of each case (images must be labelled to site and pathology declared). Measured per participant across their five pathology-positive cases and compared between groups.

Key secondary outcome(s))
1. Procedure completion time: Time (minutes/seconds) to complete each simulated OGD, captured automatically by the simulator; summarised per participant across 10 cases and compared between groups.
2. Adherence to photo-documentation guidance: Number and distribution of anatomical sites imaged per case (e.g., proportion of required landmarks captured); summarised per participant and compared between groups.
3. Additional descriptive measure: Baseline trainee experience and knowledge relevant to OGD quality and photo-documentation from the pre-study questionnaire, used to characterise the cohort and as covariates in sensitivity analyses.

Completion date
01/12/2025

Eligibility

Key inclusion criteria
1. Surgical trainee at Senior House Officer (SHO) level or equivalent.
2. Enrolled in a postgraduate surgical training programme with exposure to upper GI endoscopy.
3. Some prior exposure to oesophagogastroduodenoscopy (observation or supervised performance).
4. Able and willing to provide informed consent.

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
16

Key exclusion criteria
1. Extensive prior independent endoscopy experience (e.g., JAG-certified).
2. Previous participation in similar OGD simulation studies.
3. Inability or unwillingness to provide informed consent.

Date of first enrolment
01/10/2025

Date of final enrolment
01/11/2025

Locations

Countries of recruitment
Ireland

Study participating centre
Royal College of Surgeons Simulation Training Center
26 York Street
Dublin
Ireland
D02 P796

Sponsor information

Organisation
Royal College of Surgeons in Ireland

ROR
https://ror.org/01hxy9878

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The data generated in this study will consist of simulation performance metrics and questionnaire responses from surgical trainees. No patient data will be collected.

De-identified individual-level data (including detection outcomes, procedure times, and photo-documentation metrics) may be shared with qualified researchers for secondary analysis upon reasonable request. Requests will be reviewed by the study team to ensure appropriate use and compliance with data protection regulations.

Data will be stored securely at the Royal College of Surgeons in Ireland (RCSI) and may be made available beginning 6 months after publication of the primary results. Access will require a data sharing agreement.

No personally identifiable information will be shared, and all data will comply with GDPR and institutional policies.

Plan to share IPD: Yes — de-identified data available on request with appropriate approvals.
Plan to share documents (e.g., protocol, analysis plan): Yes — protocol and statistical analysis plan available on request or via publication.

IPD sharing plan summary
Available on request