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Written versus verbal patient information before gastrointestinal endoscopy: a randomized trial

Submission date	Recruitment status	[_] Prospectively registered
11/02/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/02/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/12/2020	Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
001/1999

Study information

Scientific Title
Written versus verbal patient information before gastrointestinal endoscopy: a randomized trial

Study objectives
To assess the effectiveness of combined written and oral information, compared with oral information alone on the quality of information before endoscopy and the level of anxiety.

Ethics approval required
Old ethics approval format

Ethics approval(s)
No ethics approval was required for this trial in 1999. There was no specific ethic committee at the Geneva University Hospital at the time but the trial was approved by the Head of the Division of Gastroenteorlogy.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Gastrointestinal endoscopy

Interventions
Patients randomized either to receiving, along with the appointment notice, an explanatory leaflet about the upcoming examination, or to oral information delivered by each patient's doctor.

The appointment letter was sent to the patient with or without the written information leaflet within one week before endoscopy for most participants. Patient consent to participate was obtained only upon his arrival for the endoscopic procedure.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Evaluation of quality of information rated on scales between 0 (none received) and 5 (excellent), assessed immediately after the endoscopy

Key secondary outcome(s)
Patients rated the following, using a questionnaire to be filled within 24 hours and sent back by mail in a prepaid envelope:
1. Their anxiety at the time of the procedure (between none and strong)
2. How tolerable the procedure was (between very easy and very hard)
3. Their pain during the procedure (between none and strong)
4. Whether any health problems occurred as a result of the procedure (none, minor, moderate or

severe)
5. The procedure as a whole (between poor and excellent)

Completion date
01/04/1999

Eligibility

Key inclusion criteria
1. Patients scheduled for an elective digestive endoscopy (upper gastrointestinal endoscopy or colonoscopy) within three months
2. Resident in Switzerland
3. Understand French language
4. Able to fill in the study questionnaire

Note: Both inpatients and outpatients were included

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
577

Key exclusion criteria
1. Age <18 years
2. Pregnancy
3. Patients unable to give their own consent
4. Patients that had already undergone prior endoscopy

Date of first enrolment
01/01/1999

Date of final enrolment
01/04/1999

Locations

Countries of recruitment
Switzerland

Study participating centre
Division of Gastroenteorlogy
Geneve
Switzerland
1211

Sponsor information

Organisation
Geneva University Hospital (Switzerland)

ROR
https://ror.org/01m1pv723

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
This trial was internally funded by the Geneva University Hospital (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/06/2008	30/12/2020	Yes	No