

Virtual reality simulation training for health professions trainees in gastrointestinal endoscopy (Review)

Walsh CM, Sherlock ME, Ling SC, Carnahan H



**THE COCHRANE
COLLABORATION®**

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2012, Issue 6

<http://www.thecochranelibrary.com>

WILEY

TABLE OF CONTENTS

HEADER	1
ABSTRACT	1
PLAIN LANGUAGE SUMMARY	2
BACKGROUND	2
OBJECTIVES	4
METHODS	4
RESULTS	6
Figure 1.	7
Figure 2.	9
Figure 3.	11
Figure 4.	11
Figure 5.	12
Figure 6.	13
Figure 7.	13
Figure 8.	14
DISCUSSION	14
AUTHORS' CONCLUSIONS	16
ACKNOWLEDGEMENTS	16
REFERENCES	17
CHARACTERISTICS OF STUDIES	20
DATA AND ANALYSES	56
Analysis 1.1. Comparison 1 Comparison 1: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training), Outcome 1 Composite Score of Competency.	56
Analysis 1.2. Comparison 1 Comparison 1: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training), Outcome 2 Independent Procedure Completion.	57
Analysis 1.3. Comparison 1 Comparison 1: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training), Outcome 3 Performance Time.	58
Analysis 1.4. Comparison 1 Comparison 1: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training), Outcome 4 Patient Discomfort.	58
Analysis 1.5. Comparison 1 Comparison 1: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training), Outcome 5 Overall Global Rating of Performance or Competency.	59
Analysis 1.6. Comparison 1 Comparison 1: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training), Outcome 6 Visualization of Mucosa.	60
ADDITIONAL TABLES	60
APPENDICES	83
HISTORY	91
CONTRIBUTIONS OF AUTHORS	91
DECLARATIONS OF INTEREST	91
SOURCES OF SUPPORT	91
DIFFERENCES BETWEEN PROTOCOL AND REVIEW	92
INDEX TERMS	92

[Intervention Review]

Virtual reality simulation training for health professions trainees in gastrointestinal endoscopy

Catharine M Walsh¹, Mary E Sherlock², Simon C Ling¹, Heather Carnahan³

¹Division of Gastroenterology, Hepatology, and Nutrition, The Hospital for Sick Children, Toronto, Canada. ²Division of Gastroenterology & Nutrition, McMaster Children's Hospital, Hamilton, Canada. ³Department of Occupational Science and Occupational Therapy, University of Toronto, Toronto, Canada

Contact address: Catharine M Walsh, Division of Gastroenterology, Hepatology, and Nutrition, The Hospital for Sick Children, 555 University Ave, Toronto, Ontario, M5G 1X8, Canada. catharine.walsh@mail.utoronto.ca.

Editorial group: Cochrane Colorectal Cancer Group.

Publication status and date: New, published in Issue 6, 2012.

Review content assessed as up-to-date: 30 January 2012.

Citation: Walsh CM, Sherlock ME, Ling SC, Carnahan H. Virtual reality simulation training for health professions trainees in gastrointestinal endoscopy. *Cochrane Database of Systematic Reviews* 2012, Issue 6. Art. No.: CD008237. DOI: 10.1002/14651858.CD008237.pub2.

Copyright © 2012 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

ABSTRACT

Background

Traditionally, training in gastrointestinal endoscopy has been based upon an apprenticeship model, with novice endoscopists learning basic skills under the supervision of experienced preceptors in the clinical setting. Over the last two decades, however, the growing awareness of the need for patient safety has brought the issue of simulation-based training to the forefront. While the use of simulation-based training may have important educational and societal advantages, the effectiveness of virtual reality gastrointestinal endoscopy simulators has yet to be clearly demonstrated.

Objectives

To determine whether virtual reality simulation training can supplement and/or replace early conventional endoscopy training (apprenticeship model) in diagnostic oesophagogastroduodenoscopy, colonoscopy and/or sigmoidoscopy for health professions trainees with limited or no prior endoscopic experience.

Search methods

Health professions, educational and computer databases were searched until November 2011 including The Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, Scopus, Web of Science, Biosis Previews, CINAHL, Allied and Complementary Medicine Database, ERIC, Education Full Text, CBCA Education, Career and Technical Education @ Scholars Portal, Education Abstracts @ Scholars Portal, Expanded Academic ASAP @ Scholars Portal, ACM Digital Library, IEEE Xplore, Abstracts in New Technologies and Engineering and Computer & Information Systems Abstracts. The grey literature until November 2011 was also searched.

Selection criteria

Randomised and quasi-randomised clinical trials comparing virtual reality endoscopy (oesophagogastroduodenoscopy, colonoscopy and sigmoidoscopy) simulation training versus any other method of endoscopy training including conventional patient-based training, in-job training, training using another form of endoscopy simulation (e.g. low-fidelity simulator), or no training (however defined by authors) were included. Trials comparing one method of virtual reality training versus another method of virtual reality training (e.g. comparison of two different virtual reality simulators) were also included. Only trials measuring outcomes on humans in the clinical setting (as opposed to animals or simulators) were included.

Virtual reality simulation training for health professions trainees in gastrointestinal endoscopy (Review)

Copyright © 2012 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

1

Data collection and analysis

Two authors (CMS, MES) independently assessed the eligibility and methodological quality of trials, and extracted data on the trial characteristics and outcomes. Due to significant clinical and methodological heterogeneity it was not possible to pool study data in order to perform a meta-analysis. Where data were available for each continuous outcome we calculated standardized mean difference with 95% confidence intervals based on intention-to-treat analysis. Where data were available for dichotomous outcomes we calculated relative risk with 95% confidence intervals based on intention-to-treat-analysis.

Main results

Thirteen trials, with 278 participants, met the inclusion criteria. Four trials compared simulation-based training with conventional patient-based endoscopy training (apprenticeship model) whereas nine trials compared simulation-based training with no training. Only three trials were at low risk of bias. Simulation-based training, as compared with no training, generally appears to provide participants with some advantage over their untrained peers as measured by composite score of competency, independent procedure completion, performance time, independent insertion depth, overall rating of performance or competency error rate and mucosal visualization. Alternatively, there was no conclusive evidence that simulation-based training was superior to conventional patient-based training, although data were limited.

Authors' conclusions

The results of this systematic review indicate that virtual reality endoscopy training can be used to effectively supplement early conventional endoscopy training (apprenticeship model) in diagnostic oesophagogastroduodenoscopy, colonoscopy and/or sigmoidoscopy for health professions trainees with limited or no prior endoscopic experience. However, there remains insufficient evidence to advise for or against the use of virtual reality simulation-based training as a replacement for early conventional endoscopy training (apprenticeship model) for health professions trainees with limited or no prior endoscopic experience. There is a great need for the development of a reliable and valid measure of endoscopic performance prior to the completion of further randomised clinical trials with high methodological quality.

PLAIN LANGUAGE SUMMARY

Virtual Reality Simulators for Training Gastrointestinal Endoscopy

Traditionally trainees have learned to perform endoscopy in the clinical setting under the supervision of a trained endoscopist. Virtual reality computer simulators are becoming popular as a way of providing trainees with an opportunity to practice skills in a risk-free environment. This review was undertaken to determine whether virtual reality simulation training can supplement and/or replace early patient-based endoscopy training. We included randomised trials comparing virtual reality endoscopy simulation training with any other form of endoscopy training (patient-based training, no training, training using another form of endoscopy simulation) for trainees with little or no prior endoscopic experience. Thirteen trials involving 278 participants were included. All trials except one were at high risk of bias. Simulation-based endoscopy training, as compared with no training, generally appears to provide trainees with an advantage as measured by a composite score of competency, ability to complete procedures independently, time taken to complete a task, depth of endoscope insertion, overall rating of performance, number of errors and mucosal visualization. There was no conclusive evidence that simulation-based training, as compared with traditional patient-based training, provided benefit, although data were limited. The results of this review have shown that virtual reality endoscopy training can be used to supplement early traditional endoscopy training for trainees with little or no endoscopic experience.

BACKGROUND

Over the last two decades, there has been an increasing push to integrate simulation-based training into health professions educa-

tion as a way of facilitating novice skill acquisition in a low-risk environment (Issenberg 1999; Issenberg 2005).

Description of the condition

Gastrointestinal endoscopy is an important diagnostic and therapeutic tool used in the evaluation and treatment of gastrointestinal disorders (Faigel 2005). It is a technically challenging procedure, requiring considerable training for optimal performance. Traditionally, the acquisition of procedural proficiency has been based upon an apprenticeship model, with novice endoscopists learning basic skills under the supervision of experienced preceptors in the clinical setting. Gastrointestinal endoscopy, however, is uniquely challenging to teach in the clinical setting for several reasons. Patients are often only partially sedated, or even completely awake, during the procedure, and patient comfort cannot be compromised for the sake of training. Furthermore, there is an “all-or-none” phenomenon requiring the instructor to give up complete control of the endoscope in order to allow the trainee to master the technique (Dunkin 2003). Finally, the finding of pathology during a case is intermittent. Therefore, a trainee must complete a large number of procedures in order to acquire the knowledge necessary to identify, interpret and correctly manage findings (Dunkin 2003).

Description of the intervention

Virtual reality (VR) computer simulators are among the tools that have been used to enhance traditional endoscopy teaching. The use of simulation to teach gastrointestinal endoscopy dates back to 1969, with virtual reality simulators becoming commercially available in 1998 (Bar-Meir 2000; Dunkin 2003; Dunkin 2007). Using a combination of visual and haptic (tactile) interfaces, virtual reality simulators present learners with situations that resemble reality (Krummel 1998; Sturm 2007), thus allowing trainees to practice the cognitive and technical skills of a procedure under varying conditions (Sturm 2007). In addition, virtual reality simulators can provide users with objective measures of performance, such as procedural completion time, percent of mucosa visualized and degree of patient pain. Such measures can be used to help analyse trainees' actions, identify errors and may provide the opportunity for the assessment of competency (Haque 2006).

How the intervention might work

Simulated environments are purported to allow learners to acquire knowledge and build a framework of basic skills through sustained deliberate practice of relevant tasks, with the aim of better preparing novices for patient-based training (Grantcharov 2003). In addition, simulation-based instruction has the potential to improve patient safety as performance of skills on patients by novices may lead to inappropriate applications of procedures, incorrect diagnosis, lower rates of success and higher rates of complications, all of which put patients in jeopardy (Issenberg 2005; Ziv 2003). Furthermore, the simulated setting may provide a more learner-

centred educational experience, as supervisors have more time to focus on the needs of the trainee (rather than having to focus on the patient). In addition, errors can be allowed to progress in order to allow the trainee to learn from their mistakes. This can potentially serve to organize future behaviours, as trainees can use the information gained as a basis for change (Blumenthal 1994; Rasmussen 2003; Ziv 2003).

Why it is important to do this review

The growing awareness of the need for patient safety has brought the issue of simulation-based training to the forefront. Because of ethical and medicolegal considerations, gaining experience on patients is becoming increasingly unacceptable during the early stages of training (Kneebone 2001). Virtual reality simulators are becoming popular as a means of providing trainees with the opportunity for the rehearsal of psychomotor and perceptual skills in a risk-free environment, so that they may attain some degree of proficiency prior to performance in the clinical setting. Furthermore, there has been a paradigm shift towards outcomes-based education throughout the health care professions, with increasing emphasis on the use of simulation modalities for competency-based evaluation (Frank 2005; Hatala 2005; Langsley 1991; Scalese 2008; Swing 2002).

Simulation technology has the potential to reduce the costs of training as staff endoscopists have been shown to be more productive when performing procedures independently (as compared with supervising trainees) (McCashland 2000). However in reality, simulation training carried out on virtual reality simulators may not save money due to the high costs associated with acquiring and maintaining such equipment. It is therefore important to ensure skills gained through simulation-based training positively transfer to the clinical environment.

Although health professions education is placing increasing reliance on simulation-based training, the effectiveness of virtual reality gastrointestinal endoscopy simulators has yet to be clearly demonstrated (Haque 2006; Sturm 2008; Sutherland 2006). While previous reviews of endoscopy virtual reality simulation training have been completed (Haque 2006; Sturm 2008; Sutherland 2006), none have included a comprehensive search of educational and computer literature databases. Furthermore, a number of additional randomised controlled trials have since been completed (Ferlitsch 2010; Haycock 2010; Park 2007; Shirai 2008; Yi 2008). This review seeks to address these shortcomings by performing a systematic search of relevant health professions, educational and computer literature databases as well as the grey literature (literature produced at all levels by government, academia, business and industries, both in print and electronic formats, but which is not controlled by commercial publishers (Farace 1998)) for randomised trials evaluating the effectiveness of gastrointestinal endoscopy virtual reality simulation training.

OBJECTIVES

To determine whether virtual reality simulation training can supplement and/or replace early conventional endoscopy training (apprenticeship model) in diagnostic oesophagogastrroduodenoscopy, colonoscopy and/or sigmoidoscopy for health professions trainees with limited or no prior endoscopic experience.

METHODS

Criteria for considering studies for this review

Types of studies

We considered only randomised controlled trials and quasi-randomised studies (method of allocating participants to treatment not strictly random), irrespective of language, blinding or publication status. Cohort studies and case-control studies were excluded. In addition, we considered abstracts reporting randomised controlled trials and quasi-randomised studies presented since January 2009. Studies published in abstract format were only considered if original outcome data could be retrieved from the abstract or following contact with the authors.

Types of participants

Health professions trainees including physicians (medical students, residents, fellows and practitioners), nurses and physician assistants with limited or no prior endoscopy experience. For the purposes of this review, limited endoscopic experience is defined as (1) previous performance of no greater than 10 cases of the procedure under study in the clinical or simulated setting and/or (2) any level of experience in performing other gastrointestinal endoscopic procedures (oesophagogastrroduodenoscopy, colonoscopy and sigmoidoscopy).

Types of interventions

We included trials comparing virtual reality endoscopy (oesophagogastrroduodenoscopy, colonoscopy and sigmoidoscopy) simulation training versus any other method of endoscopy training including conventional patient-based training, in-job training, training using another form of endoscopy simulation (e.g. low-fidelity simulator), or no training (however defined by authors). We also included trials comparing one method of virtual reality training versus another method of virtual reality training (e.g. comparison of two different virtual reality simulators).

Types of outcome measures

We included only trials measuring outcomes on humans (as opposed to animals or simulators) in the clinical setting.

Primary outcomes

(1) Composite score of competency in performing endoscopy (as defined by authors).

Secondary outcomes

- (1) Independent procedure completion (objective measure).
- (2) Performance time (objective measure of the time taken to perform the evaluation task(s) post-training).
- (3) Complication or critical flaw occurrence.
- (4) Independent insertion depth (objective measure of the distance to which the participant passed the endoscope unassisted).
- (5) Patient discomfort (as defined by authors).
- (6) A single measure providing an overall global rating of performance or competency in performing endoscopy (as defined by the authors).
- (7) Error Rate (number of undesirable movements, as defined by the authors).
- (8) Visualization of mucosa (as defined by authors).

Search methods for identification of studies

Electronic searches

We searched the following electronic health professions, educational and computer literature databases for publications addressing the above clinical problem:

- (1) *The Cochrane Central Register of Controlled Trials (CENTRAL)*
- (2) *MEDLINE*
- (3) *EMBASE*
- (4) *Scopus*
- (5) *Web of Science* (including (a) *Science Citation Index Expanded*; (b) *Social Sciences Citation Index*; (c) *Arts & Humanities Citation Index*; (d) *Conference Proceedings Citation Index - Science* and (e) *Conference Proceedings Citation Index - Social Science*)
- (6) *Biosis Previews*
- (7) *CINAHL*
- (8) *Allied and Complementary Medicine Database*
- (9) *ERIC*
- (10) *Education Full Text*
- (11) *CBCA Education*
- (12) *Career and Technical Education*
- (13) *Expanded Academic ASAP*
- (14) *ACM Digital Library*
- (15) *IEEE Xplore*
- (16) *Abstracts in New Technologies and Engineering*

(17) *Computer & Information Systems Abstracts*

The grey literature was also searched including:

- (1) *metaRegister of controlled trials* (active and archived registers)
- (2) *Dissertations & Theses*
- (3) *Index to Theses*

We have provided the search strategies in [Appendix 1](#) with the time span for the searches.

Searching other resources

(1) The reference lists of the studies and review articles identified using the computer-assisted search were also searched by hand to identify further relevant studies.

(2) We also searched abstracts and proceedings of major gastrointestinal, educational and surgical meetings presented since January 2009 (Gastrointestinal: Digestive Diseases Week (2009-11), Canadian Digestive Diseases Week (2009-11), British Society of Gastroenterology (2009-11), and United European Gastroenterology Week (2009-10); Educational: The Association for Medical Education in Europe Conference (2009-11), Research in Medical Education Conference (2009-10), Canadian Conference on Medical Education (2009-11); Surgical: American College of Surgery Clinical Congress (2009-10), The Society of American Gastrointestinal and Endoscopic Surgeons Conference (2009-11), European Association for Endoscopic Surgery Congress (2009-10)).

Data collection and analysis

Data were collected on customised data extraction forms and analysis was performed as described below.

Selection of studies

All titles and abstracts identified by the literature search, as described above, were independently reviewed by CMW and MES for eligibility. CMW and MES independently reviewed the full text articles of potentially eligible abstracts and identified the trials for inclusion. Excluded trials with the reasons for exclusion were documented by CMW and MES. HC and SCL adjudicated any differences in opinion. CMW and MES independently extracted the data listed below.

Data extraction and management

Using a customized data extraction form, CMW and MES independently extracted the data listed below:

- (1) General article information: title, authors, publication year, language of publication, country where study was performed.
- (2) Year of conduct of trial.
- (3) Study design: randomisation process, allocation concealment, blinding.

(4) Sample size.

(5) Study participants: inclusion/exclusion criteria, years participants were enrolled, health profession (physicians (medical students, residents, fellows and practitioners), nurses or physician assistants), level of training, endoscopy experience, numbers randomised, baseline characteristics (age, gender).

(7) Endoscopy procedure under study (oesophagogastroduodenoscopy, colonoscopy and/or sigmoidoscopy).

(8) Intervention: name of virtual reality endoscopy simulator, training task, duration of training.

(9) Comparison: nature of comparison group (conventional patient-based training, in-job training, training using another form of endoscopy simulation (e.g. low-fidelity simulator), no training, training using another method of virtual reality training), training task (if applicable), duration of training (if applicable).

(10) Outcomes assessed, assessment method and time to assessment.

(11) Data on the primary outcome measures (as described above).

(12) Data on the secondary outcome measures (as described above).

(13) Methodological quality (as described below).

(14) Sample size calculation.

Assessment of risk of bias in included studies

The methodological quality of included studies was independently assessed by CMW and MES, without masking of the study names, using the Cochrane Collaboration's domain-based tool for assessing risk of bias ([Higgins 2011](#)). Factors assessed included: sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, and selective outcome reporting.

Measures of treatment effect

When abstracting data from studies reporting learning curves (multiple points across time) ([Cohen 2006](#); [Ferlitsch 2010](#); [Sedlack 2004](#); [Sedlack 2007](#)), the first assessment interval was used for analysis and plots, in order to minimize the potential effect of variable clinical training on the outcomes over time. A meta-analysis according to the recommendations of the Cochrane Collaboration ([Higgins 2011](#)) was performed. The statistical package Revman 5.1, provided by the Cochrane Collaboration was used to analyse and synthesise data ([RevMan 2011](#)). For dichotomous data, such as independent procedure completion (yes/no), the impact of the intervention was expressed as a relative risk with 95% confidence intervals where data were available. Relative risk was used due to its ease of interpretation. For continuous data such as performance time, composite score, independent insertion depth, and patient discomfort, the effect size was estimated by computing the standardized mean difference with 95% confidence intervals where data were available.

Dealing with missing data

Authors of trials were contacted for further details and asked to provide original data if the published paper or abstract contained insufficient or unclear information. If there was doubt as to whether trials shared the same participants - completely or partially (by identifying common authors or centres), the authors of the trials were contacted to clarify whether the trial has been duplicated. Any differences in opinion were resolved through discussion under the guidance of HC and SCL.

Assessment of heterogeneity

Eligible studies were evaluated independently by CMW and MES for clinical and methodological heterogeneity. Due to significant clinical and methodological heterogeneity it was not possible to combine trial data and thus a meta-analysis was not performed. In the protocol we planned to explore heterogeneity using the Cochrane Chi-Square test (Q-test) with the alpha level of significance set at 0.10. We also planned to estimate the degree of heterogeneity using the I^2 statistic which describes the percentage of total variation across studies that results from heterogeneity rather than chance. A value of 25% is considered to indicate low heterogeneity, 50% moderate heterogeneity and 75% high heterogeneity (Higgins 2003).

Assessment of reporting biases

In our protocol we intended to examine publication bias by means of a funnel plot (Egger 1997; Macaskill 2001), if there are sufficient eligible trials. Asymmetry in the funnel plot of trial size against treatment effect was to be used to assess the risk of publication bias. We planned to perform linear regression to determine the funnel plot asymmetry (Egger 1997).

Data synthesis

A priori we planned to pool data for meta-analysis if participant groups were similar and the studies assessed the same intervention with the same comparator, and had similar definitions of outcome measures (determined by consensus). Data was not to be pooled for meta-analysis if a high degree of heterogeneity was detected (i.e. $I^2 \geq 75\%$). A random-effects or fixed-effects model was to be used depending on the presence or absence of heterogeneity. For the fixed effects model, weighting was to be performed using the Mantel-Haenszel method. If a random-effects model was used, studies were to be weighted using the DerSimonian & Laird method.

Subgroup analysis and investigation of heterogeneity

If sufficient data were available, subgroup analysis was to be performed for:

- (1) Type of endoscopy procedure under study (oesophagogastroduodenoscopy, colonoscopy, and sigmoidoscopy)
- (2) Level of participant endoscopy experience (no prior versus limited endoscopy experience).

Sensitivity analysis

If sufficient data were available, sensitivity analysis was to be performed including and excluding:

- (1) Poor quality studies (trials with adequate methodology compared to trials with unclear or inadequate methodologies)
- (2) Studies published only in abstract form.

RESULTS

Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#); [Characteristics of studies awaiting classification](#).

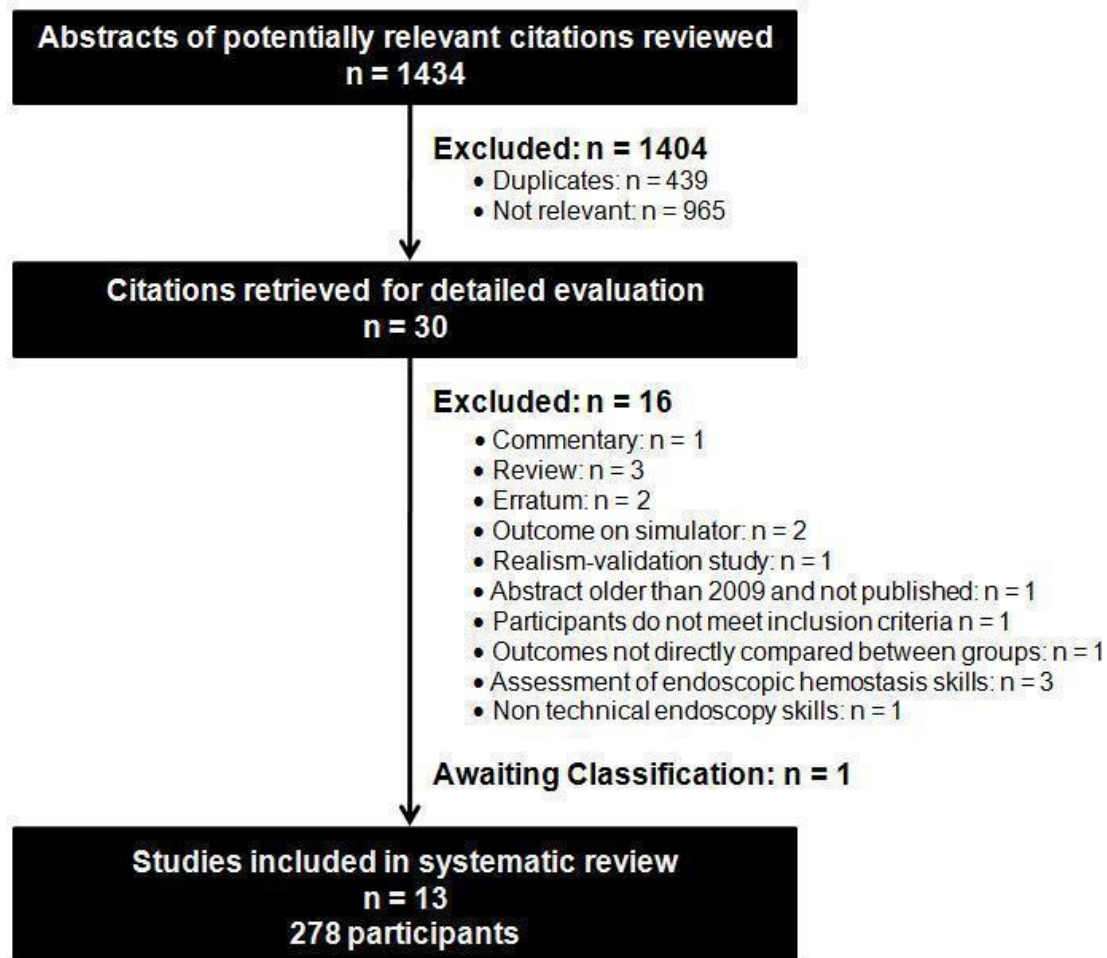
See: [Characteristics of included studies](#); [Characteristics of excluded studies](#); [Characteristics of studies awaiting classification](#)

Results of the search

A total of 1434 potentially relevant references were identified. 1429 abstracts were identified through electronic searches of *The Cochrane Central Register of Controlled Trials* (n = 106), *MEDLINE* (n = 289), *EMBASE* (n = 338), *Scopus* (n = 198), *Web of Science* (n = 121) and other databases (n = 377). 435 duplicate references and 965 clearly irrelevant references were excluded through the review of abstracts. In addition, 5 potentially relevant abstracts were identified from the proceedings of major gastrointestinal, educational and surgical meetings presented since January 2009; 4 of which were duplicates.

In total 30 references were retrieved for further assessment. No additional references were identified though a manual search of the references lists of the identified trials. 16 references were excluded for the reasons listed in the table '[Characteristics of excluded studies](#)'. No corresponding published reports were identified for one trial which was identified from a trial register (Rosch 2011). Further information from the authors of this trial was not obtained; therefore, this study was included in the table '[Characteristics of studies awaiting classification](#)'. An overview of our search results is provided in [Figure 1](#).

Figure 1. Figure 1: Selection of studies for systematic review of the effect of virtual reality simulation training for health professions trainees in gastrointestinal endoscopy



Included studies

In total, 13 trials with 278 participants were included. Four trials (Gerson 2003; Haycock 2010; Sedlack 2004a; Shirai 2008) compared virtual reality training versus conventional patient-based endoscopy training (apprenticeship model) and nine trials (Ahlberg 2005; Cohen 2006; Di Giulio 2004; Ferlitsch 2010; Park 2007; Sedlack 2004; Sedlack 2007; Tuggy 1998; Yi 2008) compared virtual reality training versus no intervention. No trials were identified which compared virtual reality training to another form of endoscopy simulation (e.g. low-fidelity simulator) or which compared different methods of virtual reality training. Six trials (Ahlberg 2005; Cohen 2006; Haycock 2010; Park 2007; Sedlack 2004; Yi 2008) studied training in colonoscopy, three (Gerson 2003; Sedlack 2004a; Tuggy 1998) studied sigmoidoscopy and

four (Di Giulio 2004; Ferlitsch 2010; Sedlack 2007; Shirai 2008) oesophagogastroduodenoscopy. The details of the trials such as methodological quality, inclusion and exclusion criteria and the outcomes measured are shown in the table 'Characteristics of included studies.'

4 trials (Cohen 2006; Di Giulio 2004; Sedlack 2004; Sedlack 2007) compared the virtual reality training in gastroenterology trainees (medical residents and/or fellows) only. One trial (Haycock 2010) included participants from any healthcare background (e.g., physicians, nurses) or position recognized by the training institution as appropriate for training in colonoscopy. One trial (Ahlberg 2005) compared virtual reality training in both gastroenterology trainees (medical residents and/or fellows) and surgical residents. Two trials (Yi 2008; Shirai 2008) stated that the

participants were residents and/or fellows but did not state their discipline. The other five trials (Ferlitsch 2010; Gerson 2003; Park 2007; Sedlack 2004a; Tuggy 1998) included internal medicine, family medicine and/or surgical residents without any prior experience in endoscopy.

Two trials (Ahlberg 2005; Sedlack 2004) that studied training in colonoscopy included participants with prior experience in oesophagogastroduodenoscopy, and one study (Haycock 2010) included trainees who had previously performed less than 25 colonoscopies or flexible sigmoidoscopies; however, none of the participants had performed more than 1 procedure (colonoscopy and/or flexible sigmoidoscopy). One study (Park 2007) included trainees who had been the primary endoscopist for less than 3 procedures of any type, and one study (Cohen 2006) included trainees who had prior experience in oesophagogastroduodenoscopy and flexible sigmoidoscopy, but had performed fewer than 10 previous colonoscopies (the procedure under study). One study (Yi 2008) did not state participants' previous endoscopy experience. The remaining seven trials (Di Giulio 2004; Ferlitsch 2010; Gerson 2003; Sedlack 2004a; Sedlack 2007; Shirai 2008; Tuggy 1998; Yi

2008) included participants with no prior endoscopy experience. Further details regarding the simulators used, training tasks and outcomes evaluated are shown in Table 1.

Excluded studies

16 trials were excluded for the reasons listed under the table 'Characteristics of excluded studies.'

Risk of bias in included studies

See: Characteristics of included studies (risk of bias tables)

We considered only three trials (Ahlberg 2005; Cohen 2006; Haycock 2010) to be of low risk of bias. Six trials (Di Giulio 2004; Ferlitsch 2010; Gerson 2003; Sedlack 2004; Sedlack 2004a; Yi 2008) were considered to be of high risk of bias as sequence generation was not random and/or there was no blinding of outcome assessment. The remaining 4 trials (Park 2007; Sedlack 2007; Shirai 2008; Tuggy 1998) were at unclear risk of bias as the method of randomisation and/or blinding of outcome assessment was unclear. The risk of bias is summarised in Figure 2.

Figure 2. Figure 2: Risk of bias summary: review authors' judgments about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)
Ahlberg 2005	+	+	+	+		+	+
Cohen 2006	+	?	+	+		+	+
Di Giulio 2004	+	?	+	+		+	-
Ferlitsch 2010	?	?	+	+		+	-
Gerson 2003	-	-	+	+		+	-
Haycock 2010	+	?	+	+		+	+
Park 2007	?	?	+	+		+	+
Sedlack 2004	?	?	+	+		+	-
Sedlack 2004a	?	?	+	+		+	-
Sedlack 2007	?	?	+	+		+	?
Shirai 2008	?	?	+	+		+	+
Tuggy 1998	?	?	+	+		+	?
Yi 2008	-	?	+	+		+	?

Allocation

The allocation sequence was adequately generated in three trials (Cohen 2006; Di Giulio 2004; Haycock 2010). Two trials (Gerson 2003; Yi 2008) reported inadequate methods for sequence generation. The other eight trials (Ahlberg 2005; Ferlitsch 2010; Park 2007; Sedlack 2004; Sedlack 2004a; Sedlack 2007; Shirai 2008; Tuggy 1998) did not describe the sequence generation process utilized. One trial (Ahlberg 2005) reported using appropriate procedures to minimize or eliminate bias in allocation concealment. Allocation concealment was inadequate in one trial (Gerson 2003). None of the remaining eleven trials (Cohen 2006; Di Giulio 2004; Ferlitsch 2010; Haycock 2010; Park 2007; Sedlack 2004; Sedlack 2004a; Sedlack 2007; Shirai 2008; Tuggy 1998; Yi 2008) reported on allocation concealment.

Blinding

Due to the nature of the intervention, the participants and personnel administering the intervention were unable to be blinded; however, the outcome was not likely to have been influenced by the lack of blinding. Blinding of the outcome assessment was adequate in five trials (Ahlberg 2005; Cohen 2006; Haycock 2010; Park 2007; Shirai 2008). Five trials (Di Giulio 2004; Ferlitsch 2010; Gerson 2003; Sedlack 2004; Sedlack 2004a) reported inadequate assessor blinding. The remaining three trials (Sedlack 2007; Tuggy 1998; Yi 2008) did not report on assessor blinding or provided insufficient information to permit judgement.

Incomplete outcome data

All thirteen trials (Ahlberg 2005; Cohen 2006; Di Giulio 2004; Ferlitsch 2010; Gerson 2003; Haycock 2010; Park 2007; Sedlack 2004; Sedlack 2004a; Sedlack 2007; Shirai 2008; Tuggy 1998; Yi 2008) addressed incomplete outcome data.

Selective reporting

All thirteen trials (Ahlberg 2005; Cohen 2006; Di Giulio 2004; Ferlitsch 2010; Gerson 2003; Haycock 2010; Park 2007; Sedlack 2004; Sedlack 2004a; Sedlack 2007; Shirai 2008; Tuggy 1998; Yi 2008) were free of selective outcome reporting.

Other potential sources of bias

None of the trials reported intention-to-treat analysis. Only four trials (Ferlitsch 2010; Gerson 2003; Haycock 2010; Park 2007) reported a sample size calculation. None of the trials utilized adequately validated outcome measures. While the authors of one study (Park 2007) reported the use of a validated Global Performance Score, no reference or details of validation were provided. One other study (Haycock 2010) utilized this same Global Performance Score. In addition this study (Haycock 2010) utilized subsections of the UK Joint Advisory Group colonoscopy Direct Observation of Procedural Skills which has been previously validated (Barton 2008); however, the abbreviated version utilized has not been validated. Another trial (Cohen 2006) utilized a previously developed outcome instrument (Cass 1996); however, once again there is no literature to suggest this instrument has been systematically validated.

Effects of interventions

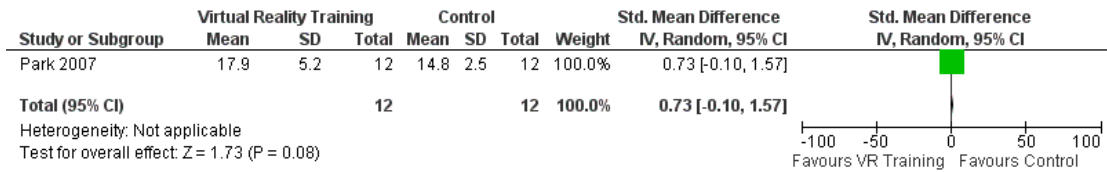
13 trials with 278 participants were included in this review. Only outcomes assessed on humans in the clinical setting are reported. Given the substantial clinical and methodological heterogeneity it was not appropriate to pool study data in order to perform a meta-analysis. In addition, several trials did not provide sufficient data for inclusion in a meta-analysis. Instead, we present the results of the studies, categorized by outcome measure, in tabular form. The level of statistical significance across groups is reported where available.

Primary Outcomes

(1) Composite Score of Competency in Performing Endoscopy (as defined by authors).

A composite score of competency (as defined by authors) was reported in two trials (Haycock 2010; Park 2007). One of these trials (Park 2007) showed a statistically significant increased composite score of competency in the virtual reality training group as compared with the control group. However, the second trial (Haycock 2010) showed no significant difference in either of the two composite scores of competency measured in the trial. The results are summarized in Table 2, Analysis 1.1 and Figure 3.

Figure 3. Outcome: Composite Score of Competency (Analysis 1.1) Comparison: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training) Note: Only studies with sufficient data to analyse outcome of interest included in this analysis



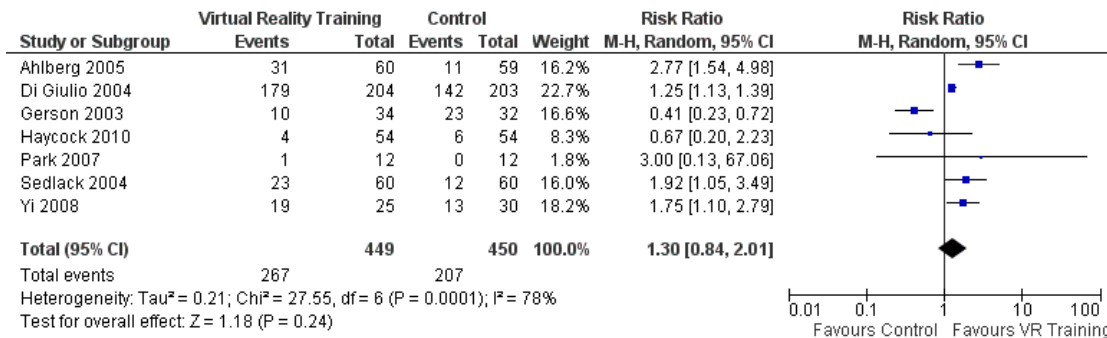
Secondary Outcomes

(1) Independent procedure completion (objective measure).

Independent procedure completion was reported as an outcome in seven trials (Ahlberg 2005; Di Giulio 2004; Gerson 2003; Haycock 2010; Park 2007; Sedlack 2004; Yi 2008). The meta-analysis showed that the virtual reality group had a significantly higher number of independent procedure completions than the control group (RR 1.30, 95% CI 0.84 to 2.01; 7 studies) (Analysis 1.2). Four trials (Ahlberg 2005; Di Giulio 2004; Sedlack 2004; Yi 2008) reported a statistically significant higher number of in-

dependent procedure completions in the virtual reality training group as compared to the control group. Alternatively, one trial that compared virtual reality training versus conventional patient-based endoscopy training (Gerson 2003) reported a statistically significant lower number of independent procedure completions in the virtual reality training group. The remaining two trials (Haycock 2010; Park 2007) found no significant difference between the two groups. The results are summarized in Table 3, Analysis 1.2 and Figure 4.

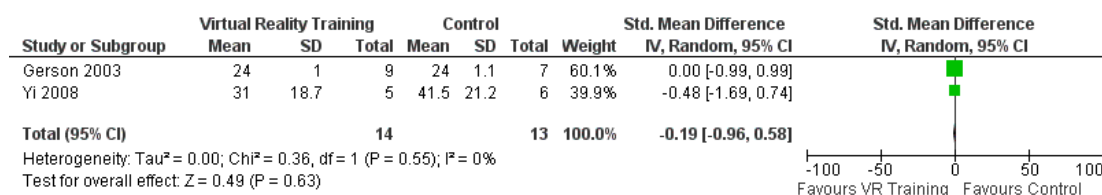
Figure 4. Outcome: Independent Procedure Completion (Analysis 1.2) Comparison: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training) Note: only studies with sufficient data to analyse outcome of interest included in this analysis



(2) Performance time (objective measure of the time taken to perform the evaluation task(s) post-training).

Nine trials (Ahlberg 2005; Di Giulio 2004; Ferlitsch 2010; Gerson 2003; Haycock 2010; Sedlack 2004; Shirai 2008; Tuggy 1998; Yi 2008) reported performance time (time taken to perform the evaluation task(s)) as an outcome. Three trials showed a statistically significant faster time for the virtual reality training group as compared to the control group (Ahlberg 2005; Ferlitsch 2010; Yi 2008). One trial (Tuggy 1998) showed no significant difference in performance time after 5 hours of simulator training; however, the virtual reality training group performed the evaluation task significantly faster after 6-10 hours of simulation training. There was no significant difference in performance time in the remaining five trials (Di Giulio 2004; Gerson 2003; Haycock 2010; Sedlack 2004; Shirai 2008) which reported this outcome. The results are summarized in Table 4, Analysis 1.3 and Figure 5.

Figure 5. Outcome: Performance Time (Analysis 1.3) Comparison: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training) Note: only studies with sufficient data to analyse outcome of interest included in this analysis



(3) Complication or critical flaw occurrence.

The occurrence of complications or critical flaws was reported as an outcome in five trials (Ahlberg 2005; Di Giulio 2004; Gerson 2003; Park 2007; Sedlack 2004a). All five trials reported no complications or critical flaws in either group. The results are summarized in Table 5.

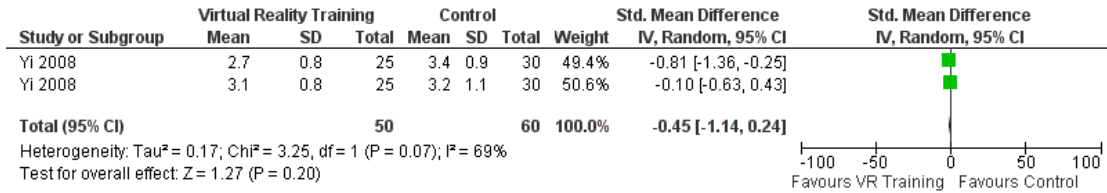
(4) Independent insertion depth (objective measure of the distance to which the participant passed the endoscope unassisted).

Independent insertion depth (the distance to which the participant passed the endoscope unassisted) was reported as an outcome in three trials (Ahlberg 2005; Haycock 2010; Sedlack 2007). The virtual reality training group inserted the endoscope significantly further in two trials (Ahlberg 2005; Sedlack 2004) and there was no significant difference between groups in one trial (Haycock 2010). The results are summarized in Table 6.

(5) Patient discomfort (as defined by authors).

Eight trials (Ahlberg 2005; Cohen 2006; Ferlitsch 2010; Gerson 2003; Sedlack 2004; Sedlack 2004a; Tuggy 1998; Yi 2008) reported patient discomfort (as defined by authors) as an outcome. Pain was patient-rated in seven trials (Ahlberg 2005; Ferlitsch 2010; Gerson 2003; Sedlack 2004; Sedlack 2004a; Tuggy 1998; Yi 2008) and rated by an assessing physician in one trial (Cohen 2006). Patient discomfort was statistically significantly lower in the virtual reality training group in three trials (Ahlberg 2005; Sedlack 2004; Sedlack 2004a). One trial (Yi 2008) reported significantly lower anus discomfort in the virtual reality training group but no difference between groups in patient-based ratings of abdominal pain. There was no significant difference found between the two groups in the remaining four trials (Cohen 2006; Ferlitsch 2010; Gerson 2003; Tuggy 1998). The results are summarized in Table 7, Analysis 1.4 and Figure 6.

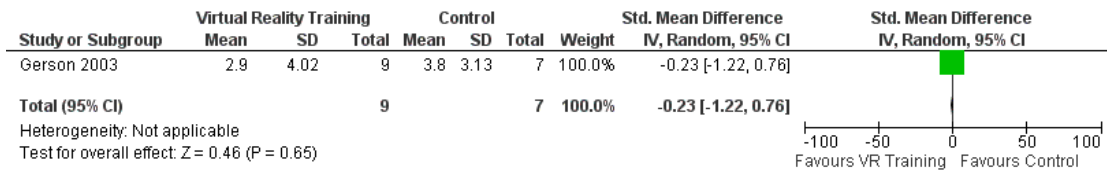
Figure 6. Outcome: Patient Discomfort (Analysis 1.4) Comparison: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training) Note: only studies with sufficient data to analyse outcome of interest included in this analysis



(6) *A single measure providing an overall global rating of performance or competency in performing endoscopy (as defined by the authors).*

Five trials (Cohen 2006; Di Giulio 2004; Gerson 2003; Sedlack 2004a; Sedlack 2007) reported an overall rating of performance or competency as an outcome. Two trials (Cohen 2006; Di Giulio 2004) showed statistically significantly more positive ratings in the virtual reality trained group. In contrast, one trial (Gerson 2003) showed statistically significantly less positive ratings in the virtual reality trained group and two trials (Sedlack 2004a; Sedlack 2007) showed no significant difference between groups. The results are summarized in Table 8, Analysis 1.5 and Figure 7.

Figure 7. Outcome: Overall Global Rating of Performance or Competency (Analysis 1.5) Comparison: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training) Note: only studies with sufficient data to analyse outcome of interest included in this analysis



(7) *Error Rate (number of undesirable movements, as defined by the authors).*

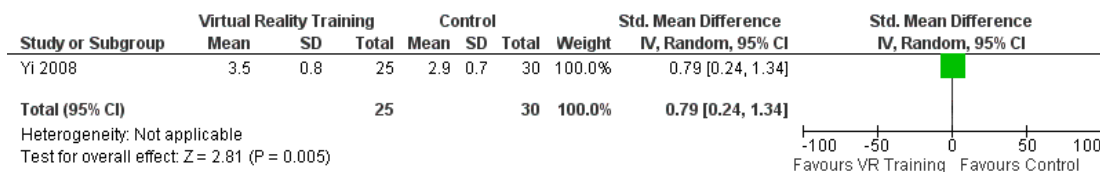
Error rate (number of undesirable movements, as defined by the authors) was reported as an outcome in one trial (Tuggy 1998) which showed statistically significantly fewer directional errors in virtual reality trained group after 5 and 6-10 hours of simulation training. The results are summarized in Table 9.

(8) *Visualization of mucosa (as defined by authors).*

Visualization of the mucosa (as defined by the authors) was reported as an outcome in four trials (Sedlack 2004; Sedlack 2004a;

Tuggy 1998; Yi 2008). Visualization was significantly greater in the virtual reality trained group in two trials (Sedlack 2004; Yi 2008). In one trial (Tuggy 1998) there was no significant difference in mucosal visualization after 5 hours of simulation training; however, the virtual reality group had significantly greater visualization after 6-10 hours of simulation training. One trial (Sedlack 2004a) showed no significant difference in visualization between groups. The results are summarized in Table 10, Analysis 1.6 and Figure 8.

Figure 8. Outcome: Visualization of Mucosa (Analysis 1.6) Comparison: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training) Note: only studies with sufficient data to analyse outcome of interest included in this analysis



Other Reported Outcomes

A large number of other outcomes were reported in the thirteen studies (for example, whether analgesic drugs were given (yes/no), number of times manual assistance was required (n), completion of retroflexion (yes/no), ability to recognize pathology (yes/no) and ability to insert in a safe manner (1-5 Likert scale)); however, the data for these outcomes are not shown as they are non-validated measures which were not included *a priori* as outcomes in this systematic review as they were felt to be of minimal clinical relevance.

Subgroup Analysis

A priori subgroup analysis was planned for the type of procedure (oesophagogastroduodenoscopy, colonoscopy, and sigmoidoscopy) and level of participant endoscopy experience (no prior versus limited endoscopy experience). However, subgroup analyses were not performed because of the few trials available in each category.

Sensitivity Analysis

A priori sensitivity analysis was planned including and excluding poor quality studies and studies published only in abstract form. However, sensitivity analysis was not performed due to the few trials available in each category.

Funnel Plot

Given the heterogeneity of the outcomes reported and the low number of trials reporting similar outcomes, a funnel plot was not constructed.

DISCUSSION

Training of new endoscopists has primarily followed the time honoured concept of 'see one, do one, teach one,' with novices learning basic skills under the supervision of experienced preceptors in the clinical setting. However, over the last two decades there has been an increasing push to incorporate simulation-based instruction into medical training as a means for novices to master basic skills in a low-risk controlled environment prior to performance on real patients. As Vozenilek *et al* point out, "the concept of 'learning by doing' has become less acceptable, particularly when

invasive procedures and high-risk care are required." (Vozenilek 2004, pg 1149)

This review was undertaken to determine whether virtual reality simulation training can supplement and/or replace early conventional endoscopy training (apprenticeship model) in diagnostic oesophagogastroduodenoscopy, colonoscopy and/or sigmoidoscopy for health professions trainees with limited or no prior endoscopic experience. While there may be compelling reasons to increase the integration of virtual reality simulation into endoscopy training, from the evidence available, simulation-based training has yet to be shown to be equivalent or superior to conventional endoscopy training (apprenticeship model) for health professions trainees.

Summary of main results

Thirteen trials with 278 participants met the inclusion criteria.

Simulation-based training versus no training

Nine studies, evaluating oesophagogastroduodenoscopy, colonoscopy and sigmoidoscopy, compared simulation-based training with no intervention. Simulation-based training prior to patient-based training appears to provide participants with some advantage over their untrained controls as measured by composite score of competency, independent procedure completion, performance time, independent insertion depth, overall rating of performance or competency, error rate and visualization. The one trial (Park 2007) which reported a composite score of competency as an outcome measure showed a statistically significant increased score in the virtual reality training group as compared with the control group. Four (Ahlberg 2005; Di Giulio 2004; Sedlack 2004; Yi 2008) out of five trials which reported the outcome independent procedure completion showed that trainees who received virtual reality simulation-based training were able to complete more procedures independently as compared with their untrained peers. Three (Ahlberg 2005; Ferlitsch 2010; Yi 2008) of the six trials which reported the outcome of performance time showed that trainees who received virtual reality simulation-based training were able to complete procedures significantly faster, and one trial (Tuggy 1998) showed that while trainees were not faster after 5 hours of simulation-based training, their performance time was significantly quicker, as compared to controls, after 6-10 hours

of training. Both trials (Ahlberg 2005; Sedlack 2004) which reported the outcome of independent insertion depth showed that trainees who received virtual reality simulation-based training were able to insert the endoscope significantly further independently as compared with their untrained peers. The one trial (Tuggy 1998) which reported error rate as an outcome showed that participants who received virtual reality simulation-based training had fewer directional errors as compared with their untrained peers. Two (Cohen 2006; Di Giulio 2004) of the three trials which reported an overall rating of performance or competency showed statistically significantly more positive ratings for virtual reality simulation trained participants. Finally two (Sedlack 2004; Yi 2008) of the three trials which reported visualization as an outcome showed that trainees who received simulation-based training had greater visualization, and one trial (Tuggy 1998) showed that while there was no difference between groups after 5 hours of simulation-based training, after 6-10 hours of training those trainees who virtual reality training had significantly greater visualization.

Simulation-based training versus conventional patient-based endoscopy training (apprenticeship model)

Four studies, evaluating oesophagogastroduodenoscopy, colonoscopy and sigmoidoscopy, compared simulation-based training with conventional patient-based endoscopy training (apprenticeship model). There was no conclusive evidence that simulation-based training, as compared with conventional endoscopy training provided benefit. There was no significant difference between groups as measured by composite score of competency (Haycock 2010), performance time (Gerson 2003; Haycock 2010; Shirai 2008), complication or critical flaw occurrence (Gerson 2003; Sedlack 2004a), independent insertion depth (Haycock 2010), and visualization (Sedlack 2004a). One (Sedlack 2004a) of the two studies which reported patient discomfort as an outcome measure found a significant training advantage for the virtual reality group. Alternatively, one (Gerson 2003) of the two studies that reported independent procedure completion and an overall rating of performance or competency found that trainees who received simulation-based training were able to complete fewer procedures independently and received statistically significantly more negative overall ratings of performance as compared to those receiving conventional patient-based endoscopy training.

Overall completeness and applicability of evidence

With thirteen trials assessing the effect of virtual reality simulation-based training, more conclusive results might have been expected. However, included studies were of small sample sizes, with only 278 participants across 13 studies, thus limiting their ability to detect differences between training methods. Most of the published trials were underpowered to detect a true clinical difference and were not designed to show equivalence. There was also consider-

able variability in outcome measures across studies thus limiting our ability to compare outcomes. In addition, none of the studies utilized outcomes which were adequately validated.

Furthermore, the virtual reality simulation-based training interventions varied considerably between studies making comparisons difficult. The simulation-based training sessions may not have been intensive or long enough to provide benefit. Tuggy *et. al.* (Tuggy 1998) examined outcomes after 5 hours and 6-10 hours of simulation-based training; however, a training benefit was only demonstrated after 6-10 hours of simulation-based training, indicating that there may be a minimum length of training required to achieve benefit. In addition, trainees were provided with instruction during the entirety of simulation-based training in only two studies (Ahlberg 2005; Sedlack 2004a), and minimal tutoring and feedback was provided in an additional two studies (Ferlitsch 2010; Haycock 2010). Simply providing trainees with access to simulators, does not guarantee that they will be used optimally. It is clear from the literature that appropriate augmented (extrinsic) feedback and instruction is needed for the acquisition of gastrointestinal endoscopy skills (Issenberg 2005; Walsh 2009). Mahmood and colleagues (Mahmood 2004), who examined whether novices were able to learn the skill of colonoscopy through the use of a simulator in the absence of structured external feedback, found no improvement in performance on the simulator over successive trials in the absence of augmented feedback; indicating that extrinsic feedback is essential to facilitate clinical skill acquisition. In addition, in a recent review of simulation-based medical education, feedback was identified as the most important feature for effective learning in a simulated setting (Issenberg 2005).

Quality of the evidence

The results of this review should be interpreted with caution. Overall, the methodological quality of included studies was poor with only three trials (Cohen 2006; Di Giulio 2004; Haycock 2010) used adequate methods for randomisation, one (Ahlberg 2005) reported allocation concealment, and the assessors were blinded in five trials (Ahlberg 2005; Cohen 2006; Haycock 2010; Park 2007; Shirai 2008). In addition, none of the studies utilized adequately validated outcome measures. While the authors of two studies (Haycock 2010; Park 2007) reported the use of a validated Global Performance Score, no reference or details of validation were provided. One study (Haycock 2010) utilized subsections of the UK Joint Advisory Group colonoscopy Direct Observation of Procedural Skills which has been previously validated (Barton 2008); however, the abbreviated version utilized has not been validated. One other trial (Cohen 2006) utilized a previously developed outcome instrument (Cass 1996); however, once again there is no literature to suggest this instrument has been systematically validated. From the current results, there appears to be no clear relationship between study findings and study quality. The three studies (Ahlberg 2005; Cohen 2006; Haycock 2010) which were

of lower risk of bias, as compared with the other included trials, reported mixed results with respect to the outcomes they assessed.

Potential biases in the review process

Limitations in study quality, inadequate reporting of methodological detail, the imprecise and/or sparse data for most outcomes, important inconsistencies across trials, and a high or unclear risk of bias in all but three studies decrease the overall quality of evidence. Therefore the conclusions of this review should be interpreted with caution. Variability in the training regimens as well as the timing and definitions of outcome measurements, and absence of valid and reliable objective measures of performance for use in evaluating the competence of clinicians performing endoscopy would all contribute to inaccuracies in the assessment of the intervention effects.

Agreements and disagreements with other studies or reviews

Three previous reviews (Sturm 2008; Sutherland 2006; Haque 2006) of virtual reality surgical simulators have included studies on virtual reality endoscopy simulation-based training. Our findings are in agreement with the most recent and comprehensive review (Sturm 2008) which concluded that simulation-based training prior to patient-based training seemed to provide participants with some advantage over their untrained colleagues; however, the results were not overwhelmingly conclusive. Only one study which compared simulation-based training with conventional patient-based endoscopy training was included, which found no benefit. An older review by Sutherland *et al* (Sutherland 2006) concluded that it has yet to be shown that virtual reality simulation-based training is better than other forms of endoscopy training, and a review by Haque *et al* (Haque 2006) only included one randomised trial assessing the skill of endoscopy. No additional trials were identified by the authors of previous review articles.

AUTHORS' CONCLUSIONS

Implications for practice

Although it was not possible to pool study data, we can deduce from the results of the studies included that simulation-based training, as compared with no training, generally appears to provide participants with some advantage over their untrained peers as measured by composite score of competency, independent procedure completion, performance time, independent insertion depth, overall rating of performance or competency, error rate and visualization. The results of this systematic review indicate that virtual reality endoscopy training can be used to effectively supplement early conventional endoscopy training (apprenticeship

model) in diagnostic oesophagogastroduodenoscopy, colonoscopy and/or sigmoidoscopy for health professions trainees with limited or no prior endoscopic experience. Alternatively, there was no conclusive evidence that simulation-based training, as compared with conventional patient-based endoscopy training (apprenticeship model), provided benefit, although data were limited. There is therefore insufficient evidence to advise for or against the use of virtual reality simulation-based training as a replacement for early conventional endoscopy training (apprenticeship model) for health professions trainees with limited or no prior endoscopic experience. As mentioned previously, outcome data is limited, training was of short duration in all trials, none of the trials assessed virtual reality training as part of a comprehensive endoscopy training curriculum, and only three studies were at low risk of bias; therefore, these results should be interpreted with caution.

Implications for research

Further research is needed to help establish the potential use of virtual reality simulation-based training to supplement and/or replace conventional endoscopy training.

1. Research is necessary that systematically develops a reliable and valid objective measure of endoscopic performance for use in evaluating the competence of clinicians performing endoscopy.
2. Once a reliable and valid outcome measure has been developed, further high quality, adequately powered, randomised trials in virtual reality simulation-based endoscopy training need to be conducted and reported according to the CONSORT statement (Moher 2001).
3. Randomised trials assessing broader competencies relevant to the skill of endoscopy, such as communication skills and clinical reasoning are needed.
4. Studies comparing the cost of simulation-based training with other forms of training are needed.
5. What are the characteristics of instruction and feedback required to optimise skill transfer to the clinical setting?
6. What is the nature and duration of endoscopy simulation-based training required to optimise skill transfer to the clinical setting?
7. Is training using a high-fidelity virtual reality simulator in isolation superior to endoscopy simulation training using a low-fidelity simulator in isolation and/or a progressive approach to simulation training utilizing both low-fidelity and high-fidelity simulators?

ACKNOWLEDGEMENTS

(1) Ms. Elizabeth Uleryk (Director, Hospital Library, The Hospital for Sick Children) for assisting with the electronic search strategy.

(2) Dr. Prakesh Shah and Dr. Joseph Beyene for their teaching and guidance during the preparation of this protocol. This protocol was prepared as part of the University of Toronto Health Policy, Management and Evaluation course HAD 5308H (Evidence Synthesis: Systematic Reviews and Meta-Analysis) which they directed.

(3) The Cochrane Colorectal Cancer Group for the support that they have provided.

REFERENCES

References to studies included in this review

Ahlberg 2005 *{published and unpublished data}*

* Ahlberg G, Hultcrantz R, Jaramillo E, Lindblom A, Arvidsson D. Virtual reality colonoscopy simulation: a compulsory practice for the future colonoscopist?. *Endoscopy* 2005;**37**(12):1198–1204. [PUBMED: 16329017[uid]]

Cohen 2006 *{published data only}*

* Cohen J, Cohen SA, Vora KC, Xue X, Burdick JS, Bank S, et al. Multicenter, randomized, controlled trial of virtual-reality simulator training in acquisition of competency in colonoscopy. *Gastrointestinal Endoscopy* 2006;**64**(3):361–8. [PUBMED: 16923483[uid]]

Di Giulio 2004 *{published data only}*

* Di Giulio E, Fregonese D, Casetti T, Cestari R, Chilovi F, D'Ambra G, et al. Training with a computer-based simulator achieves basic manual skills required for upper endoscopy: a randomized controlled trial. *Gastrointestinal Endoscopy* 2004;**60**(2):196–200. [PUBMED: 15278044[uid]]

Ferlitsch 2010 *{published data only}*

* Ferlitsch A, Schoeff R, Puspoeck A, Miehsler W, Schoeniger-Hekele M, Hofer H, et al. Effect of virtual endoscopy simulator training on performance of upper gastrointestinal endoscopy in patients: a randomized controlled trial. *Endoscopy* 2010;**42**(12):1049–56. [PUBMED: 20972956[uid]]

Gerson 2003 *{published data only}*

* Gerson LB, Van Dam J. A prospective randomized trial comparing a virtual reality simulator to bedside teaching for training in sigmoidoscopy. *Endoscopy* 2003;**35**(7):569–75. [PUBMED: 12822091[uid]]

Haycock 2010 *{published and unpublished data}*

* Haycock A, Koch AD, Familiari P, van Delft F, Dekker E, Petruzzello L, et al. Training and transfer of colonoscopy skills: a multinational, randomized, blinded, controlled trial of simulator versus bedside training. *Gastrointestinal Endoscopy* 2010;**71**(2):298–307. [PUBMED: 19889408[uid]]

Park 2007 *{published data only}*

Park J, MacRae H, Musselman LJ, Rossos P, Hamstra SJ, Wolman S, et al. Randomized controlled trial of virtual reality simulator training: transfer to live patients. *American Journal of Surgery* 2007;**194**(2):205–11. [PUBMED: 17618805[uid]]

Sedlack 2004 *{published data only}*

* Sedlack RE, Kolars JC. Computer simulator training enhances the competency of gastroenterology fellows at colonoscopy: results of a pilot study. *American Journal of Gastroenterology* 2004;**99**(1):33–7. [PUBMED: 14687137[uid]]

Sedlack 2004a *{published data only}*

* Sedlack RE, Kolars JC, Alexander JA. Computer simulation training enhances patient comfort during endoscopy. *Clinical Gastroenterology and Hepatology* 2004;**2**(4):348–52. [PUBMED: 15067632[uid]]

Sedlack 2007 *{published data only}*

* Sedlack RE. Validation of computer simulation training for esophagogastroduodenoscopy: pilot study. *Journal of Gastroenterology and Hepatology* 2007;**22**(8):1214–9. [PUBMED: 17559386[uid]]

Shirai 2008 *{published data only}*

* Shirai Y, Yoshida T, Shiraishi R, Okamoto T, Nakamura H, Harada T, et al. Prospective randomized study on the use of a computer-based endoscopic simulator for training in esophagogastroduodenoscopy. *Journal of Gastroenterology and Hepatology* 2008;**23**(7 Pt 1):1046–50. [PUBMED: 18554236[uid]]

Tuggy 1998 *{published data only}*

* Tuggy ML. Virtual reality flexible sigmoidoscopy simulator training: impact on resident performance. *Journal of the American Board of Family Practice* 1998;**11**(6):426–33. [PUBMED: 9875997[uid]]

Yi 2008 *{published data only}*

* Yi SY, Ryu KH, Na YJ, Woo HS, Ahn W, Kim WS, et al. Improvement of colonoscopy skills through simulation-based training. *Studies in Health Technology and Informatics* 2008;**132**:565–7. [PUBMED: 18391369[uid]]

References to studies excluded from this review

Ahmad 2003 *{published data only}*

Ahmad A, Alnoah Z, Kochman ML, Krevsky B, Peikin SR, Mercogliano G, et al. Endoscopic simulator enhances training of colonoscopy in a randomized, prospective, blinded trial [abstract]. *Gastrointestinal Endoscopy* 2003;**57**(5):AB110.

Cohen 2007 *{published data only}*

Cohen J, Cohen S A, Vora K C. Erratum: Multicenter, randomized, controlled trial of virtual-reality simulator training in acquisition of competency in colonoscopy (*Gastrointestinal Endoscopy* 2006;**64**(3):361-8). *Gastrointestinal Endoscopy* 2007;**65**(4):740.

Costamagna 2007 *{published data only}*

Costamagna G. The impact of simulators on training in digestive endoscopy. *Digestive and Liver Disease* 2007;**39**(1):79-80.

Eversbusch 2004 *{published data only}*

Eversbusch A, Grantcharov T P. Learning curves and impact of psychomotor training on performance in simulated colonoscopy: a randomized trial using a virtual reality endoscopy trainer. *Surgical Endoscopy* 2004;**18**(10):1514-8.

Gerson 2004 *{published data only}*

Gerson L B, Van Dam J. Erratum: A prospective randomized trial comparing a virtual reality simulator to bedside teaching for training in sigmoidoscopy (*Endoscopy* 2003;**35**(7):569-75). *Endoscopy* 2004;**36**(2):185.

Haque 2006 *{published data only}*

Haque S, Srinivasan S. A meta-analysis of the training effectiveness of virtual reality surgical simulators. *IEEE Transactions on Information Technology in Biomedicine* 2006;**10**(1):51-8.

Hochberger 2005 *{published data only}*

Hochberger J, Matthes K, Maiss J, Koebnick C, Hahn E G, Cohen J. Training with the compactEASIE biologic endoscopy simulator significantly improves hemostatic technical skill of gastroenterology fellows: a randomized controlled comparison with clinical endoscopy training alone. *Gastrointestinal Endoscopy* 2005;**61**(2):204-15.

Koch 2011 *{published data only}*

Koch AD, Ekkelenkamp VE, Haringsma J, Schoon EJ, De Man RA, Kuipers EJ. Tu1453 Prolonged colonoscopy simulator training leads to improved performance during patient-based assessment [abstract]. *Gastrointestinal Endoscopy* 2011;**73**(4S):AB414-5.

Kruglikova 2010 *{published data only}*

Kruglikova I, Grantcharov TP, Drewes AM, Funch-Jensen P. The impact of constructive feedback on training in gastrointestinal endoscopy using high-fidelity virtual-reality simulation: a randomised controlled trial. *Gut* 2010;**59**(2):181-5.

Lightdale 2010 *{published data only}*

Lightdale JR, Jiang H, Fredette HE, Atmadja ML, Heard L, Weinstock P. T1030A Randomized controlled trial of simulation-based training vs. discussion-based education

sessions for improving communication and teamwork in the endoscopy unit [abstract]. *Gastroenterology* 2010;**138**(5 (Supplement 1)):S472-3.

Maiss 2006 *{published data only}*

Maiss J, Prat F, Wiesnet J, Proeschel A, Matthes K, Peters A, et al. The complementary Erlangen active simulator for interventional endoscopy training is superior to solely clinical education in endoscopic hemostasis--the French training project: a prospective trial. *European Journal of Gastroenterology & Hepatology* 2006;**18**(11):1217-25.

Maiss 2007 *{published data only}*

Maiss J, Millermann L, Heinemann K, Naegel A, Peters A, Matthes K, et al. The compactEASIE is a feasible training model for endoscopic novices: a prospective randomised trial. *Digestive and Liver Disease* 2007;**39**(1):70-78; discussion 79-80.

Matthes 2007 *{published data only}*

Matthes K, Cohen J. Does simulator training in colonoscopy reduce procedure-related complications. *Techniques in Gastrointestinal Endoscopy* 2007;**9**(4):242-5.

Mohamed 2009 *{published data only}*

Mohamed R, Ramen M. Does a formal colonoscopy curriculum improve colonoscopy performance in the first month of training? [abstract]. *Canadian Journal of Gastroenterology* 2009;**23**(Supplement A):081.

Sturm 2008 *{published data only}*

Sturm LP, Windsor JA, Cosman PH, Cregan P, Hewett PJ, Maddern GJ. A systematic review of skills transfer after surgical simulation training. *Annals of Surgery* 2008;**248**(2):166-179.

Yi 2007 *{published data only}*

Yi SY, Woo HS, Ahn W, Kim WS, Lee DY. Clinical evaluation of the KAIST-Ewha Colonoscopy Simulator I. *Studies in Health Technology and Informatics* 2007;**125**(21):512-4.

References to studies awaiting assessment

Rosch 2011 *{published data only}*

Rosch T. NCT01405443. Simulator training for gastrointestinal endoscopy - how much simulator training is required to acquire proficiency in gastrointestinal endoscopy?. clinicaltrials.gov/ct2/show/NCT01405443 (accessed 27 April 2012).

Additional references

Bar-Meir 2000

Bar-Meir S. A new endoscopic simulator. *Endoscopy* 2000;**32**(11):898-900.

Barton 2008

Barton R. Validity and reliability of an accreditation assessment for colonoscopy [abstract]. *Gut* 2008;**57**(Suppl 1):A2.

Blumenthal 1994

Blumenthal D. Making medical errors into "medical treasures". *JAMA* 1994;**272**(23):1867-8.

Cass 1996

Cass OW, Freeman ML, Cohen J, et al. Acquisition of competency in endoscopic skills (ACES) during training: a multicentre study [abstract]. *Gastrointestinal Endoscopy* 1996;**43**:308.

Dunkin 2003

Dunkin BJ. Flexible endoscopy simulators. *Seminars in Laparoscopic Surgery* 2003;**10**(1):29–35.

Dunkin 2007

Dunkin B, Adrales GL, Apelgren K, Mellinger JD. Surgical simulation: a current review. *Surgical Endoscopy* 2007;**21**(3):357–66.

Egger 1997

Egger M, Davey Smith G, Schneider M, Minder C. Bias in meta-analysis detected by a simple graphical test. *BMJ* 1997;**315**(7109):629–34.

Faigel 2005

Faigel DO, Baron TH, Lewis B, Petersen B, Petrini J, Popp JW, et al. for the ASGE Taskforce on Ensuring Competence in Endoscopy and the American College of Gastroenterology Executive and Practice Management Committees. Ensuring competence in endoscopy. 2005. www.asge.org/WorkArea/showcontent.aspx?id=3384. Oak Brook, IL: ASGE Press, (accessed 27 April 2012).

Farace 1998

Farace DJ, Frantzen J, editors. Perspectives on the design and transfer of scientific and technical information. Proceedings of the GL'97 Conference: Third International Conference on Grey Literature; 1997 November 13-14; Luxembourg. Proceedings of the GL'97 Conference: Third International Conference on Grey Literature; 1997 November 13-14; Luxembourg. Amsterdam: GreyNet/TransAtlantic, 1998.

Frank 2005

Frank JR, editor. *The CanMEDS 2005 physician competency framework. Better standards. Better physicians. Better care.* Ottawa: The Royal College of Physicians and Surgeons of Canada, 2005.

Grantcharov 2003

Grantcharov TP, Bardram L, Funch-Jensen P, Rosenberg J. Learning curves and impact of previous operative experience on performance on a virtual reality simulator to test laparoscopic surgical skills. *American Journal of Surgery* 2003;**185**(2):146–9.

Hatala 2005

Hatala R, Kassen BO, Nishikawa J, Cole G, Issenberg SB. Incorporating simulation technology in a Canadian internal medicine specialty examination: a descriptive report. *Academic Medicine* 2005;**80**(6):554–6.

Higgins 2003

Higgins JP, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. *BMJ* 2003;**327**(7414):557–60.

Higgins 2011

Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. www.cochrane-handbook.org.

Issenberg 1999

Issenberg SB, McGaghie WC, Hart IR, Mayer JW, Felner JM, Petrusa ER, et al. Simulation technology for health care professional skills training and assessment. *JAMA* 1999;**282**(9):861–6.

Issenberg 2005

Issenberg SB, McGaghie WC, Petrusa ER, Lee Gordon D, Scales RJ. Features and uses of high-fidelity medical simulations that lead to effective learning: A BEME systematic review. *Medical Teacher* 2005;**27**:10–28.

JAG Central Office 2010

Joint Advisory Group Central Office. Summative DOPS Assessment Form - Colonoscopy and Flexible Sigmoidoscopy [updated 07 April 2010]. www.thejag.org.uk/TrainingforEndoscopists/DOPSForms.aspx (accessed 27 April 2012).

Kneebone 2001

Kneebone R, ApSimon D. Surgical skills training: simulation and multimedia combined. *Medical education* 2001;**35**(9):909–15.

Krummel 1998

Krummel TM. Surgical simulation and virtual reality: the coming revolution. *Annals of Surgery* 1998;**228**(5):635–7.

Langsley 1991

Langsley DG. Medical competence and performance assessment. A new era. *JAMA* 1991;**266**(7):977–80.

Macaskill 2001

Macaskill P, Walter SD, Irwig L. A comparison of methods to detect publication bias in meta-analysis. *Statistics in Medicine* 2001;**20**(4):641–54.

Mahmood 2004

Mahmood T, Darzi A. The learning curve for a colonoscopy simulator in the absence of any feedback: no feedback, no learning. *Surgical Endoscopy* 2004;**18**:1224–30.

McCashland 2000

McCashland T, Brand R, Lyden E, de Garmo P. The time and financial impact of training fellows in endoscopy. CORI Research Project. Clinical Outcomes Research Initiative. *The American Journal of Gastroenterology* 2000;**95**(11):3129–32.

Moher 2001

Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. *Lancet* 2001;**357**(9263):1191–4.

Rasmussen 2003

Rasmussen J. The role of error in organizing behaviour. 1990. *Quality and safety in health care* 2003;**12**(5):377–83.

RevMan 2011

The Nordic Cochrane Centre, The Cochrane Collaboration. Review Manager (RevMan). 5.1. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2011.

Scalese 2008

Scalese RJ, Obeso VT, Issenberg SB. Simulation technology for skills training and competency assessment in medical education. *Journal of General Internal Medicine* 2008;**23** Suppl 1:46–9.

Sedlack 2002

Sedlack RE. Development of a colonoscopy curriculum and performance based assessment criteria on a computer-based endoscopy simulator. *Academic Medicine* 2002;**77**:750–1.

Sturm 2007

Sturm L, Windsor J, Cregan P, Hewett P, Cosman P, Maddern G. Surgical simulation training: skills transfer to the operating room. ASERNIP-S Report No. 61. Adelaide, South Australia: ASERNIP-S, 2007. www.surgeons.org/media/300327/Surgicalsimulation_systematicreview.pdf (accessed 27 April 2012).

Sutherland 2006

Sutherland LM, Middleton PF, Anthony A, Hamdorf J, Cregan P, Scott D, Maddern GJ. Surgical simulation: A systematic review. *Annals of Surgery* 2006;**243**(3):291–300.

Swing 2002

Swing SR. Assessing the ACGME general competencies: general considerations and assessment methods. *Academic Emergency Medicine* 2002;**9**(11):1278–88.

Vassiliou 2010

Vassiliou MC, Kaneva PA, Poulou BK, Dunkin BJ, Marks JM, Sadik R, et al. Global Assessment of Gastrointestinal Endoscopic Skills (GAGES): a valid measurement tool for technical skills in flexible endoscopy. *Surgical Endoscopy* 2010;**24**(8):1834–41.

Vozenilek 2004

Vozenilek J, Huff JS, Reznick M, Gordon JA. See one, do one, teach one: advanced technology in medical education. *Academic Emergency Medicine* 2004;**11**:1149–54.

Walsh 2009

Walsh CM, Ling SC, Wang CS, Carnahan H. Concurrent versus terminal feedback: it may be better to wait. *Academic Medicine* 2009;**84**(10 (Supplement)):S54–7.

Ziv 2003

Ziv A, Wolpe PR, Small SD, Glick S. Simulation-based medical education: an ethical imperative. *Academic Medicine* 2003;**78**(8):783–8.

* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Ahlberg 2005

Methods	<p>Study design: Prospective, randomised clinical trial.</p> <p>Endoscopy Procedure: Colonoscopy.</p> <p>Language of publication: English.</p> <p>Number of centres: Multicentre (8).</p> <p>Year(s) of conduct of trial: Not stated.</p> <p>Generation of the allocation sequence: Blinded random draw of numbers contained within sealed envelopes</p> <p>Allocation concealment: Adequate (sealed envelope).</p> <p>Blinding of assessors: Adequate (physician assessors and patients blinded).</p> <p>Inclusion of all randomised participants: 100%.</p> <p>Sample size calculation: None.</p>
Participants	<p>Country: Sweden.</p> <p>Number: 12 randomised and analysed.</p> <p>Inclusion criteria: Surgical and gastroenterology residents (postgraduate years 2-5) with experience in gastroscopy (minimum of 20 individually performed procedures) who were designated to start colonoscopy training</p> <p>Exclusion criteria: Prior experience in colonoscopy (performing or assisting).</p> <p>Health profession: Medical trainees (surgery (n = 10) and gastroenterology (n = 2) residents)</p> <p>Level of training: Postgraduate years 2-5.</p> <p>Endoscopy experience: Minimum of 20 individually performed gastroscopy procedures</p> <p>Sex: 10 male, 2 female.</p> <p>Age: Not stated.</p>
Interventions	<p>Prior to undergoing the training task, all participants were given the same theoretical study material, containing a booklet on colonoscopy together with a free sample instructive CD on colonoscopy (New technology and technique by Williams, Way and Sakai)</p> <p>Participants were randomly assigned to two groups:</p> <p>GROUP 1: Virtual reality simulator training (n = 6)</p> <ul style="list-style-type: none"> - Simulator: Simulator: AccuTouch™ virtual reality endoscopy simulator version 1.3 (Immersion Medical, Inc., Gaithersburg, Maryland, USA) - Duration of training and/or training endpoint: Participants practiced until predefined expert level of performance reached (see below) - Description of intervention: Participants practiced “under strict supervision” on the simulator for a median time of 20 hours (range 15-25) during 1-2 hour sessions, over at least 4 days. All patient cases in the introduction, biopsy and polypectomy modules were used. Participants practiced until a predefined expert level of performance was reached on an examination case (case 6 in the introductory series). Expert level of performance was defined as: (1) ability to intubate the caecum within 7 minutes without the use of sedation, a “virtual attending,” simulation tips, and external view. The use of assistance tools (e.g. abdominal pressure, shifting patient position) were allowed; (2) More than

	<p>97% of the procedure time without patient discomfort and no period of severe or extreme discomfort; (3) navigation to the caecum with less than 1500ml of air insufflated and (4) navigation to the caecum with less than 15% of procedure time being in “red-out.” Expert level of performance was defined by assessing five experienced endoscopists (>1000 procedures each) and calculating the mean performance quality parameters on case 6 in the introductory section from all experts after a period of familiarization with the simulator. Participants could attempt the examination case (case 6 in the introductory section) at any time, but they had to fulfil all parameters in the expert criterion in order to pass.</p> <p>- Observation, instruction and feedback: Participants practiced on the simulator “under strict supervision.” Feedback was given to the trainee after each completed trial and at any given time comparison with expert level of performance could be made. A safe technique for manoeuvring the scope was taught. Use of the instructional aides from the simulator (e.g. sedation, “virtual attending,” simulation tips, external view, “find scope tip,” shifting position of patient and assistance with local pressure) were allowed during practice. It was not stated whether participants had access to the performance quality parameters generated by the simulator during practice.</p> <p>GROUP 2: No intervention (n = 6)</p> <p>- Description of intervention: No intervention.</p> <p>- Observation, instruction and feedback: None.</p>	
<p>Outcomes</p>	<p>Time to assessment: After completion of training, participants in the simulator-trained group started to do their individual colonoscopies within 1 week. Participants in the control group started after studying the theoretical material</p> <p>Assessment model: Ten colonoscopies were completed (maximum 60 minutes overall procedure time and/or maximum 15 minutes per segment - rectosigmoid angle, sigmoid colon sigmoid-descending colon junction, descending colon, left flexure, transverse colon, right flexure, ascending colon, caecum) under the supervision and evaluation of a blinded supervisor who was instructed not to guide the participant</p> <p>Details of patients used for live assessment: All patients, without a history of previous abdominal surgery, designated to undergo diagnostic colonoscopy</p> <p>Outcome measures:</p> <ol style="list-style-type: none"> (1) Time to reach caecum (min) or total procedure time in unsuccessful cases (min) (2) Completed procedure rate (intubation of caecum within given time limits) (n) (3) Segment of colon where procedure was stopped (9 consecutive segments - rectosigmoid angle, sigmoid colon sigmoid-descending colon junction, descending colon, left flexure, transverse colon, right flexure, ascending colon, caecum) (4) Reason for stopping (if applicable) (5) Analgesic drugs given (yes/no) (6) Complications (n) (7) Maximum discomfort (rated by patient, visual analogue scale) 	
<p>Notes</p>	<p>Funding: Not stated.</p>	
<p><i>Risk of bias</i></p>		
<p>Bias</p>	<p>Authors’ judgement</p>	<p>Support for judgement</p>

Random sequence generation (selection bias)	Low risk	Unclear: Blinded random draw of numbers contained within sealed envelopes Quote: "...a series of envelopes in a numbered sequence and with every second designated to training. Envelopes were drawn in a blinded fashion when each trainee was randomised." (personal correspondence)
Allocation concealment (selection bias)	Low risk	Adequate: Sealed envelopes. Quote: "...using the sealed envelope method."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Adequate: Accounted from missing outcome data from the 1 procedure in the control group which was not analysed Quote: "One procedure in the control group series was excluded because of poor bowel preparation" and "in one patient examined in the trained group series, an obstructive tumour was found in the transverse colon; this procedure was registered as successful."
Selective reporting (reporting bias)	Low risk	Adequate: Analysis and results are in accordance with the predefined study protocol
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Adequate: Unable to blind resident participants due to nature of intervention (outcome not likely to be influenced by lack of blinding)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Adequate: Assessing physicians and patients were blinded to residents training method Quote: "The patients were blinded concerning the pupils training status." Quote: "The supervisors were blinded concerning the pupils training status."

Methods	<p>Study design: Prospective, randomised clinical trial.</p> <p>Endoscopy Procedure: Colonoscopy.</p> <p>Language of publication: English.</p> <p>Number of centres: Multicentre (16).</p> <p>Year(s) of conduct of trial: Not stated (2 years).</p> <p>Generation of the allocation sequence: Random-number table.</p> <p>Allocation concealment: Not stated.</p> <p>Blinding of assessors: Adequate (physician assessors blinded).</p> <p>Inclusion of all randomised participants: (45/49) 91.84%</p> <p>Sample size calculation: None.</p>
Participants	<p>Country: USA.</p> <p>Number: 45 analysed (49 randomised but 4 participants withdrew after randomisation because of protocol violations during the training phase)</p> <p>Inclusion criteria: First year gastroenterology fellows starting fellowship at teaching institutions in the New York metropolitan area over 2 years whose training director agreed to adhere to the protocol and to delay any performance of colonoscopy for the first 8 weeks of the fellowship</p> <p>Exclusion criteria: Previous formal training in colonoscopy (> 10 cases) and an inability to comply with the training schedule</p> <p>Health profession: Medical trainees (gastroenterology fellows).</p> <p>Level of training: First year fellows.</p> <p>Endoscopy experience: Participants in the 'virtual reality simulator training' group performed an average of 67 previous gastroscopies and 4 flexible sigmoidoscopies. Participants in the 'no intervention' group performed on average 80 previous gastroscopies and 5 flexible sigmoidoscopies</p> <p>Sex: Not stated.</p> <p>Age: Not stated.</p>
Interventions	<p>Prior to undergoing the training task, all participants attended general lectures on colonoscopy as part of a didactic endoscopy course given to all incoming fellows, which emphasized key principles, such as application of torque, reduction of loops and careful examination of pathology during scope withdrawal</p> <p>Participants were randomly assigned to two groups:</p> <p>GROUP 1: Virtual reality simulator training (n = 22)</p> <ul style="list-style-type: none"> - Simulator: GI Mentor™ endoscopy simulator (Simbionix USA Corp., Cleveland, OH, USA) - Duration of training and/or training endpoint: 10 hours over 8 weeks (5, 2 hours private simulator sessions) - Description of intervention: Received supervised orientation to the simulator during the first week of fellowship. Over the next 8 weeks, fellows had five 2-hour private simulator training sessions. Each hour of training followed a standard protocol of activities (warm-up hand-eye coordination exercises and performance of 2 specific simulated procedures each hour). In total, 10 different cases were used during the simulator training program. Fellows kept a log of attempted procedures and performed no colonoscopies in the clinical setting prior to completion of their simulation training - Observation, instruction and feedback: Supervised orientation to GI mentor sim-

	<p>ulator during the first week of fellowship, along with instructions about the simulator training sessions to be completed. Simulation training was unsupervised. It was not stated whether participants had access to the performance quality parameters generated by the simulator during practice.</p> <p>GROUP 2: No intervention (n = 23) - Description of intervention: No intervention. - Observation, instruction and feedback: None.</p>	
<p>Outcomes</p>	<p>Time to assessment: Approximately 8 weeks after starting fellowship. Participants in the 'no intervention' group who were from an individual training program did not begin performing supervised colonoscopy training until the same time that the fellows in the 'virtual reality simulator training' group at their institution completed their simulation training</p> <p>Assessment model: 200 colonoscopies were performed on live patients (or number performed prior to study completion, which ever happened first), under the supervision and evaluation of an attending endoscopists. Fellows were responsible for having their attending fill out the evaluation form. Participants kept a log of colonoscopies completed. Outcomes were compared between groups for every group of 20 cases (i.e., procedures 0-20, 21-40, 41-60, etc.)</p> <p>Details of patients used for live assessment: Not specified.</p> <p>Outcome measures:</p> <ol style="list-style-type: none"> (1) Objective competency as defined as: ability to reach the transverse colon and caecum without assistance, and the ability to correctly recognize and identify abnormalities (2) Overall rating of competency (rated by attending, 1-5 Likert scale: 1 = totally unskilled, 5 = competent and expedient) (3) Patient-discomfort level (rated by attending, 1-5 Likert scale: 1 = very comfortable to 5 = severe pain) (4) Median number cases required to reach 90% competency (n) (5) Usefulness of simulation training (self-rated, questionnaire) 	
<p>Notes</p>	<p>Funding: None stated (simulator donated).</p>	
<p>Risk of bias</p>		
<p>Bias</p>	<p>Authors' judgement</p>	<p>Support for judgement</p>
<p>Random sequence generation (selection bias)</p>	<p>Low risk</p>	<p>Adequate: Random-number table. Quote: "Those who met entry criteria and consented to participate were randomised into 2 groups, with a 50% chance of being placed in either group. The method of sequence generation was a random-number table."</p>
<p>Allocation concealment (selection bias)</p>	<p>Unclear risk</p>	<p>Unclear: Not specified.</p>

Cohen 2006 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Adequate: Accounted for missing outcome data. Quote: "51 first-year gastroenterology fellows, from 16 hospitals, were approved to participate. Two were excluded because of prior colonoscopy experience, and 4 others dropped out after randomisation because of protocol violations during the training phase, leaving 45 who completed the study."
Selective reporting (reporting bias)	Low risk	Adequate: Analysis and results are in accordance with the predefined study protocol
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Adequate: Unable to blind participants or personnel due to nature of intervention (outcome not likely to be influenced by lack of blinding)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Adequate: Assessing physicians were blinded to the training status of participants. Quote: "Proctors filling out the individual evaluation forms remained blinded as to whether the particular fellows did or did not receive prior simulator training."

Di Giulio 2004

Methods	<p>Study design: Prospective, randomised clinical trial.</p> <p>Endoscopy Procedure: Oesophagogastroduodenoscopy (EGD).</p> <p>Language of publication: English.</p> <p>Number of centres: Multicentre (7).</p> <p>Year(s) of conduct of trial: 2000 (March - May)</p> <p>Generation of the allocation sequence: Randomisation list for each site</p> <p>Allocation concealment: Not stated.</p> <p>Blinding of assessors: Inadequate (physician assessors were not blinded)</p> <p>Inclusion of all randomised participants: 100%</p> <p>Sample size calculation: None.</p>
Participants	<p>Country: Italy.</p> <p>Number: 22 randomised and analysed.</p> <p>Inclusion criteria: Gastroenterology trainees.</p> <p>Exclusion criteria: Prior direct experience with performance of endoscopy.</p> <p>Health profession: Medical trainees (gastroenterology trainees).</p> <p>Level of training: Participants were in the 'early phase of training' of a 5-year program</p> <p>Endoscopy experience: No direct experience with the performance of endoscopy.</p> <p>Sex: Not stated.</p>

	<p>Age: Not stated.</p>
<p>Interventions</p>	<p>Prior to undergoing the training task, all participants took part in a 2-hour session in which the workings of the endoscope were explained to them by an expert endoscopist and correct methods for performance of upper endoscopy were described</p> <p>Participants were randomly assigned to two groups:</p> <p>GROUP 1: Virtual reality simulator training (n = 11)</p> <ul style="list-style-type: none"> - Simulator: GI Mentor™ endoscopy simulator (Symbionix Ltd., Lod, Isreal) - Duration of training and/or training endpoint: 10 hours over 3-5 sessions - Description of intervention: Participants received basic directions by an instructor with regard to use of the simulator and then completed 10 hours of training in 3-5 sessions without supervision. Participants were permitted to try each of the 10 available simulated cases within the times and in the sequence they preferred. - Observation, instruction and feedback: Simulation-based training was not supervised. It was not stated whether participants had access to performance quality parameters generated by the simulator during practice. <p>GROUP 2: No intervention (n = 11)</p> <ul style="list-style-type: none"> - Description of intervention: No intervention. - Observation, instruction and feedback: None.
<p>Outcomes</p>	<p>Time to assessment: Not stated.</p> <p>Assessment model: 20 consecutive oesophagogastroduodenoscopies on patients scheduled for diagnostic endoscopy, under the supervision and evaluation of an attending physician. Participants were required to keep a procedural logbook detailing procedure duration, number of attempts at intubation, and in event of failure, the reasons for interruption of the procedure and/or the need for assistance in completing the procedure.</p> <p>Details of patients used for live assessment: Patients were excluded if they were less than 18 years of age, pregnant, had prior digestive surgery, major risk factors for the procedure (severe respiratory failure, severe cardiac failure, patients in an intensive care unit, gastrointestinal bleeding), coagulation abnormalities and/or dysphagia. Patients were premeditated with midazolam (2.5 mg intravenously) or diazepam (5mg intravenously) and topical anaesthesia was induced by spraying lidocaine.</p> <p>Outcome measures:</p> <ol style="list-style-type: none"> (1) Completeness of procedure (rated by attending, “complete” = oesophageal intubation achieved, participant identified, within 20 minutes, all anatomical landmarks (oesophagogastric mucosal junction, gastric angulus, pylorus) and performed certain basic manoeuvres (aspiration of gastric juice, pylorus intubation in no more than 3 attempts, duodenal bulb exploration, intubation of the second part of the duodenum and retroflexion) with or without verbal direction; “procedure failure” = incomplete procedure) (2) Overall judgement of performance based on “completeness” of the examination, the need for assistance, and the presumed difficulty of the procedure. (rated by attending, 0-10 Likert scale with a procedure receiving a score of 5 or less being classified as “negative” and a procedure receiving a score of 6 or more as “positive” : 0 = bad; 10 = good) (3) Number of times manual assistance was required and reason (n) (4) Number of times verbal assistance was required and reason (n) (5) Number of identified or missed lesion (n). (6) Number of complications (n).

	(7) Failure to effect oesophageal intubation (yes/no) (8) Number of attempts at oesophageal intubation (n).	
Notes	Funding: None stated.	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Adequate: Randomisation list. Quote: "...trainees were randomised into two groups by using randomisation lists created independently in each hospital."
Allocation concealment (selection bias)	Unclear risk	Unclear: Not specified.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Adequate: Missing outcome data accounted for. Quote: "6 trainees in the SIM group and 7 in the non-SIM group performed one or two procedures less than planned because of the temporary assignment to other clinical activities." and "No attempted procedure was excluded from statistical analysis."
Selective reporting (reporting bias)	Low risk	Adequate: Analysis and results are in accordance with the predefined study protocol
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Adequate: Unable to blind participants or personnel due to nature of intervention (outcome not likely to be influenced by lack of blinding)
Blinding of outcome assessment (detection bias) All outcomes	High risk	Inadequate: Assessing physicians were not blinded to the training status of participants. Quote: "The instructors were not blinded as to whether trainees had or had not used the simulator."

Methods	<p>Study design: Prospective, randomised clinical trial. Endoscopy Procedure: Oesophagogastroduodenoscopy (EGD). Language of publication: English. Number of centres: Single centre. Year(s) of conduct of trial: 2003-2007 Generation of the allocation sequence: Not stated. Allocation concealment: Not stated. Blinding of assessors: Inadequate (Physician assessors not blinded, patients blinded) Inclusion of all randomised participants: 100%. Sample size calculation: Yes.</p>
Participants	<p>Country: Austria. Number: 28 enrolled and analysed. Inclusion criteria: At least 3rd-year residents in internal medicine. Exclusion criteria: Previous endoscopy training. Health profession: Medical trainees (internal medicine residents). Level of training: At least 3rd year residents. Endoscopy experience: None. Sex: 19-male, 9 female (7 males and 7 females in VR group). Age: Mean age 31 years (range: 28-37 years).</p>
Interventions	<p>Participants were randomly assigned to two groups:</p> <p>GROUP 1: Virtual reality simulator training (n = 14)</p> <ul style="list-style-type: none"> - Simulator: GI Mentor™ endoscopy simulator (Simbionix USA Corp., Cleveland, OH, USA) - Duration of training and/or training endpoint: 2 hours per day of structured training for 5-20 hours total (their choice). Median training time was 10 hours (range 5-20 hours) - Description of intervention: 2 hours per day of structured training (5-20 hours total) on the virtual endoscopy simulator. Participants were permitted to practice using 20 virtual EGD cases, haptic (targeted steering) training games “Endobasket” and “Endobubble.” - Observation, instruction and feedback: Trainers were present for the first 2 hours of simulator training. It was not stated whether participants had access to performance quality parameters generated by the simulator during practice. <p>GROUP 2: No intervention (n = 14)</p> <ul style="list-style-type: none"> - Description of intervention: No intervention. - Observation, instruction and feedback: None. <p>After the training task, all participants received equal instruction and training in EGD including instruction in handling the endoscope, observing 5-10 EGD examinations by experts and withdrawing the endoscope 3-5 times from the descending duodenum in patients. Participants were introduced to pathological findings of the upper gastrointestinal tract, using an endoscopic atlas and CD. Participants were trained in one-hand steering technique, were allowed to try to intubate the oesophagus twice before the attending physician took over the scope, were allowed to try to perform pyloric passage twice before they were assisted by the attending and performed routine biopsies.</p>

<p>Outcomes</p>	<p>Time to assessment: Not stated. Assessment model: Observed and evaluated by expert endoscopists (performed > 5000 EGD) performing their first 10 EGD on consecutive patients who met inclusion criteria (listed below). 14 of 28 participants were assessed while performing their 51-60th EGD on consecutive patients who met inclusion criteria Details of patients used for live assessment: Patients scheduled for diagnostic EGD and unwilling to undergo sedation. Patients wanting to have concomitant sedation, or requiring therapeutic interventions were excluded. Outcome measures: (1) Time from the first attempt at oesophageal intubation until the descending part of the duodenum reached (2) Time between the first attempt at oesophageal intubation and the end of the investigation (3) Technical accuracy (evaluated by recording whether the novice endoscopist was able to intubate the oesophagus (“unaided”), whether manual help by the expert was needed (“expert help”), or if the expert had to take over (“expert takeover”)) (4) Pyloric passage (evaluated as “unaided,” requiring “expert help,” or requiring “expert takeover”) (5) Retroflexion (J-maneuver) in the gastric fundus (evaluated as “unaided,” requiring “expert help,” or requiring “expert takeover”) (6) Diagnostic accuracy (evaluated as the number of pathological entities found or missed) (7) Discomfort and pain (evaluated immediately after EGD using patient questionnaire that used two 100mm visual analogue scales for discomfort and pain)</p>	
<p>Notes</p>	<p>Funding: None stated.</p>	
<p>Risk of bias</p>		
<p>Bias</p>	<p>Authors’ judgement</p>	<p>Support for judgement</p>
<p>Random sequence generation (selection bias)</p>	<p>Unclear risk</p>	<p>Unclear: Method of sequence generation not specified. Quote: “Randomization was performed by a member of the department not involved into the study. A group of 4-6 residents started every 6 months. Their names, each written on a piece of paper, were drawn out of a box after calling of “group C” or group S”.”</p>
<p>Allocation concealment (selection bias)</p>	<p>Unclear risk</p>	<p>Unclear: Not specified.</p>
<p>Incomplete outcome data (attrition bias) All outcomes</p>	<p>Low risk</p>	<p>Adequate: No missing outcome data. Analysis was performed on all patients randomised</p>

Selective reporting (reporting bias)	Low risk	Adequate: Analysis and results are in accordance with the predefined study protocol
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Adequate: Unable to blind participants or personnel due to nature of intervention (outcome not likely to be influenced by lack of blinding)
Blinding of outcome assessment (detection bias) All outcomes	High risk	Inadequate: Assessing physicians were not blinded to the training status of participants. Assessing patients were blinded. Quote: "The experts were informed about the training status of the endoscopic novices (i.e., which were simulator-trained), but the patients were not." And "Patients were blind to the training status of the trainee (i.e., whether they had simulator training or not, and the number of patient endoscopies they had performed)

Gerson 2003

Methods	<p>Study design: Prospective, randomised clinical trial.</p> <p>Endoscopy Procedure: Sigmoidoscopy.</p> <p>Language of publication: English.</p> <p>Number of centres: Single centre (2 sites).</p> <p>Year(s) of conduct of trial: 2001.</p> <p>Generation of the allocation sequence: Sequential allocation.</p> <p>Allocation concealment: No.</p> <p>Blinding of assessors: Inadequate (physician assessors not blinded, patients blinded)</p> <p>Inclusion of all randomised participants: 100%</p> <p>Sample size calculation: Yes</p>
Participants	<p>Country: USA.</p> <p>Number: 16 enrolled and analysed.</p> <p>Inclusion criteria: Internal medicine residents.</p> <p>Exclusion criteria: Any prior experience with flexible sigmoidoscopy, observation of sigmoidoscopy as part of a clinical rotation, or prior use of an endoscopic simulator</p> <p>Health profession: Medical trainees (internal medicine residents).</p> <p>Level of training: 8/16 first year residents (VR group: 2/9, Control group: 6/7)</p> <p>Endoscopy experience: No sigmoidoscopy experience (EGD experience not stated).</p> <p>Sex: 12 males, 4 females (No significant difference between groups)</p> <p>Age (mean± SD): VR group: 29.4 ± 1.1 and Control group: 28 ± 0.8 (No significant difference between groups)</p>
Interventions	<p>Participants were randomly assigned to two groups:</p> <p>GROUP 1: Virtual reality simulator training (n = 9)</p>

	<p>- Simulator: AccuTouch™ virtual reality endoscopy simulator (Immersion Medical, Inc., Gaithersburg, Maryland, USA)</p> <p>- Duration of training and/or training endpoint: 2 weeks (unlimited simulator access)</p> <p>.</p> <p>- Description of intervention: Unlimited simulator use during a 2 week period (average time (mean ± SEM): 138 ± 28 minutes; average number cases (mean ± SEM): 12.8 ± 2.9 minutes). Participants were instructed to review all didactic modules and complete all 6 practice cases on the simulator</p> <p>- Observation, instruction and feedback: Not observed and no external instruction provided. Participants permitted to use simulator teaching features (“virtual attending physician” and external view of colon) during each examination. Performance quality parameters were provided to participants by the simulator after each procedure, including: procedure time, insertion length, degree of air insufflation, percentage of mucosa visualized, time in red-out, patient discomfort, recognition of pathology, occurrence of perforation, performance of retroflexion.</p> <p>GROUP 2: Conventional patient-based endoscopy training (n = 7)</p> <p>- Duration of training and/or training endpoint: 2 weeks (10 sigmoidoscopic examinations).</p> <p>- Description of intervention: 10 sigmoidoscopic examinations during a 2 week period (average time: 300 minutes) performed with a video colonoscope</p> <p>- Observation, instruction and feedback: An attending gastroenterologist observed each participant’s procedures and was instructed to teach the resident using his or her own teaching preferences and techniques. Participants were expected to learn how to advance the colonoscope independently by the end of the ten sessions.</p>
<p>Outcomes</p>	<p>Time to assessment: Not stated.</p> <p>Assessment model: Five sigmoidoscopic examinations (insertion and withdrawal) were completed, under the supervision and evaluation of an attending gastroenterologist who provided no coaching during the test examinations. Participants were expected to perform retroflexion at the completion of the sigmoidoscopy and were required to notify the attending when the splenic flexure was identified and if any pathology was encountered. If the participant encountered difficulty the attending was allowed to take over until the resident could continue</p> <p>Details of patients used for live assessment: Asymptomatic patients referred for routine colorectal cancer screening via flexible sigmoidoscopy</p> <p>Outcome measures:</p> <ol style="list-style-type: none"> (1) Independent completion (yes/no) (2) Examination duration (time) (3) Required assistance (yes/no) (4) Flexure recognition (yes/no) (5) Completion of retroflexion (yes/no) (6) Ability to recognize pathology (yes/no) (7) Expert global rating (rated by attending, 1-5 Likert scale: 1 = unable to clear the rectum; 2 = unable to clear the rectosigmoid junction; 3 = unable to pass one turn without assistance; 4 = able to perform independently, but more than 20 min required; 5 = independent examination less than 20 min in duration) (8) Level of patient comfort/discomfort (rated by patient, 1-5 Likert scale: 1 = strongly agree; 2 = agree; 3 = not sure; 4 = disagree; 5 = strongly disagree)

Gerson 2003 (Continued)

	(9) Patient satisfaction (rated by patient, 1-5 Likert scale: 1 = strongly agree; 2 = agree; 3 = not sure; 4 = disagree; 5 = strongly disagree) (10) Technical competence (rated by patient, 1-5 Likert scale: 1 = strongly agree; 2 = agree; 3 = not sure; 4 = disagree; 5 = strongly disagree)	
Notes	Funding: None stated.	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Inadequate: sequential allocation. Quote: "Residents were assigned in a sequential fashion by one of the investigators to a simulator-trained group or a traditional teaching group."
Allocation concealment (selection bias)	High risk	Inadequate: not concealed. Quote: "Neither the investigators nor participating residents were blinded to the group assignment."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Adequate: No missing outcome data. Analysis was performed on all patients randomised
Selective reporting (reporting bias)	Low risk	Adequate: Analysis and results are in accordance with the predefined study protocol
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Adequate: Unable to blind participants or personnel due to nature of intervention (outcome not likely to be influenced by lack of blinding)
Blinding of outcome assessment (detection bias) All outcomes	High risk	Inadequate: Assessing physicians were not blinded and participating patients were blinded to residents training method Quote: "The attending physicians grading the test cases were not blinded to the mode of training." Quote: "Participating patients were blinded to the residents training method."

Methods	<p>Study design: Prospective, randomised clinical trial.</p> <p>Endoscopy Procedure: Colonoscopy</p> <p>Language of publication: English.</p> <p>Number of centres: Multicentre (4).</p> <p>Year(s) of conduct of trial: Not stated.</p> <p>Generation of the allocation sequence: Computer generated, block randomisation protocol (8 per block, enrolled by sub investigator and randomised to simulator vs. traditional patient-based bedside training)</p> <p>Allocation concealment: No.</p> <p>Blinding of assessors: Adequate (physician assessors blinded).</p> <p>Inclusion of all randomised participants: (36/40) 90%</p> <p>Sample size calculation: Yes</p>
Participants	<p>Country: United Kingdom, Netherlands, Italy</p> <p>Number: 40 enrolled and 36 analysed.</p> <p>Inclusion criteria: Any medical background (physicians, surgeons, nurses) or position recognized by the training institution as appropriate for training in colonoscopy</p> <p>Exclusion criteria: Performance of > 25 previous colonoscopies or flexible sigmoidoscopies, previous participation in an intensive colonoscopy training course, colonoscopy training or simulator training study, performance of > 10 laparoscopic surgical procedures</p> <p>Health profession: Any health profession background (Medical trainees (general trainee, specialist in training), nurses, etc.)</p> <p>Level of training: Not stated.</p> <p>Endoscopy experience: Colonoscopies observed (VR group: 15, Control group: 45), colonoscopies assisted (VR group: 0, Control group: 1)</p> <p>Sex: VR group: 6 males, 13 females and Control group: 10 males, 8 females (No significant difference between groups)</p> <p>Age (mean± SD): VR group: 31 (26-33) and Control group: 28 (26-30) (No significant difference between groups)</p>
Interventions	<p>Prior to undergoing the training task, all participants received a standardized tutorial on the fundamentals of colonoscopy. All participants then performed 3 validated pre-test simulator cases to assess baseline performance.</p> <p>Participants were randomly assigned to two groups:</p> <p>GROUP 1: Virtual reality simulator training (n = 18)</p> <ul style="list-style-type: none"> - Simulator: Endo TS-1™ Olympus colonoscopy simulator (Olympus Keymed, Southend, UK) - Duration of training and/or training endpoint: 16 hours - Description of intervention: 16 hours of standardized simulator training. The training package included knowledge and skill-based learning with formative assessments in a multi-media environment and incorporated a simulated 3-D image viewer. It was structured in a sequential fashion to introduce the skills and knowledge needed to progress from rectum to caecum - Observation, instruction and feedback: Trainers expected to provide minimal tutoring and feedback <p>GROUP 2: Conventional patient-based endoscopy training (n = 18)</p>

	<p>- Duration of training and/or training endpoint: 16 hours (minimum 8 colonoscopies) - Description of intervention: 16 hours of patient-based training (4 half-day sessions) by an expert trainer using a ScopeGuide 3-D endoscopic imager. Participants performed a minimum of 8 colonoscopies under 1:1 supervision. Recommendations made for topics to be covered aiming to standardize training. All trainees taught to use single-handed, 1-person technique for colonoscopy, but instructor otherwise told to provide 'usual' training for a novice colonoscopist. Observation, instruction and feedback: Use of ScopeGuide imager. Instructor told to teach single-handed, 1 person technique, but instructor otherwise told to provide 'usual' training for a novice colonoscopist. Details of instruction and feedback not stated</p>	
<p>Outcomes</p>	<p>Time to assessment: Not stated Assessment model: Three patient-based colonoscopies were completed, under the supervision and evaluation of an expert assessor. Assessors were asked not to provide any assistance (verbal, practical) unless there were safety concerns. A ScopeGuide 3-D endoscopic imager view used for all colonoscopies performed. Procedures terminated at 20 minutes or earlier if caecal intubation achieved (confirmed by visualization of 2 of 3 landmarks (ileocaecal valve, appendix orifice, triradiate fold) and imager view compatible with tip of endoscope in caecum) . An assessment was repeated if a procedure was terminated due to patient factors (e.g. poor prep, poor patient tolerance) Details of patients used for live assessment: < 75 years old, no history of pelvic or colonic surgery or difficult colonoscopy. Outcome measures: (1) Procedural proficiency (rated by attending using an abbreviated version of the UK Joint Advisory Group colonoscopy Direct Observation of Procedural Skills assessment form (JAG Central Office 2010) which rated 9 domains of 'endoscopic skills during insertion and withdrawal' on a 1-4 point scale) (2) Global score (rated by attending using Global Performance Score assessment form (Park 2007) which rates 7 domains on a 1-5 Likert Scale: atraumatic technique, colonoscopy advancement, use of instrument controls, flow of procedure, use of assistants, knowledge of specific procedure, overall performance) (3) Time to completion (4) Depth of insertion (cm and anatomical position)</p>	
<p>Notes</p>	<p>Funding: None stated.</p>	
<p><i>Risk of bias</i></p>		
<p>Bias</p>	<p>Authors' judgement</p>	<p>Support for judgement</p>
<p>Random sequence generation (selection bias)</p>	<p>Low risk</p>	<p>Adequate: Computer generated, block randomisation Quote: "...randomised into subjects (simulator training) and controls (patient-based training) by the lead investigator, by using a computer-generated, block randomisation protocol with 8 per block."</p>

Allocation concealment (selection bias)	Unclear risk	Unclear: Not specified.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Adequate: Accounted for missing outcome data. Quote: "Forty trainees were randomised, with 36 completing the study. Two trainees did not start because of limitations in availability of endoscopy sessions, 1 trainee completed the simulator pre-training assessment but had to leave for personal reasons before commencing the training, and 1 trainee completed the training and simulator assessments but did not complete all 3 patient-based assessment cases."
Selective reporting (reporting bias)	Low risk	Adequate: Analysis and results are in accordance with the predefined study protocol
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Adequate: Unable to blind participants or personnel due to nature of intervention (outcome not likely to be influenced by lack of blinding) Quote: "Participants, sub investigators, and trainers in each institution were not blinded to the group allocation."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Adequate: Assessing physicians were blinded. Quote: "An expert assessor blinded to the group allocation of the trainee was present during all assessments."

Park 2007

Methods	<p>Study design: Prospective, randomised clinical trial. Endoscopy Procedure: Colonoscopy. Language of publication: English. Number of centres: Single centre. Year(s) of conduct of trial: Not stated. Generation of the allocation sequence: Not stated. Allocation concealment: Not stated. Blinding of assessors: Adequate (physician assessors blinded). Inclusion of all randomised participants: (24/28) 85.71% Sample size calculation: Yes</p>
Participants	<p>Country: Canada. Number: 28 enrolled and 24 analysed. Inclusion criteria: Internal medicine and surgery residents.</p>

	<p>Exclusion criteria: Experience in endoscopy defined as the primary endoscopists for 3 procedures of any type</p> <p>Health profession: Medical trainees (internal medicine and surgery residents)</p> <p>Level of training: Postgraduate years 1-3.</p> <p>Endoscopy experience: < 3 endoscopic procedures (of any kind) performed.</p> <p>Sex: Details not stated (No significant difference between groups)</p> <p>Age: Details not stated (No significant difference between groups)</p>
<p>Interventions</p>	<p>Prior to undergoing the training task, all participants viewed an introduction to colonoscopy video and were given the opportunity to familiarize themselves with the components and handling of a colonoscope. No formal instruction was given at this time. All participants then performed 1 pre-test simulator sequence to assess baseline performance. Between the VR simulator pre-test and the test in the clinical setting participants both groups were allowed to attend and view colonoscopies performed by faculty endoscopists as per their normal experience during a clinical rotation. They did not receive specific teaching regarding the technical aspects of endoscopy or perform any procedures prior to their clinical test</p> <p>Participants were randomly assigned to two groups:</p> <p>GROUP 1: Virtual reality simulator training (n = 12)</p> <ul style="list-style-type: none"> - Simulator: Simulator: AccuTouch™ virtual reality endoscopy simulator version 1.2 (Immersion Medical, Inc., Gaithersburg, Maryland, USA) - Duration of training and/or training endpoint: 2-3 hours - Description of intervention: Participants practiced independently for 2-3 hours (average time (mean ± SEM): 125 ± 37 minutes) on the simulator during which time they had access to the range of six available simulator cases. - Observation, instruction and feedback: Participants were not observed and no external instruction was provided. Simulator training included the use of all simulator-based resources (e.g. computer-generated anatomical views). 14 performance quality parameters were provided to participants by the simulator after each procedure, including: procedure time, insertion length, degree of air insufflation, percentage of mucosa visualized, time in red-out, patient discomfort, recognition of pathology, occurrence of perforation, performance of retroflexion <p>GROUP 2: No intervention (n = 12)</p> <ul style="list-style-type: none"> - Description of intervention: No intervention. - Observation, instruction and feedback: None.
<p>Outcomes</p>	<p>Time to assessment: Within 2 weeks (range 2-14 days) of their simulator pre-test and training</p> <p>Assessment model: One colonoscopy (insertion only, maximum 30 minutes) was completed under the supervision and evaluation of 1 of 3 blinded attending endoscopists (different from the pre-test examiner) who allowed the participants as much independence as possible while ensuring patient safety, and could provide verbal instruction if necessary. If, in the opinion of the attending the resident was not making progress, the attending was permitted to take control of the colonoscope and navigate through the difficult section before returning it to the resident. If the test procedure was terminated due to patient factors (e.g. extensive diverticulosis) the resident was given the opportu-</p>

	<p>nity to repeat the procedure on a second suitable patient.</p> <p>Details of patients used for live assessment: Patients between ages 40-75 years with no previous colon or rectal resection, no history of difficulty colonoscopy (secondary to anatomy or patient compliance), and no history of inflammatory bowel disease</p> <p>Outcome measures:</p> <p>(1) Global performance score (rated by attending, 1-5 Likert scale of 7 domains: atraumatic technique, colonoscope advancement, use of instrument controls, flow of procedure, use of assistants, knowledge of specific procedure, overall performance)</p> <p>(2) Ability to independently reach the caecum (yes/no)</p> <p>(3) Number of critical flaws (perforation or significant bleeding) during the procedure (n)</p>	
Notes	Funding: Yes (peer reviewed research grant).	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Unclear: Method of sequence generation not specified. Quote: "...residents were randomly assigned to 1 of 2 groups."
Allocation concealment (selection bias)	Unclear risk	Unclear: Not specified.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Adequate: Accounted for missing outcome data. Quotes: "4 residents (2 in each group) were unable to complete the clinical phase because of scheduling difficulties, and their data were excluded from analyses." and "Procedures were terminated on 1 occasion in each group because of patient-related factors (difficulty anatomy). Each of these residents performed a colonoscopy on a second suitable patient, and only evaluations from the second procedure were included in the analysis."
Selective reporting (reporting bias)	Low risk	Adequate: analysis and results are in accordance with the predefined study protocol
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Adequate: Unable to blind participants or personnel due to nature of intervention (outcome not likely to be influenced by lack of blinding)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Adequate: Assessing physicians were blinded. Quote: "...under the supervision of 1 of 3 faculty

	endoscopist evaluators (different from the pre-test examiner) blinded to the residents training group.”
--	---------------------------------------------------------------------------------------------------------

Sedlack 2004

Methods	<p>Study design: Prospective, randomised clinical trial.</p> <p>Endoscopy Procedure: Colonoscopy.</p> <p>Language of publication: English.</p> <p>Number of centres: Single centre.</p> <p>Year(s) of conduct of trial: Not stated.</p> <p>Generation of the allocation sequence: Not stated.</p> <p>Allocation concealment: Not stated.</p> <p>Blinding of assessors: Inadequate (physician assessors not blinded, patients not stated)</p> <p>Inclusion of all randomised participants: 100%.</p> <p>Sample size calculation: None.</p>
Participants	<p>Country: USA</p> <p>Number: 8 randomised and analysed.</p> <p>Inclusion criteria: First year gastroenterology fellows who had completed 2 months of oesophagogastroduodenoscopy training</p> <p>Exclusion criteria: Prior colonoscopy training or simulator experience.</p> <p>Health profession: Medical trainees (gastroenterology fellows)</p> <p>Level of training: First year fellows.</p> <p>Endoscopy experience: 2 months of oesophagogastroduodenoscopy training, no prior colonoscopy training or simulator experience</p> <p>Sex: 5 males, 3 females</p> <p>Age: Not stated.</p>
Interventions	<p>Participants were randomly assigned to two groups:</p> <p>GROUP 1: Virtual reality simulator training (n = 4)</p> <ul style="list-style-type: none"> - Simulator: AccuTouch™ virtual reality endoscopy simulator version 1.1 (Immersion Medical, Inc., Gaithersburg, Maryland, USA) - Duration of training and/or training endpoint: 6 hours (over 2 days). - Description of intervention: 6 hours of simulator training over a 2 day period, comprising a brief multimedia tutorial followed by the performance of 10-25 simulated colonoscopies (average 21, range 19-26). 6 colonoscopy scenarios of varying complexity were used. Simulator curriculum previously validated (Sedlack 2002). - Observation, instruction and feedback: Not stated. It was not stated whether participants had access to the performance quality parameters generated by the simulator during practice. <p>GROUP 2: No intervention (n = 4)</p> <ul style="list-style-type: none"> - Description of intervention: No intervention (see 'Note' section below). - Observation, instruction and feedback: None.

Outcomes	<p>Time to assessment: Not stated.</p> <p>Assessment model: 4-8 week of patient-based colonoscopy training during which participants were supervised and evaluated by 1 of 38 faculty gastroenterologists during one-half day (i.e. 4 hour) assignment intervals. Outcomes were compared between groups for procedures 1-15, 16-30, 31-45 and 46-60</p> <p>Details of patients used for live assessment: Not specified.</p> <p>Outcome measures:</p> <ol style="list-style-type: none"> (1) Time to reach maximum insertion (min) (2) Depth of unassisted insertion (1 = rectum, 2 = sigmoid, 3 = splenic flexure, 4 = hepatic flexure, 5 = caecum, 6 = terminal ileum) (3) Independent procedure completion (yes/no, defined as independently reaching the caecum or terminal ileum) (4) Ability to identify endoscopic landmarks (rated by attending, 1-5 Likert scale, 1 = strongly disagree, 4 = neutral, 7 = strongly agree) (5) Ability to insert in a safe manner (rated by attending, 1-5 Likert scale, 1 = strongly disagree, 4 = neutral, 7 = strongly agree) (6) Ability to adequately visualize mucosa on withdrawal (rated by attending, 1-5 Likert scale, 1 = strongly disagree, 4 = neutral, 7 = strongly agree) (7) Ability to respond appropriately to patient discomfort (rated by attending, 1-5 Likert scale, 1 = strongly disagree, 4 = neutral, 7 = strongly agree) (8) Patient discomfort (rated by patient, 10 point scale: 1 = minimal or no pain, 10 = worst pain of life) (9) Faculty productivity during the training phase (number of procedures completed) (10) Faculty productivity during the assessment phase (number of procedures completed) 	
Notes	<p>Funding: None stated.</p> <p>- The authors state “the remaining 4 fellows served as a control group and underwent traditional colonoscopy training consisting of staff-supervised patient-based colonoscopy.” However, the performance of participants in both groups was evaluated (and compared) in the clinical setting from the first procedure they completed; therefore, Group 2 was considered to have ‘no intervention’ prior to evaluation</p>	
Risk of bias		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Unclear: method of sequence generation not specified. Quote: “8 fellows were randomly assigned to 1 of 2 different colonoscopy training curricula.”
Allocation concealment (selection bias)	Unclear risk	Unclear: Not specified.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Adequate: No missing outcome data. Analysis was performed on all patients randomised

Sedlack 2004 (Continued)

Selective reporting (reporting bias)	Low risk	Adequate: Analysis and results are in accordance with the predefined study protocol
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Adequate: Unable to blind participants or personnel due to nature of intervention (outcome not likely to be influenced by lack of blinding)
Blinding of outcome assessment (detection bias) All outcomes	High risk	Inadequate: Assessing physicians were not blinded to the training status of participants. It was not stated whether the assessing patients were blinded. Quote: "... evaluating staff were not blinded to the type of training curriculum that the fellow underwent..."

Sedlack 2004a

Methods	<p>Study design: Prospective, randomised clinical trial. Endoscopy Procedure: Flexible sigmoidoscopy. Language of publication: English. Number of centres: Single centre. Year(s) of conduct of trial: 2001-2002. Generation of the allocation sequence: Not stated. Allocation concealment: Not stated. Blinding of assessors: Inadequate (physician assessors not blinded, patients not stated) Inclusion of all randomised participants: 100% Sample size calculation: None.</p>
Participants	<p>Country: USA. Number: 38 randomised and analysed. Inclusion criteria: Second year internal medicine residents. Exclusion criteria: Prior endoscopy experience. Health profession: Medical trainees (internal medicine residents) Level of training: Second year residents. Endoscopy experience: None. Sex: Not stated. Age: Not stated.</p>
Interventions	<p>Participants were randomly assigned to two groups:</p> <p>GROUP 1: Virtual reality simulator training followed by conventional patient-based endoscopy training (n = 19) - Simulator: AccuTouch™ virtual reality endoscopy simulator version 1.1.1 (Immersion Medical, Inc., Gaithersburg, Maryland, USA) - Duration of training and/or training endpoint: 3-hours simulator-based training followed by 6 hours (over 2 days) patient-based endoscopy training - Description of intervention: 3-hours of simulator-based training under the supervi-</p>

	<p>sion of a senior gastroenterology fellow, comprised of a brief multimedia tutorial followed by the performance of 8-10 simulated sigmoidoscopies (average 9, range 6-11). 6 sigmoidoscopy scenarios of varying complexity were used. Simulator training was followed by 2 additional afternoons (3 hours per day) of staff-supervised patient-based endoscopy training</p> <p>- Observation, instruction and feedback:</p> <ul style="list-style-type: none"> • Simulated setting: "Under the supervision of a senior gastroenterology fellow." It was not stated whether participants had access to the performance quality parameters generated by the simulator during practice. • Clinical setting: "Staff-supervised." <p>GROUP 2: Conventional patient-based endoscopy training (n = 19)</p> <p>- Duration of training and/or training endpoint: 9 hours (over 3 days) patient-based endoscopy training.</p> <p>- Description of intervention: 3 afternoons (3 hours per day) of staff-supervised patient-based endoscopy training.</p> <p>- Observation, instruction and feedback: "Staff-supervised."</p>	
Outcomes	<p>Time to assessment: Not specified.</p> <p>Assessment model: One afternoon (3 hours) of staff-supervised patient-based endoscopy</p> <p>Details of patients used for live assessment: Not specified.</p> <p>Outcome measures:</p> <ol style="list-style-type: none"> (1) Patient discomfort (rated by patient, 1-10 Likert scale: 1 = no pain, 10 = worst pain of life) (2) Resident's ability to perform flexible sigmoidoscopy independently (rated by attending and self-rated, 1-10 Likert scale: 1 = strongly agree, 5 = neutral, 10 = strongly disagree) (3) Resident's ability to identify pathology (rated by attending and self-rated, 1-10 Likert scale: 1 = strongly agree, 5 = neutral, 10 = strongly disagree) (4) Resident's ability to identify landmarks (rated by attending and self-rated, 1-10 Likert scale: 1 = strongly agree, 5 = neutral, 10 = strongly disagree) (5) Resident's ability to respond to patient discomfort (rated by attending and self-rated, 1-10 Likert scale: 1 = strongly agree, 5 = neutral, 10 = strongly disagree) (6) Resident's ability to insert scope safely (rated by attending and self-rated, 1-10 Likert scale: 1 = strongly agree, 5 = neutral, 10 = strongly disagree) (7) Resident's ability to adequately visualize mucosa on withdrawal (8) Resident's ability to routinely reach 40cm (rated by attending and self-rated, 1-10 Likert scale: 1 = strongly agree, 5 = neutral, 10 = strongly disagree) (9) Resident's ability to perform biopsies (rated by attending and self-rated, 1-10 Likert scale: 1 = strongly agree, 5 = neutral, 10 = strongly disagree) (10) Faculty productivity during training (number of procedures completed). 	
Notes	Funding: None stated.	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement

Sedlack 2004a (Continued)

Random sequence generation (selection bias)	Unclear risk	Unclear: method of sequence generation not specified. Quote: "19 subjects were randomly assigned to complete independently a 3-hour simulator-based training curriculum and the other 19 residents underwent staff-supervised patient-based training."
Allocation concealment (selection bias)	Unclear risk	Unclear: Not specified.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Adequate: No missing outcome data. Analysis was performed on all patients randomised
Selective reporting (reporting bias)	Low risk	Adequate: Analysis and results are in accordance with the predefined study protocol
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Adequate: Unable to blind participants or personnel due to nature of intervention (outcome not likely to be influenced by lack of blinding)
Blinding of outcome assessment (detection bias) All outcomes	High risk	Inadequate: Assessing physicians were not blinded to the training status of participants. It was not stated whether the assessing patients were blinded. Quote: "... the evaluating staff was not blinded to the training curriculum undertaken by the residents..."

Sedlack 2007

Methods	<p>Study design: Prospective, randomised clinical trial.</p> <p>Endoscopy Procedure: Oesophagogastroduodenoscopy.</p> <p>Language of publication: English.</p> <p>Number of centres: Single centre.</p> <p>Year(s) of conduct of trial: Not stated.</p> <p>Generation of the allocation sequence: Not stated.</p> <p>Allocation concealment: Not stated.</p> <p>Blinding of assessors: Adequate (Physician assessors blinded).</p> <p>Inclusion of all randomised participants: 100%</p> <p>Sample size calculation: None.</p>
Participants	<p>Country: USA</p> <p>Number: 8 randomised and analysed.</p> <p>Inclusion criteria: First year gastroenterology fellows.</p> <p>Exclusion criteria: Prior endoscopy or simulator experience.</p> <p>Health profession: Medical trainees (gastroenterology fellows).</p>

	<p>Level of training: First year fellows. Endoscopy experience: None. Sex: Not stated. Age: Not stated.</p>
Interventions	<p>Participants were randomly assigned to two groups:</p> <p>GROUP 1: Virtual reality simulator training (n = 4)</p> <ul style="list-style-type: none"> - Simulator: GI Mentor II™ simulator (Simbionix USA, Cincinnati, OH, USA) - Duration of training and/or training endpoint: 6 hours (over 2 days). - Description of intervention: 6 hours of simulation training in EGD over two consecutive afternoons immediately prior to beginning patient-based training. Simulation training was comprised of a 15 minute introduction to the use of the simulator by a supervising staff member, followed by self-directed, sequential progression through a curriculum consisting of 20 EGD simulation scenarios (two modules made up of 10 cases each). For the first case and every fourth case thereafter, the participant completed a standardized scenario (module 1, case 3) to allow tracking of learning curves during simulation training. Participants were required to complete at least 21 cases (average 22 cases, range 21-25) - Observation, instruction and feedback: 15-min introduction to the use of the simulator by a supervising staff member followed by self-directed simulator use. It was not stated whether participants had access to the performance quality parameters generated by the simulator during practice. <p>GROUP 2: No Intervention (n = 4)</p> <ul style="list-style-type: none"> - Description of intervention: No intervention. - Observation, instruction and feedback: None.
Outcomes	<p>Time to assessment: Assessment began the day following simulation-based training and continued for four weeks</p> <p>Assessment model: The initial 4 weeks of staff-supervised patient-based EGD training. Each participant's performance was rated by the supervising staff member at the end of each training day, based on observation of the fellow's performance. Outcomes were compared between groups for procedures performed on days 1-5, 6-10, and 11-15</p> <p>Details of patients used for live assessment: Not specified.</p> <p>Outcome measures:</p> <ol style="list-style-type: none"> (1) Intubates safely (rated by attending, 1-5 Likert scale: 1 = strongly disagree, 4 = neutral, 7 = strongly agree) (2) Reaches the second portion of the duodenum expediently (rated by attending, 1-5 Likert scale: 1 = strongly disagree, 4 = neutral, 7 = strongly agree) (3) Completes the procedure without hands-on assistance (rated by attending, 1-5 Likert scale: 1 = strongly disagree, 4 = neutral, 7 = strongly agree) (4) Uses sedation appropriately (rated by attending, 1-5 Likert scale: 1 = strongly disagree, 4 = neutral, 7 = strongly agree) (5) Recognizes and responds to patient discomfort (rated by attending, 1-5 Likert scale: 1 = strongly disagree, 4 = neutral, 7 = strongly agree) (6) Is competent to perform EGD independently (rated by attending, 1-5 Likert scale: 1 = strongly disagree, 4 = neutral, 7 = strongly agree)

Notes	Funding: Yes (research grant).	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Unclear: method of sequence generation not specified. Quote: "...carried out in a randomised, controlled trial, where each of the eight first-year fellows was randomly assigned to one of two possible EGD training curricula."
Allocation concealment (selection bias)	Unclear risk	Unclear: Not specified.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Adequate: No missing outcome data. Analysis was performed on all patients randomised
Selective reporting (reporting bias)	Low risk	Adequate: Analysis and results are in accordance with the predefined study protocol
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Adequate: Unable to blind participants or personnel due to nature of intervention (outcome not likely to be influenced by lack of blinding)
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear: Participants instructed not to disclose their training status but blinding was not confirmed Quote: "Fellows were instructed not to reveal their arm of training to the evaluating staff but no other steps were specifically taken to ensure that evaluations were completed only by blinded staff members." And "although fellows were instructed not to disclose to their teaching staff the training arm to which they were assigned, specific blinding was not queried for individual evaluators."

Methods	<p>Study design: Prospective, randomised clinical trial.</p> <p>Endoscopy Procedure: Oesophagogastroduodenoscopy.</p> <p>Language of publication: English.</p> <p>Number of centres: Single centre.</p> <p>Year(s) of conduct of trial: October 2004 - March 2006.</p> <p>Generation of the allocation sequence: Not stated.</p> <p>Allocation concealment: Not stated.</p> <p>Blinding of assessors: Adequate (Physician assessors blinded).</p> <p>Inclusion of all randomised participants: 100%</p> <p>Sample size calculation: None.</p>
Participants	<p>Country: Japan</p> <p>Number: 20 randomised and analysed.</p> <p>Inclusion criteria: Residents rotating through gastroenterology.</p> <p>Exclusion criteria: Prior experience in performing endoscopy.</p> <p>Health profession: Medical residents.</p> <p>Level of training: Not stated.</p> <p>Endoscopy experience: No prior experience in performing endoscopy.</p> <p>Sex (M:F):</p> <ul style="list-style-type: none"> • Virtual reality simulator training group: 5:5 • Conventional endoscopy training group: 6:4 <p>Age (mean ± SD):</p> <ul style="list-style-type: none"> • Virtual reality simulator training group: 26 ± 0.77 year • Conventional endoscopy training group: 27 ± 1.91 years
Interventions	<p>All participants received a 3 hour explanation regarding manipulation of an endoscope, endoscopic observation, and endoscopic diagnosis of common diseases.</p> <p>Participants were randomly assigned to two groups:</p> <p>GROUP 1: Virtual reality simulator training followed by conventional patient-based endoscopy training (n = 10)</p> <ul style="list-style-type: none"> - Simulator: GI Mentor™ endoscopy simulator (Simbionix USA Corp., Cleveland, OH, USA) - Duration of training and/or training endpoint: Five 1 hour simulator training sessions within 2 weeks followed by 15 hours bedside teaching - Description of intervention: Five 1 hour sessions of simulator training within 2 weeks. First, the level-1 EndoBubble and EndoBasket tasks were performed three times each, and then EGD training modules were completed. Case 1-1 was performed in each session and the remaining time was used for other cases of the EGD module. Participants also received 15 hours of bedside training during which they could observe EGD performed by experienced doctors and work as an assistant, but were not allowed to perform EGD on patients - Observation, instruction and feedback: Not stated. <ul style="list-style-type: none"> • Simulated setting: “The residents were not supervised or instructed during the simulator training.” It was not stated whether participants had access to performance quality parameters generated by the simulator during practice. • Clinical setting: Staff-supervised, otherwise not specified. <p>GROUP 2: Conventional patient-based endoscopy training (n = 19)</p>

	<p>- Description of intervention: 15 hours of bedside training during which participants could observe EGD performed by experienced doctors and work as an assistant, but were not allowed to perform EGD on patients.</p> <p>- Observation, instruction and feedback: Staff-supervised, otherwise not specified.</p>
Outcomes	<p>Time to assessment: Not stated (“after completion of training schedules”).</p> <p>Assessment model:</p> <p>Two EGD procedures carried out (within one week of each other) on volunteer patients without sedation, under the supervision and evaluation of 2 attending physicians who simultaneously assessed the procedures independently of each other. After the first evaluation, the supervisors gave the resident some advice (provided orally) to improve their skills. The time limit for each item assessed (see below), besides from insertion into the oesophagus and insertion into the third part of the duodenum, was set at 2 min. Up to three attempts were allowed for insertion into the oesophagus, crossing the oesophagogastric junction, passing through the pyloric ring, and insertion into the third part of the duodenum. Instructions were provided when the supervisor considered the manoeuvre risky or when the endoscope remained at the same site for 2 minutes or greater. A manoeuvre was defined as risky when there was a possibility of mucosal injury or perforation due to insertion of the endoscope without any confirmation of the position of the lumen. When the response to the instructions was inadequate a supervisor assumed direct charge of the procedure until the next item at which time the participant resumed.</p> <p>Details of patients used for live assessment:</p> <p>Volunteers who were doctors and residents in the department. There was no significant difference in age or sex between the volunteers used within each group. Some of the volunteers had duodenal ulcer scars, hiatus hernia, or reflux oesophagitis, but the authors commented that these findings were not considered to have an influence on the difficulty of performing EGD</p> <p>Outcome measures:</p> <p>(1) Total procedure time (min).</p> <p>The following outcomes rated by two attendings (mean score used for analysis) using a 1-5 Likert scale: 1 = direct assistance by the supervisor was required; 2 = instructions were required; 3 = the resident could performed the manoeuvre without receiving instructions from the supervisor; 4 = skill was good, but not as good as that of the supervising physician; 5 = the resident could perform the manoeuvre as well as the supervising physician.</p> <p>(2) Insertion into the oesophagus. (3) Crossing the oesophagogastric junction (EGJ). (4) Passing from the EGJ into the gastric antrum. (5) Passing through the pyloric ring. (6) Examination of the duodenal bulb. (7) Insertion into the third part of the duodenum. (8) Examination of the gastric antrum. (9) Examination of the gastric angle. (10) Manipulation for retroflexion. (11) Looking down the gastric body. (12) Viewing the fornix.</p>

Notes	Funding: Yes (research grant).	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Unclear: method of sequence generation not specified. Quote: "10 residents were each randomised to simulator and non-simulator groups by envelopes."
Allocation concealment (selection bias)	Unclear risk	Unclear: Not specified. Quote: "10 residents were each randomised to simulator and non-simulator groups by envelopes."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Adequate: No missing outcome data. Analysis was performed on all patients randomised
Selective reporting (reporting bias)	Low risk	Adequate: Analysis and results are in accordance with the predefined study protocol
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Adequate: Unable to blind participants or personnel due to nature of intervention (outcome not likely to be influenced by lack of blinding)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Adequate: assessing physicians and participating patients were blinded to the training status of participants. Quote: "The supervising physicians.... were unaware of whether the residents belonged to the simulator or non-simulator group." Quote: "The volunteers did not know whether the residents were in the simulator group or not."

Methods	<p>Study design: Prospective, randomised clinical trial.</p> <p>Endoscopy Procedure: Flexible sigmoidoscopy.</p> <p>Language of publication: English.</p> <p>Number of centres: Single centre.</p> <p>Year(s) of conduct of trial: Not stated.</p> <p>Generation of the allocation sequence: Not stated.</p> <p>Allocation concealment: Not stated.</p> <p>Blinding of assessors: Not stated.</p> <p>Inclusion of all randomised participants: 100%.</p> <p>Sample size calculation: None.</p>
Participants	<p>Country: USA</p> <p>Number: 10 randomised and analysed.</p> <p>Inclusion criteria: Family medicine residents.</p> <p>Exclusion criteria: Prior flexible sigmoidoscopy experience.</p> <p>Health profession: Family medicine residents.</p> <p>Level of training: Not stated.</p> <p>Endoscopy experience: No prior flexible sigmoidoscopy experience</p> <p>Sex: Not stated.</p> <p>Age: Not stated.</p>
Interventions	<p>Participants were randomly assigned to two groups:</p> <p>GROUP 1: Virtual reality simulator training (n = 5)</p> <ul style="list-style-type: none"> - Simulator: Gastro-Sim™ flexible sigmoidoscopy simulator (Interact Medical) - Duration of training and/or training endpoint: 10 hours total (5 prior to first live patient examination). - Description of intervention: 5 hours simulation training prior to the first live patient examination and up to an additional 5 hours after the first live patient examination and prior to the second live patient examination - Observation, instruction and feedback: No guidance or training on the skills required for sigmoidoscopy other than what was encountered during the simulation. It was not stated whether participants had access to the performance quality parameters generated by the simulator during practice. <p>GROUP 2: No intervention (n = 5)</p> <ul style="list-style-type: none"> - Description of intervention: No intervention received prior to the first live patient. After the first live patient examination (and before the second) this group of residents was allowed to access the simulator to complete 5 hours of training - Observation, instruction and feedback: None.
Outcomes	<p>Time to assessment: Not stated</p> <p>Assessment model: Residents were placed in matched pairs, consisting of one resident from Group 1 and one resident from Group 2. For the first examination, the two residents in each matched pair sequentially performed a flexible sigmoidoscopy procedure on the same patient to reduce the risk of encountering a different colon structure, which could affect performance. Residents were monitored by an experienced sigmoidoscopist who inserted and retracted the sigmoidoscope at the command of the resident. The trainee performed all steering and torque maneuvers. Examinations were videotaped. For the second examination the two residents in each matched pair once again sequentially</p>

	<p>performed a flexible sigmoidoscopy procedure on the same patient. During this second examination, the paired residents performed the procedure on the volunteer patient which they had not previously examined</p> <p>Details of patients used for live assessment: Two live patient volunteers who were health men aged 25-35 who were compensated for their participation in the study</p> <p>Outcome measures:</p> <p>(1) Time to reach 30cm, 40cm, and maximal insertion (sec).</p> <p>(2) Total examination time (sec).</p> <p>(3) Total time in red-out (sec)</p> <p>(4) Quality of visualization of the colon walls (rated by attending, 1-3 Likert scale: 1 = organized, 2 = adequate, 3 = haphazard)</p> <p>(5) Estimated percentage of the colon visualized (rated from the videotape, %)</p> <p>(6) Directional errors defined as the inability of the examiner to direct the sigmoidoscopy correctly toward the lumen when it was visualized (n)</p> <p>(7) Pain (rated by patient).</p> <p>(8) Perceived confidence of the examiner (rated by patient).</p> <p>(9) Duration of examination (rated by patient).</p>	
Notes	Funding: None Stated.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Unclear: method of sequence generation not specified. Quote: "The volunteers were randomly assigned to an experimental (n=5) and a matched control (n=5 group)."
Allocation concealment (selection bias)	Unclear risk	Unclear: Not specified.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Adequate: No missing outcome data. Analysis was performed on all patients randomised
Selective reporting (reporting bias)	Low risk	Adequate: Analysis and results are in accordance with the predefined study protocol
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Adequate: Unable to blind participants or personnel due to nature of intervention (outcome not likely to be influenced by lack of blinding)
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear: participating patients were blinded to the experience and training status of participants; however, it is unclear whether the assessing physicians

Tuggy 1998 (Continued)

		<p>were blinded</p> <p>Quote: "The patient was blinded to the experience of the examiner and to which arm of the study the trainee was assigned."</p> <p>Quote: "...before the examinations the residents read a prepared script...requesting that they not reveal to which arm of the study they were assigned."</p>
--	--	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Yi 2008

Methods	<p>Study design: Quasi-randomised clinical trial.</p> <p>Endoscopy Procedure: Colonoscopy.</p> <p>Language of publication: English.</p> <p>Number of centres: Single centre.</p> <p>Year(s) of conduct of trial: October 2006 - February 2007</p> <p>Generation of the allocation sequence: Not stated.</p> <p>Allocation concealment: Not stated.</p> <p>Blinding of assessors: Not stated.</p> <p>Inclusion of all randomised participants: 100%.</p> <p>Sample size calculation: None.</p>
Participants	<p>Country: South Korea.</p> <p>Number: 11 assigned to two groups and analysed.</p> <p>Inclusion criteria: Not stated.</p> <p>Exclusion criteria: Not stated.</p> <p>Health profession: Medicine (fellows and residents)</p> <p>Level of training: Not stated (fellows and residents).</p> <p>Endoscopy experience: Not stated.</p> <p>Sex (M:F): 2:9</p> <p>Age: Not stated.</p>
Interventions	<p>All participants received basic instruction for the operation of the colonoscope and colonoscopy</p> <p>Participants were assigned (non-randomly) to two groups:</p> <p>GROUP 1: Virtual reality simulator training (n = 5)</p> <ul style="list-style-type: none"> - Simulator: KAIST-Ewha Colonoscopy Simulator II. - Duration of training and/or training endpoint: Until achievement of established training goals (scoring system based on performance criteria derived from experts' profiles) - Description of intervention: Participants practiced the targeted skills of colonoscopy using two training scenarios with different colon flexures and degrees of difficulty. Training scenario A was designed to teach practical skills to navigate the colon applying torque and up-down angulations. Scenario B was designed to teach skills to manage a loop formed in the sigmoid colon. Participants were required to practice until they reached all established training goals (scoring system based on performance criteria derived from experts' profiles). The average training time was 229.4 (range: 82-377) minutes for sce-

	<p>nario A (53.4 (range 26-100) procedures) and 232 (range 141-414) minutes for scenario B (68.2 (range: 33-105) procedures)</p> <p>- Observation, instruction and feedback: Not stated. It was not stated whether participants had access to performance quality parameters generated by the simulator during practice</p> <p>GROUP 2: No intervention (n = 6)</p> <p>- Description of intervention: No intervention.</p> <p>- Observation, instruction and feedback: None.</p>	
<p>Outcomes</p>	<p>Time to assessment: Not stated.</p> <p>Assessment model: 5 colonoscopies under the supervision of experts</p> <p>Details of patients used for live assessment: Average age for the virtual reality simulator training group was 49.6 (range 24-71) and the average age for the no intervention group was 53.5 (range 25-79)</p> <p>Outcome measures:</p> <p>(1) Insertion time (min).</p> <p>(2) Success rate.</p> <p>(3) Number of red-outs.</p> <p>(4) Number of air inflations.</p> <p>(5) Number of loop formations.</p> <p>(6) Number of abdominal pressure applications.</p> <p>(7) Number of changes in patient posture.</p> <p>(8) Mucosal visualization (rated by attending, 1-5 Likert scale: 1 = poor; 5 = excellent)</p> <p>(9) Overall performance accuracy (rated by attending, 1-5 Likert scale: 1 = poor; 5 = excellent)</p> <p>(10) Extent of abdominal pain (rated by patient. 1-5 Likert scale: 1 = no pain; 5 = worst pain)</p> <p>(11) Extent of abdominal inflation (rated by patient. 1-5 Likert scale: 1 = no pain; 5 = worst pain)</p> <p>(12) Extent of anus discomfort (rated by patient. 1-5 Likert scale: 1 = no pain; 5 = worst pain).</p>	
<p>Notes</p>	<p>Funding: Yes (research grant).</p>	
<p>Risk of bias</p>		
<p>Bias</p>	<p>Authors' judgement</p>	<p>Support for judgement</p>
<p>Random sequence generation (selection bias)</p>	<p>High risk</p>	<p>Inadequate: non-random allocation. Quote: "The fellows and residents were divided in two groups."</p>
<p>Allocation concealment (selection bias)</p>	<p>Unclear risk</p>	<p>Unclear: Not specified.</p>
<p>Incomplete outcome data (attrition bias) All outcomes</p>	<p>Low risk</p>	<p>Adequate: No missing outcome data. Analysis was performed on all patients randomised</p>

Selective reporting (reporting bias)	Low risk	Adequate: Analysis and results are in accordance with the predefined study protocol
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Adequate: Unable to blind participants or personnel due to nature of intervention (outcome not likely to be influenced by lack of blinding)
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear: Not specified.

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Ahmad 2003	Abstract from a scientific conference prior to 2008 for which no published report of this trial was identified
Cohen 2007	Erratum notice for included study Cohen 2006 .
Costamagna 2007	Commentary.
Eversbusch 2004	Outcome measured in the simulated setting.
Gerson 2004	Erratum notice for included study Gerson 2003
Haque 2006	Meta-analysis.
Hochberger 2005	Assessment of endoscopic homeostasis skills (interventional endoscopy). Outcome measured in the simulated setting
Koch 2011	Outcomes not directly compared between groups.
Kruglikova 2010	Outcome measured in the simulated setting.
Lightdale 2010	Intervention was simulation training aimed at developing skills in communication and teamwork in the endoscopy unit as opposed to virtual reality endoscopy simulation training
Maiss 2006	Assessment of endoscopic homeostasis skills (interventional endoscopy). Outcome measured in the simulated setting
Maiss 2007	Assessment of endoscopic homeostasis skills (interventional endoscopy). Outcome measured in the simulated setting

(Continued)

Matthes 2007	Review.
Mohamed 2009	Participants do not meet inclusion criteria for review (completed > 10 colonoscopies prior to intervention), randomisation unclear
Sturm 2008	Systematic review.
Yi 2007	A realism-validation study. Not a randomised trial.

Characteristics of studies awaiting assessment [ordered by study ID]

Rosch 2011

Methods	Study design: Prospective, randomised clinical trial. Endoscopy Procedure: Colonoscopy and oesophagogastroduodenoscopy (EGD). Number of centres: Single centre. Year(s) of conduct of trial: 2011 Sample size calculation: None.
Participants	Country: Germany Number: Estimated sample size is 36. Inclusion criteria: Physicians in residency or fellowship programs requiring training in flexible endoscopy (gastroenterology, internal medicine, surgery) Exclusion criteria: Prior flexible endoscopy experience. Health profession: Gastroenterology, internal medicine, and surgery residents. Level of training: Not stated. Endoscopy experience: None.
Interventions	Participants randomly assigned to three groups (3 different training intervals on an endoscopy simulator): GROUP 1: Basic virtual reality simulator training - Simulator: Simbionix simulator. - Duration of training and/or training endpoint: 1 hour EGD simulator training and 1 hour colonoscopy simulator training - Description of intervention: A theory lecture on EGD. 1 hour simulator training for EGD. 30 minutes supervised training. Supervised endoscopy. A theory lecture on colonoscopy. One hour simulator training for colonoscopy. 30 minutes supervised training. Supervised endoscopy. Group will be followed up for 2 weeks training time - Observation, instruction and feedback: Not clearly stated. GROUP 2: Intermediate virtual reality simulator training - Simulator: Simbionix simulator. - Duration of training and/or training endpoint: 3 hours EGD simulator training and 3 hours colonoscopy simulator training - Description of intervention: A theory lecture on EGD. 3 hours simulator training for EGD. 60 minutes supervised training. Supervised endoscopy. A theory lecture on colonoscopy. 3 hours simulator training for colonoscopy. 60 minutes supervised training. Supervised endoscopy. Group will be followed up for 4 weeks training time - Observation, instruction and feedback: Not clearly stated. GROUP 3: Expanded virtual reality simulator training

Rosch 2011 (Continued)

	<p>- Simulator: Simbionix simulator.</p> <p>- Duration of training and/or training endpoint: 5 hours EGD simulator training and 5 hours colonoscopy simulator training</p> <p>- Description of intervention: A theory lecture on EGD. 5 hours simulator training for EGD. 90 minutes supervised training. Supervised endoscopy. A theory lecture on colonoscopy. 5 hours simulator training for colonoscopy. 90 minutes supervised training. Supervised endoscopy. Group will be followed up for 6 weeks training time</p> <p>- Observation, instruction and feedback: Not clearly stated.</p>
Outcomes	<p>Time to assessment: Group 1 (basic training) evaluated after 1 week of training, Group 2 (intermediate training) evaluated after 2 weeks of training and Group 3 (expanded training) evaluated after 3 weeks of training</p> <p>Assessment model: Proficiency scores evaluated by a supervising physician blinded to group allocation</p> <p>Details of patients used for live assessment: Not stated.</p> <p>Outcome measures:</p> <p>(1) Validated proficiency score based - Global assessment for Gastrointestinal Endoscopy (Vassiliou 2010) based on intubation, scope navigation, ability to keep a clear endoscopic visualization and instrumentation</p>
Notes	<p>Funding: None stated.</p> <p>- There is no published report of this trial which was identified from a trial registry</p>

DATA AND ANALYSES

Comparison 1. Comparison 1: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training)

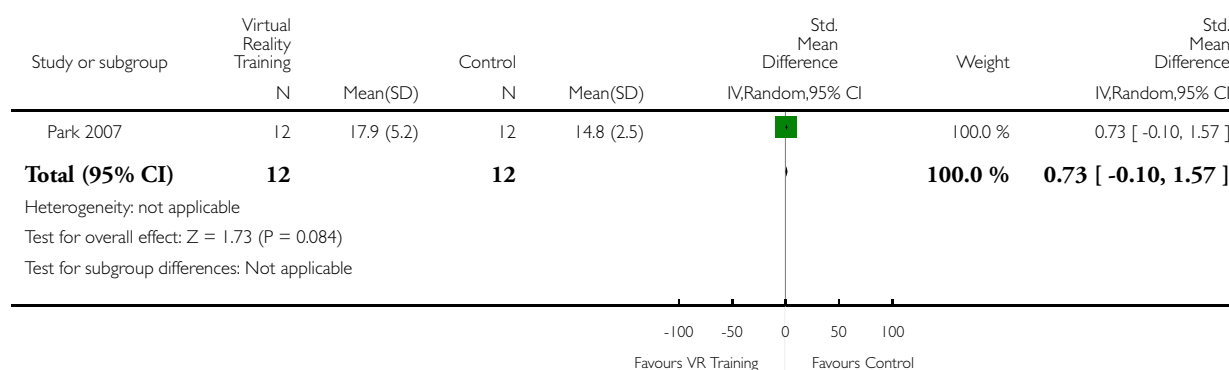
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Composite Score of Competency	1	24	Std. Mean Difference (IV, Random, 95% CI)	0.73 [-0.10, 1.57]
2 Independent Procedure Completion	7	899	Risk Ratio (M-H, Random, 95% CI)	1.30 [0.84, 2.01]
3 Performance Time	2	27	Std. Mean Difference (IV, Random, 95% CI)	-0.19 [-0.96, 0.58]
4 Patient Discomfort	1	110	Std. Mean Difference (IV, Random, 95% CI)	-0.45 [-1.14, 0.24]
5 Overall Global Rating of Performance or Competency	1	16	Std. Mean Difference (IV, Random, 95% CI)	-0.23 [-1.22, 0.76]
6 Visualization of Mucosa	1	55	Std. Mean Difference (IV, Random, 95% CI)	0.79 [0.24, 1.34]

Analysis 1.1. Comparison 1 Comparison 1: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training), Outcome 1 Composite Score of Competency.

Review: Virtual reality simulation training for health professions trainees in gastrointestinal endoscopy

Comparison: 1 Comparison 1: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training)

Outcome: 1 Composite Score of Competency

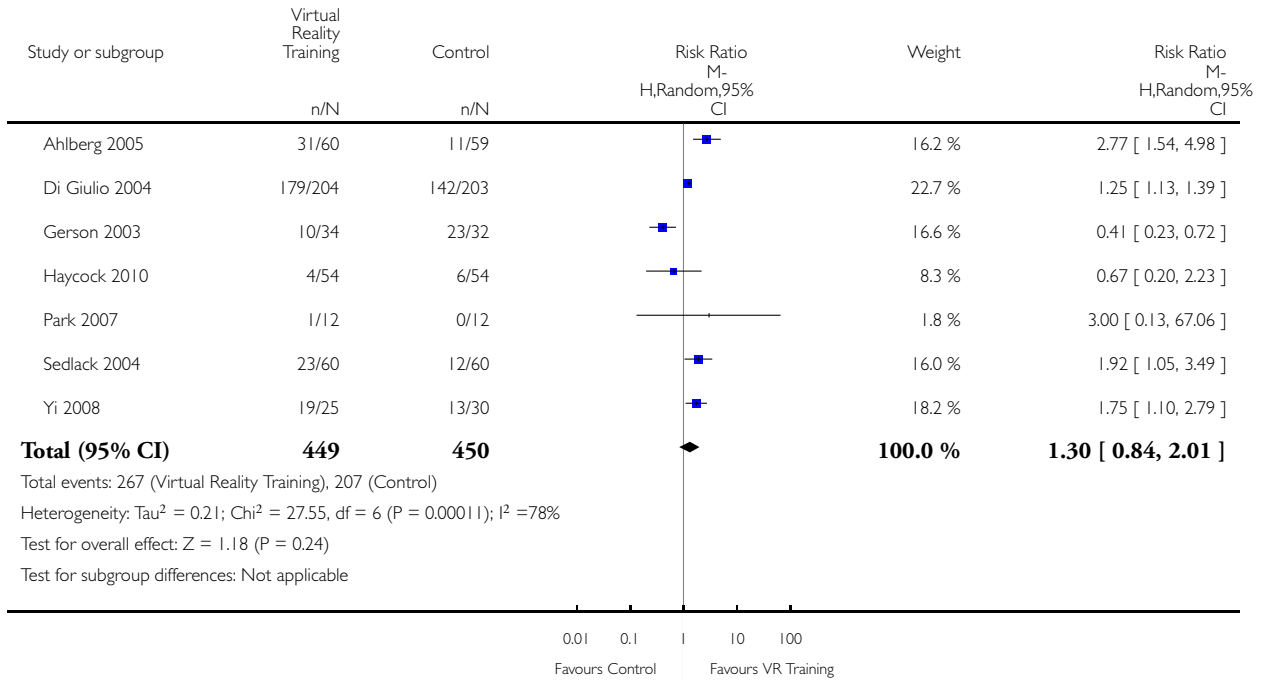


Analysis 1.2. Comparison 1 Comparison 1: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training), Outcome 2 Independent Procedure Completion.

Review: Virtual reality simulation training for health professions trainees in gastrointestinal endoscopy

Comparison: 1 Comparison 1: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training)

Outcome: 2 Independent Procedure Completion

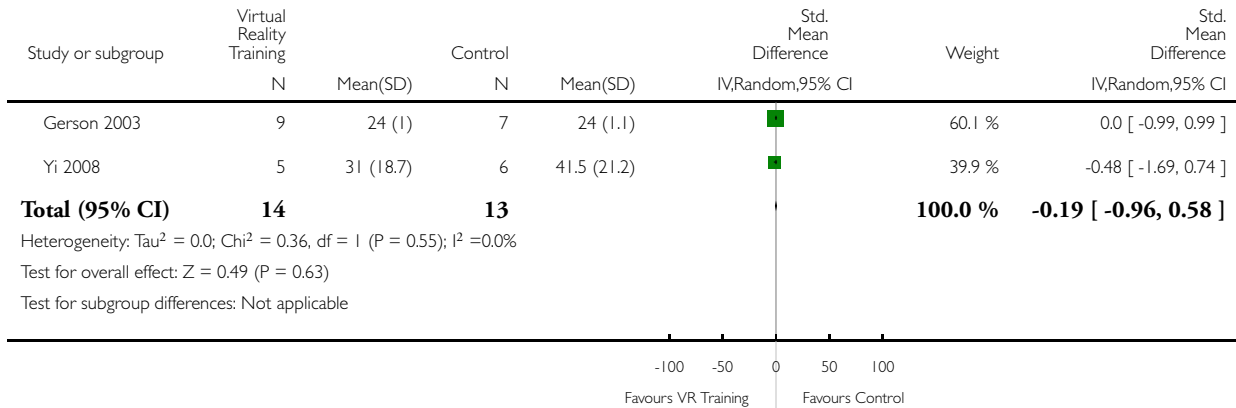


Analysis 1.3. Comparison 1 Comparison 1: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training), Outcome 3 Performance Time.

Review: Virtual reality simulation training for health professions trainees in gastrointestinal endoscopy

Comparison: 1 Comparison 1: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training)

Outcome: 3 Performance Time

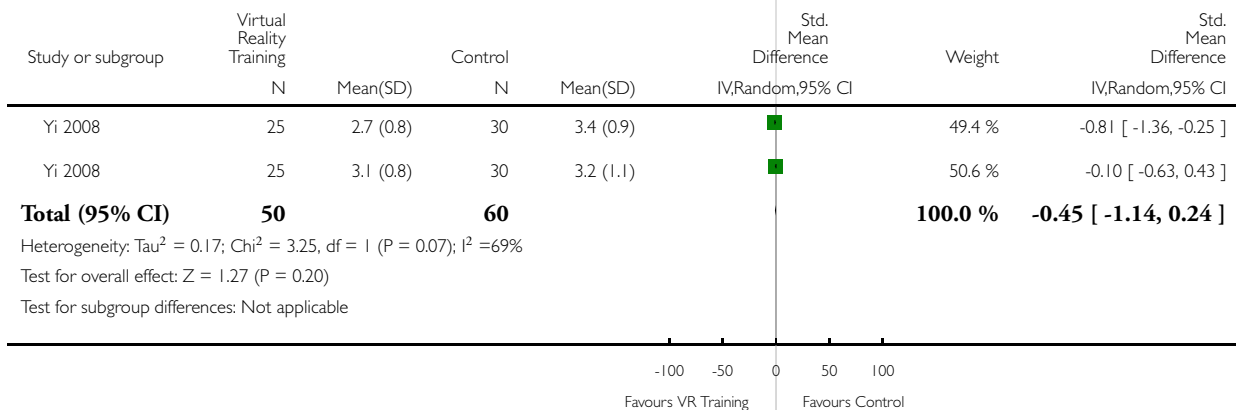


Analysis 1.4. Comparison 1 Comparison 1: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training), Outcome 4 Patient Discomfort.

Review: Virtual reality simulation training for health professions trainees in gastrointestinal endoscopy

Comparison: 1 Comparison 1: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training)

Outcome: 4 Patient Discomfort

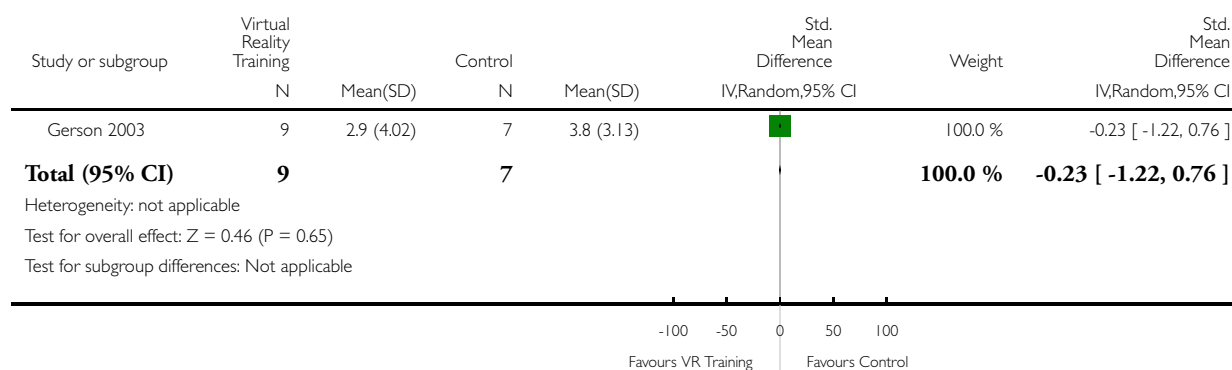


Analysis 1.5. Comparison 1 Comparison 1: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training), Outcome 5 Overall Global Rating of Performance or Competency.

Review: Virtual reality simulation training for health professions trainees in gastrointestinal endoscopy

Comparison: 1 Comparison 1: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training)

Outcome: 5 Overall Global Rating of Performance or Competency

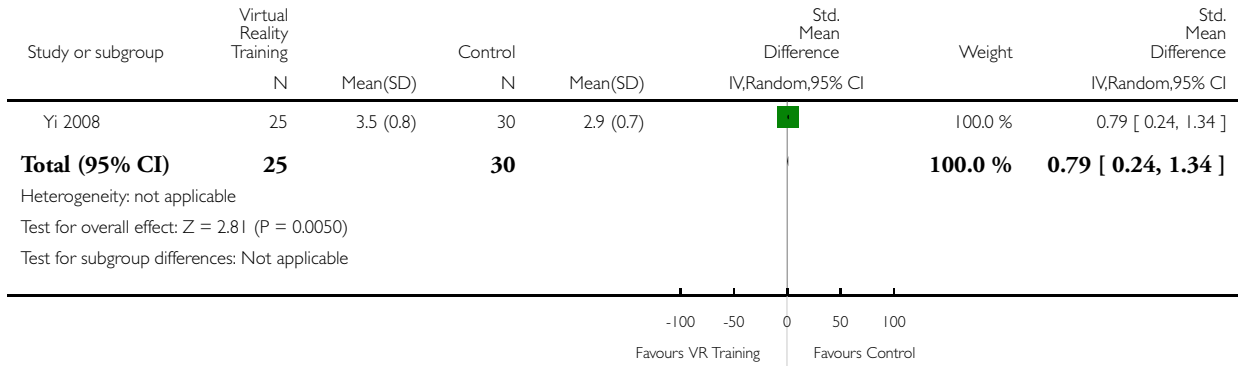


Analysis 1.6. Comparison 1 Comparison 1: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training), Outcome 6 Visualization of Mucosa.

Review: Virtual reality simulation training for health professions trainees in gastrointestinal endoscopy

Comparison: 1 Comparison 1: Virtual Reality Endoscopy Simulation Training versus Control (other method of endoscopy training or no training)

Outcome: 6 Visualization of Mucosa



ADDITIONAL TABLES

Table 1. Table 1: Details of Training and Assessment

Study	Simulator	Procedure	Train- ing Endpoint for VR Sim- ulator Train- ing Group	Comparison Group	Assessment in the Clini- cal Setting	Assessment Scoring	Assessment Validation
Ahlberg 2005	AccuTouch™ VR endoscopy simulator.	Colonoscopy.	Attainment of pre- defined expert level of per- formance on a VR examina- tion case (1- 2 hours VR training over at least 4 days, median total time = 20 hours)	No interven- tion.	10 patient- based colono- scopies.	Objective: (1) Time (time to reach cae- cum or total procedure time in unsuc- cessful cases) (2) Com- pleted proce- dure rate. (3) Seg- ment of colon where proce- dure stopped.	Not stated.

Table 1. Table 1: Details of Training and Assessment (Continued)

						<p>(4) Analgesic drugs given. (5) Complications.</p> <p>Rater-based (rated by blinded assessor): (1) Reason for stopping procedure (if applicable).</p> <p>Rater-based (rated by blinded patient): (1) Maximum discomfort.</p>	
Cohen 2006	GI Mentor™ VR endoscopy simulator.	Colonoscopy.	10 hours VR training (5 two-hour sessions over a maximum of 8 weeks)	No intervention.	200 patient-based colonoscopies (or number performed prior to study completion). Outcomes were compared for every group of 20 cases (i.e., procedures 0-20, 21-40, 41-60, etc.)	<p>Objective: (1) Objective competence defined as (a) ability to reach transverse colon and caecum without assistance and (b) ability to correctly recognize and identify abnormalities (2) Median number cases required to reach 90% competence.</p> <p>Rater-based (rated by blinded assessor): (1) Overall rating of com-</p>	Authors report evaluation form (rating ability to reach transverse colon and caecum, ability to correctly recognize and identify abnormalities and overall competency) used in previous study (Cass 1996). Other measures not stated.

Table 1. Table 1: Details of Training and Assessment (Continued)

							petency. (2) Patient-discomfort.	
							Rater-based (self-rated): (1) Usefulness of simulation training.	
Di 2004	Giulio	GI Mentor™ VR endoscopy simulator.	EGD.	10 hours VR training. (over 3-5 sessions).	No intervention.	20 consecutive patient-based EGDs.	Objective: (1) Number of times manual assistance required. (2) Number of times verbal assistance required. (3) Number of identified or missed lesion. (4) Number of complications. (5) Failure to effect oesophageal intubation. (6) Number of attempts at oesophageal intubation. Rater-based (rated by non-blinded assessor): (1) Completeness of procedure. (2) Overall judgement of performance.	Not stated.
Ferlitsch 2010		GI Mentor™ VR endoscopy simulator.	EGD.	2 hours VR train-	No intervention.	10 consecutive patient-	Objective: (1) Total time.	The authors stated

Table 1. Table 1: Details of Training and Assessment (Continued)

			ing per day for 5-20 hours total (range 5-20 hours, median 10 hours)		based EGDs. Outcomes were compared for procedures 1-10 and 51-60	(2) Time to reach descending duodenum. (3) Diagnostic accuracy. Rater-based (rated by non-blinded assessor): (1) Intubation of oesophagus completed “unaided, ” with “expert help” or “expert takeover.” (2) Pyloric passage completed “unaided, ” with “expert help” or “expert takeover.” (3) Retroflexion in gastric fundus completed “unaided, ” with “expert help” or “expert takeover.” Rater-based (rated by blinded patient): (1) Discomfort.	that the “parameters chosen in our evaluation were suitable for discriminating endoscopic examinations performed by experts from those performed by beginners, documenting the validity of the method.”
Gerson 2003	AccuTouch™ VR endoscopy simulator.	Sigmoidoscopy.	2 weeks unlimited VR training (average time (mean ± SEM): 138 ± 28 minutes)	Conventional patient-based training (10 sigmoidoscopies in clinical setting over 2 weeks)	5 patient-based sigmoidoscopies.	Objective: (1) Independent completion. (2) Examination duration. (3) Requirement for assistance.	Not Stated.

Table 1. Table 1: Details of Training and Assessment (Continued)

						<p>(4) Flexure recognition. (5) Completion of retroflexion. (6) Ability to recognize pathology.</p> <p>Rater-based (rated by non-blinded assessor): (1) Expert global rating.</p> <p>Rater-based (rated by blinded patient): (1) Level of patient comfort/discomfort. (2) Patient satisfaction. (3) Technical competence.</p>	
Haycock 2010	Endo TS-1™ Olympus colonoscopy simulator	Colonoscopy.	16 hours.	Conventional patient-based training (16 hours, minimum 8 colonoscopies)	3 patient-based colonoscopies.	<p>Objective: (1) Time to completion. (2) Depth of insertion.</p> <p>Rater-based (rated by blinded assessor): (1) Modified UK Joint Advisory Group (JAG) Colonoscopy Direct Observation of Procedural Skills</p>	The UK JAG DOPS form has been validated as a whole (Barton 2008); however, the abbreviated version utilized in this study has not been validated. The authors report the Global Performance Score is 'val-

Table 1. Table 1: Details of Training and Assessment (Continued)

						(DOPS) assessment form (JAG Central Office 2010). (2) Global Performance Score (Park 2007).	validated'; however, no details of validation provided in reference source (Park 2007). Other measures not stated.
Park 2007	AccuTouch™ VR endoscopy simulator.	Colonoscopy.	2-3 hours VR training.	No intervention.	1 patient-based colonoscopy.	Objective: (1) Ability to independently reach the caecum. (2) Number of critical flaws. Rater-based (rated by blinded assessor): (1) Global Performance Score.	Authors report Global Performance Score is 'validated'; however, no reference or details of validation provided Other measures not stated.
Sedlack 2004	AccuTouch™ VR endoscopy simulator.	Colonoscopy.	6 hours VR training over 2 days. Previously validated curriculum (Sedlack 2002).	No intervention.	4-8 weeks of patient-based colonoscopy training. Outcomes were compared between groups for procedures 1-15, 16-30, 31-45 and 46-60	Objective: (1) Time to reach maximum insertion. (2) Depth of insertion. (3) Independent procedure completion. (4) Faculty productivity. Rater-based (rated by non-blinded assessor): (1) Ability	Not stated.

Table 1. Table 1: Details of Training and Assessment (Continued)

						<p>to identify endoscopic landmarks.</p> <p>(2) Ability to insert in a safe manner.</p> <p>(3) Ability to adequately visualize mucosa on withdrawal.</p> <p>(4) Ability to respond appropriately to patient discomfort.</p> <p>Rater-based (rated by patient, unclear if blinded):</p> <p>(1) Patient discomfort.</p>	
Sedlack 2004a	AccuTouch™ VR endoscopy simulator.	Sigmoidoscopy.	3 hours VR training followed by 6 hours (over 2 days) patient-based endoscopy training	Conventional patient-based training (9 hours over 3 days).	3 hours of patient-based flexible sigmoidoscopy.	<p>Objective:</p> <p>(1) Faculty productivity.</p> <p>Rater-based (rated by non-blinded assessor and self-rated):</p> <p>(1) Resident's ability to respond to patient discomfort.</p> <p>(2) Resident's ability to perform flexible sigmoidoscopy independently</p> <p>(3) Resident's ability to identify pathology.</p>	Not stated.

Table 1. Table 1: Details of Training and Assessment (Continued)

						<p>(4) Resident's ability to identify landmarks.</p> <p>(5) Resident's ability to insert scope safely.</p> <p>(6) Resident's ability to adequately visualize mucosa on withdrawal</p> <p>(7) Resident's ability to routinely reach 40cm.</p> <p>(8) Resident's ability to perform biopsies.</p> <p>Rater-based (rated by patient, unclear if blinded):</p> <p>(1) Patient discomfort.</p>	
Sedlack 2007	GI Mentor™ VR endoscopy simulator.	EGD.	6 hours VR training (over 2 days).	No intervention.	4 weeks patient-based EGD training. Outcomes were compared between groups for procedures performed on days 1-5, 6-10, and 11-15	<p>Objective:</p> <p>- None</p> <p>Rater-based (rated assessor, unclear if blinded):</p> <p>(1) Intubates safely.</p> <p>(2) Reaches the second portion of the duodenum expeditiously.</p> <p>(3) Completes the procedure without hands-on assistance.</p> <p>(4) Uses sedation appropriate.</p>	Not stated.

Table 1. Table 1: Details of Training and Assessment (Continued)

						ately. (5) Recognizes and responds to patient discomfort. (6) Is competent to perform EGD independently.	
Shirai 2008	GI Mentor™ VR endoscopy simulator.	EGD.	Five 1-hour VR training sessions over 2 weeks plus 15 hours patient-based training (observed or assisted)	Conventional patient-based training (15 hours, observed or assisted)	2 patient-based EGDs.	<p>Objective: (1) Total procedure time.</p> <p>Rater-based (rated by blinded assessor): (1) Insertion into the oesophagus. (2) Crossing the oesophago-gastric junction (EGJ). (3) Passing from the EGJ into the gastric antrum. (4) Passing through the pyloric ring. (5) Examination of the duodenal bulb. (6) Insertion into the third part of the duodenum. (7) Examination of the gastric antrum. (8) Examination of the gas-</p>	Not stated.

Table 1. Table 1: Details of Training and Assessment (Continued)

						<p>tric angle. (9) Manipulation for retroflexion. (10) Looking down the gastric body. (11) Viewing the fornix.</p>	
Tuggy 1998	Gastro-Sim™ VR endoscopy simulator.	Sigmoidoscopy.	5 hours VR training.	No intervention.	1 patient-based flexible sigmoidoscopy.	<p>Objective: (1) Time to reach 30cm, 40cm, and maximal insertion. (2) Total examination time. (3) Total time in red-out.</p> <p>Rater-based (rated by assessor, unclear if blinded): (1) Estimated percentage of colon visualized. (2) Number of directional errors. (3) Quality of visualization of colon walls.</p> <p>Rater-based (rated by blinded patient): (1) Pain. (2) Perceived confidence of the examiner. (3) Duration of examination.</p>	Not stated.

Table 1. Table 1: Details of Training and Assessment (Continued)

Yi 2008	KAIST-Ewha Colonoscopy Simulator.	Colonoscopy.	Attainment of predefined expert level of performance on VR simulator (2 practice scenarios, mean practice time 229.4 (53.4 procedures) and 232 minutes (68.2 procedures) for scenario A and B)	No intervention.	5 patient-based colonoscopies.	<p>Objective:</p> <ol style="list-style-type: none"> (1) Insertion time. (2) Success rate. (3) Number of red-outs. (4) Number of air inflations. (5) Number of loop formations. (6) Number of abdominal pressure applications. (7) Number of changes in patient posture. <p>Rater-based (rated by assessor, unclear if blinded):</p> <ol style="list-style-type: none"> (1) Mucosal visualization (rated by attending). (2) Overall performance accuracy. (3) Extent of abdominal pain. (4) Extent of abdominal inflation. (5) Extent of anus discomfort. 	Not stated.
---------	-----------------------------------	--------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------	--------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------

EGD = oesophagogastroduodenoscopy

VR = virtual reality

Table 2. Table 2: Summary of Outcomes - Composite Score of Competency in Performing Endoscopy

Study	Procedure	Comparison Group	Method	VR versus No Training	VR versus Conventional Endoscopy Training
Haycock 2010	Colonoscopy	Conventional patient-based training	<p>1) Procedural proficiency (rated by attending using abbreviated version of UK JAG DOPS colonoscopy assessment form which rated 9 domains of 'endoscopic skills during insertion and withdrawal' on a 1-4 point scale)</p> <p>2) Global performance score (rated by attending, 7 domains rated on a 1-5 Likert scale: atraumatic technique, colonoscope advancement, use of instrument controls, flow of procedure, use of assistants, knowledge of specific procedure, overall performance)</p>		<p>1) Procedural proficiency (JAG DOPS) Median score 16 (IQR (14, 22) for VR group versus 18 (IQR 14, 21) for control group No significant difference between groups, P = 0.92</p> <p>2) Global performance Median score 18 (IQR 14, 19) for VR group versus 17 (IQR 14, 19) for control group No significant difference between groups, P = 0.35</p>
Park 2007	Colonoscopy	No training	Global performance score (rated by attending, 7 domains rated on a 1-5 Likert scale: atraumatic technique, colonoscope advancement, use of instrument controls, flow of procedure, use of assistants, knowledge of specific procedure, overall performance)	Mean score 17.9 (SD 5.2) for VR group versus 14.8 (SD 2.5) for control group SMD 0.73 [-0.10, 1.57] VR trained group had significantly higher scores, P = 0.04	

DOPS = Direct Observation of Procedural Skills

IQR = Interquartile range

JAG = Joint Advisory Group

SD = Standard deviation

SMD = Standardized mean difference

VR = Virtual reality

Table 3. Table 3: Summary of Outcomes - Independent Procedure Completion

Study	Procedure	Comprison Group	Method	VR versus No Training	VR versus Conventional Endoscopy Training
Ahlberg 2005	Colonoscopy	No training	Completed procedure rate (intubation of caecum within given time limit)	RR 2.77 [1.54, 4.98] VR trained group completed significantly more procedures independently, P = 0.0011	
Di Giulio 2004	EGD	No training	Number of complete procedures (Completeness of procedure (rated by attending, "complete" = oesophageal intubation achieved, participant identified, within 20 minutes, all anatomical landmarks (oesophagogastric mucosal junction, gastric angulus, pylorus) and performed certain basic manoeuvres (aspiration of gastric juice, pylorus intubation in no more than 3 attempts, duodenal bulb exploration, intubation of the second part of the duodenum and retroflexion) without verbal direction)	RR 1.25 [1.13, 1.39] VR trained group completed significantly more procedures independently, P < 0.0001	
Gerson 2003	Sigmoidoscopy	Conventional patient-based training	Independent completion (yes/no)		RR 0.41 [0.23, 0.72] VR trained group completed significantly fewer procedures, P = 0.02
Haycock 2010	Colonoscopy	Conventional patient-based training	Completion of case - insertion to caecum independently (yes/no)		RR 0.67 [0.20, 2.23] No significant difference between groups, P = 0.51

Table 3. Table 3: Summary of Outcomes - Independent Procedure Completion (Continued)

Park 2007	Colonoscopy	No training	Ability to independently reach the caecum (yes/no)	RR 3.00 [0.13, 67.06] No significant difference between groups, P > 0.05	
Sedlack 2004	Colonoscopy	No training	Independent procedure completion defined as independently reaching the caecum or terminal ileum (yes/no)	RR 1.92 [1.05, 3.49] VR trained group completed significantly more procedures, P = 0.027 (procedures 1-15)	
Yi 2008	Colonoscopy	No training	Success rate	RR 1.75 [1.10, 2.79] VR trained group completed significantly more procedures, P = 0.006	

IQR = Interquartile range

JAG = Joint Advisory Group

SD = Standard deviation

SMD = Standardized mean difference

VR = Virtual reality

Table 4. Table 4: Summary of Outcomes - Performance Time

Study	Procedure	Comparison Group	Method	VR versus No Training	VR versus Conventional Endoscopy Training
Ahlberg 2005	Colonoscopy	No training	Time to reach caecum in successful cases (min)	Median 30 min (IQR17-38) for VR group versus 40 min (IQR 25-45) control group VR trained group significantly faster, P = 0.008	
Di Giulio 2004	EGD	No training	Duration of procedure (defined as the length of time the light source was switched on)	Mean 10.5 min for VR group versus 12.4 min for control group No significant difference between groups, P > 0.05	

Table 4. Table 4: Summary of Outcomes - Performance Time (Continued)

Ferlitsch 2010	EGD	No training	Time between the first attempt at oesophageal intubation until the descending part of duodenum was reached (measured after 10 endoscopic examinations)	Mean 239 secs (range 50-620) for VR group versus 310 secs (range 110-720) for control group VR trained group significantly faster, $P < 0.0001$ (procedures 1-10)	
Gerson 2003	Sigmoidoscopy	Conventional patient-based training	Examination duration (min)		Mean 24 min (SEM 1.0) for VR group versus 24 min (SEM 1.1.) for control group SMD 0.00 [-0.99, 0.99] No significant difference between groups, $P > 0.05$
Haycock 2010	Colonoscopy	Conventional patient-based training	Time to completion in complete cases		Median 20 min (IQR: 20, 20) for VR group versus 20 min (IQR 19, 20) for control group No significant difference between groups, $P < 0.11$
Sedlack 2004	Colonoscopy	No training	Time to reach maximum insertion (min)	Median 23 min (IQR 19-30) for VR group versus 23 min (IQR 20-30) for control No significant difference between groups, $P = 0.16$ (procedures 1-15)	
Shirai 2008	EGD	Conventional patient-based training	Total procedure time (min)		14:40 min (12:15-16:07) for VR group versus 14:05 min (13:30-16:00) for control group No significant difference between groups, $P > 0.05$

Table 4. Table 4: Summary of Outcomes - Performance Time (Continued)

Tuggy 1998	Sigmoidoscopy	No training	Total examination time (sec)	<p><i>5 hours VR training:</i> Mean 530 sec for VR group after 5 hours training versus 654 sec for control group No significant difference between groups, P = 0.31</p> <p><i>6-10 hours VR training:</i> Mean 323 sec for VR group after 6-10 hours training versus 654 sec for control group VR group significantly faster, P = 0.01</p>
Yi 2008	Colonoscopy	No training	Total insertion time (min)	<p>Mean 31 min (SD 18.7) for VR group versus 41.5 min (SD 21.2) for control group SMD -0.48 [-1.69, 0.74] VR trained group significantly faster, P = 0.028</p>

IQR = Interquartile range

SD = Standard deviation

SEM = Standard error of the mean

SMD = Standardized mean difference

VR = Virtual reality

Table 5. Table 5: Summary of Outcomes - Complication or Critical Flaw Occurrence

Study	Procedure	Comparison Group	Method	VR versus No Training	VR versus Conventional Endoscopy Training
Ahlberg 2005	Colonoscopy	No training	Complications (n)	<p>No complications in either group No significant difference between groups, P > 0.05</p>	

Table 5. Table 5: Summary of Outcomes - Complication or Critical Flaw Occurrence (Continued)

Di Giulio 2004	EGD	No training	Complications (n)	No complications in either group No significant difference between groups, $P > 0.05$	
Gerson 2003	Sigmoidoscopy	Conventional patient-based training	Adverse events (n)		No adverse events occurred in either group No significant difference between groups, $P > 0.05$
Park 2007	Colonoscopy	No training	Number of critical flaws (perforation or bleeding) during the procedure (n)	No complications in either group No significant difference between groups, $P > 0.05$	
Sedlack 2004a	Sigmoidoscopy	Conventional patient-based training	Number of adverse events (n)		No complications in either group No significant difference between groups, $P > 0.05$

n = number

Table 6. Table 6: Summary of Outcomes - Independent Insertion Depth

Study	Procedure	Comparison Group	Method	VR versus No Training	VR versus Conventional Endoscopy Training
Ahlberg 2005	Colonoscopy	No training	Segment of colon where procedure was stopped (9 consecutive segments - rectosigmoid angle, sigmoid colon sigmoid-descending colon junction, descending colon, left flexure, transverse colon, right flexure, ascending colon, caecum)	VR trained group: 3% rectosigmoid angle, 8% sigmoid colon, 7% sigmoid-descending colon, 13% left flexure, 7% transverse colon, 7% right flexure, 3% ascending colon and 52% caecum Control group: 10% rectosigmoid angle, 5% sigmoid colon, 17% sigmoid-descending colon, 3.5% descending colon, 15%	

Table 6. Table 6: Summary of Outcomes - Independent Insertion Depth (Continued)

				left flexure, 10% transverse colon, 12% right flexure, 8.5% descending colon and 19% caecum VR trained group inserted endoscope significantly further, $P < 0.05$	
Haycock 2010	Colonoscopy	Conventional patient-based training	Maximum tip position (sigmoid, descending, transverse, ascending caecum)		VR trained group: 54% sigmoid, 15% descending, 20% transverse, 0% ascending, 11% caecum Control group: 52% sigmoid, 22% descending, 15% transverse, 4% ascending, 7% caecum No difference between groups, $P = 0.73$
Sedlack 2004	Colonoscopy	No training	Depth of unassisted insertion (1 = rectum, 2 = sigmoid, 3 = splenic flexure, 4 = hepatic flexure, 5 = caecum, 6 = terminal ileum)	Median 4 (IQR 3-5) for VR group versus 3 (IQR 2-4) for control VR trained group inserted endoscope significantly further, $P = 0.003$ (procedures 1-15)	

IQR = Interquartile range

VR = Virtual reality

Table 7. Table 7: Summary of Outcomes - Patient Discomfort

Study	Procedure	Comparison Group	Method	VR versus No Training	VR versus Conventional Endoscopy Training
Ahlberg 2005	Colonoscopy	No training	Maximum discomfort (rated by patient, visual analogue scale)	Median 4 (IQR 2.5-6) for VR group versus 5 (IQR 4-7) for control group Significantly less pain in VR trained group, P	

Table 7. Table 7: Summary of Outcomes - Patient Discomfort (Continued)

				= 0.02	
Cohen 2006	Colonoscopy	No training	Patient discomfort level (rated by attending, 1-5 Likert scale: 1 = very comfortable to 5 = severe pain)	Mean 25.7 for VR group versus 31.4 for control group No significant difference between groups, P = 0.42 (procedures 1-20)	
Ferlitsch 2010	EGD	No training	Pain and discomfort (rated by patient, 2 separate 10-cm visual analogue scales for pain and discomfort)	<i>Discomfort:</i> Median discomfort for 1 st 10 procedures was 16 (range 0-98) for VR group versus 20 (range 9-100) for control group No significant difference in discomfort between groups, P = 0.53 (procedures 1-10) <i>Pain:</i> Median pain for 1 st 10 procedures was 9 (range 0-100) for VR group versus 8 (1-100) for control group No significant difference in pain between groups, P = 0.24 (procedures 1-10)	
Gerson 2003	Sigmoidoscopy	Conventional patient-based training	Level of patient pain and discomfort (rated by patient, 1-5 Likert scale: 1 = strongly agree; 2 = agree; 3 = not sure; 4 = disagree; 5 = strongly disagree)		53% patients in the VR group versus 42% in the control group agreed they "had a lot of pain" 43% patients in the VR group versus 31% in the control group agreed the procedure "caused great discomfort" No significant difference between groups, P > 0.05

Table 7. Table 7: Summary of Outcomes - Patient Discomfort (Continued)

Sedlack 2004	Colonoscopy	No training	Patient discomfort (rated by patient, 10 point scale: 1 = minimal or no pain, 10 = worst pain of life)	Median patient-rated discomfort 2 (IQR 1-4) for VR group versus 4 (IQR 1.5-5) for control group Statistically significantly less pain in VR trained group, P = 0.019 (procedures 1-15)	
Sedlack 2004a	Sigmoidoscopy	Conventional patient-based training	Pa-tient discomfort (rated by patient, 1-10 Likert scale: 1 = no pain, 10 = worst pain of life)		Median patient-rated discomfort 3 (IQR 2-5) for VR group versus 4 (IQR 2-6) for control group Statistically significantly less pain in VR trained group, P < 0.01
Tuggy 1998	Sigmoidoscopy	No training	Pain scale (rated by patient)	No significant difference between groups, P > 0.05	
Yi 2008	Colonoscopy	No training	Extent of abdominal pain and anus discomfort (rated by patient. 1-5 Likert scale: 1 = no pain; 5 = worst pain)	<i>Abdominal Pain:</i> Mean patient-rated abdominal pain 3.1 (SD 0.8) for VR group and 3.2 (SD 1.1) for the control group SMD: -0.10 [-0.63, 0.43] <i>Anus Discomfort:</i> Mean patient-rated anus discomfort 2.7 (SD 0.8) for the VR group and 3.4 (SD 0.9) for the control group SMD: -0.81 [-1.36, -0.25]	

IQR = Interquartile range

SD = Standard deviation

SMD = Standardized mean difference

VR = Virtual reality

Table 8. Table 8: Summary of Outcomes - Overall Global Rating of Performance or Competency

Study	Procedure	Comparison Group	Method	VR versus No Training	VR versus Conventional Endoscopy Training
Cohen 2006	Colonoscopy	No training	<p>Overall objective rating of competency (ability to reach the transverse colon and the caecum without assistance, and the ability to correctly recognize and identify abnormalities)</p> <p>Overall subjective rating of competency (rated by attending, 1-5 Likert scale: 1 = totally unskilled, 5 = competent and expedient)</p>	<p><i>Objective Competency:</i> Mean score 50.4 for VR group versus 40.9 for control group Statistically significantly more positive ratings in VR trained group, P = 0.06 (procedures 1-20)</p> <p><i>Subjective Competency:</i> Mean score 47.6 for VR group versus 36.6 for control group Statistically significantly more positive ratings in VR trained group, P = 0.08 (procedures 1-20)</p>	
Di Giulio 2004	EGD	No training	<p>Expert global rating of performance based on “completeness” of the examination, the need for assistance, and the presumed difficulty of the procedure. (rated by attending, 0-10 Likert scale with a procedure receiving a score of 5 or less being classified as “negative” and a procedure receiving a score of 6 or more as “positive” : 0 = bad; 10 = good)</p>	<p>86.8% positive scores for VR group versus 56.7% for control group Statistically significantly more positive ratings in VR trained group, P = < 0.0001</p>	
Gerson 2003	Sigmoidoscopy	Conventional patient-based training	<p>Expert global rating (rated by attending, 1-5 Likert scale: 1 = unable to clear the rectum; 2 = unable to</p>		<p>Mean score 2.9 (SEM 0.2) for VR group versus 3.8 (SEM 0.2) for control group SMD -0.23 [-1.22, 0.</p>

Table 8. Table 8: Summary of Outcomes - Overall Global Rating of Performance or Competency (Continued)

			clear the rectosigmoid junction; 3 = unable to pass one turn without assistance; 4 = able to perform independently, but more than 20 mins required; 5 = independent examination less than 20 mins duration)		76] VR group had significantly lower scores than the control group, P < 0.001
Sedlack 2004a	Sigmoidoscopy	Conventional patient-based training	Expert global rating of competence to perform endoscopy independently (rated by attending, 1-10 Likert scale: 1 = strongly agree; 5 = neutral; 10 = strongly disagree)		Median score 8 (IQR 7-9) for VR for VR group versus 8 (IQR 7-9) for control group No significant difference between groups, P = 0.893
Sedlack 2007	EGD	No training	Expert global rating of competence to perform EGD independently (rated by attending, 1-7 Likert scale: 1 = strongly disagree; 4 = neutral; 7 = strongly agree)		No significant difference between groups, P > 0.05 (procedure days 1-5)

IQR = Interquartile range

mins = minutes

SEM = Standard error of the mean

SMD = Standardized mean difference

VR = Virtual reality

Table 9. Table 9: Summary of Outcomes - Error Rate

Study	Procedure	Comparison Group	Method	VR versus No Training	VR versus Conventional Endoscopy Training
Tuggy 1998	Sigmoidoscopy	No Training	Directional errors defined as the inability of the examiner to direct the sigmoidoscopy correctly toward the lumen when it was visualized	5 hours VR training: Mean 2.8 in VR group versus 8.6 in control group Statistically significantly fewer	

Table 9. Table 9: Summary of Outcomes - Error Rate (Continued)

			(n)	directional errors in VR trained group, P = 0.01 6-10 hours VR training: Mean 1.6 in VR group versus 8.6 in control group Statistically significantly fewer directional errors in VR trained group, P < 0.01	
--	--	--	-----	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--

n = number

VR = Virtual reality

Table 10. Table 10: Summary of Outcomes - Visualization of Mucosa

Study	Procedure	Comparison Group	Method	VR versus No Training	VR versus Conventional Endoscopy Training
Sedlack 2004	Colonoscopy	No Training	Adequacy of mucosal visualization on withdrawal (1 = strongly disagree, 4 = neutral, 7 = strongly agree)	Median 6.0 (IQR 6.0-7.0) for VR group versus 6.0 (IQR 5.0-7.0) for control group Significantly greater visualization in VR trained group, P = 0.009 (procedures 1-15)	
Sedlack 2004a	Sigmoidoscopy	Conventional patient-based training	Adequacy of mucosal visualization on withdrawal (1 = strongly agree, 5 = neutral, 10 = strongly disagree)		Median 7 (IQR 3-8) for VR group versus 5 (IQR 4-7) for control group No significant difference between groups, P = 0.33
Tuggy 1998	Sigmoidoscopy	No Training	% of colon visualized (assessed from videotapes of procedures)	5 hours VR training: Mean 55% in VR group versus 45% in control group No significant difference between groups, P = 0.60	

Table 10. Table 10: Summary of Outcomes - Visualization of Mucosa (Continued)

				6-10 hours VR training: Mean 79% in VR group versus 45% in control group Significantly greater visualization in VR trained group, P = 0.02	
Yi 2008	Colonoscopy	No Training	Mucosal visualization (1 = poor, 5 = excellent)	Mean 3.5 (SD 0.8) in VR trained group versus 2.9 (SD 0.7) in control group Significantly greater visualization in VR trained group, P = 0.002 SMD	

IQR = Interquartile range

SD = Standard deviation

VR = Virtual reality

APPENDICES

Appendix I. Search strategies for identification of studies

Database	Period	Search Strategy Used
The Cochrane Central Register of Controlled Trials (CENTRAL)	Issue 4/4, 2011	#1 endoscop* OR colonoscop* OR sigmoidoscop* OR duodenoscop* OR gastroscop* OR proctoscop* OR esophagoscop* OR eosphagoscop* OR oesphagoscop* OR esophagoduodenoscop* OR eosophagoduodenoscop* OR oesophagoduodenoscop* OR esophagogastroduodenoscop* OR eosophagogastroduodenoscop* OR oesophagogastroduodenoscop* OR rectoscop* #2 virtual realit* OR simulat* #3 (#1 AND #2)

(Continued)

MEDLINE (from OVID)	1948 - November Week 3 2011	<p>#1 endoscopy, gastrointestinal/ or endoscopy, digestive system/ or colonoscopy/ or sigmoidoscopy/ or duodenoscopy/ or gastroscopy/ or proctoscopy/ or esophagoscopy/ or (gastrointestinal adj2 endoscop*) or (intestin* adj2 endoscop*) or colonoscop* or sigmoidoscop* or duodenoscop* or gastroscop* or proctoscop* or esophagoscop* or eosphagoscop* or oesophagoscop* or esophagoduodenoscop* or esophagoduodenoscop* or oesophagoduodenoscop* or esophagogastroduodenoscop* or esophagogastroduodenoscop* or oesophagogastroduodenoscop* or rectoscop* or (upper adj2 endoscop*).mp</p> <p>#2 programmed instruction as topic/ or computer-assisted instruction/ or diagnosis, computer-assisted/ or surgery, computer-assisted/ or video-assisted surgery/ or computer simulation/ or user-computer interface/ or video games/ or ((virtual adj2 realit*) or (virtual adj realis*) or VR or simulat*).mp</p> <p>#3 (clinical trial, all or clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or clinical trial or comparative study or controlled clinical trial or evaluation studies or meta analysis or multicenter study or randomized controlled trial or validation studies). pt. or randomized controlled trials as topic/ or controlled clinical trials as topic/ or double-blind method/ or random allocation/ or single-blind method/ or (rct or rcts or random* or placebo* or cct or ccts or (control* adj2 trial*).mp. or ((singl* or doubl* or tripl* or trebl*) adj2 (mask* or blind*)) .mp</p> <p>#4 (#1 and #2 and #3)</p>
EMBASE (from OVID)	1980 - 2011 Week 49	<p>#1 digestive tract endoscopy/ or esophagogastroduodenoscopy/ or esophagoscopy/ or gastrointestinal endoscopy/ or gastroscopy/ or intestine endoscopy/ or colonoscopy/ or duodenoscopy/ or rectoscopy/ or sigmoidoscopy/ or ((gastrointestinal adj2 endoscop*) or (intestin* adj2 endoscop*) or colonoscop* or sig-</p>

(Continued)

		<p>moidoscop* or duodenoscop* or gastroscop* or proctoscop* or esophagoscop* or eosphagoscop* or oesophagoscop* or esophagoduodenoscop* or eosophagoduodenoscop* or oesophagoduodenoscop* or esophagogastroduodenoscop* or eosophagogastroduodenoscop* or oesophagogastroduodenoscop* or rectoscop* or (upper adj2 endoscop*).mp</p> <p>#2 computer assisted diagnosis/ or simulation/ or computer simulation/ or disease simulation/ or vignette/ or educational technology/ or teaching/ or computer assisted surgery/ or virtual reality/ or ((computer* or video*) adj5 assist* adj5 (instruct* or teach* or educat*)).mp. or ((virtual adj2 realit*) or (virtual adj realis*) or VR or simulat*).mp. or (video* adj5 game*).mp</p> <p>#3 comparative study/ or intermethod comparison/ or controlled study/ or exp clinical trial/ or control group/ or double blind procedure/ or single blind procedure/ or triple blind procedure/ or randomization/ or (rct or rcts or random* or placebo* or cct or ccts or (control* adj2 trial*)).mp. or ((singl* or doubl* or tripl* or trebl*) adj2 (mask* or blind*)).mp. or ct.fs</p> <p>#4 (#1 and #2 and #3)</p>
<p>Scopus</p>	<p>1960 - December 15, 2011</p>	<p>#1 TITLE-ABS-KEY("gastrointestinal endoscop*" OR "intestinal endoscop*")</p> <p>#2 TITLE-ABS-KEY(colonoscop* OR sigmoidoscop* OR duodenoscop* OR gastroscop* OR proctoscop* OR esophagoscop* OR eosphagoscop* OR oesophagoscop* OR esophagoduodenoscop* OR eosophagoduodenoscop* OR oesophagoduodenoscop* OR esophagogastroduodenoscop* OR eosophagogastroduodenoscop* OR oesophagogastroduodenoscop* OR "upper endoscop*" OR rectoscop*)</p> <p>#3 TITLE-ABS-KEY(simulat* OR vr OR "virtual realit*" OR cai OR "computer assisted instruct*" OR "computer assisted diagnos*" OR "computer assisted surger*")</p> <p>#4 TITLE-ABS-KEY(trial OR trials OR randomisation OR randomisation OR random OR randomised)</p> <p>#5 ((#1 OR #2) AND #3 AND #4)</p>

(Continued)

<p>Web of Science (includes (a) Science Citation Index Expanded; (b) Social Sciences Citation Index; (c) Arts & Humanities Citation Index; (d) Conference Proceedings Citation Index - Science and (e) Conference Proceedings Citation Index - Social Science</p>	<p>Science Citation Index Expanded (1900 - December 15, 2011) Social Sciences Citation Index (1956 - December 15, 2011) Arts & Humanities Citation Index (1975 - December 15, 2011) Conference Proceedings Citation Index - Science (1990 - December 15, 2011) Conference Proceedings Citation Index - Social Science (1990 - December 15, 2011)</p>	<p>#1 TS=(“gastrointestinal endoscop*” OR “intestinal endoscop*”OR colonoscop* OR sigmoidoscop* OR duodenoscop* OR gastroscop* OR proctoscop* OR esophagoscop* OR eosphagoscop* OR oesphagoscop* OR esophagoduodenoscop* OR eosophagoduodenoscop* OR oesophagoduodenoscop* OR esophagogastroduodenoscop* OR eosophagogastroduodenoscop* OR oesophagogastroduodenoscop* OR “upper endoscop*” OR rectoscop*) #2 TS=(simulat* OR vr OR “virtual realit*” OR cai OR “computer assisted instruct*” OR “computer assisted diagnos*” OR “computer assisted surger”*) #3 TS=(trial OR trials OR randomization OR randomisation OR random OR randomized or randomised) #4 (#1 AND #2 AND #3)</p>
<p>Biosis previews (from ISI Web of Knowledge)</p>	<p>1980 - December 15, 2011</p>	<p>#1 TS=(“gastrointestinal endoscop*” OR “intestinal endoscop*”OR colonoscop* OR sigmoidoscop* OR duodenoscop* OR gastroscop* OR proctoscop* OR esophagoscop* OR eosphagoscop* OR oesphagoscop* OR esophagoduodenoscop* OR eosophagoduodenoscop* OR oesophagoduodenoscop* OR esophagogastroduodenoscop* OR eosophagogastroduodenoscop* OR oesophagogastroduodenoscop* OR “upper endoscop*” OR rectoscop*) #2 TS=(simulat* OR vr OR “virtual realit*” OR cai OR “computer assisted instruct*” OR “computer assisted diagnos*” OR “computer assisted surger”*) #3 TS=(trial OR trials OR randomization OR randomisation OR random OR randomized) #4 (#1 AND #2 AND #3)</p>
<p>CINAHL (from EBSCO)</p>	<p>1982 - December 22, 2011</p>	<p>#1 KW=duodenoscop* OR gastroscop* OR proctoscop* OR esophagoscop* OR eosophagoscop* OR oesophagoscop* OR esophagoduodeno- scop* OR eosophagoduodenoscop* OR oesophagoduodenoscop*OR esophagogastroduodenocop* OR eosophagogastroduo-</p>

(Continued)

		<p>denoscop* OR oesophagogastroduodenoscop*OR rectoscop*</p> <p>#2 (MH "Endoscopy") or (MH "Endoscopy, Gastrointestinal") or (MH "Colonoscopy+") or (MH "Gastroscope") or (MH "Proctoscopy") or (MH "Endoscopy, Digestive System")</p> <p>#3 KW=virtual* OR VR OR simulat* OR cai OR "computer assisted"</p> <p>#4 (MH "Diagnosis, Computer Assisted") or (MH "Computer Assisted Instruction") or (MH "Programmed Instruction") or (MH "Simulations") or (MH "Computer Simulation") or (MH "Virtual Reality") or (MH "Video Games")</p> <p>#5 KW=rct OR RCTS OR random* OR placebo* OR CCT OR CCTS OR "Controlled Trial*"</p> <p>#6 (MH "Clinical Trials+")</p> <p># 7 (#1 OR #2) AND (#3 OR #4) AND (#5 or #6)</p>
Allied and complementary Medicine Database (from OVID)	1985 - December 12 2011	<p>#1 endoscopy/</p> <p>#2 (endoscop* or colonoscop* or sigmoidoscop* or duodenoscop* or gastroscoop* or proctoscop* or esophagoscop* or eosphagoscop* or oesphagoscop* or esophagoduodenoscop* or eosophagoduodenoscop* or oesophagoduodenoscop* or esophagogastroduodenoscop* or eosophagogastroduodenoscop* or oesophagogastroduodenoscop* or rectoscop*).mp</p> <p>#3 (#1 or #2)</p> <p>#4 vitual reality/ or computer assisted instruction/ or computer simulation/ or (simulat* or vr or (virtual adj2 realit*) or (virtual adj2 realis*) or cai or computer assisted instruct* or computer assisted diagnos* or (computer adj2 (assisted adj2 surger*))).mp</p> <p>#5 (#3 and #4)</p>
ERIC (from OVID)	1965 - November 2011	<p>#1 (((gastrointestinal or intesin*) adj2 endoscop*) or colonoscop* or endoscop* or sigmoidoscop* or duodenoscop* or gastroscoop* or proctoscop* or esophagoscop* or eosphagoscop* or oesophagoscop* or esophagoduodenoscop* or eosophagoduodenoscop*)</p>

(Continued)

		denoscop* or oesophagoduodenoscop* or (upper adj2 endoscop*) or rectoscop* or esophagogastroduodenoscop* or esophagogastroduodenoscop* or oesophagogastroduodenoscop*).mp #1 ((gastrointestinal adj2 endoscop*) or colonoscop* or endoscop* or sigmoidoscop* or duodenoscop* or gastroscop* or proctoscop* or esophagoscop* or eosphagoscop* or oesphagoscop* or esophagoduodenoscop* or esophagoduodenoscop* or oesophagoduodenoscop* or (upper adj2 endoscop*) or rectoscop* or esophagogastroduodenoscop* or esophagogastroduodenoscop* or oesophagogastroduodenoscop*).mp
Education Full Text (from Wilson Web)	1983 - December 12 2011	#1 (colonoscop* OR endoscop* OR sigmoidoscop* OR duodenoscop* OR gastroscop* OR proctoscop* OR esophagoscop* OR eosphagoscop* OR oesphagoscop* OR esophagoduodenoscop* OR esophagoduodenoscop* OR oesophagoduodenoscop* OR esophagogastroduodenoscop* OR eosphagogastroduodenoscop* OR oesophagogastroduodenoscop* OR rectoscop*)
CBCA Education (from Proquest)	1972 - December 12, 2011	#1 (colonoscop* OR endoscop* OR sigmoidoscop* OR duodenoscop* OR gastroscop* OR proctoscop* OR esophagoscop* OR eosphagoscop* OR oesphagoscop* OR esophagoduodenoscop* OR esophagoduodenoscop* OR oesophagoduodenoscop* OR esophagogastroduodenoscop* OR eosphagogastroduodenoscop* OR oesophagogastroduodenoscop* OR rectoscop*)
Career and Technical Education (from Proquest)	1975 - December 12, 2011	#1 ALL(endoscop* OR colonoscop* OR sigmoidoscop*) OR ALL(duodenoscop* OR gastroscop* OR proctoscop*) OR ALL(esophagoscop* OR eosphagoscop* OR oesophagoscop*) OR ALL(esophagoduodenoscop* OR eosophagoduodenoscop* OR oesophagoduodenoscop*) OR ALL(esophagogastroduodenoscop* OR eosophagogastroduodenoscop* OR oesophagogastroduodenoscop*)

(Continued)

		<p>scop*) OR ALL(rectoscop*)</p> <p>#2 ALL(simulat* OR VR OR (“virtual re- alit*)) OR ALL(cai OR (“computer based train*)) OR (“computer assist*))</p> <p>#3 ALL(Random* NEAR/3 trial*) OR ALL(random* OR trial*)</p> <p>#4 (#1 AND #2 AND #3)</p>
Expanded Academic ASAP	1980 - December 14, 2011	<p>#1 Keyword (endoscop* OR colono- scop* OR sigmoidoscop* OR duodeno- scop* OR gastroscop* OR proctoscop* OR esophagoscop* OR eosophagoscop* OR oesophagoscop*OR esophagodu- denoscop* OR eosophagoduodenoscop* OR oeosophagoduodenoscop*OR esopha- gogastroduodenoscop* OR eosophagoga- stroduodenoscop* OR oesophagoga- stroduodenoscop*OR rectoscop*)</p> <p>#2 Keyword (simulat* OR VR OR “vir- tual reinit”) OR cai OR “computer based train”) OR “computer assist*)</p> <p>#3 Keyword (“Random* n3 trial”) OR ran- dom* OR trial*)</p> <p>#4 (#1 AND #2 AND #3)</p>
ACM Digital Library (from ACM Portal)	1985 - December 12, 2011	#1 endoscopy “virtual reality” simulat*
IEEE Xplore	1982 - December 12, 2011	<p>#1 (duodenoscopy OR gastroscopy OR proctoscopy OR esophagoscopy OR eosophagoscopy OR oesophagoscopy OR esophagodu- denoscopy OR eosophagoduodenoscopy OR oesophagoduodenoscopy OR esopha- gogastroduodenoscopy OR eosophagoga- stroduodenoscopy OR oesophagodu- denoscopy OR rectoscopy) AND (virtual OR cai OR ‘computer assisted’ OR ‘com- puter based’ OR simulation OR simulated OR simulations)</p>
Abstracts in New Technologies and En- gineering (from Proquest)	1981 - December 12, 2011	<p>#1 ALL(endoscop* OR colonoscop* OR sigmoidoscop*) OR ALL(duodenoscop* OR gastroscop* OR proctoscop*) OR ALL (esophagoscop* OR eosophagoscop* OR oesophagoscop*) OR ALL(esophagodu- denoscop* OR eosophagoduodenoscop* OR oeosophago- duodenoscop*) OR ALL(esophagogastro-</p>

(Continued)

		<p>duodenoscop* OR eosophagogastroduodenoscop* OR oesophagogastroduodenoscop* OR ALL(rectoscop*)</p> <p>#2 ALL(simulat* OR VR OR (“virtual reality*”) OR ALL(cai OR (“computer based train*”) OR (“computer assist*”)))</p> <p>#3 ALL(Random* NEAR/3 trial*) OR ALL(random* OR trial*)</p> <p>#4 (#1 AND #2 AND #3)</p>
<p>Computer & Information Systems Abstracts (from Proquest)</p>	<p>1981 - December 12, 2011</p>	<p>#1 ALL(endoscop* OR colonoscop* OR sigmoidoscop*) OR ALL(duodenoscop* OR gastroscop* OR proctoscop*) OR ALL(esophagoscop* OR eosophagoscop* OR oesophagoscop*) OR ALL(esophagoduodenoscop* OR eosophagoduodenoscop* OR oesophagoduodenoscop*) OR ALL(esophagogastroduodenoscop* OR eosophagogastroduodenoscop* OR oesophagogastroduodenoscop*) OR ALL(rectoscop*)</p> <p>#2 ALL(simulat* OR VR OR (“virtual reality*”) OR ALL(cai OR (“computer based train*”) OR (“computer assist*”)))</p> <p>#3 ALL(Random* NEAR/3 trial*) OR ALL(random* OR trial*)</p> <p>#4 (#1 AND #2 AND #3)</p>
<p><i>metaRegister of controlled trials</i> (active registers: http://www.controlled-trials.com/mrct/ and archived registers: www.controlled-trials.com/mrct/archived)</p>	<p>December 22, 2011</p>	<p>#1 (virtual reality* OR VR OR simulat* OR cai OR computer assisted instruct* OR computer based train* OR computer assisted train*) AND (endoscop* OR colonoscop* OR sigmoidoscop* OR duodenoscop* OR gastroscop* OR proctoscop* OR esophagoscop* OR eosophagoscop* OR oesophagoscop* OR esophagoduodenoscop* OR eosophagoduodenoscop* OR oesophagoduodenoscop* OR esophagogastroduodenoscop* OR eosophagogastroduodenoscop* OR oesophagogastroduodenoscop* OR rectoscop*)</p>
<p>Dissertations & Theses (from ProQuest)</p>	<p>1861 - December 22, 2011</p>	<p>#1 ALL(endoscop* OR colonoscop* OR sigmoidoscop*) OR ALL(duodenoscop* OR gastroscop* OR proctoscop*) OR ALL(esophagoscop* OR eosophagoscop* OR oesophagoscop*) OR ALL(esophagoduodenoscop* OR eosophagoduodenoscop* OR oesophagoduodenoscop*)</p>

(Continued)

		duodenoscop*) OR ALL(esophagogastro- duodenoscop* OR eosophagogastroduo- denoscop* OR oesophagogastroduo- denoscop*) OR ALL(rectoscop*) #2 ALL(simulat* OR VR OR (“virtual re- alit*)) OR ALL(cai OR (“computer based train*)) OR (“computer assist*)) #3 ALL(Random* NEAR/3 trial*) OR ALL(random* OR trial*) #4 (#1 AND #2 AND #3)
Index to Theses	1716 - December 22, 2011	#1 (“virtual realit*” OR simulat*) AND (endoscop* OR colonoscop* OR sigmoi- doscop* OR duodenoscop* OR gastro- scop* OR proctoscop* OR esophago- scop* OR esophagoscop* OR oesophago- scop* OR esophagoduodenoscop* OR oesophagoduodenoscop* OR oesophago- duodenoscop* OR esophagogastroduo- denoscop* OR eosophagogastroduo- denoscop* OR oesophagogastroduo- denoscop* OR rectoscop*)

HISTORY

Protocol first published: Issue 1, 2010

Review first published: Issue 6, 2012

CONTRIBUTIONS OF AUTHORS

Catharine M. Walsh and Mary E. Sherlock performed an independent assessment of article abstracts to assess eligibility for inclusion in the review. Both were responsible for data extraction and analysis. The final review manuscript writing was the responsibility of Catharine M. Walsh. Heather Carnahan and Simon C. Ling provided supervisory support and content expert advice.

DECLARATIONS OF INTEREST

None known

SOURCES OF SUPPORT

Internal sources

- New Source of support, Not specified.

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We removed the word 'subjective' from the outcome "single measure providing an overall global rating of performance or competency in performing endoscopy" to align with the literature on rater-based assessments. The methods were updated to indicate that we used Review Manager 5.1 ([RevMan 2011](#)) and Cochrane Collaboration's updated domain-based tool for assessing risk of bias ([Higgins 2011](#)), and that abstracts reporting randomised and quasi-randomised studies presented between January 2009 - September 2011 were considered. Our search strategy was updated to indicate that we did not separately search the Cochrane Colorectal Cancer Group Specialised Register (SRCOLOCA). In addition, we did not search Education Abstracts @ Scholars Portal as we no longer have access to this database. The search strategies for the following databases were updated: (1) Career and Technical Education, (2) Expanded Academic ASAP, (3) Abstracts in New Technologies and Engineering and (3) Computer and Information Systems Abstracts. Finally we indicated that when abstracting data from studies reporting learning curves (multiple points across time), the first assessment interval was used for analysis and plots, in order to minimize the potential effect of variable clinical training on the outcomes over time.

INDEX TERMS

Medical Subject Headings (MeSH)

*Computer Simulation; Endoscopy, Gastrointestinal [*education]; Health Occupations [*education]; Randomized Controlled Trials as Topic

MeSH check words

Humans