

# Effectiveness of digital feedback on patient experience and 30-day complications after screening colonoscopy: a randomized health services study



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## ABSTRACT

**Background and study aims** European guidelines (ESGE) recommend measuring patient experience and 30-day complication rate after colonoscopy. We compared digital and paper-based feedback on patients' experience and 30-day complications after screening colonoscopy.

**Patients and methods** Screenees attending for primary screening colonoscopies in two centers from September 2015 to December 2016 were randomized (1:1) to an intervention arm (choice of feedback method) or control arm (routine paper-based feedback). Participants in the intervention arm could choose preferred feedback method (paper-based, automated telephone or online survey) and were contacted by automated telephone 30 days after colonoscopy to assess complications. Control group participants self-reported complications. Primary and secondary endpoints were response rates to feedback and complications questionnaire, respectively.

**Results** There were 1,281 and 1,260 participants in the intervention and control arms, respectively. There was no significant difference in response rate between study groups (64.8% vs 61.5%;  $P=0.08$ ). Free choice of feedback improved response for participants identified as poor responders: younger than 60 years (60.8% vs 54.7%;  $P=0.031$ ), male (64.0% vs 58.6%;  $P=0.045$ ) and in small non-public center (56.2% vs 42.5%;  $P=0.043$ ).

In the intervention arm, 1,168 participants (91.2%) answered the phone call concerning complications. A total of 79 participants (6.2%) reported complications, of which two (0.2%) were verified by telephone as clinically relevant. No complications were self-reported in the control group.

**Conclusion** The overall response rate was not significantly improved with digital feedback, yet the technology yielded significant improvement in participants defined as poor responders. Our study demonstrated feasibility and efficacy of digital patient feedback about complications after colonoscopy.

## Introduction

Patient experience and complication rates are two of the seven key performance measures for colonoscopy defined by the European Society of Gastrointestinal Endoscopy (ESGE) guidelines [1].

Since 2014, the Polish Colorectal Cancer Screening Programme (PCSP) has routinely used the Gastronet questionnaire to measure patient-reported outcomes [2]. Gastronet is a Norwegian quality-assurance (QA) program that was initiated in 2003 [3]. Patients fill in the questionnaire at home 1 day after colonoscopy and send it back via traditional mail. Gastronet has proven to be an important QA platform, and a network for research on quality issues, including endoscopy technique and technologies – far beyond strict quality assurance [3–9]. Gastronet addresses an uncovered need to integrate reports on performance from health care providers with those from patients and this information can be used for research to improve health services. Gastronet also includes self-reporting of complications [4] and it is currently considered the best source of information on colonoscopy complications in Norway.

Even well-developed QA tools, however, are often only partially effective. Identified barriers involve patients, professionals, interactions among professionals in teams, the organizational context and the economic, political, and cultural context. Having this in mind, there are several drawbacks to the current, paper-based Gastronet questionnaire. First, the patient questionnaire response rate is lower than expected [10], not reaching the 90% response rate recommended by the guidelines [1]. Second, it is time-consuming to scan and read paper-based questionnaires, which impedes use of the tool on nationwide level in more densely populated countries like Poland. Third, it is costly to return patient questionnaires via standard mail. Fourth, the current complications assessment in Poland and Norway is not sufficient, as it relies only on active self-reporting.

In 2015, around 80% of households in Poland had Internet access and around 90% of the Polish population used mobile phones [11]. Widespread and constantly increasing access to digital media provides good background for development and implementation of electronic QA questionnaires, which can possibly overcome drawbacks of the current paper questionnaires.

This study aimed to investigate whether free choice of feedback form (paper questionnaire, automated telephone response system or online questionnaire) results in better response rates than the current, paper-based Gastronet form. Moreover, we evaluated whether digital feedback is a valid method of obtaining information on screening colonoscopy complications.

## Patients and methods

### PCSP design and subjects

The design of PCSP has been described previously [2]. Briefly, it is a programmatic, primary colonoscopy screening with roll-out that began in 2012. All individuals aged 55 to 64 years who live

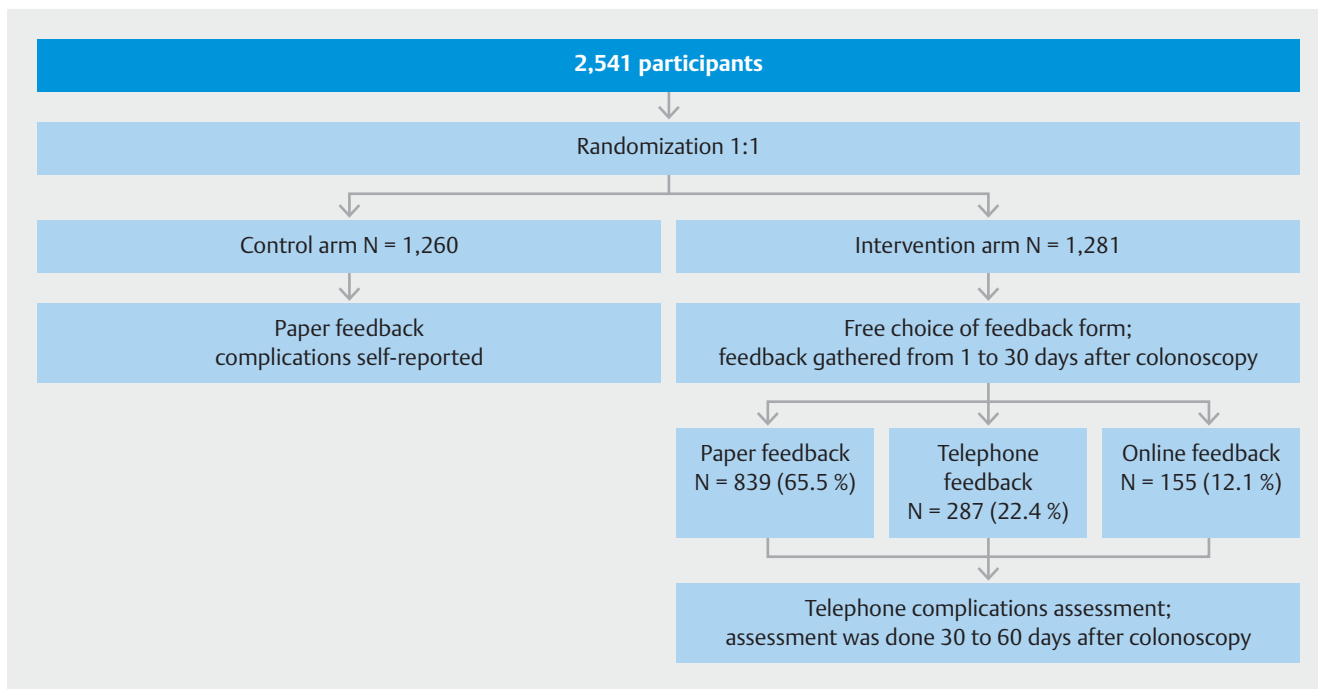
in the geographic target area of a screening center are considered eligible, but the program excludes people with a colorectal cancer (CRC) diagnosis or previous screening colonoscopy. An updated list of eligible individuals is acquired yearly from the national population registry so that letters of invitation can be mailed. The central screening database includes patient data, colonoscopy and histopathology reports, responses to the Gastronet questionnaire, and information on screening centers and endoscopists.

### Randomized controlled trial design

In our study, we included all primary colonoscopies performed within the PCSP framework in two centers; in one from September 1, 2015 to December 31, 2016 and in the other from September 1, 2015 to December 31, 2015. On registration to the screening program, consecutive patients were randomized in a 1:1 ratio to either the control arm (practice as usual, paper-based Gastronet filled in 1 day after colonoscopy) or the intervention arm (free choice of paper or digital feedback), as shown in the flowchart in ► Fig. 1. Randomization was stratified by age and gender and automatically generated using a computer-based randomization system. Participants randomized to the intervention arm were asked about their preferred method of feedback (paper-based, automated telephone or online survey) and were asked for the corresponding contact information (mobile phone regardless of feedback type and email if online questionnaire was applied). We did not choose the digital-only options in the intervention arm as in the initial focus group evaluation, 60% of patients would not use the digital method of feedback when given a choice and leaving only digital options would hamper the response rate. In the intervention study arm, patients were informed about a planned contact 30 days after the procedure to assess complications. The general design of the intervention arm is presented in ► Fig. 2. The primary endpoint was participant response to the feedback questionnaire. The secondary endpoint was participant response to the complications questionnaire 30 days after telephone contact or self-reported complication on Gastronet paper questionnaire received by the PCSP bureau. The study was registered as a randomized health services study [12] at the Finnish Cancer Registry (registration number 008\_2015\_2\_RHS, registry access <http://www.cancer.fi/rhs/>).

### Gastronet questionnaire and digital implementation

The questionnaire (both paper-based and digital) includes five closed-ended questions: (1) Were you satisfied with center's quality? (yes; no); (2) Was the procedure painful? (no; yes, slightly; yes, moderately; yes, very); (3) Did you feel any discomfort or colicky abdominal pain after the procedure? (no; yes, slightly; yes, moderately; yes, very). If the answer to (3) was yes, how long did you feel the aforementioned symptoms? (<1 hour; 1–3 hours; 3–6 hours; >6 hours); (4) Are you satisfied with information on the procedure itself and its results? (yes; no); (5) Did you experience any involuntary leakage on your way back home? (yes; no). The language of all of the questions and answers had been validated previously.



► Fig. 1 Study flowchart.

All screenees in the control arm and those in the intervention arm who chose paper feedback were given the paper Gastronet questionnaire to be filled in at home on the day after colonoscopy. The paper questionnaire was sent back via mail (in a prepaid return envelope) to the coordinating office, where the forms were scanned and automatically uploaded into the screening program database.

For screenees who chose automated telephone response, an SMS was sent the day after the procedure, between 10 a.m. and noon, to remind them about planned contact. Patients were permitted to respond if they were not able to give the feedback on that particular day. In that case, contact could be on the next day (2 days after colonoscopy). Either way, the automated telephone call was made between 5 p.m. and 7 p.m. After 2 days, patients that did not reply to the first SMS, answer the phone or complete the telephone survey received another SMS to which they could reply to trigger a telephone contact at their convenience for 30 days after the procedure.

Screenees who chose the online questionnaire option received an email with a password-protected link to the questionnaire. The online questionnaire could be filled in for 30 days after the endoscopic procedure.

### Complications assessment

Screenees in the control group did not receive any intervention in terms of complications assessment. Data on complications were assessed routinely (self-reported by patients on the paper Gastronet form).

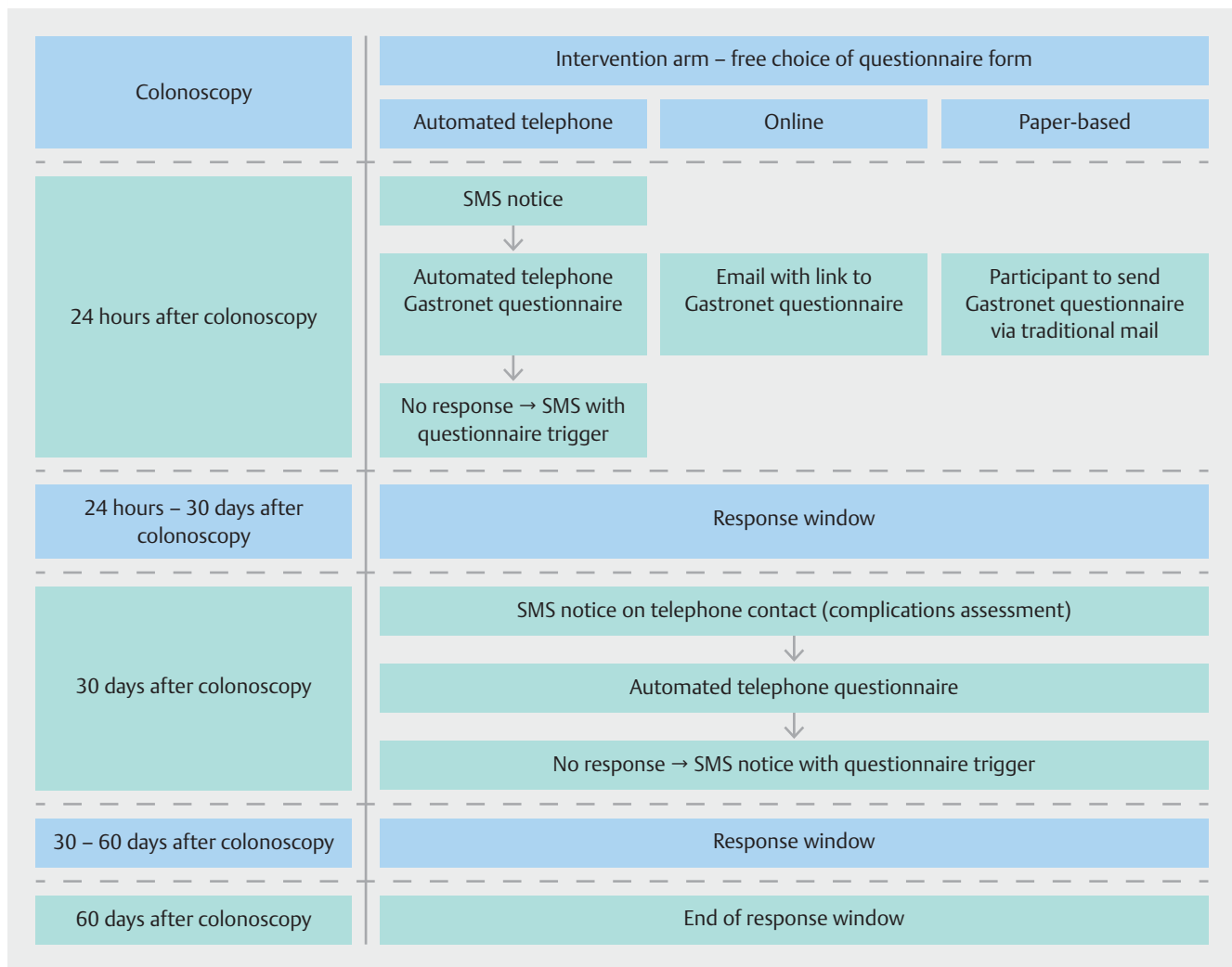
Screenees in the intervention arm were contacted again for complications assessment 30 days after the procedure. The complications questionnaire includes up to four closed-type

questions: (1) Did you have any rectal bleeding during last 30 days? (yes; no); (2) If yes: did the bleeding require hospitalization? (yes; no); (3) Did you have strong abdominal pain during last 30 days that required hospitalization? (yes; no); (4) If yes, was any surgical procedure necessary? (yes; no). Regardless of the first method of contact (paper, telephone or email), the patients received (between 10 a.m. and noon) an SMS reminder on planned telephone contact about complications. Screenees were able to respond if they were not able to give the feedback on the current day. In that case, the contact took place on the following day. Either way, the automated telephone call was made between 5 p.m. and 7 p.m. As for non-compliers to “the-day-after” response described above, non-compliers to telephone-based assessment of complications received another SMS to which they could reply to trigger a telephone contact at their convenience.

Later, data on complications received from the telephone survey were verified via phone call from the PCSP bureau personnel to assess whether the complication truly took place and the nature of it. Moreover, data collected with telephone contact in the intervention arm were compared with the routine practice method of obtaining data on complications (self-reported by screenees).

### Statistical analysis

The power calculation was based on a patient questionnaire response rate within 2 weeks from the procedure (due to postal delay). We expected an increase in patient questionnaire response rate from 80% in the paper-based Gastronet group (data from Gastronet program at the participating centers in Poland at the beginning of the trial) to 85% in the intervention



► **Fig. 2** Intervention arm design.

group. Randomization was performed in a 1:1 ratio, stratified by age and gender. Randomization was automatically performed within central database, handling enrollment and arm assignment. To detect the difference in response rate with a power of 0.90 at the 5% level of significance, the study required 1,212 individuals randomized to each of two groups. Assuming no dropout in the control arm (practice as usual) and maximum of 5% dropout in the intervention arm, we planned to include approximately 1,260 individuals in each arm. Chi square test and exact Fisher test were used to compare the groups. All tests were performed at 0.05 significance level. Statistical analyses were performed using Stata software, version 13.1 (Stata Corporation, College Station, Texas, United States).

## Results

### Baseline Characteristics

► **Fig. 1** is the study flowchart. We included a total of 2,541 participants, randomized in a 1:1 ratio either to the intervention arm (1,281 participants) or the control arm (1,260 parti-

cipants). Mean age was 59.88 years (SD 3.08) and 59.86 years (SD 3.04) and the male to female ratio was 1.04 and 1.05 for the intervention and control arm, respectively. Differences in participant characteristics between the intervention and control arms were not statistically significant. In the intervention arm, 155 participants (12.1%) chose the online survey, 287 (22.4%) chose the automated telephone survey and 839 (65.5%) chose the paper-based survey. The first center included 2,323 participants (1,176 and 1,147 in the intervention and control arms, respectively) and the second center included 218 participants (105 and 113 in the intervention and control arms, respectively).

### Gastronet response rate and survey results

The response rate for the total study population was 63.2%. Overall response rate was lower in participants aged less than 60 years compared to older individuals (57.8% vs 68.1%,  $P < 0.001$ ), male participants 61.3% vs 65.1% for women,  $P = 0.05$ , and in the smaller, private center no. 2, 49.1% compared to 64.5% in the larger center no. 1 ( $P < 0.001$ ). ► **Table 1** shows a

► **Table 1** Gastronet questionnaire response rates (%).

	Intervention arm (free choice of paper, telephone or web-based questionnaire) (N = 1281)	Control arm (paper based) (N = 1260)	P value
Total (N = 2,541)	64.8% (N = 830)	61.5% (N = 775)	0.08
Per center			
Center 1 (N = 2,323)	65.6% (N = 771)	63.4% (N = 727)	0.273
Center 2 (N = 218)	56.2% (N = 59)	42.5% (N = 48)	0.043
Per participant age			
<60 years old (N = 1,219)	60.8% (N = 376)	54.7% (N = 329)	0.031
≥60 years old (N = 1,322)	68.5% (N = 454)	67.7% (N = 446)	0.756
Per participant gender			
Women (N = 1,243)	65.6% (N = 412)	64.5% (N = 397)	0.697
Men (N = 1,298)	64.0% (N = 418)	58.6% (N = 378)	0.045
Choice of paper questionnaire in the intervention arm (839 participants)			
	67.7% (N = 568)	61.5% (N = 775)	0.004
Choice of telephone questionnaire in the intervention arm (287 participants)			
	57.8% (N = 166)	61.5% (N = 775)	0.251
Choice of web-based questionnaire in the intervention arm (155 participants)			
	61.9% (N = 96)	61.5% (N = 775)	0.918

The response rate refers to properly filled in questionnaire.  
P values refer to differences between control and intervention arm.

comparison of response rates in the intervention and control arms. There was no statistically significant difference between the intervention and control arms (64.8% vs 61.5%,  $P=0.08$ ). However, on subgroup analysis, we found a statistically significant increase in response rates for younger patients, males and patients from the smaller center in the intervention arm.

► **Table 2** lists responses to Gastronet questions with regards to study arms. Statistically significant differences in answers for some questions was due to higher number of invalid answers in the intervention arm. Invalid answers were noted for 1.9% of paper questionnaires and in 9.6% of telephone surveys ( $P<0.001$ ). No invalid answers were noted in online questionnaires. Colonoscopy was moderately or severely painful in 17.3% and 15.6% of participants from the intervention and control arms, respectively. Significant pain (moderate or severe) after colonoscopy was reported in 13.3% and 10.5% of participants from the intervention and control arms, respectively.

### Complications questionnaire coverage, response rate and complications rate

► **Fig. 3** shows results of the complication questionnaire in the intervention arm. A total of 79 participants (6.2% of intervention arm) reported complications – 69 reported bleeding and 14 abdominal pain requiring hospital stay (4 reported both complications). On telephone call, most reported complications were verified as administrative errors, leaving only two participants (0.2%) who reported clinically relevant complica-

tions – one had post-polypectomy bleeding requiring hospital admission and one had appendicitis with appendectomy day after screening colonoscopy, without any procedures (polypectomy and/or biopsy).

In contrast, no participants in the control group reported any complications (self-reported).

## Discussion

Today, health care should include modern pathways for patient feedback. Novel technologies meet with patient acceptance in different medical fields [13, 14]. Given the previously observed suboptimal response rate to the Gastronet questionnaire [10], we were seeking alternative feedback methods to meet the ESGE quality criteria [1]. Our study, to the best of our knowledge the first in a screening population, demonstrated feasibility of digital patient feedback. Moreover, this is the first study with such large sample size, evaluating utility of new technologies on the health service level. We observed an increased overall feedback response rate. The difference, however, was smaller than assumed and not statistically significant. Lack of significance is probably due to too small a sample size, which was calculated to detect 5% difference. However, because this was a unique intervention, we had no previous data on which to base our calculations. Still, in the intervention arm, most patients chose the paper questionnaire, which may be attributed to old-

► **Table 2** Comparison of responses to Gastronet questions by study group.

	Intervention arm	Control arm	P value
Were you satisfied with center's quality?			
Yes	99.0%	98.8%	0.93
No	0.4%	0.5%	
NA	0.6%	0.7%	
Was the procedure painful?			
No pain	51.5%	53.0%	0.73
Slight pain	30.6%	31.1%	
Moderate pain	11.3%	10.4%	
Severe pain	6.0%	5.2%	
NA	0.6%	0.3%	
Did you feel any discomfort or colicky abdominal pain after the procedure?			
No	54.5%	55.2%	0.005
Yes, slightly	31.1%	34.3%	
Yes, moderately	8.3%	7.4%	
Yes, very	5.0%	3.1%	
NA	1.1%	0	
Are you satisfied with information on the procedure itself and its results?			
No	1.0%	0.7%	0.019
Yes	92.8%	95.9%	
Partially	4.6%	3.0%	
NA	1.6%	0.4%	
Did you experience any involuntary leakage on your way back home?			
Yes	8.9%	8.3%	0.17
No	89.9%	91.3%	
NA	1.2%	0.4%	

NA, non-applicable (invalid answer)  
Percentage values do not add up to 100% as there were a small number of invalid answers (i. e. pressing inappropriate button during phone survey or not answering or giving more than one response in paper questionnaire).

er age. However, we assume that in the upcoming years, patient preference will probably shift towards digital methods.

Importantly, we observed a significant difference for all subpopulations suffering from too low response rate (poor responders). These subpopulations include: younger participants (age <60 years), men and participants screened at one of the centers. Participants younger than 60 years had generally lower response rates, which most likely can be attributed to the fact that most of them are still active workers [15], and therefore, they have less time to perform all the procedures associated with sending back a paper questionnaire. For younger participants, response with a telephone (and system programmed

1,281 participants

8.8 % participants (N = 11) did not answer the phone

33.6 % participants (N = 430) did not finish the questionnaire

93.8 % participants (N = 1,202) did not report any complications

6.2 % participants (N = 79) reported complications

Telephone verification of reported complications

25 complications clinically irrelevant

46 invalid answers

0.2 % participants had complication:  
appendectomy (N = 1)  
post-polypectomy bleeding (N = 1)

► **Fig. 3** Responses to complications questionnaire (including verification process).

such that the call was placed after working hours) or a web-based survey had a significant advantage over the paper version. On the other hand, men were generally observed to be less responsive to medical interventions than women [16, 17]. In the case of PCSP, it results in worse program participation and lower response rate to Gastronet questionnaire (historical PCSP data were not shown). Regarding one of the centers with low response rates, we have previously observed significant differences between centers in PCSP, which we attribute to differing ways of handling the questionnaire (e. g., hand out by an administrative worker versus nurse or endoscopist). However, it is not possible to identify the precise source of the problem. Geographical or demographical differences were not relevant, as both centers are located in the same city.

We did not find significant differences between the control and intervention arms regarding patient satisfaction with center quality (► **Table 2**). There were significantly different answers on satisfaction with information on the procedure and results. However, the proportion of patients clearly not satisfied was similar in both groups (the significance could be attributed to invalid answers). Also, we observed significantly different answers regarding pain after the procedure. The trial was not designed to explore differences in pain between groups and we did not analyze whether they were significantly different with regard to previously reported results on factors associated with painful colonoscopy [10]. On the other hand, the paper questionnaire could be filled in by patient either too early (right

after procedure) or too late (a few days after), resulting in biased answers. The telephone survey was performed exactly 1 day after the procedure, so the answer to this question could have been more precise.

Response rate improvement is the first milestone towards better understanding of patients' experience with a colonoscopy screening program [10], ultimately leading to quality improvement. In the recent ESGE guidelines on quality in colonoscopy [1], measuring patient experience was one of seven key performance measures. This further implies the importance of response rate improvement. We cannot be certain of the opinions of patients who did not respond to the Gastronet questionnaire nor do we know if they were satisfied, and so, did not respond, or felt their responses would not matter, or were so unsatisfied that they did not want any further interaction. Unfortunately, there is no literature providing unbiased insight into reasons for non-response and non-response also may reflect cultural differences.

In the medical field, most interventions to improve patient feedback focus not on experience, but on ability to tailor medical interventions [14]. For example, in the field of chronic obstructive pulmonary disease, digital intervention focuses on self-monitoring of symptoms, leading to improved self-management and earlier intervention of medical professional [18]. Self-monitoring through a digital diary also has been tested in various other fields, such as diabetes [19] or acquired brain injury [20]. To date, no trials exist on utility of digital tools to monitor patient experience associated with colonoscopy or screening in general. All studies measuring patient satisfaction, experience or pain associated with colonoscopy have been based solely on either paper-based feedback sent by patients (e.g. Gastronet, VAS, GRS) or measurement at the treatment site [3, 7, 9, 21–25]. To gather the most objective and varied information on patient satisfaction, utilization of new technologies should lead to significant improvement in this field.

Another important aspect covered by this trial is the feasibility of digital assessment of colonoscopy complications. The previously mentioned ESGE guidelines emphasize the importance of monitoring complications by including complication rate as one of the key performance measures. As per definition of complications [26], we in fact monitored unscheduled further endoscopy procedures and emergency interventions, focusing on post-colonoscopy bleeding and perforation. We used an automated phone call as a "screening for complications," allowing us to select participants to verify answers. Even though false-positive reporting of complications did occur, in-person verification was necessary only for a relatively small sample of participants (6.2%). This method has several strengths. It is cheap, fast and does not require additional workforce. It is not reliant on access to registries of hospitalizations and deaths. The very general nature of the questions reduces patient reluctance to respond, leaving collection of more detailed information for the verification call. Because the call is automated, patients are more open to answering the questions that might be embarrassing. Data on complications can be gathered more efficiently than with a paper-based questionnaire, because the evaluation covers 30 days after colonos-

copy, whereas the paper questionnaire could be sent back before a complication occurred. An automated phone call, however, does have several limitations. The rate of response to the complications questionnaire was similar to the overall response rate to Gastronet, which resulted in one-third of patients not giving feedback on adverse events. There also is a significant risk that patients with complications will report incorrectly (stating that there were no complication) or will not responding to the phone call, and there is a lack of objectivity in comparison to analysis of registries or hospital records. However, the main task of this trial was to show feasibility of automated monitoring. In terms of this goal, the system proved its usefulness. Moreover, complication rates after colonoscopy were similar to those reported previously in different settings [27–30]. The next step is to implement this approach on a nationwide scale, focus on conveying the importance of monitoring both to screening program staff and participants and objectify the findings through analysis of appropriate registries (hospitalization and deaths), as the colonoscopy quality guidelines suggest [1, 31, 32]. We believe this approach will significantly increase response rates, leading to more objective complication monitoring.

Our study has several strengths. It is the first trial to show the feasibility and effectiveness of digital feedback in endoscopy and CRC screening settings. Moreover, this is one of a few trials in this area of health services that was designed as a randomized trial. It is worth noting that taking a digital approach to feedback is a relatively new phenomenon in the field of medicine, therefore, the main goal of the first trials (including this one) is to show the feasibility of digital systems. On the other hand, there are a few limitations. We did not observe a significant increase in response rate in the intervention group; it was seen only in specific subgroups (suboptimal responders). The subgroups were not predefined, however, they emerged using natural criteria: different sex, different centers etc. There is still uncertainty about the colonoscopy experience of a large group of non-responders. However, even though the trial was not designed in non-inferiority fashion, we believe that the effect of free choice of feedback method is not worse than traditional, paper-based Gastronet. Second, probably due to the small setting of trial (only two centers in one city), we did not observe more significant changes. Third, we had no objective method of verifying complications and we did not verify medical documentation for all participants or in central registries.

## Conclusion

In conclusion, our study showed the feasibility and effectiveness of an automated system for monitoring patient feedback and complications after screening colonoscopy. As the medical field becomes more patient- and technology-oriented, such changes in health services should become more prevalent.

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## Competing interests

None

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